As filed with the Securities and Exchange Commission on June 15, 2020.

Registration No. 333-238738

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

AMENDMENT NO. 2
TO
FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

Progenity, Inc.

(Exact name of registrant as specified in its charter)

Delaware	8071	27-3950390
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

4330 La Jolla Village Drive, Suite 200
San Diego, CA 92122
(855) 293-2639
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Harry Stylli, Ph.D.
Chairman and Chief Executive Officer
Progenity, Inc.
4330 La Jolla Village Drive, Suite 200
San Diego, CA 92122
(855) 293-2639
(Name, address, including zip code, and telephone number, including area code, of agent for service)

With copies to:

Michelle Hodges Ryan A. Murr Branden C. Berns Gibson, Dunn & Crutcher LLP 3161 Michelson Drive Irvine, CA 92612-4412 (949) 451-3954	Clarke Neumann General Counsel Progenity, Inc. 4330 La Jolla Village Drive, Suite 200 San Diego, CA 92122 (855) 293-2639	B. Shayne Kennedy Michael E. Sullivan Chris G. Geissinger Latham & Watkins LLP 650 Town Center Drive, 20th Floor Costa Mesa, California 92626 (714) 540-1235

Approximate date of commencement of proposed sale to the public: As soon as practicable after this registration statement becomes effective.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☐

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☐
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☐

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered(1)	Proposed Maximum Offering Price Per Share(2)	Proposed Maximum Aggregate Offering Price(2)	Amount of Registration Fee(3)
Common Stock, par value $0.001 per share	7,666,667	$16.00	$122,666,672	$15,923

(1) Includes 1,000,000 additional shares that the underwriters have the option to purchase from the registrant. See "Underwriting."
(2) Estimated solely for purposes of calculating the registration fee in accordance with Rule 457(a) under the Securities Act of 1933, as amended.
(3) The registrant previously paid filing fees of $12,980 in connection with a previous filing of its registration statement on Form S-1 (File No. 333-238738), which registration statement contemplated a proposed maximum offering price of $100,000,000.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to such Section 8(a), may determine.

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The information in this prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is declared effective. This prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to completion, dated June 15, 2020

6,666,667 Shares

PROGENITY, INC.

Common Stock

$ per share

- Progenity, Inc. is offering 6,666,667 shares.
- We anticipate that the initial public offering price will be between $14.00 and $16.00 per share.
- This is our initial public offering and no public market currently exists for our shares.
- Proposed Nasdaq Global Select Market trading symbol: "PROG."

This investment involves risk. See "Risk Factors" beginning on page 16.

We are an "emerging growth company" as defined under the federal securities laws and, as such, may elect to comply with certain reduced public company reporting requirements in future reports after the completion of this offering. See "Prospectus Summary—Implications of Being an Emerging Growth Company."

	Per Share	Total
Initial public offering price	$	$
Underwriting discount(1)	$	$
Proceeds, before expenses, to Progenity, Inc.	$	$

(1) See "Underwriting" beginning on page 216 for additional information regarding underwriting compensation.

The underwriters have a 30-day option to purchase up to 1,000,000 additional shares of common stock from us at the initial public offering price less the underwriting discount.

Certain of our existing stockholders, including those affiliated with members of our Board, have indicated an interest in purchasing an aggregate of up to approximately $50 million of shares of our common stock in this offering at the initial public offering price per share and on the same terms as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares of common stock to any of these potential purchasers, and any of these potential purchasers could determine to purchase more, fewer or no shares of common stock in this offering. The underwriters will receive the same underwriting discount and commissions on these shares of common stock as they will on any other shares of common stock sold to the public in this offering.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved the securities described herein or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares of common stock to our investors on or about , 2020.

Piper Sandler **Wells Fargo Securities**

Baird **Raymond James**

BTIG

The date of this prospectus is , 2020.

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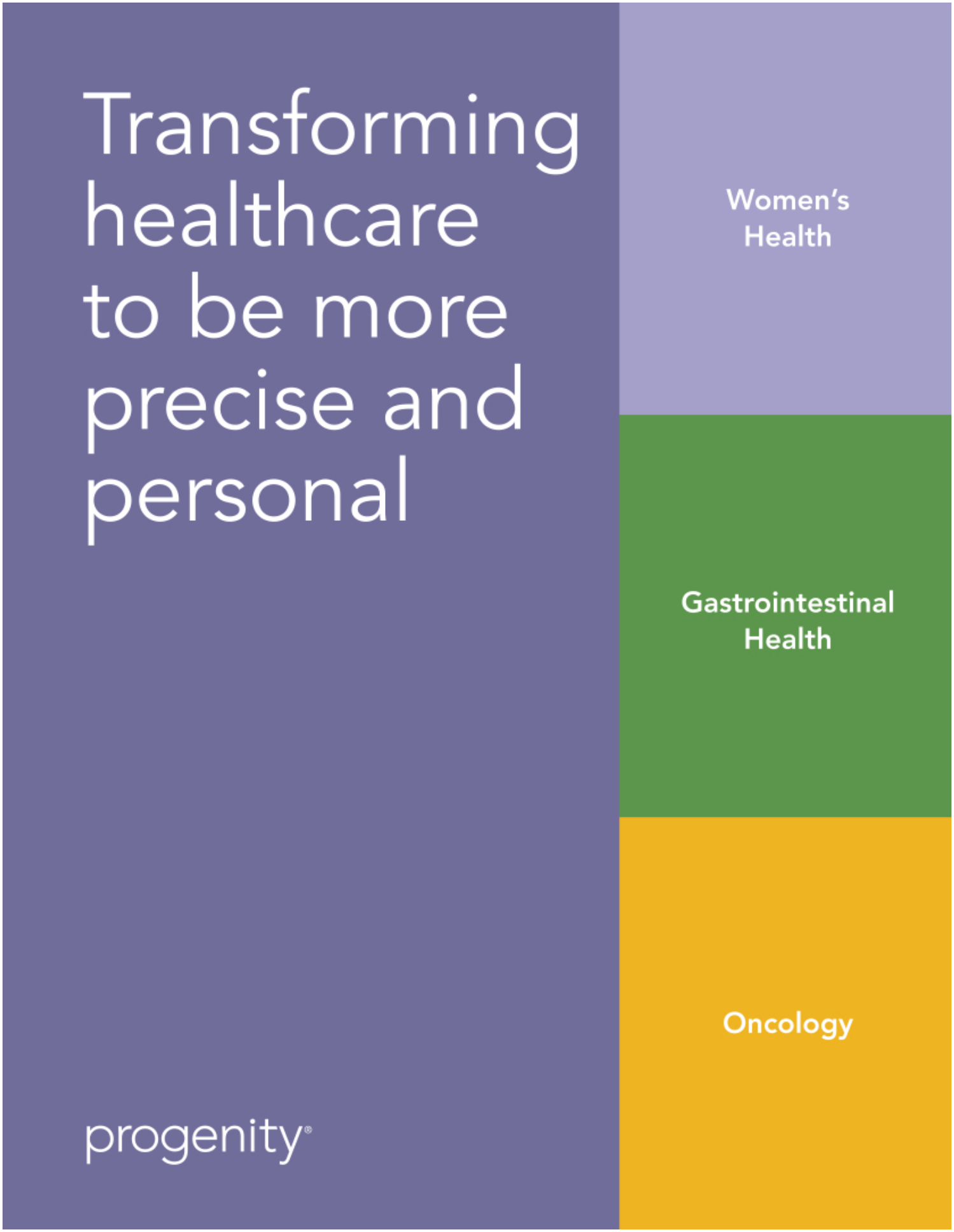

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We have not, and the underwriters have not, authorized anyone to provide you with information other than that contained in this prospectus or in any free writing prospectus we may authorize to be delivered or made available to you. We take no responsibility for and cannot provide any assurance as to the reliability of any other information others may give you. We are not, and the underwriters are not, making an offer to sell shares of our common stock in any jurisdiction where the offer or sale is not permitted. The information in this prospectus or any free writing prospectus is accurate only as of its

date, regardless of its time of delivery or of any sale of shares of our common stock. Our business, financial condition, results of operations, and prospects may have changed since that date.

For investors outside the United States: We have not, and the underwriters have not, done anything that would permit this offering, or possession or distribution of this prospectus, in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of our common stock and the distribution of this prospectus outside of the United States.

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus. This summary does not contain all of the information that you should consider before deciding to invest in our common stock. You should read the entire prospectus carefully, including "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," and our financial statements and notes to those financial statements included elsewhere in this prospectus, before making an investment decision. Some of the statements in this summary constitute forward-looking statements, see "Special Note Regarding Forward-Looking Statements." In this prospectus, unless the context requires otherwise, references to "we," "us," "our," "Progenity" or the "company" refer to Progenity, Inc. and, where appropriate, its subsidiaries. Additionally, references to "Board" refer to the board of directors of Progenity, Inc.

Our Company

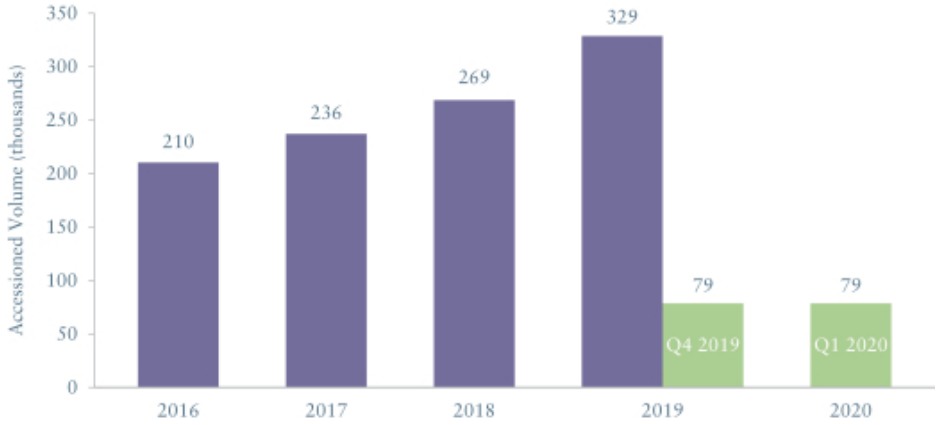
We are a biotechnology company with an established track record of success in developing and commercializing molecular testing products as well as innovating in the field of precision medicine. We believe that we are a market-leading provider of *in vitro* molecular tests designed to improve lives by providing actionable information that helps guide patients and physicians in making critical and timely medical decisions during various life stages, such as family planning, pregnancy, or navigating a complex disease diagnosis. Our vision is to transform healthcare to become more precise and personal by improving diagnoses of disease and improving patient outcomes through localized treatment with targeted therapies. We apply a multi-omics approach, combining genomics, epigenomics, proteomics, and metabolomics, to our molecular testing products and to the development of a suite of investigational ingestible devices and drug/device combinations designed to provide precise diagnostic sampling and drug delivery solutions.

Since 2010, our molecular testing business has achieved consistent year-over-year test volume growth through our robust product portfolio and our strong commercial organization. Our internal core competencies, deep research and development pipeline and strategic acquisitions of novel technologies have fueled our innovation in women's health, supporting the development and launch of complementary molecular testing products that inform critical healthcare decision-making across a woman's lifetime.

In 2015, we launched both our Innatal Prenatal Screen, a Non-Invasive Prenatal Testing, or NIPT, offering, and our Preparent Carrier Test, followed by the launch of our Riscover Hereditary Cancer Test in 2017. Our current molecular testing products collectively address a combined market of more than $2.5 billion in the United States alone. We offer molecular tests with market-leading performance and turnaround times, supported by end-to-end workflow solutions that increase administrative efficiencies. Along with our comprehensive menu of molecular tests, we offer patients pre-test education, clear and timely results, and on-demand genetic counseling. We are committed to providing patients and physicians with empathetic communication and support during critical moments to help empower and prepare patients and their families to make critical life decisions.

Since our inception, we have accessioned approximately 1.5 million tests in the United States and the growth rate of our test volume was accelerating over a multi-year period, including early 2020. However, we are currently observing a slowdown in volume growth as a result of the COVID-19 pandemic. The figure below shows our test volume growth from 2016 through 2019, as well as the first quarter of 2020, in which quarter we observed volumes largely consistent with the fourth quarter of 2019 despite the challenges presented by the COVID-19 pandemic. We believe our business is resilient and we have observed positive signs of recovery so far.

Test Volume Growth



Our commercial team of more than 150 individuals actively engages with physicians and their staff to emphasize the clinical need for our products, educate them on clinical value, and facilitate their ability to order our molecular tests. We place special emphasis on our customers' needs and journey with their patients. We ensure they are fully equipped with all the tools they need to discuss and educate their patients about the benefits of NIPT, carrier screening, and hereditary cancer screening, and also provide the added confidence that our genetic counselors are there to support them when needed.

We continue to innovate to drive the clinical and competitive differentiation of our molecular tests. For example, our next generation Innatal Prenatal Screen (Innatal 4th Generation) is designed to provide the same highly reliable results but with a faster turnaround time and at a much lower cost to us.

We are developing a rule-out test for preeclampsia. Based on our estimates, annually, over 700,000 pregnant women in the United States experience signs and symptoms that could be attributed to preeclampsia, which can cause serious, even fatal, complications for both mother and baby. Preeclampsia is the second most common cause of maternal death worldwide and is currently diagnosed by observing risk factors and common symptoms, such as high blood pressure, rather than diagnosing the actual condition itself. This approach often leads to false positive diagnoses and provides limited clinical utility, which can each lead to unnecessary hospitalizations and medical costs. We are developing a test that we believe has the potential to address these shortcomings by ruling out the condition itself (rather than merely detecting its symptoms) through testing for certain biomarkers. We believe that identifying non-preeclamptic pregnancies would improve patient outcomes while lowering the cost burden of preeclampsia to the U.S. healthcare system, estimated to be approximately $1.03 billion for mothers and $1.15 billion for infants annually. We believe the total addressable market for our preeclampsia test is approximately $3 billion per year in the United States alone.

We believe our future success will be driven by continued capture of market share by our molecular testing business and new revenue streams resulting from our diversified product development pipeline, both within and beyond women's health. Our core expertise in complex assay development, bioinformatics, and scalable commercial laboratory operations lends itself to a variety of potential applications. We are also developing a novel pipeline of precision medicine product candidates designed to provide solutions for gastrointestinal, or GI, disorders. This pipeline includes both diagnostic applications, targeted drug delivery in the GI tract at the site of disease, and the oral delivery of

biologics. We believe these product candidates, if successfully developed, have the potential to address unmet healthcare needs by more precisely identifying and treating chronic GI diseases, such as small intestinal bacterial overgrowth, or SIBO, and inflammatory bowel disease, or IBD.

Our Strengths

We attribute our commercial success and future growth prospects to the following:

- ***A leading molecular testing business with clinical and competitive product advantages***. Our products are built on a foundation of molecular genetic expertise, excellence in bioinformatics, and dedication to women's health and reproductive medicine. We have built a robust product portfolio through efficient in-house development, clinical laboratory partnerships, and strategic acquisitions. Our tests have achieved market-leading reliability and performance benchmarks within their respective market categories.
- ***Integrated product offering***. We offer integrated molecular tests and end-to-end support services that enable physicians to seamlessly incorporate genetic testing into their office workflow and offer the convenience of ordering multiple tests from one source. Our workflow solutions customize the experience of working with us for a range of physician practice sizes and capabilities, lowering barriers to adoption of genetic testing. We also utilize a specialized team dedicated to integrating our systems with our healthcare providers' electronic medical record, or EMR, systems, opening bidirectional connectivity to streamline test ordering and reporting. We deliver easy-to-understand results and our customer support services provide convenient access to board-certified genetic counselors. We believe that these services collectively create substantial value and lead to customer loyalty.
- ***Breadth and depth of R&D capabilities driving breakthrough innovation***. We have built a first class research and development, or R&D, organization capable of harnessing and translating novel technologies into innovative platforms and product solutions as we strive to remain at the forefront of customer needs. Our technical expertise along the product development spectrum includes assay design, bioinformatics, and analytical and clinical validation and enables us to leverage existing knowledge to solve new challenges.
- ***Precision medicine platform targeting a large, underserved market***. We are developing an innovative and potentially scalable product platform that we believe will support the advancement of our precision medicine pipeline. This platform approach is based on an innovative capsule, which we believe could represent a paradigm shift from existing diagnostic and therapeutic approaches. We believe this platform has the potential to address significant unmet medical needs in the GI space, including the challenges in diagnosing, treating, and monitoring diseases without the repeated use of invasive procedures, such as upper GI endoscopies, colonoscopies, and biopsies.
- ***Comprehensive intellectual property portfolio***. We have retained worldwide rights to our internally-developed and acquired molecular testing and precision medicine technologies. We hold over 425 issued patents and pending patent applications that include claims that are directed to a range of molecular testing and precision medicine-related methods, systems, and compositions surrounding our suite of current and future products. In addition, we believe that our trade secrets and other know-how provide additional barriers to entry.
- ***Proven leadership with industry expertise***. Our senior management team and board of directors consist of veteran biotechnology and molecular testing professionals with deep industry experience. These individuals have extensive experience with numerous well-regarded biotechnology and diagnostic companies. Through their many years of experience, they have developed strong relationships with key thought leaders and medical societies.

Our Strategy

Our vision is to build upon our expertise and core competencies in molecular testing to transform healthcare to become more precise and personal in our existing markets as well as in new developmental fields such as ingestible diagnostics and targeted therapeutics. To realize our vision, we intend to:

- ***Expand market opportunity for our existing molecular tests***. We believe there is a significant opportunity to expand and further penetrate the markets for each of our existing molecular tests. We intend to accomplish this by working with industry groups and payors to increase payor policy coverage, educating patients, physicians, and payors on the clinical utility of our tests, and highlighting the cost efficiency and time savings provided by our tests and workflow solutions.
- ***Leverage our robust R&D capabilities to drive breakthrough innovation***. We seek to combine innovation with the technologies underlying our existing platforms to disrupt the current diagnostics and treatment paradigms. Through our robust research and development pipeline, we seek to unlock novel approaches that will drive improvement of patient outcomes in prenatal and perinatal medicine, gastroenterology, and oncology, increase the precision of medical research and diagnosis through ingestible sampling technologies, and create a new category of treatment options through proprietary drug/device combinations.
- ***Continue to expand and strengthen our direct sales force***. We believe that our specialized sales force is key to educating our customers about the clinical need for our molecular tests and our end-to-end workflow solutions. We are continuously optimizing market coverage of our highly qualified sales force and identifying new growth opportunities using a customized and targeted account profiling and messaging approach that better reflects our value proposition.
- ***Enhance our customer support services***. Our goal is to be a trusted and valued partner to our customers by delivering market-leading test performance and service to further integrate genetic testing into their workflow. We intend to expand upon our Progenity Partnerships program, our proprietary customer support services platform, to further streamline patient identification and selection for testing and enhance our customized physician and patient management initiatives. In addition, we intend to expand upon our patient management tools, which streamline and enhance the patient experience, including patient education, payor pre-authorization, easy-to-read test results, and access to genetic counselors.
- ***Develop and commercialize a disruptive precision medicine platform of GI diagnostics and therapeutics***. Our precision medicine platform is focused on addressing an unmet medical need of patients with GI disorders or related diseases. Leveraging an autonomous localization technology, we are developing a noninvasive, ingestible capsule platform, with investigational devices and drug/device combinations designed for both diagnostic and therapeutic purposes. We believe our product candidates, if successfully developed and approved or cleared, could become the first precision medicine products to diagnose and treat at the site of the disease within the GI tract. Ultimately, we intend to pursue commercialization of such product candidates ourselves or via strategic partnership.

Our Molecular Tests

We have developed proprietary, low-cost, high-throughput platforms for our Innatal, Preparent, and Riscover molecular testing products. Our platforms exploit proprietary developments in a number of key molecular biology applications, bioinformatic algorithms, and innovative clinical reporting. Our assay

platforms are designed to deliver increased performance at lower costs compared to alternative methods and have a flexible architecture, designed to allow for rapid product development iteration cycles with best in class performance.

Our molecular tests provide accurate, reliable, and fast test results while simplifying ordering, pre-test education, processing, testing, reporting, counseling, and billing for physicians and patients. We currently offer tests with clinical utility that enable physicians to deliver clinical decision support for, and address the medical needs of, patients and their families. We complement these tests with our proprietary suite of end-to-end workflow solutions, enabling us to educate physicians, patients, and payors on the benefits and clinical utility of genetic testing. In addition, we offer physicians the convenience of ordering multiple tests from one source, integrate our services seamlessly into their practices, and deliver easy-to-understand results and genetic counseling support.

We own and operate a licensed Clinical Laboratory Improvement Amendments, or CLIA, certified and College of American Pathologists, or CAP, accredited laboratory located in Ann Arbor, Michigan specializing in the molecular testing market serving women's health providers in the obstetric, gynecological, fertility, and maternal fetal medicine specialty areas in the United States. Distribution is managed by a dedicated sales force and a field operations team who support all logistical functions in receiving clinical samples to the laboratory for analysis. Through our affiliation with Mattison Pathology, LLP, a Texas limited liability partnership doing business as Avero Diagnostics, located in Lubbock and Irving, Texas, our operations have expanded to provide anatomic and molecular pathology tests in the United States.

We support patients and physicians during patients' critical life decisions with our current suite of high-quality molecular tests:

- **Innatal Prenatal Screen:** A noninvasive prenatal test offered to women early in pregnancy to screen for risk of fetal chromosomal conditions, such as Down syndrome, trisomy 13, and trisomy 18, and sex chromosome disorders
- **Preparent Carrier Test:** An expanded carrier screen that is performed on women or couples before conception or early in a pregnancy to identify if they carry certain mutations that cause genetic diseases
- **Riscover Hereditary Cancer Test:** A hereditary cancer screen that looks for genetic mutations associated with elevated risk for certain hereditary cancers in an asymptomatic patient
- **Resura Prenatal Test for Monogenic Disease:** A test for monogenic diseases that is the first commercially available, custom-designed solution for families at-risk for rare diseases
- **Anatomic and Molecular Pathology Tests:** A broad portfolio of anatomic and molecular pathology tests and specialized genetic tests we offer through Avero Diagnostics

Our Product Candidates in Development

Next Generation Innatal Prenatal Screen (Innatal 4th Generation)

We are developing a proprietary single molecule DNA counting assay utilizing advanced optics with custom chemistry and molecular biology that we believe will represent a substantial improvement to our existing Innatal platform, with simplified and more cost-effective assay workflow resulting in the same high clinical quality and reliability but with an up to 50% reduction in turnaround time and a substantial reduction in cost of goods sold for our NIPT. We have completed the feasibility assessment for this test and are in the process of completing the optimization process. If successfully developed, we currently anticipate a commercial launch of this product by the end of 2021.

Preeclampsia Rule-Out Test

Preeclampsia is a hypertensive condition of pregnancy involving multiple pathways that usually occurs in the second half of pregnancy. According to the Preeclampsia Foundation, preeclampsia occurs in 5% to 8% of pregnancies in the United States and is one of the leading causes of premature birth and maternal and neonatal morbidity and mortality. The current standard of care evaluations for preeclampsia are often inconclusive and inaccurate. The only consensus treatment for preeclampsia is delivery of the baby, regardless of gestational age, which results in unnecessary hospital admissions, preterm births, and additional healthcare costs. Suspected preeclampsia before 37 weeks of gestation often results in preterm birth complications, thus a rule-out test with high negative predictive value for preeclampsia could provide the extra days and weeks of gestational development which are critical for positive infant health outcomes. While positive predictive testing is believed by some companies to be beneficial, the 2019 ACOG bulletin on gestational hypertension and preeclampsia stated that due to the relatively low positive predictive values (8% to 33%) of diagnostic tools, those tools cannot predict preeclampsia and should remain investigational. Our preeclampsia rule-out test is not diagnostic, as it is designed to rule out (exclude) the disorder and rely on a high negative predictive value, or NPV, to provide physicians and other care givers with a novel adjunctive laboratory assessment to manage patients suspected of having preeclampsia. Preeclampsia is often indistinguishable from chronic and gestational hypertension, which are treated and managed differently; and therefore must be differentiated from true preeclampsia to avoid unnecessary preterm births.

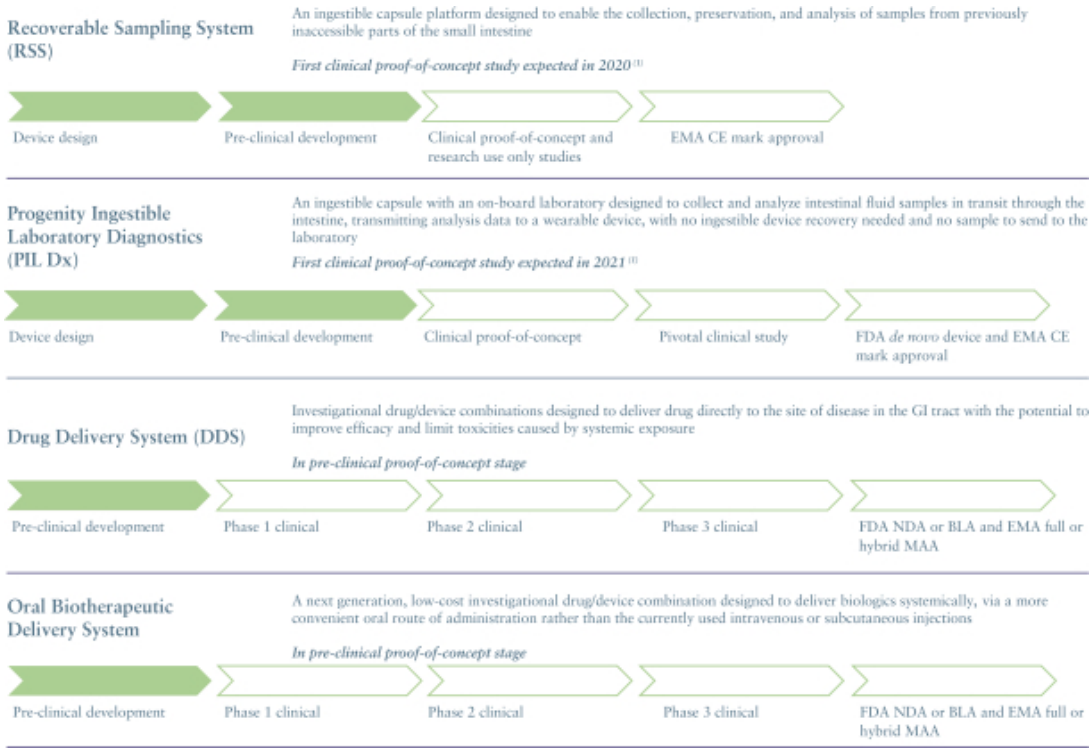
To address this problem, we are developing a proprietary proteomics platform to support novel clinical tests focused on the quantitative measurement of multiple proteins. This multi-analyte platform is designed to detect complications and diseases manifesting from multiple complex biological pathways to provide insight into disease progression and to assist in clinical management. The platform is built on automated instrumentation, which is a Class I, 510(k) exempt device commonly found in clinical laboratories, which we believe will enable expansion of the platform into multiple clinical sites. We have developed reagents, including high affinity and specific antibodies, which we believe will deliver a differentiating platform focused on performance, sensitivity, and specificity.

Through this proteomics platform, we are developing a noninvasive, high sensitivity, multi-analyte blood-based test designed to assist in the clinical assessment and medical care decision-making process of physicians who care for pregnant women presenting with signs and symptoms of preeclampsia between 28 to 37 weeks of gestational age. We believe a risk assessment test that exhibits high NPV could provide a significant improvement in the ability to manage preeclampsia by ruling out the active condition, thereby obviating the cost and risk of further diagnosis and treatment in high-cost settings. We believe our preeclampsia test, if successfully developed, will have the potential to impact the cadence and amount of patient visits and timing of indicated delivery, potentially saving the healthcare system money while also improving patient care for both mother and baby. By designing the test to have high sensitivity and NPV rates, we expect the test, if and when offered, to be well suited to complement existing tools already part of the current standard of care, giving clinicians an additional strong, objective tool with which to better manage hypertensive disorders during pregnancy. To this end, we have completed the optimization phase of development for our preeclampsia rule-out test and have met the design specifications in a cohort of over 800 subjects. In addition, we have secured the clinical verification and validation sample sets for this test and we are in the process of processing and analyzing these samples for verification purposes. If successfully developed, we anticipate a targeted commercial launch of this product in the second quarter of 2021. However, we cannot predict whether the COVID-19 pandemic or other factors will impact the timing of our commercial launch. For example, see “Risk Factors—The recent and ongoing COVID-19 pandemic could materially affect our operations, as well as the business or operations of third parties with whom we conduct business. Our business could be adversely affected

by the effects of other future health epidemics or pandemics in regions where we or third parties on which we rely have significant business operations."

Precision Medicine for GI-Related Disorders

We are also developing a proprietary ingestible capsule platform designed to help diagnose and treat GI disorders at the site of disease, with the goal of addressing significant unmet needs and supporting affected patient populations by improving patient outcomes through precision medicine. Our investigational capsules are being developed for both diagnostic and therapeutic applications in disorders such as SIBO and inflammatory disorders, such as IBD. Our precision medicine development pipeline includes:



(1) We cannot predict whether the COVID-19 pandemic or other factors will impact the timing of our clinical trials and studies. For example, see "Risk Factors—The recent and ongoing COVID-19 pandemic could materially affect our operations, as well as the business or operations of third parties with whom we conduct business. Our business could be adversely affected by the effects of other future health epidemics or pandemics in regions where we or third parties on which we rely have significant business operations."

Our approach is founded on the development of innovative technologies that are designed to diagnose and treat at the site of the disease. Using this platform, we intend to develop diagnostic and therapeutic solutions for a broad range of disorders, but our initial focus is on SIBO and inflammatory disorders such as IBD. These disorders are difficult to treat due to the challenges in diagnosing these conditions and monitoring the treatment response without the repeated use of invasive procedures such as upper GI endoscopies, colonoscopies, and biopsies. From the therapeutic perspective, the most effective approved therapies for IBDs such as ulcerative colitis and Crohn's disease, are currently potent immunomodulatory

drugs such as Humira and Xeljanz. Unlike the efficacy seen with other immunological disorders such as rheumatoid arthritis and psoriasis, we believe the efficacy of these potent agents for IBD is suboptimal. This can partly be explained by the inadequate bioavailability of the drug in the GI tract when administered by traditional oral capsules or by injection or infusion, even at high doses and because of the inability to increase dosage due to dose-limiting systemic toxicity. We believe a significant opportunity exists for a device that can diagnose GI-related disorders without an endoscopy or colonoscopy and a device that can deliver drugs in a targeted manner directly to the site of disease.

To address these GI-related disorders, we are currently developing four therapeutic solutions for use with our precision medicine drug/device combinations: PGN-001, which is a GI-targeted adalimumab for use with the Oral Biotherapeutic Delivery System and the Drug Delivery System, or DDS; PGN-300, which is a GI-targeted vedolizumab for use with DDS and potentially the Oral Biotherapeutic Delivery System; PGN-600, which is a GI-targeted tofacitinib for use with DDS; and PGN-OB2, which is a GLP-1 analog for use with the Oral Biotherapeutic Delivery System. We believe that both the Oral Biotherapeutic Delivery System and DDS will have the potential to be used in combination with other therapeutics in addition to those described above.

Our precision medicine product platform is based on our own multi-disciplinary research developed over the last five years and also in-licensed and acquired intellectual property from Medimetrics. Three of our four ingestible medical device product candidates utilize autonomous localization technology. This technology is designed to enable both diagnostic and therapeutic capsule types to autonomously determine their location within the GI tract. The autonomous localization technology is based on a proprietary LED light and photodetector sensor array that detects reflected light in the GI tract and uses a proprietary algorithm to determine anatomical locations of interest, for example, the pyloric and ileocecal transition. Of note, this technology differs from other GI tract localization technologies that rely on pH levels and other physiological factors which are not specific and are highly variable and also differs from delayed release drug delivery systems such as pH sensitive capsules and MMX technology. Our PIL Dx capsules are designed to work with a remote radio frequency, or RF, detector device that externally monitors all sensor measurements and can transmit results of GI tract testing. Our core technology is also designed to allow for precise sample collection of intestinal fluids at a predetermined location and analysis in the GI tract. Additionally, certain of the capsules we have under development have temperature sensors that are designed to measure the temperature of the surrounding environment and a microchip oscillator that is designed to keep time. See “Business—Precision Medicine for GI-Related Disorders” for more information on the anticipated regulatory pathway for the product candidates in our precision medicine capsule development pipeline.

We have a GI-focused laboratory in Irving, Texas to support our precision medicine platform. We believe that the technologies under development will provide quantitative analysis for the RSS capsule and the PIL Dx capsule, as well as for precision medicine-related studies. The team members located at the laboratory are developing and validating reagents and assays to analyze protein, nucleic acid, metabolite, and bacterial analytes. The assays will be used for a range of nonclinical and clinical studies in conditions including SIBO and IBD, and in oncology.

Risks Associated with Our Business

Investing in our common stock involves significant risks. You should carefully consider the risks described in “Risk Factors” before making a decision to invest in our common stock. If we are unable to successfully address these risks and challenges, our business, financial condition, results of operations, or prospects could be materially adversely affected. In such case, the trading price of our common stock

would likely decline, and you may lose all or part of your investment. Below is a summary of some of the risks we face.

- The recent and ongoing COVID-19 pandemic could materially affect our operations, as well as the business or operations of third parties with whom we conduct business.
- We currently receive and expect to continue to receive a significant portion of our revenues from our women's health-related NIPT and carrier screening products, and if our efforts to further increase the use and adoption of these products fail, our business will be harmed.
- We have incurred losses in the past, and we may not be able to achieve or sustain profitability in the future.
- We operate in a highly competitive business environment.
- Our success depends on our ability to improve and enhance our current products and develop new product candidates, which is complex and costly and the results are uncertain.
- We are still developing our precision medicine platform and to date have generated no products or product revenue. There can be no assurance that we will develop any precision medicine products that deliver diagnostic or therapeutic solutions, or, if developed, that such product candidates will be authorized for marketing by regulatory authorities, or will be commercially successful. This uncertainty makes it difficult to assess our future prospects and financial results.
- Although we have implemented compliance policies and have an internal audit function, we cannot ensure that our employees will fully adhere to such policies.
- Operating our business will require a significant amount of cash, and our ability to generate sufficient cash depends on many factors, some of which are beyond our control. We expect to need to raise additional capital after this offering, and if we cannot raise additional capital when needed, we may have to curtail or cease operations.
- We may not be able to obtain and maintain the third-party relationships that are necessary to develop, commercialize, and manufacture some or all of our product candidates.
- We rely on a limited number of suppliers or, in some cases, single suppliers, for some of our laboratory instruments and materials and may not be able to find replacements or immediately transition to alternative suppliers.
- We have increased the size of our organization and expect to further increase it in the future, and we may experience difficulties in managing this growth. If we are unable to manage the anticipated growth of our business, our future revenue and operating results may be adversely affected.
- If third-party payors do not adequately reimburse us or our customers for any new products, they might not be purchased or used, which may adversely affect our revenue and profits.
- We may be unable to expand or maintain third-party payor coverage and reimbursement for our Innatal, Preparent, and other tests, or may be required to refund any reimbursements already received.
- If we or our commercial partners act in a manner that violates healthcare laws or otherwise engage in misconduct, we could face substantial penalties and damage to our reputation, and our business operations and financial condition could be adversely affected.

- Third-party claims of intellectual property infringement could result in litigation or other proceedings, which would be costly and time-consuming, and could limit our ability to commercialize our products.

Corporate and Other Information

We were incorporated in Delaware in January 2012 under the name Ascendant MDx, Inc., and we later changed our name in August 2013 to Progenity, Inc. Through our predecessor, Ascendant MDx, a California corporation, we commenced our operations in 2010. Our corporate office is located at 4330 La Jolla Village Drive, Suite 200, San Diego, CA 92122, and our telephone number is (855) 293-2639. Our website is *www.progenity.com*. The information on, or that can be accessed through, our website is not part of this prospectus and is not incorporated by reference herein.

The Progenity logo, "Innatal®," "Preparent®," "Riscover®," "Resura®," and other trademarks, trade names or service marks of Progenity appearing in this prospectus are the property of Progenity, as is the Progenity corporate name. All other service marks, trademarks, and trade names appearing in this prospectus are the property of their respective owners. Solely for convenience, trademarks and trade names referred to in this prospectus appear without the ® and ™ symbols, but those references are not intended to indicate that we will not assert, to the fullest extent under applicable law, our rights, or that the applicable owner will not assert its rights, to these service marks, trademarks, and trade names.

Implications of Being an Emerging Growth Company

We are an emerging growth company, as defined in Section 2(a) of the Securities Act of 1933, as amended, or the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including relief from the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, less extensive disclosure obligations regarding executive compensation in our registration statements, periodic reports and proxy statements, exemptions from the requirements to hold a nonbinding advisory vote on executive compensation, and exemptions from stockholder approval of any golden parachute payments not previously approved. In particular in this prospectus, we expect to provide only two years of audited consolidated financial statements and have not included all of the executive compensation-related information that would be required if we were not an emerging growth company. As a result, our stockholders may not have access to certain information that they may deem important. We may also elect to take advantage of other reduced reporting requirements in future filings. We could be an emerging growth company for up to 5 years, although circumstances could cause us to lose that status earlier, including if our total annual gross revenues exceed $1.07 billion, if we issue more than $1.0 billion in non-convertible debt during any three-year period, or if the market value of our common stock held by non-affiliates exceeds $700 million as of June 30 of any year.

In addition, the JOBS Act also provides that an emerging growth company may take advantage of the extended transition period provided in the Securities Act for complying with new or revised accounting standards. An emerging growth company may therefore delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, as a result, will not be subject to the same implementation timing for new or revised accounting standards as are required of other public companies that are not emerging growth companies, which may make comparison of our consolidated financial information to those of other public companies more difficult.

THE OFFERING

Common stock offered by us	6,666,667 shares.
Option to purchase additional shares of common stock	The underwriters have a 30-day option to purchase up to 1,000,000 additional shares of our common stock.
Common stock to be outstanding immediately after this offering	45,163,795 shares (or 46,163,795 shares if the underwriters exercise in full their option to purchase the additional shares of our common stock).
Use of proceeds	We expect that our net proceeds from this offering will be approximately $89.0 million, at an assumed public offering price of $15.00 per share (the midpoint of the price range set forth on the cover of this prospectus), and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the proceeds of this offering to support our operations, to invest in our molecular testing research and development program, to invest in research and development with respect to our precision medicine platform, and for working capital and general corporate purposes. See "Use of Proceeds" for additional information.
Risk factors	You should carefully read and consider the information set forth in "Risk Factors," together with all of the other information set forth in this prospectus, before deciding whether to invest in our common stock.
Proposed Nasdaq Global Select Market symbol	"PROG"

The number of shares of common stock to be outstanding after this offering (i) is based on 35,712,214 shares of our common stock (including shares of our preferred stock outstanding on an as-converted basis) outstanding as of March 31, 2020, (ii) includes 19,994 shares of our common stock issued subsequent to March 31, 2020, (iii) includes 719,398 shares of our common stock (on an as-converted basis) issuable upon the conversion of 4,444,444 shares of our Series B Preferred Stock issued subsequent to March 31, 2020, (iv) includes 2,045,522 shares of our common stock issuable pursuant to an adjustment in the conversion rate of all of our shares of Series B Preferred Stock outstanding as of the date hereof that occurs when the public offering price per share of common stock is less than $16.68, based on a public offering price of $15.00 (the midpoint of the price range set forth on the cover page of this prospectus), and (v) excludes the following:

- 3,678,520 shares of our common stock issuable upon the exercise of stock options outstanding as of March 31, 2020 under our 2011 Incentive Stock Plan, Second Amended and Restated 2012 Stock Plan, 2015 Consultant Stock Plan, and Third Amended and

Restated 2018 Equity Incentive Plan, or the 2018 Plan, at a weighted average exercise price of $7.90 per share;

- 990,463 shares of our common stock issuable upon the settlement of restricted stock units outstanding as of March 31, 2020, 83,079 of which we expect to be issued for vested restricted stock units under our 2018 Plan on the date on which any restrictions imposed by the underwriters in connection with this offering have expired;
- 114,614 restricted stock units and 230,402 options to purchase shares of our common stock granted subsequent to March 31, 2020 at a weighted-average exercise price of $12.76 per share;
- 4,707,604 shares of our common stock reserved for future issuance pursuant to future awards under our 2018 Plan, as well as any automatic increase in the number of shares of common stock reserved for future issuance under this plan;
- 510,000 shares of our common stock to be reserved for future issuance under our 2020 Employee Stock Purchase Plan, which will become effective immediately prior to the completion of this offering, as well as any automatic increase in the number of shares of common stock reserved for future issuance under this plan;
- 400,160 shares of our common stock (on an as-converted basis) issuable upon exercise of an outstanding Series B Preferred Stock Purchase Warrant at an exercise price of $13.90 per share, including 40,461 shares issuable pursuant to an adjustment in the conversion rate of all of our shares of Series B Preferred Stock outstanding as of the date hereof that occurs when the public offering price per share of common stock is less than $16.68, based on a public offering price of $15.00 (the midpoint of the price range set forth on the cover page of this prospectus); and
- 1,250,000 shares of our common stock issuable upon conversion of an unsecured convertible promissory note, based on a public offering price of $15.00 (the midpoint of the price range set forth on the cover page of this prospectus).

Except as otherwise noted, we have presented the information in this prospectus based on the following assumptions:

- the conversion, in accordance with our existing seventh amended and restated certificate of incorporation, of all shares of preferred stock outstanding as of the date hereof into 33,443,562 shares of our common stock based on a public offering price of $15.00 (the midpoint of the price range set forth on the cover page of this prospectus), including 2,045,522 shares of our common stock issued pursuant to an adjustment in the conversion rate of all of our shares of Series B Preferred Stock outstanding on the date hereof that occurs when the public offering price per share of common stock is less than $16.68, which conversion will occur immediately prior to the completion of this offering;
- the automatic conversion of an unsecured convertible promissory note into 1,250,000 shares of our common stock, based on a public offering price of $15.00 (the midpoint of the price range set forth on the cover page of this prospectus);
- the automatic conversion of an outstanding Series B Preferred Stock Purchase Warrant exercisable for shares of our Series B Preferred Stock into a warrant exercisable for 400,160 shares of our common stock based on a public offering price of $15.00 (the midpoint of the price range set forth on the cover page of this prospectus), including 40,461 shares issuable pursuant to an adjustment in the conversion rate of all of our shares of Series B Preferred

Stock outstanding as of the date hereof that occurs when the public offering price per share of common stock is less than $16.68, based on a public offering price of $15.00 (the midpoint of the price range set forth on the cover page of this prospectus);

- the one-for-6.178 reverse stock split of our common stock and a proportional adjustment to the conversion ratio of our preferred stock effected on June 10, 2020;
- no exercise by the underwriters of their option to purchase additional shares of our common stock in this offering;
- no exercise of outstanding stock options or vesting of restricted stock units after June 15, 2020; and
- the filing and effectiveness of our eighth amended and restated certificate of incorporation with the Secretary of State of the State of Delaware, which will occur immediately prior to the completion of this offering. See "Description of Capital Stock—Our Certificate of Incorporation and Our Bylaws."

Certain of our existing stockholders, including those affiliated with members of our Board, have indicated an interest in purchasing an aggregate of up to approximately $50 million of shares of our common stock in this offering at the initial public offering price per share and on the same terms as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares of common stock to any of these potential purchasers, and any of these potential purchasers could determine to purchase more, fewer or no shares of common stock in this offering. The underwriters will receive the same underwriting discount and commissions on these shares of common stock as they will on any other shares of common stock sold to the public in this offering.

SUMMARY CONSOLIDATED FINANCIAL DATA

The following summary consolidated statement of operations data for the years ended December 31, 2018 and 2019 are derived from our audited consolidated financial statements included elsewhere in this prospectus. The following summary consolidated statement of operations data for the three months ended March 31, 2019 and 2020 and the summary consolidated balance sheet data as of March 31, 2020 are derived from our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus. Our unaudited interim condensed consolidated financial statements were prepared on the same basis as our audited consolidated financial statements and, in our opinion, reflect all adjustments, consisting only of normal recurring adjustments, that are necessary for the fair statement of our unaudited interim condensed consolidated financial statements.

The historical results presented below are not necessarily indicative of the results to be expected for any future period, and our interim results are not necessarily indicative of the results to be expected for the full year or any future period. This information should be read in conjunction with "Risk Factors," "Capitalization," "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Selected Consolidated Financial Data," and our financial statements and the related notes included elsewhere in this prospectus. Our financial statements are prepared in accordance with generally accepted accounting principles in the United States, or GAAP.

	Year Ended December 31,		Three Months Ended March 31,	
	2018	2019	2019	2020
	(in thousands, except share and per share data)		(in thousands, except share and per share data) (unaudited)	
Revenue	$ 127,974	$ 143,985	$ 47,507	$ 16,828
Cost of sales	92,076	100,492	24,421	26,570
Gross profit	35,898	43,493	23,086	(9,742)
Operating expenses:				
Research and development	48,712	63,400	15,248	11,240
Selling and marketing	50,187	58,888	15,567	14,436
General and administrative	51,238	61,324	14,278	17,108
Total operating expenses	150,137	183,612	45,093	42,784
Loss from operations	(114,239)	(140,119)	(22,007)	(52,526)
Interest expense	(9,091)	(9,199)	(2,269)	(2,302)
Equity loss of equity method investee	(2,327)	—	—	—
Interest and other income, net	1,801	575	257	(20)
Loss before taxes	(123,856)	(148,743)	(24,019)	(54,848)
Income tax expense (benefit)	5,250	(706)	—	(37,696)
Net loss	$ (129,106)	$ (148,037)	$ (24,019)	$ (17,152)
Dividend paid to preferred stockholders	—	(3,652)	(3,652)	—
Stock dividend on exchange of Series A-1 for Series B Preferred Stock	—	(27,637)	—	—
Stock dividend on Series B Preferred Stock	—	(49,501)	—	—
Net loss attributable to common stockholders	$ (129,106)	$ (228,827)	$ (27,671)	$ (17,152)
Net loss per share attributable to common stockholders, basic and diluted	$ (27.72)	$ (46.87)	$ (5.88)	$ (3.43)
Weighted average number of shares outstanding, basic and diluted	4,657,337	4,882,662	4,705,641	4,993,393
Pro forma loss per share, basic and diluted (unaudited)(1)		$ (5.49)		$ (0.49)
Pro forma weighted average shares outstanding, basic and diluted (unaudited)(1)		26,961,445		35,063,069

(1) See Notes 2 and 13 to our audited consolidated financial statements and Notes 2 and 13 to our unaudited condensed consolidated financial statements included elsewhere in this prospectus for an explanation of the method used to calculate our net loss per share attributable to common stockholders, basic and diluted; pro forma net loss attributable to common stockholders, basic and diluted; and the weighted average shares used in the computation of these per share amounts.

	As of March 31, 2020		
	Actual	Pro Forma(1)	Pro Forma As-Adjusted(2)
	(in thousands) (unaudited)		
Selected Balance Sheet Data:			
Cash and cash equivalents	$ 11,646	$ 11,646	$ 100,646
Total assets	110,951	110,951	199,951
Total indebtedness(3)	71,779	71,779	71,779
Total liabilities	195,745	195,745	195,745
Preferred stock	112	—	—
Accumulated deficit	(365,630)	(365,630)	(365,630)
Total stockholders' equity (deficit)	(84,794)	(84,794)	4,206

(1) The pro forma column reflects the conversion, in accordance with the sixth amended and restated certificate of incorporation, in effect as of March 31, 2020, of all shares of preferred stock outstanding into 30,678,642 shares of our common stock, which will occur immediately prior to the completion of this offering.

(2) The pro forma as-adjusted column reflects $89.0 million in proceeds from the issuance and sale of shares of our common stock in this offering, based on an assumed public offering price of $15.00 per share (the midpoint of the price range set forth on the cover of this prospectus) and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each $1.00 increase (decrease) in the assumed public offering price would increase (decrease) the pro forma as-adjusted amount of each of cash and cash equivalents, total assets, and total stockholders' equity (deficit) by $6.2 million, assuming that the number of shares offered by us, as set forth on the cover of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each increase (decrease) of 1,000,000 shares in the number of shares offered by us, as set forth on the cover of this prospectus, would increase (decrease) the pro forma as-adjusted amount of each of cash and cash equivalents, total assets, and total stockholders' equity (deficit) by $14.0 million, assuming no change in the assumed public offering price per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

(3) Total indebtedness includes mortgages payable of $3.3 million and a note payable of $68.5 million, each as of March 31, 2020.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this prospectus, including our financial statements and related notes, before deciding whether to purchase shares of our common stock. If any of the following risks actually occurs, our business, financial condition, operating results, reputation, and prospects could be materially and adversely affected. In that event, the price of our common stock could decline and you could lose part or all of your investment. Additional risks not presently known to us, or that we presently deem immaterial, may also negatively impact us.

Risks Related to Our Business and Industry

The recent and ongoing COVID-19 pandemic could materially affect our operations, as well as the business or operations of third parties with whom we conduct business. Our business could be adversely affected by the effects of other future health epidemics or pandemics in regions where we or third parties on which we rely have significant business operations.

Our business and its operations, including but not limited to our laboratory operations, sales and marketing efforts, supply chain operations, research and development activities, and fundraising activities, could be adversely affected by health epidemics in regions where we have business operations, and such health epidemics could cause significant disruption in the operations of third parties upon whom we rely. For example, in December 2019, a novel strain of coronavirus, SARS-CoV-2, causing a disease referred to as COVID-19, was reported to have surfaced in Wuhan, China. Since then, COVID-19 has spread to other countries and throughout the United States. In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic, and the U.S. government imposed restrictions on travel between the United States, Europe, and certain other countries. Further, the President of the United States declared the COVID-19 pandemic a national emergency. Since March 2020, numerous state and local jurisdictions, including the jurisdictions where our headquarters and laboratories are located, have imposed, and others in the future may impose, quarantines, shelter-in-place orders, executive, and similar government orders for their residents to control the spread of COVID-19. The State of California, the State of Michigan, and the State of Texas have each commenced their re-opening processes based on state and local government orders.

In response to these public health directives and orders, we have implemented work-from-home policies for substantially all of our employees. The effects of the executive orders, the shelter-in-place orders, and our work-from-home policies may negatively impact productivity, disrupt our business, and delay our preclinical and clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition. We continue to monitor state and local quarantine, shelter-in-place, executive, and similar government orders and have begun reopening our offices to allow employees to return to the office, as needed, in accordance with our reopening plan, which is based on a phased approach that is appropriately tailored for each of our offices, with a focus on employee safety and optimal work environment.

Quarantines, shelter-in-place, executive, and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases, could impact personnel at third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials we use or require to conduct our business, including product development, which would disrupt our supply chain. In particular, some of our suppliers of certain materials used in our laboratory operations and research and development activities are located in areas that are subject to executive orders and shelter-in-place orders. While many

of these materials may be obtained from more than one supplier, port closures and other restrictions resulting from the COVID-19 pandemic or future pandemics may disrupt our supply chain or limit our ability to obtain sufficient materials to operate our business. To date, we are aware of certain suppliers for our research and development activities who have experienced operational delays directly related to the COVID-19 pandemic.

In addition, we expect our preclinical and clinical trials may be affected by the COVID-19 pandemic. For example, while we originally intended to commence our pilot clinical study for PIL Dx in 2020, we now expect that timeline will be delayed due to circumstances and uncertainties created by the COVID-19 pandemic and expect to instead commence this study in 2021. If COVID-19 continues to spread in the United States and elsewhere, we may experience additional disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- delays in receiving authorization from local regulatory authorities to initiate our planned clinical trials;
- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials, including interruption in global shipping that may affect the transport of clinical trial materials;
- changes in local regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;
- risk that participants enrolled in our clinical trials will acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- interruptions or delays in preclinical studies due to restricted or limited operations at our research and development laboratory facilities;
- delays in necessary interactions with local regulators, ethics committees, and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- refusal of the FDA to accept data from clinical trials in affected geographies; and
- interruption or delays to our sourced discovery and clinical activities.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically, including a significant reduction in laboratory testing volumes. In addition,

reimbursements for our tests may also be delayed if third-party payors' processing is impacted by the COVID-19 pandemic and work-from-home policies and other operational limitations mandated by federal, state, and local governments as a result of the pandemic. While the potential economic impact brought by COVID-19, and the duration of such impact, may be difficult to assess or predict, the widespread pandemic has resulted in significant disruption of global financial markets, which could reduce our ability to access capital and negatively affect our future liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 and related government orders and restrictions could materially affect our business and the value of our common stock.

The COVID-19 pandemic continues to evolve rapidly. The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems, or the global economy as a whole.

We currently receive and expect to continue to receive a significant portion of our revenues from our women's health-related NIPT and carrier screening products, and if our efforts to further increase the use and adoption of these products fail, our business will be harmed.

We currently receive and expect to continue to receive a significant portion of our revenues from the sales of our women's health-related NIPT product, Innatal, and our carrier screening products, including Preparent. We undertake efforts to increase the awareness and adoption of Innatal and Preparent among laboratories, clinics, clinicians, physicians, payors, and patients. Continued and additional market acceptance of Innatal and Preparent and our ability to attract new customers are key elements to our future success. The market demand for NIPT and carrier screening tests has grown in recent years and is evolving, but this market trend may not continue. Demand for Innatal and Preparent is affected by a number of factors, many of which are beyond our control, including the recommendation of our products by physicians, the timing and development of new products by our competitors, and reimbursement from payors.

Our ability to increase sales of our products and establish greater levels of adoption and reimbursement for our products is uncertain for many reasons, including, among others:

- we may be unable to demonstrate to laboratories, clinics, clinicians, physicians, payors, and patients that our products are superior to alternatives with respect to value, convenience, accuracy, scope of coverage, and other factors;
- third-party coverage and reimbursement are currently primarily limited to high-risk pregnancies and may not gain acceptance for use in the average-risk pregnancy population or for the screening of microdeletions, limiting the overall addressable market;
- third-party payors may set the amounts of reimbursement at prices that reduce our profit margins or do not allow us to cover our expenses;
- we may not be able to maintain and grow effective sales and marketing capabilities;
- our sales and marketing efforts may fail to effectively reach customers or communicate the benefits of our products;
- superior alternatives to our products may be developed and commercialized;
- we may experience supply constraints, including due to the failure of our key suppliers to provide required sequencing instruments and reagents;
- the U.S. Food and Drug Administration, or FDA, may decline to exercise enforcement discretion over laboratory developed tests, or LDTs, and begin asserting regulatory oversight over LDTs and/or may apply a unified, risk-based regulatory framework applicable to all *in vitro* clinical tests, including LDTs; and

- the FDA or other U.S. or foreign regulatory or legislative bodies may adopt new regulations or policies or take other actions that impose significant restrictions on our ability to market our products.

If the market and our market share for our women's health-related NIPT and carrier screening products fail to grow or grow more slowly than expected, our business, operating results, and financial condition would be adversely affected.

We have incurred losses in the past, and we may not be able to achieve or sustain profitability in the future.

In the future, we expect to incur significant costs in connection with the development, approval, and commercialization of enhanced, improved, or new products. Even if we succeed in creating such products from these investments, those innovations still may fail to result in commercially successful products.

Other than revenues from our molecular testing business, we do not expect to generate revenues from other sources in the immediate future. It is possible that we will not generate sufficient revenue from the sale of our products to cover our costs, including research and development expenses related to furthering our product pipeline, and achieve or sustain profitability. Since we or any collaborators or licensees may not successfully develop additional products, obtain required regulatory authorizations, manufacture products at an acceptable cost or with appropriate quality, or successfully market and sell such products with desired margins, our expenses may continue to exceed any revenues we may receive. Our operating expenses also will increase as and if, among other things:

- our earlier-stage product candidates move into later-stage clinical development, which is generally more expensive than early-stage development;
- additional technologies or products are selected for development;
- we pursue development of our molecular tests or other product candidates for new uses;
- we increase the number of patents we are prosecuting or otherwise expend additional resources on patent prosecution or defense; or
- we acquire or in-license additional technologies, product candidates, products, or businesses.

We operate in a highly competitive business environment.

The industries in which we operate are highly competitive and require an ongoing, extensive search for technological innovation. They also require, among other things, the ability to effectively develop, test, commercialize, market, and promote products, including communicating the effectiveness, safety, and value of products to actual and prospective healthcare providers. Other competitive factors in our industries include quality and price, product technology, reputation, customer service, and access to technical information.

Our women's health-related NIPT and carrier screening tests are molecular tests, which are used by obstetricians and gynecologists, maternal fetal medicine specialists, and *in vitro* fertilization specialists. The principal competition for our NIPT and carrier screening tests comes from existing testing methods, technologies, and products, including other molecular NIPT and carrier screening tests offered by our competitors. The molecular testing field is characterized by rapid technological changes, frequent new product introductions, changing customer preferences, emerging competition, evolving industry standards, reimbursement uncertainty, and price competition. Many companies in this market are offering, or may soon offer, products and services that compete with our tests, in some cases at a lower cost than ours, and healthcare providers may choose to recommend the tests of our competitors. Moreover, established, traditional first-line testing prenatal methods, such as serum protein

measurement, where doctors measure certain hormones in the blood, and invasive prenatal diagnostics tests like amniocentesis, have been used for many years and are therefore practices that are difficult to change or supplement. Our conception and pre-implantation genetic screening products face competition from various laboratories that offer or seek to offer similar solutions. We also compete against companies providing hereditary cancer screening tests. For more information on our molecular testing competitors, see "Business—Competition in Molecular Testing."

We expect any of our future precision medicine products to face substantial competition from major pharmaceutical companies, biotechnology companies, academic institutions, government agencies, and public and private research institutions. The larger competitors have substantially greater financial and human resources, as well as a much larger infrastructure than we do. For more information on our precision medicine competitors, see "Business—Competition in Precision Medicine."

Additionally, we compete to acquire the intellectual property assets that we require to continue to develop and broaden our product portfolio. In addition to our in-house research and development efforts, we seek to acquire rights to new intellectual property through corporate acquisitions, asset acquisitions, licensing, and joint venture arrangements. Competitors with greater resources may acquire intellectual property that we seek, and even where we are successful, competition may increase the acquisition price of such intellectual property or prevent us from capitalizing on such acquisitions, licensing opportunities, or joint venture arrangements. If we fail to compete successfully, our growth may be limited.

It is possible that developments by our competitors could make our products or technologies less competitive or obsolete. Our future growth depends, in part, on our ability to provide products which are more effective than those of our competitors and to keep pace with rapid medical and scientific change. Sales of our existing products and any future products may decline rapidly if a new product is introduced by a competitor, particularly if a new product represents a substantial improvement over any of our existing products. In addition, the high level of competition in our industry could force us to reduce the price at which we sell our products or require us to spend more to market our products.

Many of our competitors have greater resources than we have. This enables them, among other things, to spread their marketing and promotion costs over a broader revenue base. In addition, we may not be able to compete effectively against our competitors because their products and services are superior. Our current and future competitors could have greater experience, technological and financial resources, stronger business relationships, broader product lines and greater name recognition than us, and we may not be able to compete effectively against them. Increased competition is likely to result in pricing pressures, which could harm our revenues, operating income, or market share. If we are unable to compete successfully, we may be unable to increase or sustain our revenues or achieve or sustain profitability.

Our success depends on our ability to improve and enhance our current products and new product candidates, which is complex and costly and the results are uncertain.

Effective execution of research and development activities and the timely introduction of enhanced, improved, or new products and product candidates to the market are important elements of our business strategy. However, the development of enhanced, improved, or new products and product candidates is complex, costly, and uncertain and requires us to, among other factors, accurately anticipate patients', clinicians', and payors' needs, and emerging technology trends. For more information on our current research and development efforts, see "Business—Our Research and Development Activities."

In the development of enhanced, improved, or new products and product candidates, we can provide no assurance that:

- we will develop any products that meet our desired target product profile and address the relevant clinical need or commercial opportunity;
- any products that we develop will prove to be effective in clinical trials, platform validations, or otherwise;
- we will obtain necessary regulatory authorizations, in a timely manner or at all;
- any products that we develop will be successfully marketed to and ordered by healthcare providers;
- any products that we develop will be produced at an acceptable cost and with appropriate quality;
- our current or future competitors will not introduce products similar to ours that have superior performance, lower prices, or other characteristics that cause healthcare providers to recommend, and consumers to choose, such competitive products over ours; or
- third parties do not or will not hold patents in any key jurisdictions that would be infringed by our products.

These and other factors beyond our control could delay our launch of enhanced, improved, or new products and product candidates.

The research and development process in our industries generally requires a significant amount of time from the research and design stage through commercialization. The launch of such new products requires the completion of certain clinical development and/or assay validations in the commercial laboratory. This process is conducted in various stages, and each stage presents the risk that we will not achieve our goals. We may not be able to complete clinical development for any planned product in a timely manner. Such development and/or validation failures could prevent or significantly delay our ability to obtain FDA clearance or approval as may be necessary or desired, obtain approval by entities that provide oversight over LDTs, such as the State of New York, or launch any of our planned products and product candidates. At times, it may be necessary for us to abandon a product in which we have invested substantial resources. Without the timely introduction of new product candidates and improvements or enhancements of our current products, our products may become obsolete over time and our competitors may develop products that are more competitive, in which case our business, operating results, and financial condition will be harmed.

We are still developing our precision medicine platform and to date have generated no precision medicine products or product revenue. There can be no assurance that we will develop any precision medicine products that deliver diagnostic or therapeutic solutions, or, if developed, that such product candidates will be authorized for marketing by regulatory authorities, or will be commercially successful. This uncertainty makes it difficult to assess our future prospects and financial results.

Our operations with respect to our precision medicine platform to date have been limited to developing our platform technology, undertaking pre-clinical studies and clinical trials, and conducting research to identify potential product candidates. To date, we have only conducted clinical trials to evaluate whether our platform technology enables identification of the location of our ingestible medical device, which we refer to as an ingestible capsule, within the gastrointestinal tract.

We seek to develop a suite of ingestible capsules for both diagnostic and therapeutic solutions. However, medical device and related diagnostic and therapeutic product development is a highly speculative undertaking and involves a substantial degree of uncertainty. Our precision medicine platform has not

yet demonstrated an ability to generate revenue or successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields such as ours. Consequently, the ability to accurately assess the future operating results or business prospects of our precision medicine platform is significantly more limited than if we had an operating history or approved commercial precision medicine products. Our success in developing commercial products that are based on our precision medicine platform will depend on a variety of factors, many of which are beyond our control, including, but not limited to:

- the outcomes from our product development efforts;
- competition from existing products or new products;
- the timing of regulatory review and our ability to obtain regulatory marketing authorizations of our product candidates;
- potential side effects of our product candidates that could delay or prevent receipt of marketing authorizations or cause an approved or cleared product to be taken off the market; and
- the ability of third-party manufacturers to manufacture our product candidates in accordance with current good manufacturing practices, or cGMP, for the conduct of clinical trials and, if approved or cleared, for successful commercialization.

Even if we are able to develop one or more commercial precision medicine products, we expect that the operating results of these products will fluctuate significantly from period to period due to the factors above and a variety of other factors, many of which are beyond our control, including, but not limited to:

- the entry of products that compete with our products;
- market acceptance of our product candidates, if approved or cleared;
- our ability to establish and maintain an effective sales and marketing infrastructure for our products;
- the ability of patients or healthcare providers to obtain coverage or sufficient reimbursement for our products;
- our ability, as well as the ability of any third-party collaborators, to obtain, maintain and enforce intellectual property rights covering our products, product candidates and technologies, and our ability to develop, manufacture and commercialize our products, product candidates, and technologies without infringing on the intellectual property rights of others; and
- our ability to attract and retain key personnel with the appropriate expertise and experience to manage our business effectively.

Accordingly, the likelihood of the success of our precision medicine platform must be evaluated in light of these many potential challenges and variables.

The development of new product candidates will require us to undertake clinical trials, which are costly, time-consuming, and subject to a number of risks.

The development of new product candidates, including development of the data necessary to obtain clearance or approval for such product candidates, is costly, time-consuming, and carries with it the risk of not yielding the desired results. The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of clinical trials do not necessarily predict success in future clinical trials. Many companies in the pharmaceutical and biotechnology

industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier development, and we could face similar setbacks. The design of a clinical trial can determine whether its results will support a product candidate's marketing authorization, to the extent required, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing authorization for the product candidates. Furthermore, limited results from earlier-stage studies may not predict results from studies in larger numbers of subjects drawn from more diverse populations over a longer period of time. Unfavorable results from ongoing preclinical studies and clinical trials could result in delays, modifications, or abandonment of ongoing or future analytical or clinical trials, or abandonment of a product development program, or may delay, limit, or prevent marketing authorizations, where required, or commercialization of our product candidates. Even if we, or our collaborators, believe that the results of clinical trials for our product candidates warrant marketing authorization, the FDA and other regulatory authorities may disagree and may not grant marketing authorizations for our product candidates.

Moreover, the FDA requires us to comply with regulatory standards, commonly referred to as the Good Clinical Practice, or GCP, requirements, for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, safety, and welfare of trial participants are protected. Other countries' regulatory agencies also have requirements for clinical trials with which we must comply. We also are required to register certain ongoing clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, enforcement action, adverse publicity, and civil and criminal sanctions.

The initiation and completion of any clinical studies may be prevented, delayed, or halted for numerous reasons. We may experience delays in our ongoing clinical trials for a number of reasons, which could adversely affect the costs, timing or successful completion of our clinical trials, including related to the following:

- we may be required to submit an investigational device exemption, or IDE, application to the FDA with respect to our medical device product candidates, which must become effective prior to commencing certain human clinical trials of medical devices, and the FDA may reject our IDE application and notify us that we may not begin clinical trials;
- regulators and other comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical trials;
- regulators and/or institutional review boards, or IRBs, or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site;
- we may not reach agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of subjects or patients required for clinical trials may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate;

- our third-party contractors, including those manufacturing products or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical trials for various reasons, including a finding that the subjects are being exposed to unacceptable health risks;
- we may have to amend clinical trial protocols or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to submit to an IRB and/or regulatory authorities for re-examination;
- regulators, IRBs, or other parties may require or recommend that we or our investigators suspend or terminate clinical research for various reasons, including safety signals or noncompliance with regulatory requirements;
- the cost of clinical trials may be greater than we anticipate;
- clinical sites may not adhere to the clinical protocol or may drop out of a clinical trial;
- we may be unable to recruit a sufficient number of clinical trial sites;
- regulators, IRBs, or other reviewing bodies may fail to approve or subsequently find fault with our manufacturing processes or facilities of third-party manufacturers with which we enter into agreement for clinical and commercial supplies, the supply of devices or other materials necessary to conduct clinical trials may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply;
- marketing authorization policies or regulations of the FDA or applicable foreign regulatory agencies may change in a manner rendering our clinical data insufficient for authorization; and
- our products may have undesirable side effects or other unexpected characteristics.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting, or completing our planned and ongoing clinical trials.

Any of these occurrences may significantly harm our business, financial condition, and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Patient enrollment in clinical trials and completion of patient follow-up depend on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, patient compliance, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product being studied in relation to other available therapies, including any new treatments that may be approved for the indications we are investigating. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and efficacy of a product candidate, or they may be persuaded to participate in contemporaneous clinical trials of a competitor's product candidate. In addition, patients participating in our clinical trials may drop out before completion of the trial or experience adverse medical events unrelated to our products. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may delay commencement or completion of the clinical trial, cause an increase in the costs of the clinical trial and delays, or result in the failure of the clinical trial.

Clinical trials must be also conducted in accordance with the laws and regulations of the FDA and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to

oversight by these governmental agencies and IRBs at the medical institutions where the clinical trials are conducted. We rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance. We depend on our collaborators and on medical institutions and CROs to conduct our clinical trials in compliance with the FDA's GCP requirements. To the extent our collaborators or the CROs fail to enroll participants for our clinical trials, fail to conduct the study to GCP requirements, or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays, or both. In addition, clinical trials that are conducted in countries outside the United States may subject us to further delays and expenses as a result of increased shipment costs, additional regulatory requirements and the engagement of non-U.S. CROs, as well as expose us to risks associated with clinical investigators who are unknown to the FDA, and different standards of diagnosis, screening and medical care.

The clinical trial process is lengthy and expensive with uncertain outcomes. We have limited data and experience regarding the safety and efficacy of our products. Results of earlier studies may not be predictive of future clinical trial results, or the safety or efficacy profile for such products.

Clinical testing is difficult to design and implement, can take many years, can be expensive, and carries uncertain outcomes. The results of preclinical studies and clinical trials of our products conducted to date and ongoing or future studies and trials of our current, planned, or future products and product candidates may not be predictive of the results of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Our interpretation of data and results from our clinical trials do not ensure that we will achieve similar results in future clinical trials. In addition, preclinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their products performed satisfactorily in preclinical studies and earlier clinical trials have nonetheless failed to replicate results in later clinical trials. Products in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and earlier clinical trials. Failure can occur at any stage of clinical testing. Our clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and non-clinical testing in addition to those we have planned.

Interim "top-line" and preliminary data from studies or trials that we announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim "top-line" or preliminary data from preclinical studies or clinical trials. Interim data are subject to the risk that one or more of the outcomes may materially change as more data become available. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Preliminary or "top-line" data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Additionally, interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could seriously harm our business.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we

choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed significant by you or others with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the top-line data that we report differ from final results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain marketing authorization for, and commercialize, product candidates may be harmed, which could seriously harm our business.

The results of our clinical trials may not support the use of our tests and other product candidates, or may not be replicated in later studies required for marketing authorizations.

As the healthcare reimbursement system in the United States evolves to place greater emphasis on comparative effectiveness and outcomes data, we cannot predict whether we will have sufficient data, or whether the data we have will be presented to the satisfaction of any payors seeking such data for determining coverage for our tests, particularly in the average-risk pregnancy population for which such data is expected to be of particular interest, in new test areas such as preeclampsia, or in precision medicine diagnostic or therapeutic applications.

The administration of clinical and economic utility studies is expensive and demands significant attention from certain members of our management team. Data collected from these studies may not be positive or consistent with our existing data, or may not be statistically significant or compelling to the medical community or payors. If the results obtained from our ongoing or future studies are inconsistent with certain results obtained from our previous studies, adoption of our products would suffer and our business would be harmed.

Peer-reviewed publications regarding our products and product candidates may be limited by many factors, including delays in the completion of, poor design of, or lack of compelling data from clinical studies, as well as delays in the review, acceptance, and publication process. If our products or product candidates or the technology underlying our current or future products or product candidates do not receive sufficient favorable exposure in peer-reviewed publications, or are not published, the rate of healthcare provider adoption of our tests and positive reimbursement coverage decisions for our tests and other products could be negatively affected. The publication of clinical data in peer-reviewed journals can be a crucial step in commercializing and obtaining reimbursement for tests, diagnostic and therapeutic products and other products, and our inability to control when, if ever, results are published may delay or limit our ability to derive sufficient revenues from any test, diagnostic or therapeutic product that is the subject of a study. The performance achieved in published studies may not be repeated in later studies that may be required to obtain FDA clearance or marketing authorizations should we decide for business reasons, or be required to submit applications to the FDA or other health authorities seeking such authorizations.

Operating our business will require a significant amount of cash, and our ability to generate sufficient cash depends on many factors, some of which are beyond our control. We expect to need to raise additional capital after this offering, and if we cannot raise additional capital when needed, we may have to curtail or cease operations.

In the future, we expect to incur significant costs in connection with our operations, including but not limited to the development, marketing authorization, and commercialization of new tests, medical devices, therapeutics, and other products. These development activities generally require a substantial investment before we can determine commercial viability, and the proceeds of this offering will not be sufficient to fully fund these activities. We expect to need to raise additional funds through public or private equity or debt financings, collaborations or licensing arrangements to continue to fund or expand our operations.

Our actual liquidity and capital funding requirements will depend on numerous factors, including:

- the scope and duration of and expenditures associated with our discovery efforts and research and development programs, including for our precision medicine platform;
- the costs to fund our commercialization strategies for any product candidates for which we receive marketing authorization or otherwise launch and to prepare for potential product marketing authorizations, as required;
- the costs of any acquisitions of complementary businesses or technologies that we may pursue;
- potential licensing or partnering transactions, if any;
- our facilities expenses, which will vary depending on the time and terms of any facility lease or sublease we may enter into, and other operating expenses;
- the scope and extent of the expansion of our sales and marketing efforts;
- the settlement or other resolution of the government investigation described below, potential litigation, and other contingencies;
- the commercial success of our products;
- our ability to obtain more extensive coverage and reimbursement for our tests and therapeutic products, if any, including in the general, average-risk patient population; and
- our ability to collect our accounts receivable.

The availability of additional capital, whether from private capital sources (including banks) or the public capital markets, fluctuates as our financial condition and market conditions in general change. There may be times when the private capital sources and the public capital markets lack sufficient liquidity or when our securities cannot be sold at attractive prices, or at all, in which case we would not be able to access capital from these sources. In addition, a weakening of our financial condition or deterioration in our credit ratings could adversely affect our ability to obtain necessary funds. Even if available, additional financing could be costly or have adverse consequences.

Additional capital, if needed, may not be available on satisfactory terms or at all. Furthermore, any additional capital raised through the sale of equity or equity-linked securities will dilute our stockholders' ownership interests and may have an adverse effect on the price of our common stock. In addition, the terms of any financing may adversely affect stockholders' holdings or rights. Debt financing, if available, may include restrictive covenants. To the extent that we raise additional funds through collaborations and licensing arrangements, it may be necessary to relinquish some rights to our technologies or grant licenses on terms that may not be favorable to us.

If we are not able to obtain adequate funding when needed, we may be required to delay development programs or sales and marketing initiatives. If we are unable to raise additional capital in sufficient amounts or on satisfactory terms, we may have to make reductions in our workforce and may be prevented from continuing our discovery, development, and commercialization efforts and exploiting other corporate opportunities. In addition, it may be necessary to work with a partner on one or more of our tests or products under development, which could lower the economic value of those products to us. Each of the foregoing may harm our business, operating results, and financial condition, and may impact our ability to continue as a going concern.

Our outstanding debt may impair our financial and operating flexibility.

As of December 31, 2019 and March 31, 2020, we had approximately $72.3 million and $71.8 million of outstanding indebtedness, respectively, composed of mortgages payable and a note payable. Certain of

our debt agreements contain various restrictive covenants and are secured by substantially all of our assets, excluding our intellectual property.

Our existing debt permits us to incur significant additional debt. Our existing debt and any additional debt we incur could:

- make it more difficult for us to satisfy our obligations under our existing debt instruments;
- increase our vulnerability to general adverse economic and industry conditions;
- limit our ability to obtain additional financing to fund our research, development, and commercialization activities, particularly when the availability of financing in the capital markets is limited;
- require a substantial portion of our cash flows from operations for the payment of principal and interest on our debt, reducing our ability to use our cash flows to fund working capital, research and development, and other general corporate requirements;
- limit our flexibility in planning for, or reacting to, changes in our business and the industries in which we operate; and
- place us at a competitive disadvantage to less leveraged competitors or competitors with a lower cost of capital.

Our ability to make principal and interest payments will depend on our ability to generate cash in the future. If we do not generate sufficient cash to meet our debt service requirements and other operating requirements, we may need to seek additional financing. In that case, it may be more difficult, or we may be unable, to obtain financing on terms that are acceptable to us or at all.

Although we have implemented compliance policies and have an internal audit function, we cannot ensure that our employees will fully adhere to such policies.

We have implemented compliance policies and procedures intended to train and monitor our sales, billing, marketing and other personnel. Our efforts to implement appropriate monitoring of such personnel are ongoing and we have experienced situations in which employees may have failed to fully adhere to our policies and applicable laws in the past. There can be no assurance that we will not experience similar issues in the future. Failure by our sales, billing, marketing, or other personnel to follow our policies and comply with applicable laws may subject us to administrative, civil, and criminal actions, penalties, damages, fines, individual imprisonment, exclusion from participation in federal healthcare programs, refunding of payments received by us, and curtailment or cessation of our operations. For additional information regarding an ongoing investigation regarding compliance with certain policies and laws, see “Business—Legal Proceedings.” In addition, commercial third-party payors may refuse to provide all or any reimbursement for tests administered, seek repayment from us of amounts previously reimbursed, and harm our ability to secure network contracts with third-party payors. For additional information regarding recent settlement agreements with commercial payors, see “Business—Reimbursement—Commercial Third-Party Payors.” Any of the foregoing could adversely affect our revenue, cash flow, and financial condition, and reduce our growth prospects. For additional information regarding these risks, see the risk factor titled “If we or our commercial partners act in a manner that violates healthcare laws or otherwise engage in misconduct, we could face substantial penalties and damage to our reputation, and our business operations and financial condition could be adversely affected.”

Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, results of operations, and financial condition.

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal, and foreign laws, requirements, and regulations governing the collection, use, disclosure,

retention, and security of personal information. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer, use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations, and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulations, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our operations, financial performance and business.

As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. In the United States, the manner in which we collect, use, access, disclose, transmit and store protected health information, or PHI, is subject to the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and the health data privacy, security and breach notification regulations issued pursuant to these statutes.

HIPAA establishes a set of national privacy and security standards for the protection of PHI, by health plans, healthcare clearinghouses, and certain healthcare providers, referred to as covered entities, and the business associates with whom such covered entities contract for services that involve the use or disclosure of PHI. HIPAA requires healthcare providers like us to develop and maintain policies and procedures with respect to PHI that is used or disclosed, including the adoption of administrative, physical, and technical safeguards to protect such information.

HIPAA further requires covered entities to notify affected individuals “without unreasonable delay and in no case later than 60 calendar days after discovery of the breach” if their unsecured PHI is subject to an unauthorized access, use or disclosure. If a breach affects 500 patients or more, covered entities must report it to the U.S. Department of Health and Human Services, or HHS, and local media without unreasonable delay (and in no case later than 60 days after discovery of the breach), and HHS will post the name of the entity on its public website. If a breach affects fewer than 500 individuals, the covered entity must log it and notify HHS at least annually. HIPAA also implemented the use of standard transaction code sets and standard identifiers that covered entities must use when submitting or receiving certain electronic healthcare transactions, including activities associated with the billing and collection of healthcare claims.

Penalties for failure to comply with a requirement of HIPAA and HITECH vary significantly depending on the failure and could include requiring corrective actions, and/or imposing civil monetary or criminal penalties. HIPAA also authorizes state attorneys general to file suit under HIPAA on behalf of state residents. Courts can award damages, costs and attorneys’ fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to sue us in civil court for HIPAA violations, its standards have been used as the basis for a duty of care claim in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI.

Certain states have also adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. In addition, California enacted the California Consumer Privacy Act, or CCPA, on June 28, 2018, which went into effect on January 1, 2020. The CCPA creates individual

privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal data. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability, and many similar laws have been proposed at the federal level and proposed or enacted in other states. Any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

In Europe, the European Union General Data Protection Regulation (2016/679), or the GDPR, went into effect in May 2018 and introduces strict requirements for processing the personal data of European Union data subjects. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. Moreover, the United Kingdom leaving the European Union could also lead to further legislative and regulatory changes. It remains unclear how the United Kingdom data protection laws or regulations will develop in the medium to longer term and how data transfer to the United Kingdom from the European Union will be regulated, especially following the United Kingdom's departure from the European Union on January 31, 2020 without a deal. However, the United Kingdom has transposed the GDPR into domestic law with the Data Protection Act 2018, which remains in force following the United Kingdom's departure from the European Union. In addition to the GDPR, individual countries in Europe, and elsewhere in the world, including but not limited to Brazil, have enacted similar data privacy legislation that applies to data subjects in those countries. This legislation imposes increased compliance obligations and regulatory risk, including the potential for significant fines for noncompliance.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, CROs, collaborators, or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation, and adversely affect our business and results of operations.

Security breaches, loss of data, and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and reputation.

In the ordinary course of our business, we collect and store sensitive data, including PHI (such as patient medical records, including test results), and personally identifiable information. We also store business and financial information, intellectual property, research and development information, trade secrets and other proprietary and business critical information, including that of our customers, payors, and collaboration partners. We manage and maintain our data utilizing a combination of on-site systems, managed data center systems and cloud-based data center systems. We are highly dependent on information technology networks and systems, including the internet, to securely process, transmit, and store critical information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure, and that of our third-party billing and collections provider and other service providers, may be vulnerable to attacks by hackers, viruses, disruptions and breaches due to employee error or malfeasance.

A security breach or privacy violation that leads to unauthorized access, disclosure or modification of, or prevents access to, patient information, including PHI, could compel us to comply with state and federal breach notification laws, subject us to mandatory corrective action and require us to verify the

correctness of database contents. Such a breach or violation also could result in legal claims or proceedings brought by a private party or a governmental authority, liability under laws and regulations that protect the privacy of personal information, such as HIPAA, HITECH, and laws and regulations of various U.S. states and foreign countries, as well as penalties imposed by the Payment Card Industry Security Standards Council for violations of the Payment Card Industry Data Security Standards. If we are unable to prevent such security breaches or privacy violations or implement satisfactory remedial measures, we may suffer loss of reputation, financial loss and civil or criminal fines or other penalties because of lost or misappropriated information. In addition, these breaches and other forms of inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above.

Unauthorized access, loss or dissemination of information could disrupt our operations, including our ability to perform tests, provide test results, bill payors or patients, process claims and appeals, provide customer assistance services, conduct research and development activities, develop and commercialize tests, collect, process and prepare company financial information, provide information about our tests, educate patients and healthcare providers about our service, and manage the administrative aspects of our business, any of which could damage our reputation and adversely affect our business. Any breach could also result in the compromise of our trade secrets and other proprietary information, which could adversely affect our competitive position.

In addition, health-related, privacy, and data protection laws and regulations in the United States and elsewhere are subject to interpretation and enforcement by various governmental authorities and courts, resulting in complex compliance issues and the potential for varying or even conflicting interpretations, particularly as laws and regulations in this area are in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business and our reputation. Complying with these laws could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business, operating results, and financial condition.

Any failure or perceived failure by us or any third-party collaborators, service providers, contractors or consultants to comply with our privacy, confidentiality, data security or similar obligations, or any data security incidents or other security breaches that result in the accidental, unlawful or unauthorized access to, use of, release of, processing of, or transfer of sensitive information, including personally identifiable information, may result in negative publicity, harm to our reputation, governmental investigations, enforcement actions, regulatory fines, litigation or public statements against us, could cause third parties to lose trust in us or could result in claims by third parties, including those that assert that we have breached our privacy, confidentiality, data security or similar obligations, any of which could have a material adverse effect on our reputation, business, financial condition or results of operations. We could be subject to fines and penalties (including civil and criminal) under HIPAA for any failure by us or our business associates to comply with HIPAA's requirements. Moreover, data security incidents and other security breaches can be difficult to detect, and any delay in identifying them may lead to increased harm. While we have implemented data security measures intended to protect our information, data, information technology systems, applications and infrastructure, and recently hired a Chief Information Officer to supervise such measures, there can be no assurance that such measures will successfully prevent service interruptions or data security incidents.

We have increased the size of our organization and expect to further increase it in the future, and we may experience difficulties in managing this growth. If we are unable to manage the anticipated growth of our business, our future revenue and operating results may be adversely affected.

As of June 1, 2020, we had 674 full-time employees worldwide. We have significantly expanded the size of our organization over the past several years, particularly personnel within our sales and marketing

and research and development groups, and we expect to continue to do so in the future. As we transition into operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial, and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining, and motivating additional employees;
- managing our internal development efforts effectively, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial, and management controls, reporting systems, and procedures.

Our future financial performance and our ability to successfully develop, market, and sell our products and product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We are engaged in extensive research and development activities, including innovation within our molecular testing business as well as furthering our novel pipeline of precision medicine product candidates. Conducting these activities will entail significant organizational complexity and require extensive effort on the part of our personnel. If we are unable to execute on our operational goals it would have a material and adverse effect on our business, financial condition, results of operations, and prospects.

If we lose the services of members of our senior management team or other key employees, we may not be able to execute our business strategy.

Our success depends in large part upon the continued service of our senior management team and certain other key employees who are important to our vision, strategic direction, and culture. Our current long-term business strategy was developed in large part by our senior management team and depends in part on their skills and knowledge to implement. We may not be able to offset the impact on our business of the loss of the services of any member of our senior management or other key officers or employees or attract additional talent. The loss of any members of our senior management team or other key employees could have a material and adverse effect on our business, operating results, and financial condition.

An inability to attract and retain highly skilled employees could adversely affect our business.

To execute our business plan, we must attract and retain highly qualified personnel. Competition for qualified personnel is intense, especially for sales, scientific, medical, laboratory, and technical personnel and especially in the areas where our headquarters and laboratory facilities are located. We have from time to time experienced, and we expect to continue to experience, difficulty in hiring and retaining employees with appropriate qualifications. Many of the companies with which we compete for experienced personnel have greater resources than we have. If we hire employees from competitors or other companies, their former employers may attempt to assert that these employees have breached their legal obligations to their former employees, resulting in a diversion of our time and resources. In addition, job candidates and existing employees often consider the value of the stock awards they receive in connection with their employment. If the perceived value of our stock awards declines, it may adversely affect our ability to attract and retain highly skilled employees. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business, operating results, and financial condition could be adversely affected.

We may not be able to obtain and maintain the third-party relationships that are necessary to develop, commercialize, and manufacture some or all of our product candidates.

We expect to depend on collaborators, partners, licensees, manufacturers, and other third parties to support our product candidate development efforts, to manufacture our product candidates and to market, sell, and distribute any products we successfully develop. Any problems we experience with any of these third parties could delay the development, commercialization, and manufacturing of our product candidates, which could harm our results of operations.

We cannot guarantee that we will be able to successfully negotiate agreements for, or maintain relationships with, collaborators, partners, licensees, manufacturers, and other third parties on favorable terms, if at all. If we are unable to obtain or maintain these agreements, we may not be able to clinically develop, manufacture, obtain regulatory authorizations for, or commercialize any future product candidates, which will in turn adversely affect our business.

We expect to expend substantial management time and effort to enter into relationships with third parties and, if we successfully enter into such relationships, to manage these relationships. In addition, substantial amounts will be paid to third parties in these relationships. However, we cannot control the amount or timing of resources our future contract partners will devote to our research and development programs, product candidates, or potential product candidates, and we cannot guarantee that these parties will fulfill their obligations to us under these arrangements in a timely fashion, if at all. In addition, while we manage the relationships with third parties, we cannot control all of the operations of and protection of intellectual property by such third parties.

We rely on third-party laboratories to perform some of our testing and further rely on third parties for sample collection, including phlebotomy services, and commercial courier delivery services, and if these services are disrupted, our business will be harmed.

A portion of our tests are performed by third-party CLIA certified laboratories. These third-party laboratories are subject to contractual obligations but are not otherwise under our control. We, therefore, do not control the capacity and quality control efforts of these third-party laboratories other than through our ability to enforce contractual obligations on volume and quality systems. In the event of any adverse developments with these third-party laboratories or their ability to perform this testing in accordance with the legal, regulatory, or commercial standards, our ability to provide test results to customers may be delayed, interrupted, or suspended. Any natural or other disasters, pandemics, acts of war or terrorism, shipping embargoes, labor unrest, or political instability or similar events at our third-party laboratories' facilities that cause a loss of testing capacity would heighten the risks that we face. Changes to or termination of our agreements or inability to renew our agreements with these parties or enter into new agreements with other laboratories that are able to perform such testing could impair, delay, or suspend our efforts to market and commercialize our tests. Such interruption could harm our reputation and lead to the loss of customers, and we may be unable to regain those customers in the future. In addition, certain third-party payors may take the position that sending out this testing to third-party laboratories is contrary to the terms of their coverage policies and/or our contract in cases where we are in-network with the payor, and may refuse to pay us for testing that we have outsourced. If any of these events occur, our business, operating results, and financial condition could suffer.

Federal and certain state laws impose anti-markup restrictions that prevent an entity from realizing a profit margin on outsourced testing. Whether we will be able to realize a profit margin on outsourced testing will be determined by the application of those laws. If we or our subsidiaries are unable to markup outsourced testing, our operating results would suffer.

Our molecular testing business depends on our ability to quickly and reliably deliver test results to our customers. We rely on third parties to perform sample collection, including phlebotomy services, and to

transport samples to our laboratory facility or the third-party laboratories that we contract with in a timely and cost-efficient manner. Disruptions in these services, whether due to any natural or other disasters, pandemics, acts of war or terrorism, shipping embargoes, labor unrest, political instability, or similar events, could adversely affect specimen integrity and our ability to process samples in a timely manner and to service our customers, and ultimately our reputation and our business. In addition, if we are unable to continue to obtain expedited delivery services on commercially reasonable terms, our operating results may be adversely affected.

In addition, our relationships with these third-party providers could be scrutinized under federal and state healthcare laws such as the federal Anti-Kickback Statute and the Stark Law to the extent these services provide a financial benefit to or relieve a financial burden for a potential referral source, or are subsequently found not to be for fair market value. If our operations are found to be in violation of any of these laws and regulations, we may be subject to administrative, civil and criminal penalties, damages, fines, individual imprisonment, exclusion from participation in federal healthcare programs, refunding of payments received by us, and curtailment or cessation of our operations, any of which could harm our reputation and adversely affect our business, operating results, and financial condition. For additional information regarding these risks, see the risk factor titled “If we or our commercial partners act in a manner that violates healthcare laws or otherwise engage in misconduct, we could face substantial penalties and damage to our reputation, and our business operations and financial condition could be adversely affected.”

We rely on a limited number of suppliers or, in some cases, single suppliers, for some of our laboratory instruments and materials and may not be able to find replacements or immediately transition to alternative suppliers on a cost-effective basis, or at all.

We source components of our technology from third parties and certain components are sole sourced. Obtaining substitute components may be difficult or require us to re-design our products or, for any product candidates for which we may obtain marketing authorization from the FDA, obtain new marketing authorization from the FDA to use a new supplier. Any natural or other disasters, acts of war or terrorism, shipping embargoes, labor unrest or political instability or similar events at our third-party manufacturers’ facilities that cause a loss of manufacturing capacity or a reduction in the quality of the items manufactured would heighten the risks that we face. Changes to, failure to renew or termination of our existing agreements or our inability to enter into new agreements with other suppliers could result in the loss of access to important components of our tests and could impair, delay or suspend our commercialization efforts. Our failure to maintain a continued and cost-effective supply of high-quality components could materially and adversely harm our business, operating results, and financial condition.

For example, Illumina, Inc., or Illumina, in San Diego, California, is currently the sole supplier of our sequencing instruments and certain reagents for Innatal and Preparent, pursuant to a supply agreement that, unless extended by mutual agreement, expires in June 2022. Without such inputs, we would be unable to run our tests and commercialize our products. In early 2013, prior to our entering into our agreement with Illumina, Illumina completed its acquisition of Verinata Health Inc., or Verinata, a direct competitor in the NIPT market. We understand Illumina supplies the same or similar instruments and related reagents to Verinata. As a result, we face heightened risk and uncertainty regarding our supply relationship with Illumina. If required, alternative sequencing platforms may not perform as well or may be more expensive and we may be unsuccessful employing such platforms in a commercially sustainable way. Any disruptions to our laboratory performance and ability to deliver our products could adversely affect our business, operating results, financial condition, and reputation. In addition, if we were required by the FDA to obtain approval for Innatal or Preparent through a pre-market approval application, or PMA, we may also be required to obtain approval of a PMA supplement prior to making any changes to Innatal or Preparent as a result of implementing an alternative sequencing platform.

The manufacturing of our products, including our precision medicine product candidates, is highly exacting and complex, and we depend on third parties to supply materials and manufacture all our products and product candidates.

Manufacturing is highly exacting and complex due, in part, to strict regulatory requirements governing the manufacture of our current and future products and product candidates, including medical devices, diagnostic products, and pharmaceutical products. We have limited personnel with experience in, and we do not own facilities for, manufacturing any products. We depend upon our collaborators and other third parties, including sole source suppliers, to provide raw materials meeting FDA quality standards and related regulatory requirements, manufacture devices, diagnostic products, and drug substances, produce drug products and provide certain analytical services with respect to our products and product candidates. The FDA and other regulatory authorities require that many of our products be manufactured according to cGMP regulations and that proper procedures be implemented to assure the quality of our sourcing of raw materials and the manufacture of our products. Any failure by us, our collaborators, or our third-party manufacturers to comply with cGMP and/or scale-up manufacturing processes could lead to a delay in, or failure to obtain, marketing authorizations. In addition, such failure could be the basis for action by the FDA, including issuing a warning letter, initiating a product recall or seizure, fines, imposing operating restrictions, total or partial suspension of production or injunctions and/or withdrawing marketing authorizations for products previously granted to us. To the extent we rely on a third-party manufacturer, the risk of noncompliance with cGMPs may be greater and the ability to effect corrective actions for any such noncompliance may be compromised or delayed.

Moreover, we expect that certain of our precision medicine product candidates, including PGN-600, PGN-001, PGN-300, and PGN-OB2, are drug/device combination products that will be regulated under the drug and biological product regulations of the Federal Food, Drug, and Cosmetic Act, or the FD&C Act, and Public Health Service Act, or PHSA, based on their primary modes of action as drugs and biologics. Third-party manufacturers may not be able to comply with cGMP regulations, applicable to drug/device combination products, including applicable provisions of the FDA's drug and biologics cGMP regulations, device cGMP requirements embodied in the Quality System Regulation, or QSR, or similar regulatory requirements outside the United States.

In addition, we or third parties may experience other problems with the manufacturing, quality control, storage or distribution of our products, including equipment breakdown or malfunction, failure to follow specific protocols and procedures, problems with suppliers and the sourcing or delivery of raw materials and other necessary components, problems with software, labor difficulties, and natural disaster-related events or other environmental factors. These problems can lead to increased costs, lost sales, damage to customer relations, failure to supply penalties, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches of products. If problems are not discovered before the product is released to the market, recalls, corrective actions, or product liability-related costs also may be incurred. Problems with respect to the manufacture, storage, or distribution of products could materially disrupt our business and have a material and adverse effect on our operating results and financial condition.

For additional information regarding our third-party suppliers and manufacturers, see "Business—Laboratories—Laboratory Supplies."

We rely on third parties to design our product candidates and conduct our preclinical research and clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

We rely and expect to continue to rely on third parties, such as engineering firms, CROs, clinical data management organizations, medical institutions, and clinical investigators, to conduct and manage our molecular testing and therapeutic product candidate design, preclinical testing, and clinical trials. Our

reliance on these third parties for research and development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with GCP requirements, the general investigational plan, and the protocols established for such trials.

These third parties may be slow to recruit patients and complete the studies. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, do not meet expected deadlines, experience work stoppages, terminate their agreements with us or need to be replaced, or do not conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we may need to enter into new arrangements with alternative third parties, which could be difficult, costly or impossible, and our clinical trials may be extended, delayed, or terminated or may need to be repeated. If any of the foregoing occur, we may not be able to obtain, or may be delayed in obtaining, marketing authorizations for our product candidates and may not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

If our laboratory facilities become inoperable, we will be unable to perform our tests and our business will be harmed.

Our laboratory or other facilities may be harmed or rendered inoperable (or samples could be damaged or destroyed) by natural or manmade disasters, including earthquakes, flooding, power outages, disease outbreaks and contamination, which may render it difficult or impossible for us to perform our tests for some period of time. The inability to perform our tests or the backlog of tests that could develop if any of our laboratory or other facilities is inoperable for even a short period of time may result in the loss of customers or harm to our reputation, and we may be unable to regain those customers in the future.

Our tests may not perform as expected and may result in reduced confidence in our products or legal claims.

Our success depends on the market's confidence that we can provide timely, reliable, high-quality test results. There is no guarantee that the accuracy and reproducibility we have demonstrated to date will continue as our business grows. We believe that our customers (healthcare providers and their patients) are likely to be particularly sensitive to test limitations and errors, including inaccurate test results and the need on occasion to perform redraws on patients. As a result, if our tests do not perform as expected, our business, operating results, financial condition, and reputation will suffer. In addition, we may be subject to legal claims arising from such limitations, errors, or inaccuracies.

Our tests use a number of complex and sophisticated biochemical and bioinformatics processes, many of which are highly sensitive to external factors. An operational or technology failure in one of these complex processes or fluctuations in external variables may result in sensitivity and specificity rates that are lower than we anticipate or that vary between test runs or in a higher than anticipated number of tests which fail to produce results. In addition, we regularly evaluate and refine our testing process. These refinements may initially result in unanticipated issues that may reduce our sensitivity and specificity rates.

Even if our newly developed product candidates receive marketing authorizations, to the extent required, they may fail to achieve market acceptance.

If we can develop enhanced, improved, or new product candidates that receive marketing authorizations, they may nonetheless fail to gain sufficient market acceptance by healthcare providers, patients, third-party payors, and others in the medical community to be commercially successful. The degree of market acceptance of any of our new product candidates following receipt of marketing authorizations, if any, will depend on a number of factors, including:

- our ability to anticipate and meet customer and patient needs;

- the timing of regulatory approvals or clearances, to the extent such are required for marketing;
- the efficacy, safety and other potential advantages, such as convenience and ease of administration, of our product candidates as compared to alternative tests or treatments;
- the clinical indications for which our product candidates are approved or cleared, or in the case of our LDTs, validated;
- concordance with clinical guidelines established by relevant professional colleges;
- compliance with state guidelines and licensure, if applicable;
- our ability to offer our product candidates for sale at competitive prices;
- the willingness of the target patient population to try our new products, and of physicians to prescribe these products;
- the strength of our marketing and distribution support;
- the availability and requirements of third-party payor insurance coverage and adequate reimbursement for our product candidates;
- the prevalence and severity of side effects and the overall safety profiles of our product candidates;
- any restrictions on the use of our product candidates together with other products and medications;
- our ability to manufacture quality products in an economic and timely manner;
- interactions of our product candidates with other medications patients are taking; and
- for ingestible product candidates, the ability of patients to take and tolerate our product candidates.

If our newly developed product candidates are unable to achieve market acceptance, our business, operating results, and financial condition will be harmed.

Additional time may be required to obtain marketing authorizations for certain of our precision medicine product candidates because they are combination products.

Some of our precision medicine product candidates are drug/device combination products that require coordination within the FDA and similar foreign regulatory agencies for review of their device and drug components. Although the FDA and similar foreign regulatory agencies have systems in place for the review and approval of combination products such as ours, we may experience delays in the development and commercialization of our product candidates due to regulatory timing constraints and uncertainties in the product development and approval process.

Our precision medicine product candidates under development include complex medical devices that, if authorized for marketing, will require training for qualified personnel and care for data analysis.

Our precision medicine product candidates under development include complex medical devices that, if authorized for marketing, will require training for qualified personnel, including physicians, and care for data analysis. Although we will be required to ensure that our precision medicine product candidates are prescribed only by trained professionals, the potential for misuse of our precision medicine product candidates, if authorized for marketing, still exists due to their complexity. Such misuse could result in adverse medical consequences for patients that could damage our reputation, subject us to costly product liability litigation, and otherwise have a material and adverse effect on our business, operating results, and financial condition.

The successful discovery, development, manufacturing, and sale of biologics is a long, expensive, and uncertain process and carries unique risks and uncertainties. Moreover, even if successful, our biologic products may be subject to competition from biosimilars.

We may develop product candidates regulated as biologics in the future in connection with our precision medicine platform. The successful development, manufacturing, and sale of biologics is a long, expensive, and uncertain process. There are unique risks and uncertainties with biologics. For example, access to and supply of necessary biological materials, such as cell lines, may be limited and governmental regulations restrict access to and regulate the transport and use of such materials. In addition, the testing, development, approval, manufacturing, distribution, and sale of biologics is subject to applicable provisions of the FD&C Act, PHSA, and regulations issued thereunder that are often more complex and extensive than the regulations applicable to other pharmaceutical products, to medical devices, or to the LDTs we currently commercialize. Manufacturing biologics, especially in large quantities, is often complicated and may require the use of innovative technologies. Such manufacturing also requires facilities specifically designed and validated for this purpose and sophisticated quality assurance and quality control procedures. Biologics are also frequently costly to manufacture because production inputs are derived from living animal or plant material, and some biologics cannot be made synthetically. Failure to successfully discover, develop, manufacture, and sell biologics could adversely impact our business, operating results, and financial condition.

Even if we are able to successfully develop biologics in the future, the Biologics Price Competition and Innovation Act, or BPCIA, created a framework for the approval of biosimilars in the United States that could allow competitors to reference data from any future biologic products for which we receive marketing approvals and otherwise increase the risk that any product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the original biologic was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full Biologics License Application, or BLA, for the competing product containing the sponsor's own pre-clinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of their product. The BPCIA is complex and is still being interpreted and implemented by the FDA. As a result, the law's ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement the BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological product candidates.

In addition, there is a risk that any of our product candidates regulated as a biologic and licensed under a BLA would not qualify for the 12-year period of exclusivity or that this exclusivity could be shortened due to congressional action or otherwise, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have been the subject of litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

In Europe, the European Commission has granted marketing authorizations for several biosimilars pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued over the past few years. In addition, companies are developing biosimilars in other countries that could compete with any biologic products that we develop. If competitors are able to obtain marketing approval for biosimilars referencing any biologic products that we develop, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences. Expiration

or successful challenge of our applicable patent rights could also trigger competition from other products, assuming any relevant exclusivity period has expired. As a result, we could face more litigation and administrative proceedings with respect to the validity and/or scope of patents relating to our biologic products.

If our future pharmaceutical product candidates are not approved by regulatory authorities, including the FDA, we will be unable to commercialize them.

In the future, we may develop pharmaceutical product candidates using our precision medicine platform that require FDA approval of a New Drug Application, or NDA, or a BLA before marketing or sale in the United States. In the NDA or BLA process, we, or our collaborative partners, must provide the FDA and similar foreign regulatory authorities with data from preclinical and clinical studies that demonstrate that our product candidates are safe and effective, or in the case of biologics, safe, pure, and potent, for a defined indication before they can be approved for commercial distribution. The FDA or foreign regulatory authorities may disagree with our clinical trial designs and our interpretation of data from preclinical studies and clinical trials. The processes by which regulatory approvals are obtained from the FDA and foreign regulatory authorities to market and sell a new product are complex, require a number of years, depend upon the type, complexity, and novelty of the product candidate, and involve the expenditure of substantial resources for research, development, and testing. The FDA and foreign regulatory authorities have substantial discretion in the drug approval process and may require us to conduct additional nonclinical and clinical testing or to perform post-marketing studies. Further, the implementation of new laws and regulations, and revisions to FDA clinical trial design guidance, may lead to increased uncertainty regarding the approvability of new drugs.

Applications for our drug or biologic product candidates could fail to receive regulatory approval for many reasons, including but not limited to the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design, implementation or results of our or our collaborators' clinical trials;
- the FDA or comparable foreign regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics;
- the population studied in the clinical program may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;
- we or our collaborators may be unable to demonstrate to the FDA, or comparable foreign regulatory authorities that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our or our collaborators' interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA, NDA, or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications, or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our or our collaborators' clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market any of our product candidates, which would seriously harm our business. In addition, the FDA may recommend advisory committee meetings for certain new molecular entities, and if warranted, require a Risk Evaluation and Mitigation Strategy, or REMS, to assure that a drug's benefits outweigh its risks. Even if we receive regulatory approval of a product, the approval may limit the indicated uses for which the drug may be marketed or impose significant restrictions or limitations on the use and/or distribution of such product.

In addition, in order to market any pharmaceutical or biological product candidates that we develop in foreign jurisdictions, we, or our collaborative partners, must obtain separate regulatory approvals in each country. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. Conversely, failure to obtain approval in one or more jurisdictions may make approval in other jurisdictions more difficult. These laws, regulations, additional requirements and changes in interpretation could cause non-approval or further delays in the FDA's or other regulatory authorities' review and approval of our and our collaborative partner's product candidates, which would materially harm our business and financial condition and could cause the price of our securities to fall.

The marketing authorization process is expensive, time-consuming, and uncertain, and we may not be able to obtain or maintain authorizations for the commercialization of some or all of our product candidates.

The product candidates associated with our precision medicine platform and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution, export, and import, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by the European Medicines Agency and comparable regulatory authorities in other countries. We have not received authorization to market any of our product candidates from regulatory authorities in any jurisdiction. Failure to obtain marketing authorization for a product candidate will prevent us from commercializing the product candidate.

Securing marketing authorizations may require the submission of extensive preclinical and clinical data and other supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy, or in the case of product candidates regulated as biologics, such product candidate's safety, purity, and potency. Securing regulatory authorization generally requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Our product candidates may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing authorization or prevent or limit commercial use.

The process of obtaining marketing authorizations, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if authorization is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. Changes in marketing authorization policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application we submit, or may decide that our data is insufficient for approval and require additional preclinical, clinical, or other studies. In addition, varying

interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent marketing authorization of a product candidate. Any marketing authorization we or our collaborators ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved medicine not commercially viable.

Accordingly, if we or our collaborators experience delays in obtaining authorization or if we or they fail to obtain authorization of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenue will be materially impaired.

Our products or product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory authorization, limit the commercial profile of an approved label or result in significant negative consequences following marketing approval, if granted.

The use of our current products and precision medicine product candidates could be associated with side effects or adverse events, which can vary in severity (from minor reactions to death) and frequency (infrequent or prevalent). Side effects or adverse events associated with the use of our product candidates may be observed at any time, including in clinical trials or when a product is commercialized. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory authorization by the FDA or other comparable foreign authorities. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects such as toxicity or other safety issues and could require us or our collaboration partners to perform additional studies or halt development or sale of these product candidates or expose us to product liability lawsuits, which would harm our business and financial results. In such an event, we may be required by regulatory agencies to conduct additional animal or human studies regarding the safety and efficacy of our product candidates, which we have not planned or anticipated or our studies could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny or withdraw approval of our product candidates for any or all targeted indications. There can be no assurance that we will resolve any issues related to any product-related adverse events to the satisfaction of the FDA or any other regulatory agency in a timely manner, if ever, which could harm our business, operating results, financial condition and prospects.

Additionally, product quality characteristics have been shown to be sensitive to changes in process conditions, manufacturing techniques, equipment or sites and other such related considerations, hence any manufacturing process changes we implement prior to or after regulatory authorization could impact product safety and efficacy.

Product-related side effects could affect patient recruitment for clinical trials, the ability of enrolled patients to complete our studies or result in potential product liability claims. We currently carry product liability insurance and we are required to maintain product liability insurance pursuant to certain of our license agreements. We believe our product liability insurance coverage is sufficient in light of our current clinical programs; however, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability, or such insurance coverage may not be sufficient to cover all losses. A successful product liability claim or series of claims brought against us could adversely affect our business, operating results, and financial condition. In addition, regardless of merit or eventual outcome, product liability claims may result in impairment of our business reputation, withdrawal of clinical study participants, costs due to related litigation, distraction of management’s attention from our primary business, initiation of investigations by regulators, substantial monetary awards to patients or other claimants, the inability to commercialize our product candidates and decreased demand for our product candidates, if authorized for commercial sale.

Additionally, if one or more of our product candidates receives marketing authorization, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may suspend, limit or withdraw marketing authorizations for such products, or seek an injunction against their manufacture or distribution;
- regulatory authorities may require additional warnings on the label including “boxed” warnings, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to change the way the product is administered or conduct additional clinical trials or post-approval studies;
- we may be required to create a REMS plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers and/or other elements to assure safe use;
- the product may become less competitive;
- we may be subject to fines, injunctions or the imposition of criminal penalties;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of a particular product candidate, if approved, and could significantly harm our business, operating results, financial condition, and prospects.

If we receive marketing authorization, regulatory agencies including the FDA and foreign authorities enforce requirements that we report certain information about adverse medical events. For example, under FDA medical device reporting regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of our device (or any similar future product) were to recur. We may fail to appreciate that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If we fail to investigate and report these events to the FDA within the required timeframes, or at all, the FDA could take enforcement action against us. Any such adverse event involving our products also could result in future corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, including any legal action taken against us, will require us to devote significant time and capital to the matter, distract management from operating our business, and may harm our reputation and financial results.

Our products, including our precision medicine product candidates under development, if authorized for marketing, may be subject to product recalls.

The FDA and similar foreign governmental authorities have the authority to require the recall of certain commercialized products over which they exercise oversight in the event of material deficiencies or defects in design or manufacture or a public health/safety issue. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture or a public health/safety issue. Manufacturers may, under their own initiative, recall a product if any material deficiency is found. The FDA requires that certain recalls of medical devices be reported to the FDA within 10 working days after the recall is initiated. We may initiate voluntary recalls involving our products in the future that we determine do not require us to notify the

FDA. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. In addition, the FDA could bring an enforcement action against us based on our failure to report the recalls when they were conducted. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Once marketed, recalls of any of our products, including our precision medicine products, would divert managerial and financial resources and could have a material and adverse effect on our business, operating results, and financial condition. A future recall announcement could harm our reputation with customers and negatively affect our sales.

Our relationship with Avero Diagnostics may be challenged, and a successful challenge could adversely affect our operating structure.

We provide anatomic and molecular pathology testing through our affiliation with Mattison Pathology, LLP, a Texas limited liability partnership doing business as Avero Diagnostics, located in Lubbock and Irving, Texas. The laws of certain states in which we operate or may operate in the future prohibit non-physician entities from practicing medicine, exercising control over physicians or engaging in certain practices such as fee-splitting with physicians. Although we believe that we have structured our affiliation with Avero Diagnostics to ensure that the physicians maintain exclusive authority regarding the delivery of medical care, there can be no assurance that these laws will be interpreted in a manner consistent with our practices or that other laws or regulations will not be enacted in the future that could have a material and adverse effect on our business, operating results, and financial condition. Regulatory authorities and other parties, including our associated physicians, may assert that, despite the management service agreement and other arrangements through which we operate, we are engaged in the prohibited corporate practice of medicine, and/or that our arrangement with Avero Diagnostics constitutes unlawful fee-splitting. If a corporate practice of medicine or fee-splitting law is interpreted in a manner that is inconsistent with our practices, we would be required to restructure or terminate our relationship with Avero Diagnostics to bring its activities into compliance with such law. A determination of noncompliance, the termination of or failure to successfully restructure this relationship could result in disciplinary action, penalties, damages, fines, and/or a loss of revenue, any of which could have a material and adverse effect on our business, operating results, and financial condition.

Defects or failures associated with our products could lead to recalls or safety alerts and negative publicity.

Manufacturing flaws, component failures, design defects, off-label uses, or inadequate disclosure of product-related information could result in an unsafe condition or the injury or death of a patient. These problems could lead to a recall of, or issuance of a safety alert relating to, our commercialized products, and result in significant costs and negative publicity. A material adverse event involving one of our products could result in reduced market acceptance and demand for all products within that brand, and could harm our reputation and our ability to market our products in the future. In some circumstances, material adverse events arising from or associated with the design, manufacture or marketing of our products could result in among other things, labeling changes reflecting the updated safety information, regulatory requirements to issue communications to prescribers and/or conduct additional studies, or the suspension or delay of regulatory reviews of our applications for new marketing authorizations. We also may undertake a voluntary recall of products, or temporarily shut down production lines based on performance relative to our own internal safety and quality monitoring and testing data. Any of these problems could disrupt our business and have a material and adverse effect on our business, operating results, and financial condition.

We may not comply with laws regulating the protection of the environment and health and human safety.

Our research and development involves, or may in the future involve, the use of hazardous materials and chemicals and certain radioactive materials and related equipment. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of biohazardous materials. Insurance may not provide adequate coverage against potential liabilities, and we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us. Additional federal, state, and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

Our failure to comply with radio frequency regulations could impair our ability to commercially distribute and market our precision medicine product candidates in the applicable country or region.

Our PIL Dx precision medicine product candidate under development includes a wireless radio frequency transmitter and receiver, and is therefore subject to equipment authorization requirements in the United States and elsewhere. In the United States and certain other countries, authorities often require advance clearance of radio frequency devices before they can be sold or marketed in these jurisdictions, subject to limited exceptions. Modifications to our precision medicine product candidate's design and specifications may require new or further marketing authorizations before we are permitted to market and sell modified precision medicine products. If we are unable to obtain any required marketing authorizations from the authorities responsible for the radio frequency regulations, the sale or use of our precision medicine product candidate could be prevented in such countries. Any such action could negatively affect our business, operating results, and financial condition.

The marketing, sale, and use of our products could result in substantial damages arising from product liability or professional liability claims that exceed our insurance coverage and resources.

The marketing, sale and use of our products could lead to product liability claims against us if someone were to allege that our test or other product failed to perform as it was designed, or caused harm to an individual, or if someone were to misinterpret test results. We may be subject to liability for errors in, a misunderstanding of, or inappropriate reliance upon, the information we provide as part of the results generated by our tests. For example, Innatal could provide a low-risk result for a chromosomal abnormality upon which a patient or physician may rely to make a conclusion about the health of the fetus, which may, in fact, have the condition because the Innatal result was a false negative. As another example, Preparent could provide a low-risk result regarding the carrier status of a disorder of an expectant parent upon which a patient or physician may rely to make a conclusion about the health of the fetus, which may, in fact, have the condition because the Preparent result was a false negative. If the resulting baby is born with the condition, the family may file a lawsuit against us claiming product liability or professional liability.

In addition, we may be subject to product liability claims and lawsuits, including potential class actions, alleging that our products have resulted in or could result in an unsafe condition or injury. The product candidates we are developing using our precision medicine platform are designed to be ingested, and there are a number of factors that could result in an unsafe condition or injury to, or death of, a patient with respect to these or other products that we sell. A product liability or professional liability claim could result in substantial damages and be costly and time-consuming for us to defend. Although we maintain product and professional liability insurance, our insurance may not fully protect us from the financial impact of defending against product liability or professional liability claims or any judgments, fines or settlement costs arising out of any such claims. Any product liability or professional liability

claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any product liability or professional liability lawsuit could harm our reputation, result in a cessation of our testing, or cause our partners to terminate existing agreements and potential partners to seek other partners, any of which could adversely impact our business, operating results, and financial condition.

Our operating results may fluctuate significantly, which could adversely impact the value of our common stock.

Our operating results, including our revenues, gross margin, profitability, and cash flows, have varied in the past and may vary significantly in the future, and period-to-period comparisons of our operating results may not be meaningful. Accordingly, our results should not be relied upon as an indication of future performance. Our operating results, including quarterly financial results, may fluctuate as a result of a variety of factors, many of which are outside of our control. Fluctuations in our results may adversely impact the value of our common stock. Factors that may cause fluctuations in our financial results include, without limitation, those listed elsewhere in this "Risk Factors" section. In addition, our results may fluctuate due to the fact that we recognize costs as they are incurred, but there is typically a delay in the related revenue recognition as we record most revenue only upon receipt of payment. Accordingly, to the extent our revenues increase, we may experience increased costs unless and until the related revenues are recognized. In addition, as we increase our internal sales and marketing and research and development efforts, we expect to incur costs in advance of achieving the anticipated benefits of such efforts. We also may face competitive pricing or reimbursement rate pressures, and we may not be able to maintain our sales volume and/or reimbursement rates in the future, which would adversely affect our business, operating results, and financial condition.

We may engage in acquisitions that could disrupt our business, cause dilution to our stockholders, or reduce our financial resources.

We have in the past entered into, and may in the future enter into, transactions to acquire other businesses, products, or technologies. Successful acquisitions require us to correctly identify appropriate acquisition candidates and to integrate acquired products or operations and personnel with our own. Should we make an error in judgment when identifying an acquisition candidate, should the acquired operations not perform as anticipated, or should we fail to successfully integrate acquired technologies, operations, or personnel, we will likely fail to realize the benefits we intended to derive from the acquisition and may suffer other adverse consequences. Acquisitions involve a number of other risks, including:

- we may not be able to make such acquisitions on favorable terms or at all;
- the acquisitions may not strengthen our competitive position, and these transactions may be viewed negatively by customers or investors;
- we may decide to incur debt with debt repayment obligations that we are unable to satisfy or that could otherwise require the use of a significant portion of our cash flow;
- we may decide to issue our common stock or other equity securities to the stockholders of the acquired company, which would reduce the percentage ownership of our existing stockholders;
- we may incur losses resulting from undiscovered liabilities of the acquired business that are not covered by any indemnification we may obtain from the seller;
- the acquisitions may reduce our cash available for operations and other uses;
- the acquisitions may divert of the attention of our management from operating our existing business; and

- the acquisitions may result in charges to earnings in the event of any write-down or write-off of goodwill and other assets recorded in connection with acquisitions.

We cannot predict the number, timing or size of future acquisitions or the effect that any such transactions might have on our business, operating results, and financial condition.

Ethical, legal, and social issues related to the use of genetic information could reduce demand for our tests.

DNA testing, such as testing that is conducted using Innatal, Preparent and our other products, has raised ethical, legal and social issues regarding privacy and the appropriate uses of the resulting information. Governmental authorities could, for social or other purposes, limit or regulate the use of genomic information or genomic testing or prohibit testing for genetic predisposition to certain conditions, particularly for those that have no known cure. Patients may also refuse to use genetic tests even if permissible, for similar reasons; they may also refuse genetic testing due to concerns regarding eligibility for life or other insurance. Ethical and social concerns may also influence U.S. and foreign patent offices and courts with regard to patent protection for technology relevant to our business. Although the Genetic Information Non-discrimination Act has criminalized the disallowance of health insurance on the basis of genetic information, modification or retraction of this federal law could dramatically reduce public demand for genetic testing. These and other ethical, legal and social issues may limit market acceptance of our tests or reduce the potential markets for products enabled by our technology platform, either of which could harm our business, operating results, and financial condition.

We may be significantly impacted by changes in tax laws and regulations or their interpretation.

U.S. and foreign governments continue to review, reform and modify tax laws. Changes in tax laws and regulations could result in material changes to the domestic and foreign taxes that we are required to provide for and pay. In addition, we are subject to regular audits with respect to our various tax returns and processes in the jurisdictions in which we operate. Errors or omissions in tax returns, process failures, or differences in interpretation of tax laws by tax authorities and us may lead to litigation, payments of additional taxes, penalties, and interest. On December 22, 2017, the Tax Cuts and Jobs Act of 2017, or TCJA, was passed into law. The TCJA has given rise to significant one-time and ongoing changes, including but not limited to a federal corporate tax rate decrease to 21% for tax years beginning after December 31, 2017, limitations on interest expense deductions, the immediate expensing of certain capital expenditures, the adoption of elements of a partially territorial tax system, new anti-base erosion provisions, a reduction to the maximum deduction allowed for net operating losses generated in tax years after December 31, 2017 and providing for indefinite carryforwards for losses generated in tax years after December 31, 2017. The legislation is unclear in many respects and could be subject to potential amendments and technical corrections, and will be subject to interpretations and implementing regulations by the Treasury and Internal Revenue Service, any of which could mitigate or increase certain adverse effects of the legislation. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation. Generally, future changes in applicable tax laws and regulations, or their interpretation and application, could have a material and adverse effect on our business, operating results, and financial condition. We urge the purchasers of our common stock in this offering to consult with their legal and tax advisors with respect to such legislation and the potential tax consequences of investing in our common stock.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

As of December 31, 2019, we had net operating loss, or NOL, carryforwards of approximately $173.6 million for federal income tax purposes, and $94.7 million for state income tax purposes. The federal NOLs will be carried forward indefinitely and the state NOLs began expiring in 2019. Utilization of these NOLs depends on many factors, including our future income, which cannot be assured. Some of

these NOLs could expire unused and be unavailable to offset our future income tax liabilities. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50 percentage point change, by value, in its equity ownership by 5% stockholders over a rolling three-year period, the corporation's ability to use its pre-change NOLs and other pre-change tax attributes to offset its post-change income may be limited. If we determine that an ownership change has occurred and our ability to use our historical NOLs is materially limited, it could harm our future operating results by effectively increasing our future tax obligations. In addition, under the TCJA, federal NOLs incurred in 2018 and in future years may be carried forward indefinitely but generally may not be carried back and the deductibility of such NOLs is limited to 80% of taxable income. On March 27, 2020, Congress enacted the Coronavirus Aid, Relief and Economic Security Act, known as the CARES Act, which provides some relief from the limitations on the utilization of NOLs and certain other tax attributes described above. During the three months ended March 31, 2020, we recorded a discrete tax benefit of $37.7 million related to the NOL carryback provisions available under the CARES Act for taxes paid in years 2013, 2014, 2015, and 2017, which we refer to as the CARES Act Tax Benefit. If any tax refund is received that is more than $5.0 million in a single year, along with other civil settlements, damages awards, and tax refunds, we have agreed to pay 65% of all such amounts received to accelerate payments to the government in connection with our proposed government settlement. See "Business—Legal Proceedings—Federal Investigation."

Reimbursement Risks Related to Our Business

If third-party payors do not adequately reimburse for any new products, they might not be purchased or used, which may adversely affect our revenue and profits.

Our future revenues and profitability will depend heavily upon the availability of coverage and adequate reimbursement from governmental and other third-party payors, both in the United States and in foreign markets, for the use of our products, including any potential products such as a test for preeclampsia, precision medicine devices, and pharmaceutical products. Coverage and reimbursement by governmental and commercial third-party payors may depend upon a number of factors, including the determination that the product and its use or administration for a particular patient is:

- a covered benefit;
- safe, effective, and medically necessary;
- appropriate for the specific patient;
- supported by guidelines established by the relevant professional college;
- approved in any states where specific assay approval is necessary;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement approval for a product from each third-party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical, and cost-effectiveness data for the use of our products to each payor. We may not be able to provide data sufficient to satisfy third-party payors that the product should be covered and reimbursed. There is substantial uncertainty whether any particular payor will cover and reimburse the use of any product incorporating new technology. Even when a payor determines that a product is eligible for reimbursement, the payor may impose coverage limitations that preclude payment for some uses that are approved by the FDA or a comparable authority. Moreover, eligibility for coverage does not imply that any product will be reimbursed in all cases or at a rate that allows us to make a profit or even cover our costs. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. In some instances, payment may only be obtained by engaging in lengthy

and costly appeals processes. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower-cost products that are already reimbursed, may be incorporated into existing payments for other products, may reflect budgetary constraints and/or imperfections in Medicare, Medicaid or other data used to calculate these rates. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or by any future relaxation of laws that restrict imports of certain medical products from countries where they may be sold at lower prices than in the United States.

There have been, and we expect that there will continue to be, federal and state proposals to constrain expenditures for medical products, which may affect payments for our products. Governmental and private entities that establish reimbursement policies, including the Centers for Medicare and Medicaid Services, or CMS, frequently change product descriptors, coverage policies, product and service codes, payment methodologies and reimbursement values. Third-party payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and both CMS and other third-party payors may have sufficient market power to demand significant price reductions. Due in part to actions by third-party payors, the healthcare industry is experiencing a trend toward containing or reducing costs through various means, including lowering reimbursement rates, limiting therapeutic class coverage, and negotiating reduced payment schedules with service providers for certain products.

Our inability to promptly obtain coverage and profitable reimbursement rates from third-party payors for our products could have a material and adverse effect on our business, operating results, and financial condition.

We may be unable to expand or maintain third-party payor coverage and reimbursement for our Innatal, Preparent, and other tests or other products.

Our business depends on our ability to obtain or maintain adequate reimbursement coverage from third-party payors. Third-party reimbursement for our testing represents a significant portion of our revenues, and we expect third-party payors such as third-party commercial payors and government healthcare programs to continue to be our most significant sources of payments in the foreseeable future. In particular, we believe that for us to achieve commercial success it will be necessary to gain acceptance from third-party payors for the screening of microdeletions and for use of NIPT in the average-risk pregnancy population, which population represents roughly 80% of the U.S. pregnancy market, and to obtain positive coverage determinations and favorable reimbursement rates from third-party payors for our tests. We did not receive reimbursement for a significant number of Innatal tests for average-risk patients that we performed in the year ended December 31, 2019. In addition, it is to be determined whether and to what extent certain of our other products, including those under development, will be covered or reimbursed. If we are unable to obtain or maintain coverage or adequate reimbursement from, or achieve in-network status with, third-party payors for our existing or future tests or other products, our ability to generate revenues will be limited. For example, healthcare providers may be reluctant to order our tests or other products due to the potential of a substantial cost to the patient if coverage or reimbursement is unavailable or insufficient.

Leading professional societies may recommend alternatives to our tests in average-risk patient populations, which may provide a basis for third-party payors not to cover or reimburse our tests in those populations.

In making coverage determinations, third-party payors often rely on practice guidelines issued by professional societies. The American College of Obstetricians and Gynecologists, or ACOG, has issued updated guidelines recommending informing pregnant women that Non-Invasive Prenatal Screening, or NIPS, is the most sensitive screening option for trisomy 13, trisomy 18, and Down syndrome, as well as of the availability of the expanded use of NIPT to screen for clinically relevant copy number variants, or CNVs, in the context of counseling that includes the risks/benefits and limitations of screening for CNVs.

A CNV is a genetic mutation in which a segment of the genome has been deleted or duplicated, including microdeletions in which a small segment of a chromosome is deleted. The International Society for Prenatal Diagnosis has issued guidelines that are supportive of performing NIPT in average-risk pregnancies, as well as high-risk pregnancies. The American College of Medical Genetics, or ACMG, has also provided support for the use of NIPT in the general population. However, the Society for Maternal Fetal Medicine, or SMFM, has issued guidelines for NIPT stating that, while all pregnant women should be informed of the option to receive NIPT, conventional screening methods, such as traditional serum screening, rather than NIPT, remain the most appropriate choice for first-line screening for average-risk pregnancies. Therefore, while we expect the ACOG and SMFM guidelines to result in an increase in the number of average-risk women who are informed of NIPT and that may request it as a result, not all third-party payors reimburse for NIPT for these average-risk patients.

Currently, Aetna, UnitedHealthcare, and a number of other third-party payors have negative coverage determinations for NIPT in average-risk patient populations, meaning that their policy is not to reimburse for NIPT for patients in the average-risk or general population. The SMFM guidelines also echoed a previous statement from SMFM that routine screening for microdeletions should not be performed. Many third-party payors do not cover microdeletions screening. We have experienced, and may continue to experience, a negative impact on third-party payors' coverage for Innatal for microdeletions, at least until additional validation data on the sensitivity and specificity of our tests becomes available. We may not be able to obtain positive coverage determinations for our tests. If third-party payors do not reimburse for NIPT for average-risk pregnancies or microdeletions in the future, our operating results would be adversely affected, particularly to the extent that we continue to perform large volumes of tests for which third-party payors do not cover.

New reimbursement methodologies applicable to our tests, including new CPT codes, may decrease reimbursement rates from third-party payors.

In the United States, the American Medical Association, or AMA, generally assigns specific billing codes for laboratory tests under a coding system known as Current Procedure Terminology, or CPT, which we and our ordering healthcare providers must use to bill and receive reimbursement for our molecular tests. Once the CPT code is established, CMS establishes payment levels and coverage rules under Medicare while private payors independently establish rates and coverage rules. A CPT code specific to NIPT for aneuploidies was implemented, effective January 1, 2015, and a CPT code for microdeletions was implemented, effective January 1, 2017. CMS has established a pricing benchmark of $802 for aneuploidy and microdeletions testing. However, our microdeletions reimbursement has decreased under this new code because third-party payors are declining to reimburse under this new code or reimbursing at a much lower rate than we had previously received. Furthermore, we cannot guarantee that we will be able to negotiate favorable rates for this code or receive reimbursement at all if we are unable to collect and publish additional data and obtain positive coverage determinations for Innatal for microdeletions. In addition, effective January 1, 2019, the AMA approved the use of a CPT code for expanded carrier screening tests, which may similarly cause reimbursement for our Preparent expanded carrier screening tests to decline. We do not currently have assay-specific CPT codes assigned for all of our tests, and there is a risk that we may not be able to obtain such codes or, if obtained, we may not be able to negotiate favorable rates for such codes.

We currently submit for reimbursement using CPT codes based on the guidance of outside coding experts and legal counsel. There is a risk that the codes we currently submit may be rejected or withdrawn or that third-party payors will seek refunds of amounts that they claim were inappropriately billed based on either the CPT code used, or the number of units billed. In addition, third-party payors may not establish positive coverage policies for our tests or adequately reimburse for any CPT code we may use, or seek recoupment for testing previously performed, which have occurred in the past.

Billing disputes with third-party payors may decrease realized revenue and may lead to requests for recoupment of past amounts paid.

Payors dispute our billing or coding from time to time and we deal with requests for recoupment from third-party payors from time to time in the ordinary course of our business, and we expect these disputes and requests for recoupment to continue. Third-party payors may decide to deny payment or recoup payment for testing that they contend to have been not medically necessary, against their coverage determinations, or for which they have otherwise overpaid, and we may be required to refund reimbursements already received. We have entered into settlement agreements with commercial payors in order to settle claims related to past billing practices that have since been discontinued. For additional information regarding these disputes, see "Business—Reimbursement—Commercial Third-Party Payors." Additionally, the Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act of 2010, or collectively, the ACA, enacted in March 2010, requires providers and suppliers to report and return any overpayments received from government payors under the Medicare and Medicaid programs within 60 days of identification. Failure to identify and return such overpayments exposes the provider or supplier to liability under federal false claims laws. Claims for recoupment also require the time and attention of our management and other key personnel, which can be a distraction from operating our business.

If third-party payors deny payment for testing, reimbursement revenue for our testing could decline. If a third-party payor successfully challenges that payment for prior testing was in breach of contract or otherwise contrary to policy or law, they may recoup payment, which amounts could be significant and would impact our operating results and financial condition, and it may decrease reimbursement going forward. We may also decide to negotiate and settle with a third-party payor in order to resolve an allegation of overpayment. Any of these outcomes, including recoupment or reimbursements, might also require us to restate our financials from a prior period, any of which could have a material and adverse effect on our business, operating results, and financial condition.

"Most favored nation" provisions in contracts with third-party payors may limit potential for revenue growth and may lead to claims for recoupment.

Some of our contracts with third-party payors contain "most favored nation" provisions, pursuant to which we have agreed that we will not bill the third-party payor more than we bill any other third-party payor. These contract provisions limit the amount we are able to charge for our products and can negatively impact revenue. We monitor our billing and claims submissions for compliance with these contractual requirements with third-party payors. If we do not successfully manage compliance with these most favored nation provisions, we may be required to forego revenues from some third-party payors or reduce the amount we bill to each third-party payor with a most favored nation clause in its contract that is violated, which would adversely affect our business, operating results, and financial condition. This situation could also subject us to claims for recoupment, which could ultimately result in an obligation to repay amounts previously earned.

When third-party payors deny coverage, we are often unable to collect from the patient or any other source and risk disputes if we attempt to do so.

If a third-party payor denies coverage, or if the patient has a large deductible or co-insurance amount, it may be difficult for us to collect from the patient, and we may not be successful in doing so. If we are in-network, we are often contractually prohibited from seeking payment from the patient. If we are out-of-network, we are often unable to collect the full amount of a patient's responsibility, despite our good faith efforts to collect. As a result, we cannot always collect the full amount due for our tests when third-party payors deny coverage, cover only a portion of the invoiced amount or the patient has a large deductible, which may cause payors to raise questions regarding our billing policies and patient collection practices. We believe that our billing policies and our patient collection practices are compliant with applicable laws; however, we have in the past received, and we may in the future receive, inquiries

from third-party payors regarding our billing policies and collection practices in these circumstances. While we have addressed these inquiries as and when they have arisen, there is no guarantee that we will be successful in addressing such concerns, and if we are unsuccessful, this may result in a third-party payor deciding to reimburse for our tests at a lower rate or not at all, seeking recoupment of amounts previously paid to us, or bringing legal action to seek reimbursement of previous amounts paid. Any of such occurrences could cause reimbursement revenue for our testing, which constitutes the large majority of our revenue, to decline. Additionally, if we were required to make a repayment, such repayment could be significant, which could have a material and adverse effect on our business, operating results, and financial condition.

Our revenues may be adversely impacted if third-party payors withdraw coverage or provide lower levels of reimbursement due to changing policies, billing complexities or other factors.

We are in-network, or under contract, with some of the third-party payors from whom we receive reimbursement; this means that we have agreements with such third-party payors that govern approval or payment terms. However, these contracts do not guarantee reimbursement for all testing we perform. For example, many third-party payors with whom we have written agreements have policies that state they will not reimburse for use of NIPT for average-risk pregnancies or for the screening of microdeletions, or do not have a policy in place to reimburse for microdeletions screening. In addition, the terms of certain of our agreements require a physician or qualified practitioner's signature on test requisitions or require other controls and procedures prior to conducting a test. In particular, third-party payors have been increasingly requiring prior authorization to be obtained prior to conducting a test as a condition to reimbursing for the test. This has placed a burden on our billing operations as we have to dedicate resources to monitor that these prior authorization requirements are met and to conduct follow-up and address issues as they arise, and has also impacted our operating results, including our gross margins, since these requirements began to take effect in 2017. To the extent we or the healthcare providers ordering our tests do not follow the prior authorization requirements, we may be subject to claims for recoupment of reimbursement amounts previously paid to us, or may not receive some or all of the reimbursement payments to which we would otherwise be entitled. This has occurred in some cases in the past and may occur in the future, which could have a material and adverse effect on our business, operating results, and financial condition.

Where we are considered to be an out-of-network provider, which is the case with some of the largest third-party payors from whom we currently receive reimbursement, such third-party payors could withdraw coverage and decline to reimburse for our tests in the future, for any reason. They can also impose prior authorization requirements through the terms of the patients' health plans. Managing reimbursement on a case-by-case basis is time-consuming and contributes to an increase in the number of days it takes us to collect on accounts, which also increases our risk of non-payment. Negotiating reimbursement on a case-by-case basis also typically results in the receipt of reimbursement at a significant discount to the list price of our tests.

Even if we are being reimbursed for our tests, third-party payors may unilaterally review and adjust the rate of reimbursement, require co-payments from patients or stop paying for our tests. Government healthcare programs and other third-party payors continue to increase their efforts to control the cost, utilization, and delivery of healthcare services by demanding price discounts or rebates and limiting coverage of, and amounts they will pay for, molecular tests. These measures have resulted in reduced payment rates and decreased utilization in the clinical laboratory industry. Because of these cost-containment measures, governmental and commercial third-party payors—including those that currently reimburse our tests—may reduce, suspend, revoke or discontinue payments or coverage at any time. Reduced reimbursement of our tests may harm our business, operating results, and financial condition.

Billing for clinical laboratory testing services is complex. We perform tests in advance of payment and without certainty as to the outcome of the billing process. In cases where we expect to receive a fixed fee

per test due to our reimbursement arrangements, we may nevertheless encounter variable reimbursement, leading to disputes over pricing and billing. Each third-party payor typically has different billing requirements, and the billing requirements of many payors have become increasingly difficult to meet. Among the factors complicating our billing of third-party payors are:

- disparity in coverage among various payors;
- disparity in information and billing requirements among payors, including with respect to prior authorization requirements and procedures and establishing medical necessity; and
- incorrect or missing billing information, which is required to be provided by the ordering healthcare provider.

These risks related to billing complexities, and the associated uncertainty in obtaining payment for our tests, could harm our business, operating results, and financial condition.

Our status as an out-of-network provider with large commercial third-party payors may cause healthcare providers to avoid recommending our tests.

We are considered to be an out-of-network provider with respect to some of the largest commercial third-party payors from whom we currently receive reimbursement. Physician groups and other healthcare providers may view this negatively and may insist upon only using reference laboratories that are in-network with their patients' insurance companies. These types of decisions could reduce our revenue, and harm our financial condition.

Changes in government healthcare policy could increase our costs and negatively impact coverage and reimbursement for our tests by governmental and other third-party payors.

The U.S. government has shown significant interest in pursuing healthcare reform and reducing healthcare costs. Government healthcare policy has been and will likely continue to be a topic of extensive legislative and executive activity in the U.S. federal government and many U.S. state governments. As a result, our business could be affected by significant and potentially unanticipated changes in government healthcare policy, such as changes in reimbursement levels by government third-party payors. Any such changes could substantially impact our revenues, increase costs, and divert management attention from our business strategy. We cannot predict the impact of governmental healthcare policy changes on our future business, operating results, and financial condition.

In the United States, the ACA was signed into law in March 2010 and significantly impacted the U.S. pharmaceutical and medical device industries, including the diagnostics sector, in a number of ways. Among other things, the ACA expanded healthcare fraud and abuse laws such as the False Claims Act and the Anti-Kickback Statute, including but not limited to required disclosures of financial arrangements with physician customers, required reporting of discovered overpayments, lower thresholds for violations, new government investigative powers, and enhanced penalties for such violations. The ACA restricts insurers from charging higher premiums or denying coverage to individuals with pre-existing conditions, and requires insurers to cover certain preventative services without charging any copayment or coinsurance, including screening for lung, breast, colorectal and cervical cancers. The ACA also created a new system of health insurance "exchanges" designed to make health insurance available to individuals and certain groups through state- or federally-administered marketplaces in addition to existing channels for obtaining health insurance coverage. In connection with such exchanges, certain "essential health benefits" are intended to be made more consistent across plans, setting a baseline coverage level. The states (and the federal government) have some discretion in determining the definition of "essential health benefits" and we do not know whether our tests or other products will fall into a benefit category deemed "essential" for coverage purposes across the plans offered in any or all of the exchanges. If any of our tests are not covered by plans offered in the health insurance exchanges, our business, operating results, and financial condition could be adversely affected.

There have been multiple attempts to repeal ACA or significantly scale back its applicability, which could negatively impact reimbursement for our testing, adversely affect our test volumes, and adversely affect our business, operating results, and financial condition. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or Texas District Court Judge, ruled that the entire ACA is invalid based primarily on the fact that the legislation enacted on December 22, 2017, informally known as the Tax Cuts and Jobs Act, repealed the tax-based shared responsibility payment imposed by the ACA, on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly referred to as the "individual mandate." On December 18, 2019, the 5th Circuit Court of Appeals upheld the Texas District Court's ruling that the individual mandate was unconstitutional, but remanded the case back to the Texas District Court to determine whether the remaining provisions of the ACA were nonetheless valid. On March 2, 2020, the U.S. Supreme Court granted the petitions for writs of certiorari to review the case, although it is unclear when a decision will be made or how the Supreme Court will rule. The repeal of this mandate means that fewer consumers will carry insurance coverage and therefore may be less likely to elect to receive our testing because they would be required to pay out of pocket for such tests. The attempts to repeal the ACA have resulted in considerable uncertainty and concern regarding, for example, a patient's election to undergo genetic screening and whether doing so may impact health insurance eligibility. Because it is unclear whether or how the ACA may change, and whether and to what extent NIPT, cancer screening or other genetic screening may be affected, we are uncertain how our business may be impacted.

In addition to the ACA, various healthcare reform proposals have also emerged from federal and state governments. The Protecting Access to Medicare Act of 2014, or PAMA, introduced a multi-year pricing program for services payable under the Clinical Laboratory Fee Schedule, or CLFS, that is designed to bring Medicare allowable amounts in line with the amounts paid by private payors. The rule issued by CMS to implement PAMA required certain laboratories to report third-party payor rates and test volumes. Since January 1, 2018, the Medicare payment rate for these tests is equal to the weighted median private payor rate reported to CMS, which for many tests is lower than the previous CLFS payment rates due to the often lower negotiated private payor rates applicable to large commercial laboratories that were required to report data to CMS. While we believe that the new rates will have minimal impact on our business, the rates have been the subject of controversy in the industry, including a lawsuit by the American Clinical Laboratory Association, and it is unclear whether and to what extent the new rates may change. The implementation of the PAMA rates has negatively impacted overall pricing and reimbursement for many clinical laboratory testing services. In addition, federal budgetary limitations and changes in healthcare policy, such as the creation of broad limits for our tests and requirements that beneficiaries of government health plans pay for, or pay for higher portions of, clinical laboratory tests or services received, could substantially diminish the utilization of our tests, increase costs and adversely affect our ability to generate revenues and achieve and sustain profitability.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level or how any such future legislation, regulation, or initiative may affect us. Current or potential future federal legislation and the expansion of government's role in the U.S. healthcare industry, as well as changes to the reimbursement amounts paid by third-party payors for our current and future tests, may adversely affect our test volumes and adversely affect our business, operating results, and financial condition.

Our revenues may be adversely affected if we are unable to successfully obtain reimbursement from the Medicare program and state Medicaid programs.

Our revenues from Medicare are currently very small and were only 2.8% of our total revenues in 2019 (before taking into account the U.S. Department of Justice, or DOJ, accrual described below), given our current product mix and the fact that our testing generally is not received by Medicare beneficiaries. As a result, we do not expect those revenues to change materially with regard to our current commercial products. However, our other products in development may be used by Medicare beneficiaries in the

future. Medicare reimbursement can affect both Medicaid reimbursement, which is relevant to NIPT and carrier screening, and reimbursement from commercial third-party payors. Specifically, fee-for-service Medicaid programs generally do not reimburse at rates that exceed Medicare's fee-for-service rates, and many commercial third-party payors set their payment rates at a percentage of the amounts that Medicare pays for testing services. Medicare reimbursement rates are typically based on the CLFS, set by CMS pursuant to a statutory formula established by Congress. Our current Medicare Part B coverage was not set pursuant to a national coverage determination by CMS. Although we believe that coverage is available under Medicare Part B even without such a determination, we currently lack the certainty afforded by a formal national coverage determination by CMS. Thus, CMS or a regional Medicare Administrative Contractor, or MAC, could issue an adverse coverage determination as to Innatal or Preparent or our future products, if any, which could influence other third-party payors, including Medicaid, and could have a material and adverse effect on our business, operating results, and financial condition.

It is estimated that nearly half of all births in the United States are to state Medicaid program recipients. Each state's Medicaid program has its own coverage determinations related to our testing, and many state Medicaid programs do not provide their recipients with coverage for our testing. Even if our testing is covered by a state Medicaid program, we must be recognized as a Medicaid provider by the state in which the Medicaid recipient receiving the services resides in order for us to be reimbursed by a state's Medicaid program. In addition, many Medicaid programs have entered into agreements with managed care plans to have the managed care plans manage the provision of healthcare to that Medicaid program's beneficiaries. In order for us to enter into contracts to offer our tests to beneficiaries who are enrolled with a Medicaid managed care plan, we must first be recognized as a Medicaid provider in that state, and then contract with the applicable Medicaid managed care program. We are currently recognized by 43 states as a Medicaid provider. It is likely that we will not be able to be recognized as a provider by additional Medicaid programs because some states require that a provider maintain a physical laboratory in that state in order to be recognized; furthermore, some states have closed provider panels, which means that the state does not intend to expand its current provider network and therefore does not intend to recognize additional Medicaid providers. Even if we are recognized as a provider in a state, if Medicare's CLFS rate for our tests are low, the Medicaid reimbursement amounts are sometimes as low, or lower, than the Medicare reimbursement rate. In addition, as noted above, each state's Medicaid program has its own coverage determinations related to our testing, and many state Medicaid programs do not provide their recipients with coverage for our testing. As a result of all of these factors, our testing is not reimbursed or only reimbursed at a very low amount by many state Medicaid programs. In some cases, a state Medicaid program's reimbursement rate for our testing might be zero dollars. Low or zero-dollar Medicaid reimbursement rates for our tests could have a material and adverse effect on our business, operating results, and financial condition.

Federal legislation will increase the pressure to reduce prices of pharmaceutical products paid for by Medicare or may otherwise seek to limit healthcare costs.

The Medicare Modernization Act, or MMA, changed the way Medicare covers and reimburses for pharmaceutical products. The legislation introduced a new reimbursement methodology based on average sales prices for pharmaceutical products that are used in hospital settings or under the direct supervision of a physician and, starting in 2006, expanded Medicare coverage for pharmaceutical product purchases by the elderly. In addition, the MMA requires the creation of formularies for self-administered pharmaceutical products and provides authority for limiting the number of pharmaceutical products that will be covered in any therapeutic class and provides for plan sponsors to negotiate prices with manufacturers and suppliers of covered pharmaceutical products. As a result of the MMA and the expansion of federal coverage of pharmaceutical products, we expect continuing pressure to contain and reduce costs of pharmaceutical products. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we may receive for any pharmaceutical product candidates that we may develop using our precision medicine platform in the future and could materially

adversely affect our business, operating results and overall financial condition. While the MMA generally applies only to pharmaceutical product benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement policies and any reduction in coverage or payment that results from the MMA may result in a similar reduction in coverage or payments from private payors.

If the validity of an informed consent from a patient is challenged, we could be precluded from billing for such patient's testing or be forced to stop performing certain tests or exclude the patient's data from clinical trial results.

We are required to ensure that all clinical data and blood samples that we receive have been collected from subjects who have provided appropriate informed consent for us to perform our testing, both commercially and in clinical trials. We seek to ensure that the subjects from whom the data and samples are collected do not retain or have conferred on them any proprietary or commercial rights to the data or any discoveries derived from them. A subject's informed consent could be challenged in the future, and the informed consent could prove invalid, unlawful, or otherwise inadequate for our purposes. Any such findings against us, or our partners, could deny us access to, or force us to stop, testing samples in a particular territory or could call into question the results of our clinical trials. We could also be precluded from billing third-party payors for tests for which informed consents are challenged, or we could be requested to refund amounts previously paid by third-party payors for such tests. We could become involved in legal challenges, which could require significant management and financial resources and adversely affect our operating results.

Regulatory and Legal Risks Related to Our Business

If we or our commercial partners act in a manner that violates healthcare laws or otherwise engage in misconduct, we could face substantial penalties and damage to our reputation, and our business operations and financial condition could be adversely affected.

We are subject to healthcare fraud and abuse regulation and enforcement by both the U.S. federal government and the states in which we conduct our business, including:

- federal and state laws and regulations governing the submission of claims, as well as billing and collection practices, for healthcare services;
- the federal Anti-Kickback Statute, which prohibits, among other things, the knowing and willful solicitation, receipt, offer or payment of remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as Medicare and Medicaid; a person does not need to have knowledge of the statute or specific intent to violate it to have committed a violation; a violation of the Anti-Kickback Statute may result in imprisonment for up to ten years and fines of up to $100,000 for each violation and administrative civil money penalties of $100,000 plus up to three times the amount of the remuneration paid; in addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the Eliminating Kickbacks in Recovery Act of 2018, or EKRA, which, among other things, prohibits knowingly or willfully paying, offering to pay, soliciting or receiving any remuneration (including any kickback, bribe, or rebate), whether directly or indirectly, overtly or covertly, in cash or in kind, to induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory, or in exchange for an individual using the services of that recovery home, clinical treatment facility, or laboratory; violation of EKRA may result in fines up to $200,000 and imprisonment of up to 10 years for each occurrence;

- the federal False Claims Act which prohibits, among other things, the presentation of false or fraudulent claims for payment from Medicare, Medicaid, or other government-funded third-party payors discussed in more detail below;
- federal laws and regulations governing the Medicare program, providers of services covered by the Medicare program, and the submission of claims to the Medicare program, as well as the Medicare Manuals issued by CMS and the local medical policies promulgated by the Medicare Administrative Contractors with respect to the implementation and interpretation of such laws and regulations;
- the federal Stark Law, also known as the physician self-referral law, which, subject to certain exceptions, prohibits a physician from making a referral for certain designated health services covered by the Medicare program (and according to case law in some jurisdictions, the Medicaid program as well), including laboratory and pathology services, if the physician or an immediate family member has a financial relationship with the entity providing the designated health services; a person who attempts to circumvent the Stark Law may be fined up to approximately $165,000 for each arrangement or scheme that violates the statute; in addition, any person who presents or causes to be presented a claim to the Medicare or Medicaid programs in violation of the Stark Law is subject to civil monetary penalties up to approximately $25,000 per claim, additional fines of up to three times the amount of reimbursement claimed;
- the federal Civil Monetary Penalties Law, which, subject to certain exceptions, prohibits, among other things, the offer or transfer of remuneration, including waivers of copayments and deductible amounts (or any part thereof), to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of services reimbursable by Medicare or a state healthcare program; any violation of these prohibitions may result in civil monetary penalties up to $20,000 for each wrongful act;
- the prohibition on reassignment by the program beneficiary of Medicare claims to any party;
- HIPAA, which, among other things, imposes criminal liability for executing or attempting to execute a scheme to defraud any healthcare benefit program, willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making false, fictitious or fraudulent statements relating to healthcare matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by HITECH, and their implementing regulations, which imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon entities subject to the law, such as health plans, healthcare clearinghouses and certain healthcare providers, known as covered entities, and their respective business associates, individuals or entities that perform services for them that involve individually identifiable health information; HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions;
- the federal transparency requirements under the Physician Payments Sunshine Act, created under the ACA, which requires, among other things, certain manufacturers of drugs, devices, biologics and medical supplies reimbursed under Medicare, Medicaid, or the Children's

Health Insurance Program to annually report to CMS information related to payments and other transfers of value provided to physicians, certain other healthcare professionals beginning in 2022, and teaching hospitals and physician ownership and investment interests, including such ownership and investment interests held by a physician's immediate family members; we believe that we are currently exempt from these reporting requirements; we cannot assure you, however, that regulators, principally the federal government, will agree with our determination, and a determination that we have violated these laws and regulations, or a public announcement that we are being investigated for possible violations, could adversely affect our business;

- federal and state laws and regulations governing informed consent for genetic testing and the use of genetic material;
- state law equivalents of the above U.S. federal laws, such as the Stark Law, Anti-Kickback Statute and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state data privacy and security laws and which may be more stringent than HIPAA; in addition, California enacted the CCPA on June 28, 2018, which went into effect on January 1, 2020; the CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal data; the CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation; the CCPA may increase our compliance costs and potential liability, and many similar laws have been proposed at the federal level and in other states; in the event that we are subject to or affected by any such privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition; and
- similar healthcare laws and data protection laws in the European Union and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of certain protected information, such as the GDPR, which imposes obligations and restrictions on the collection and use of personal data relating to individuals located in the European Economic Area, or EEA, and the United Kingdom (including health data).

Furthermore, a development affecting our industry is the increased enforcement of the federal False Claims Act and, in particular, actions brought pursuant to the False Claims Act's "whistleblower" or "*qui tam*" provisions. The False Claims Act imposes liability for, among other things, knowingly presenting, or causing to be presented, a false or fraudulent claim for payment by a federal governmental payor program. The *qui tam* provisions of the False Claims Act allow a private individual to bring civil actions on behalf of the federal government for violations of the False Claims Act and permit such individuals to share in any amounts paid by the defendant to the government in fines or settlement. When an entity is determined to have violated the False Claims Act, it is subject to mandatory damages of three times the actual damages sustained by the government, plus mandatory civil penalties of up to approximately $22,000 for each false claim. In addition, various states have enacted false claim laws analogous to the federal False Claims Act, and in some cases apply more broadly because many of these state laws apply to claims made to private payors and not merely governmental payors.

The rapid growth and expansion of our business may increase the potential for violating these laws or our internal policies and procedures designed to comply with these laws. The evolving interpretations of these laws and regulations by courts and regulators increase the risk that we may be alleged to be, or in fact found to be, in violation of these or other laws and regulations, including pursuant to private *qui tam* actions brought by individual whistleblowers in the name of the government as described above.

For example, in April 2018, we received a civil investigative demand from an Assistant U.S. Attorney for the Southern District of New York and a HIPAA subpoena issued by an Assistant U.S. Attorney for the

Southern District of California. In May 2018, we received a subpoena from the State of New York Medicaid Fraud Control Unit. Since that time, we have cooperated with federal civil and criminal investigations, and state civil investigations, regarding discontinued legacy billing practices for our NIPT and microdeletion tests and the provision of alleged kickbacks or inducements to physicians and patients. The civil investigations also include inquiries about our laboratory licenses, our enrollment in state Medicaid programs, and the laboratories that performed testing for us.

On March 31, 2020, we reached an agreement on the monetary terms with the DOJ and the State of New York (with the State of New York Attorney General representing or facilitating the interests of all States participating in the settlement, which we refer to collectively as the State AGs) with respect to relevant government health benefit programs to resolve all of the government's outstanding civil and criminal investigations, including the investigations by the U.S. Attorney's Office for the Southern District of California and the U.S. Attorney's Office for the Southern District of New York, as well as the investigation by the State AGs. The terms of this agreement in principle contemplate that we will enter into a civil settlement agreement providing that we will pay $49.0 million in the aggregate over a five-year period, structured as follows: $8.0 million upon entering into the settlement; $4.0 million in December 2020; $5.0 million in December 2021; $7.0 million in December 2022; $8.0 million in December 2023; $9.0 million in December 2024; and $8.0 million in December 2025 for a release of the civil claims and that we will enter into a non-prosecution agreement to resolve all criminal allegations. Those criminal allegations pertain to discontinued legacy billing practices for our NIPT tests. The amounts payable to the government, other than the initial $8.0 million payment, will be subject to interest at a rate of 1.25% per annum, and any or all amounts may be paid earlier at the option of the Company. The companion civil settlement agreement is expected to resolve all civil claims involving discontinued legacy billing practices for our NIPT and microdeletion tests as well as other allegations pertaining to the provision of potential kickbacks or inducements to physicians and patients. Other non-financial terms and conditions remain subject to negotiation. The final civil settlement materials are subject to final approval of the Assistant Attorney General at DOJ, a U.S. District Court judge in New York, and any other relevant parties, including any potential whistleblower and the State AGs. We also expect to enter into a corporate integrity agreement with the Department of Health and Human Services Office of Inspector General, which would be expected to impose additional compliance, reporting and disclosure obligations, and related costs in the future.

As of December 31, 2019, we had accrued an aggregate of $35.8 million associated with a potential settlement with the DOJ and the participating State AGs within accrued expenses and other current liabilities and as a reduction of revenue as reflected on the consolidated balance sheet of the Company as of December 31, 2019 and consolidated statement of operations for the year ended December 31, 2019. In addition, in the quarter ended March 31, 2020, we accrued an additional $13.2 million with respect to the total amount to be paid under the agreement in principle to the DOJ and the participating State AGs, and additional amounts for related costs as of and for the quarterly period ended March 31, 2020. Furthermore, in connection with recording the CARES Act Tax Benefit, we have agreed with the government that, if during calendar years 2020 through 2023, and as long as amounts payable to the government remain unpaid, we receive any civil settlement, damages awards, or tax refunds, to the extent that the amounts exceed $5.0 million in a calendar year, we will pay 65% of the amount received in such civil settlement, damages award, or tax refunds as an accelerated payment on the scheduled amounts set forth above, first as a dollar-for-dollar acceleration of the scheduled payment due in December 2025 and then as an accelerated payment of the scheduled payments due in each prior year, up to a maximum total acceleration of $24.96 million. During the three months ended March 31, 2020, we recorded a discrete tax benefit of $37.7 million for the CARES Act Tax Benefit, and if fully paid, we expect that the total accelerated payments to the government will be $24.5 million. Until the final documents are approved and signed, there can be no assurance that the amount we have accrued will be sufficient to cover our obligations relating to this matter. Our obligations could also increase, potentially materially, depending on a number of factors including whether or not the agreement in principle is

finalized, the terms of the final approved agreements, the parties to the settlement, the cost of complying with the terms of the settlement, including monitoring fees related to any potential corporate integrity agreement, the costs related to the settlement, and other factors.

Our inability to obtain, on a timely basis or at all, any necessary marketing authorizations for new device products, or improvements to our current offerings, could adversely affect our future product commercialization and operating results.

Our planned medical device product candidates, and potentially some of our molecular testing products such as our planned preeclampsia test, are expected to be subject to regulation by the FDA, and numerous other federal and state governmental authorities. The process of obtaining regulatory approvals or clearances to market a medical device, particularly from the FDA and regulatory authorities outside the United States, can be costly and time-consuming, and approvals or clearances might not be granted for future products on a timely basis, if at all. To ensure ongoing customer safety, regulatory agencies such as the FDA may re-evaluate their current approval or clearance processes and may impose additional requirements. In addition, the FDA and other regulatory authorities may impose increased or enhanced regulatory inspections for domestic or foreign facilities involved in the manufacture of medical devices.

We may develop new medical devices in connection with our precision medicine platform and new molecular test candidates that are regulated by the FDA as medical devices. Unless otherwise exempted, medical devices must receive one of the following marketing authorizations from the FDA before being marketed in the United States: "510(k) clearance," *de novo* classification, or PMA. The FDA determines whether a medical device will require 510(k) clearance, *de novo* classification, or the PMA process based on statutory criteria that include the risk associated with the device and whether the device is similar to an existing, legally marketed product. In the 510(k) clearance process, before a device may be marketed, the FDA must determine that a proposed device is "substantially equivalent" to a legally-marketed "predicate" device, which includes a device that has been previously cleared through the 510(k) process, a device that was legally marketed prior to May 28, 1976 (pre-amendments device), a device that was originally on the U.S. market pursuant to an approved PMA and later down-classified, or a 510(k)-exempt device. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data are sometimes required to support substantial equivalence. In the process of obtaining PMA approval, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, pre-clinical, clinical trial, manufacturing, and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. The process to obtain either 510(k) clearance or PMA will likely be costly, time-consuming, and uncertain. However, we believe the PMA process is generally more challenging. Even if we design a product that we expect to be eligible for the 510(k) clearance process, the FDA may require that the product undergo the PMA process. There can be no assurance that the FDA will approve or clear the marketing of any new medical device product that we develop. Even if regulatory approval or clearance is granted, such approval may include significant limitations on indicated uses, which could materially and adversely affect the prospects of the new medical device product.

If a medical device is novel and has not been previously classified by the FDA as Class I, II, or III, it is automatically classified into Class III regardless of the level of risk it poses. The Food and Drug Administration Modernization Act of 1997 established a route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the *de novo* classification procedure. This procedure allows a manufacturer whose novel device would automatically be classified

into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA application.

FDA marketing authorization could not only be required for new products we develop, but also could be required for certain enhancements we may seek to make to our existing tests and other products. Delays in receipt of, or failure to obtain, marketing authorizations could materially delay or prevent us from commercializing our products or result in substantial additional costs that could decrease our profitability. In addition, even if we receive FDA marketing authorizations for a new or enhanced product, the FDA may condition, withdraw, or materially modify its marketing authorization.

If we fail to comply with laboratory licensing requirements, we could lose the ability to perform our tests or experience disruptions to our business.

We are subject to CLIA, a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. CLIA regulations require clinical laboratories to obtain a certificate and mandate specific standards in the areas of personnel qualifications, administration, and participation in proficiency testing, patient test management and quality assurance. CLIA certification is also required in order for us to be eligible to bill state and federal healthcare programs, as well as many private third-party payors, for our tests. To renew these certifications, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may make random inspections of our clinical laboratory.

We are also required to maintain state licenses to conduct testing in our laboratories. We cannot provide assurance that state authorities will at all times in the future find us to be in compliance with all applicable laws. If a clinical laboratory is out of compliance, the state authority may suspend, restrict or revoke the license to operate the clinical laboratory, assess substantial civil money penalties, or impose specific corrective action plans. Any such actions could materially affect our business.

Moreover, several other states require that we hold licenses to test samples from patients in those states. We have obtained licenses from states where we believe we are required to be licensed. From time to time, we may become aware of other states that require out-of-state laboratories to obtain licensure in order to accept specimens from the state, and it is possible that other states do have such requirements or will have such requirements in the future. If we identify any other state with such requirements or if we are contacted by any other state advising us of such requirements, we expect to seek to comply with such requirements. However, there is no assurance that we will be able to obtain any such required license for the particular state.

Any sanction imposed under CLIA, its implementing regulations, or state or foreign laws or regulations governing licensure, or our failure to renew a CLIA certificate, a state license or accreditation, could have a material and adverse effect on our business, operating results and financial condition. For a discussion of a recent inquiry from the State of Texas regarding our CLIA certification, see “Business—Legal Proceedings—Texas OIG Inquiry.” CMS also has the authority to impose a wide range of sanctions, including revocation of the CLIA certification along with a bar on the ownership or operation of a CLIA-certified laboratory by any owners or operators of the deficient laboratory. If we were to lose our CLIA certification or required state licensure, we would not be able to operate our clinical laboratory and conduct our tests, in full or in particular states, which would adversely impact our business, operating results, and financial condition.

We are subject to costly and complex laws and governmental regulations.

Our precision medicine product candidates are subject to a complex set of regulations and rigorous enforcement, including by the FDA, DOJ, HHS, and numerous other federal, state, and non-U.S.

governmental authorities. To varying degrees, each of these agencies requires us to comply with laws and regulations governing the development, testing, manufacturing, labeling, marketing, and distribution of our products. As a part of the regulatory process of obtaining marketing authorization for new products and modifications to existing products, we may conduct and participate in numerous clinical trials with a variety of study designs, patient populations, and trial endpoints. Unfavorable or inconsistent clinical data from existing or future clinical trials or the market's or FDA's perception of this clinical data, may adversely impact our ability to obtain product approvals, our position in, and share of, the markets in which we participate, and our business, operating results, and financial condition. We cannot guarantee that we will be able to obtain or maintain marketing authorization for our product candidates and/or enhancements or modifications to existing products, and the failure to maintain or obtain marketing authorization in the future could have a material and adverse effect on our business, operating results, financial condition.

Both before and after a product is commercially released, we and our products are subject to ongoing and pervasive oversight of government regulators. For instance, in the case of any product candidates subject to regulation by the FDA, including those products candidates in connection with our precision medicine platform, our facilities and procedures and those of our suppliers will be subject to periodic inspections by the FDA to determine compliance with applicable regulations. The results of these inspections can include inspectional observations on FDA's Form-483, warning letters, or other forms of enforcement. If the FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our product candidates, if authorized for marketing, are ineffective or pose an unreasonable health risk, the FDA could ban products, withdraw marketing authorizations for such products, detain or seize adulterated or misbranded products, order a recall, repair, replacement, or refund of such products, refuse to grant pending marketing applications, require certificates of non-U.S. governments for exports, and/or require us to notify health professionals and others that the products present unreasonable risks of substantial harm to the public health. The FDA and other non-U.S. government agencies may also assess civil or criminal penalties against us, our officers, or employees and impose operating restrictions on a company-wide basis. The FDA may also recommend prosecution to the DOJ. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively marketing and selling our products and limit our ability to obtain future marketing authorizations, and could result in a substantial modification to our business practices and operations.

Furthermore, we occasionally receive investigative demands, subpoenas, or other requests for information from state and federal governmental agencies, and we cannot predict the timing, outcome, or impact of any such investigations. See "Business—Legal Proceedings." Any adverse outcome in one or more of these investigations could include the commencement of civil and/or criminal proceedings, substantial fines, penalties, and/or administrative remedies, including exclusion from government reimbursement programs and/or entry into corporate integrity agreements with governmental agencies. In addition, resolution of any of these matters could involve the imposition of additional, costly compliance obligations. These potential consequences, as well as any adverse outcome from government investigations, could have a material and adverse effect on our business, operating results, and financial condition.

Even if we obtain regulatory authorizations, our marketed products will be subject to ongoing regulatory review. If we fail to comply with continuing U.S. and foreign regulations, we could lose any marketing authorizations we have obtained and our business would be seriously harmed.

Even after authorization, any medical products we develop will be subject to ongoing regulatory review, including requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, and other post- market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. Any marketing authorizations that we obtain

for our product candidates may also be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw marketing authorizations;
- suspend or terminate any of our clinical studies;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities; or
- seize or detain products, or require a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory authorization is withdrawn, our business will be seriously harmed.

Moreover, the policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory authorization of our product candidates. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing authorization that we may have obtained and we may not achieve or sustain profitability.

Similarly, our commercial activities are subject to comprehensive compliance obligations under state and federal reimbursement, Sunshine Act, anti-kickback and government pricing regulations. If we make false price reports, fail to implement adequate compliance controls or our employees violate the laws and regulations governing relationships with healthcare providers, we could also be subject to substantial fines and penalties, criminal prosecution and debarment from participation in the Medicare, Medicaid, or other government reimbursement programs. For additional information regarding these risks, see "Risk Factors–If we or our commercial partners act in a manner that violates healthcare laws or otherwise engage in misconduct, we could face substantial penalties and damage to our reputation, and our business operations and financial condition could be adversely affected." Noncompliance with European Union requirements regarding safety monitoring or pharmacovigilance can also result in significant financial penalties. Similarly, failure to comply with the European Union requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

We and our commercial partners and contract manufacturers are subject to significant regulation with respect to manufacturing medical devices and therapeutic products. The manufacturing facilities on which we rely may not continue to meet regulatory requirements or may not be able to meet supply demands.

Entities involved in the preparation of medical devices and/or therapeutic products for clinical studies or commercial sale, including our manufacturers for the therapeutic products that we may develop, are subject to extensive regulation. Components of a finished medical device or therapeutic product approved for commercial sale or used in late-stage clinical studies must be manufactured in accordance with cGMP and/or QSR requirements. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We, our collaboration partners or our contract manufacturers must supply all necessary documentation in support of an NDA, a BLA, a PMA, a 510(k) application, a request for *de novo* classification, or a Marketing Authorization Application, or MAA, on a timely basis and must adhere to cGMP regulations enforced by the FDA and other regulatory agencies through their facilities inspection program. Some of our contract manufacturers may have never produced a commercially approved pharmaceutical product and therefore have not been subject to the review of the FDA and other regulators. The facilities and quality systems of some or all of our collaboration partners and third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our drug and biologic product candidates and may be subject to inspection in connection with a MAA for any of our other potential product candidates. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. Although we oversee our contract manufacturers, we cannot control the manufacturing process of, and are completely dependent on, such contract manufacturing partners for compliance with these regulatory requirements. If these facilities do not pass a pre-approval plant inspection, marketing authorizations for the products may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever.

The regulatory authorities also may, at any time following approval or clearance of a product for sale, audit the manufacturing facilities of our collaboration partners and third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical study or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

If we, our collaboration partners or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA or other applicable regulatory authority can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new product candidate, withdrawal of a marketing authorization or suspension of production. As a result, our business, operating results, and financial condition may be materially harmed.

Additionally, if supply from one approved manufacturer is interrupted, an alternative manufacturer will need to be qualified and we may need to obtain marketing authorization for a change in the manufacturer through submission of a PMA supplement, 510(k) pre-market notification, NDA or BLA supplement, MAA variation or other regulatory filing to the FDA or other foreign regulatory agencies, which could result in further delay.

These factors could cause us to incur additional costs and could cause the delay or termination of clinical studies, regulatory submissions, required marketing authorizations or commercialization of our products, including product candidates. Furthermore, if our suppliers fail to meet contractual requirements and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical studies may be delayed or we could lose potential revenue.

The FDA may modify its enforcement discretion policy with respect to LDTs in a risk-based manner, and we may become subject to extensive regulatory requirements and may be required to conduct additional clinical trials prior to continuing to sell our existing tests or launching any other tests we may develop, which may increase the cost of conducting, or otherwise harm, our business.

We currently market all of our commercial molecular tests as LDTs and may in the future market other tests as LDTs. The FDA has adopted a policy of enforcement discretion with respect to LDTs whereby the FDA does not actively enforce its regulatory requirements for such tests. However, the FDA has stated its intention to modify its enforcement discretion policy with respect to LDTs. If there are changes in FDA policy, or if the FDA disagrees that our marketed tests are LDTs or that we are marketing our tests outside the scope of the FDA's current policy of enforcement discretion, we may become subject to extensive regulatory requirements and may be required to stop selling our existing tests or launching any other tests we may develop and to conduct additional clinical trials or take other actions prior to continuing to market our tests. If the FDA allows our tests to remain on the market but there is uncertainty about our tests, if they are labeled investigational by the FDA or if labeling claims the FDA allows us to make are very limited, orders from physicians or reimbursement may decline. If required, the regulatory authorization process may involve, among other things, successfully completing additional clinical trials and submitting a 510(k) notice, or filing a *de novo* classification request or a PMA application with the FDA. If the FDA requires premarket review, our tests may not be cleared or approved on a timely basis, if at all. This could significantly increase the costs and expenses of conducting, or otherwise harm, our business.

While we believe that we are currently in material compliance with applicable laws and regulations as historically enforced by the FDA with respect to LDTs, we cannot assure you that the FDA will agree with our determination. A determination that we have violated these laws and regulations, or a public announcement that we are being investigated for possible violations, could adversely affect our business, prospects, results of operations, and financial condition.

On July 31, 2014, the FDA notified Congress of its intent to modify, in a risk-based manner, its policy of enforcement discretion with respect to LDTs. On October 3, 2014, the FDA issued two draft guidances, entitled "Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)," or the Framework Guidance, and "FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)." The Framework Guidance stated that the FDA intended to modify its policy of enforcement discretion with respect to LDTs in a risk-based manner consistent with the existing classification of medical devices. Thus, pursuant to the Framework Guidance, the FDA planned to begin to enforce its medical device requirements, including premarket submission requirements, on LDTs that have historically been marketed without FDA premarket review and oversight. Although the FDA halted finalization of the guidance in November 2016 to allow for further public discussion on an appropriate oversight approach to LDTs and to give congressional authorizing committees the opportunity to develop a legislative solution, the FDA could ultimately modify its current approach to LDTs in a way that would subject our products marketed as LDTs to the enforcement of regulatory requirements. For example, on January 13, 2017, the FDA issued a discussion paper on LDTs, which proposed a risk-based approach to oversight that would initially focus on premarket review of high-risk tests. If and when such changes to the regulatory framework occur, we could for the first time be subject to enforcement of regulatory requirements as a device manufacturer such as registration and listing requirements, medical device reporting requirements and the requirements of the FDA's QSR. Additionally, if and when the FDA begins to actively enforce its premarket submission regulations with

respect to LDTs, we may be required to obtain premarket clearance or approval for our currently marketed tests and other products we plan to commercialize as LDTs. Moreover, legislative measures have recently been proposed in Congress that, if ultimately enacted, could provide the FDA with additional authority to require premarket review of and regulate LDTs. For example, in late 2018, the FDA proposed to Congress significant reforms to the agency's regulation of LDTs that would bring all *in vitro* clinical tests, including LDTs, under a unified framework and would dramatically increase FDA oversight of LDTs. The FDA's proposal includes premarket review for certain tests, a precertification program to permit approval or clearance of a group of tests based on the review of a representative test, registration and notification requirements, quality system requirements, adverse event reporting, labeling requirements, and explicit authorities for the FDA to revoke the marketing authorization of tests and to take corrective action against test developers. Congress is considering draft legislation that largely incorporates the FDA's proposal and would increase FDA oversight of clinical laboratories and LDTs. The outcome and ultimate impact of such proposals on our business is difficult to predict at this time. Potential future increased regulation of our LDTs could also result in increased costs and administrative and legal actions for noncompliance, including warning letters, fines, penalties, product suspensions, product recalls, injunctions and other civil and criminal sanctions, which could have a material and adverse effect upon our business, operating results, and financial condition.

We may be adversely impacted by changes in laws and regulations, or in their application.

The industries in which we operate are highly regulated, and failure to comply with applicable regulatory, supervisory, accreditation, registration, or licensing requirements may adversely affect our business, operating results, and financial condition. The laws and regulations governing our research and marketing efforts are extremely complex and in many instances there are no clear regulatory or judicial interpretations of these laws and regulations, which increases the risk that we may be found to be in violation of these laws.

Furthermore, the industries in which we operate are growing, and regulatory agencies such as HHS or the FDA may apply heightened scrutiny to new developments. While we have taken steps to ensure compliance with current regulatory regimes in all material respects, given the nature of such regimes and our geographical diversity, there could be areas where we are noncompliant. Any change in the federal or state laws or regulations relating to our business may require us to implement changes to our business or practices, and we may not be able to do so in a timely or cost-effective manner. Should we be found to be noncompliant with current or future regulatory requirements, we may be subject to sanctions which could include changes to our operations, adverse publicity, substantial financial penalties and criminal proceedings, which may adversely affect our business, operating results, and financial condition by increasing our cost of compliance or limiting our ability to develop, market and commercialize our products. For additional information regarding these risks, see "Risk Factors—If we or our commercial partners act in a manner that violates healthcare laws or otherwise engage in misconduct, we could face substantial penalties and damage to our reputation, and our business operations and financial condition could be adversely affected."

In addition, there has been a recent trend of increased U.S. federal and state regulation of payments made to physicians, which are governed by laws and regulations including the Stark Law, the federal Anti-Kickback Statute, the Physician Payments Sunshine Act and the federal False Claims Act as well as state equivalents of such laws. Among other requirements, the Stark Law requires laboratories to track, and places a cap on, non-monetary compensation provided to referring physicians.

While we have a compliance plan intended to address compliance with government laws and regulations, including applicable fraud and abuse laws and regulations such as those described in this risk factor, the evolving commercial compliance environment and the need to build and maintain robust and scalable

systems to comply with regulations in multiple jurisdictions with different compliance and reporting requirements increases the possibility that we could inadvertently violate one or more of these requirements.

Changes in the way the FDA regulates the reagents, other consumables, and testing equipment we use when developing, validating, and performing our tests could result in delay or additional expense in bringing our tests to market or performing such tests for our customers.

Many of the sequencing instruments, reagents, kits and other consumable products used to perform our testing, as well as the instruments and other capital equipment that enable the testing, are offered for sale as analyte specific reagents, or ASRs, or for research use only, or RUO. ASRs are medical devices and must comply with FDA QSR provisions and other device requirements, but most are exempt from 510(k) and PMA review. Products that are intended for RUO and are labeled as RUO are exempt from compliance with FDA requirements, including the approval or clearance and other product quality requirements for medical devices. A product labeled RUO but which is actually intended for clinical diagnostic use may be viewed by the FDA as adulterated and misbranded under the FD&C Act and subject to FDA enforcement action. The FDA has said that when determining the intended use of a product labeled RUO, it will consider the totality of the circumstances surrounding distribution and use of the product, including how the product is marketed and to whom. The FDA could disagree with a supplier's assessment that the supplier's products are RUOs, or could conclude that products labeled as RUO are actually intended for clinical diagnostic use, and could take enforcement action against the supplier, including requiring the supplier to cease offering the product while it seeks clearance or approval. Suppliers of RUO products that we employ in our other tests may cease selling their respective products, and we may be unable to obtain an acceptable substitute on commercially reasonable terms or at all, which could significantly and adversely affect our ability to provide timely testing results to our customers or could significantly increase our costs of conducting business.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain, or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, cleared, or approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and clear or approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs, medical devices, and biologics or modifications to cleared or approved drugs, medical devices, and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products through April 2020, and subsequently, on March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other

regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

If the FDA does not conclude that certain of our product candidates satisfy the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for such product candidates under Section 505(b)(2) are not as we expect, the approval pathway for those product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.

We are developing proprietary product candidates, such as PGN-600, a GI-targeted tofacitinib, for which we may seek FDA approval through the Section 505(b)(2) regulatory pathway. We expect that PGN-600 will be regulated as a drug/device combination product under the drug provisions of the FD&C Act, enabling us to submit NDAs for approval of this product candidate. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the FD&C Act. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if applicable to us under the FD&C Act, would allow an NDA we submit to the FDA to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for our product candidate by potentially decreasing the amount of nonclinical and/or clinical data that we would need to generate in order to obtain FDA approval. If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, we may need to conduct additional nonclinical studies and/or clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for this product candidate, and complications and risks associated with this product candidate, would likely substantially increase. Moreover, inability to pursue the Section 505(b)(2) regulatory pathway could result in new competitive products reaching the market more quickly than our product candidate, which would likely materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that our product candidate will receive the requisite approval for commercialization.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2) over the last few years, certain pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may change its 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2). In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to certain requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our NDAs for up to 30 months or longer depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. Even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. In addition, even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee this would ultimately lead to streamlined product development or earlier approval.

Moreover, even if our product candidate is approved under Section 505(b)(2), the approval may be subject to limitations on the indicated uses for which the product may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product.

The misuse or off-label use of our products or product candidates may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, and any of these consequences could be costly to our business.

We are developing certain precision medicine product candidates, including pharmaceutical products and medical devices, which if authorized for marketing by the FDA or other regulatory authorities, will be authorized for use in specific indications and patient populations. We expect to train our marketing personnel and direct sales force not to promote our product candidates for uses outside of the FDA-approved or -cleared indications for use, which are sometimes referred to as "off-label uses." We cannot, however, prevent a physician from using our products off-label, when in the physician's independent professional medical judgment he or she deems it appropriate. There may be increased risk of injury to patients if physicians attempt to use our products off-label. Furthermore, the use of our products for indications other than those authorized for marketing by the FDA or any foreign regulatory body may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

If the FDA or any foreign regulatory body determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of an untitled letter, a warning letter, injunction, seizure, civil fine, or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority, such as false claims laws, if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil, and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations.

In addition, physicians may misuse our products or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our products are misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. As described above, product liability claims could divert management's attention from our core business, be expensive to defend and result in sizeable damage awards against us that may not be covered by insurance.

Risks Related to Our Intellectual Property

Third-party claims of intellectual property infringement could result in litigation or other proceedings, which would be costly and time-consuming, and could limit our ability to commercialize our products.

Our success depends in part on our freedom-to-operate with respect to the patents or intellectual property rights of third parties. We operate in industries in which there have been substantial litigation and other proceedings regarding patents and other intellectual property rights. Certain third parties, including our competitors or collaborators, may in the future assert that we are employing their proprietary technology without authorization or that we are otherwise infringing their intellectual property rights. The risk of intellectual property proceedings may increase as the number of products and the level of competition in our industry segments grows. Defending against infringement claims is costly and may divert the attention of our management and technical personnel. If we are unsuccessful in defending against patent infringement claims, we could be required to stop developing or commercializing products, pay potentially substantial monetary damages, and/or obtain licenses from third parties, which we may be unable to do on acceptable terms, if at all, and which may require us to make substantial royalty payments. In addition, we could encounter delays in product introductions while we attempt to develop alternative non-infringing products. Any of these or other adverse outcomes could prevent us from offering our tests, which would have a material and adverse effect on our business, operating results, and financial condition.

As we move into new markets and develop enhancements to and new applications for our products, competitors may assert their patents and other proprietary rights against us as a means of blocking or slowing our entry into such markets or our sales of such new or enhanced products or as a means to extract substantial license and royalty payments from us. Our competitors and others may have significantly stronger, larger, and/or more mature patent portfolios than we have, and additionally, our competitors may be better resourced and highly motivated to protect large, well-established markets that could be disrupted by our product candidates. In addition, future litigation may involve patent holding companies or other patent owners or licensees who have no relevant product revenues and against whom our own patents may provide little or no deterrence or protection.

In addition, our agreements with some of our customers, suppliers, and other entities with whom we do business require us to defend or indemnify these parties to the extent they become involved in infringement claims, including the types of claims described above. We could also voluntarily agree to defend or indemnify third parties if we determine it to be in the best interests of our business relationships. If we are required or agree to defend or indemnify third parties in connection with any infringement claims, we could incur significant costs and expenses that could adversely affect our business, operating results, and financial condition.

Because the industries in which we operate are particularly litigious, we are susceptible to intellectual property suits that could cause us to incur substantial costs or pay substantial damages or prohibit us from selling our precision medicine product candidates or conducting our other business.

There is a substantial amount of litigation over patent and other intellectual property rights in the industries in which we operate, including but not limited to the biotechnology, life sciences, pharmaceuticals, and medical device industries. Whether a product infringes a patent involves complex legal and factual issues, the determination of which is often uncertain. Searches typically performed to identify potentially infringed patents of third parties are often not conclusive and because patent applications can take many years to issue, there may be applications now pending, which may later result in issued patents which our current or future products may infringe. In addition, our competitors or other parties may assert that our precision medicine product candidates and the methods they employ may be covered by patents held by them. If any of our products, including our precision medicine product candidates, infringes a valid patent, we could be prevented from manufacturing or selling it unless we can obtain a license or redesign the product to avoid infringement. A license may not always be available or may require us to pay substantial royalties. We also may not be successful in any attempt to redesign our product to avoid infringement. Infringement and other intellectual property claims, with or without merit, can be expensive and time-consuming to litigate and could divert our management's attention from operating our business.

Any inability to effectively protect our proprietary technologies could harm our competitive position.

Our success and ability to compete depend to a large extent on our ability to develop proprietary products and technologies and to maintain adequate protection of our intellectual property in the United States and elsewhere. The laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States, and many companies have encountered significant challenges in establishing and enforcing their proprietary rights outside of the United States. These challenges can be caused by the absence of rules and methods for the establishment and enforcement of intellectual property rights in certain jurisdictions outside of the United States. In addition, the proprietary positions of companies in the industries in which we operate generally are uncertain and involve complex legal and factual questions. This is particularly true in the diagnostics area where the U.S. Supreme Court has issued a series of decisions setting forth limits on the patentability of natural phenomena, natural laws, abstract ideas and their applications (see, *Mayo Collaborative v. Prometheus Laboratories (2012), Association for Molecular Pathology v. Myriad Genetics (2013), and Alice Corporation v. CLS Bank (2014)*, which has made it difficult to obtain certain patents and to assess the validity of previously issued

patents). This uncertainty may materially affect our ability to defend or obtain patents or to address the patents and patent applications owned or controlled by our collaborators and licensors.

We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies are covered by valid and enforceable patents or are effectively maintained as trade secrets. Any finding that our patents or patent applications are invalid or unenforceable could harm our ability to prevent others from practicing the related technology. We cannot be certain that we were the first to invent the inventions covered by pending patent applications or that we were the first to file such applications, and a finding that others have claims of inventorship or ownership rights to our patents and applications could require us to obtain certain rights to practice related technologies, which may not be available on favorable terms, if at all. There may be times when we choose to retain advisors with academic employers who limit their employees' rights to enter into agreements which provide the kind of confidentiality and assignment provisions congruent with our consulting agreements. We may decide that obtaining the services of these advisors is worth any potential risk, and this may harm our ability to obtain and enforce our intellectual property rights. In addition, our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing similar or alternative competing products, or design around our patented technologies, and may therefore fail to provide us with any competitive advantage. Furthermore, as our issued patents expire, we may lose some competitive advantage as others develop competing products that would have been covered by the expired patents, and, as a result, may adversely affect our business, operating results, and financial condition.

We may be required to file or defend infringement lawsuits and other contentious proceedings, such as *inter partes* reviews, reexaminations, oppositions, and declaratory judgement actions, to protect our interests, which can be expensive and time-consuming. We cannot assure you that we would prevail over an infringing third party, and we may become subject to counterclaims by such third parties. Our patents may be declared invalid or unenforceable, or narrowed in scope, as a result of such litigation or other proceedings. Some third-party infringers may have substantially greater resources than us and may be able to sustain the costs of complex infringement litigation more effectively than we can. Even if we have valid and enforceable patents, competitors may still choose to offer products that infringe our patents. Further, preliminary injunctions that bar future infringement by the competitor are not often granted; therefore, remedies for infringement are not often immediately available. Even if we prevail in an infringement action, we cannot assure you that we would be fully or partially financially compensated for any harm to our business. We may be forced to enter into a license or other agreement with the third parties on terms less profitable or otherwise less commercially acceptable to us than those negotiated between a willing licensee and a willing licensor. Any inability to stop third-party infringement could result in loss in market share of some of our products, or lead to a delay, reduction, and/or inhibition of our development, manufacture, or sale of some of our products. A product produced and sold by a third-party infringer may not meet our or other regulatory standards or may not be safe for use, which could cause irreparable harm to the reputation of our products, which in turn could result in substantial loss in our market share and profits.

There is also the risk that others may independently develop similar or alternative technologies or design around our patented technologies, and our competitors or others may have filed, and may in the future file, conflicting patent claims covering technology similar or identical to ours. The costs associated with challenging conflicting patent claims could be substantial, and it is possible that our efforts would be unsuccessful and may result in a loss of our patent position and the issuance or validation of the competing claims. Should such competing claims cover our technology, we could be required to obtain rights to those claims at substantial cost.

Any of these factors could adversely affect our ability to obtain commercially relevant or competitively advantageous patent protection for our products.

"Submarine" patents may be granted to our competitors, which may significantly alter our launch timing expectations, reduce our projected market size, cause us to modify our product or process or block us from the market altogether.

The term "submarine" patent is used to denote a patent issuing from an application that was not published, publicly known or available prior to its grant. Submarine patents add substantial risk and uncertainty to our business. Submarine patents may issue to our competitors covering our precision medicine product candidates or our pipeline candidates and thereby cause significant market entry delay, defeat our ability to market our products or cause us to abandon development and/or commercialization of a product or molecule.

The issuance of one or more submarine patents may harm our business by causing substantial delays in our ability to introduce a product candidate or other product into the U.S. market.

If we are not able to adequately protect our trade secrets, know-how, and other proprietary information, the value of our technology and products could be significantly diminished.

We rely on trade secret protection and proprietary know-how protection for our confidential and proprietary information, and we have taken security measures to protect this information. These measures, however, may not provide adequate protection for our trade secrets, know-how, or other proprietary information. For example, although we have a policy of requiring our consultants, advisors and collaborators to enter into confidentiality agreements and our employees to enter into invention, non-disclosure and, where lawful, noncompete agreements, we cannot assure you that such agreements will provide for a meaningful protection of our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure of information, including as a result of breaches of our physical or electronic security systems, or as a result of our employees failing to abide by their confidentiality obligations during or upon termination of their employment with us. Any action to enforce our rights is likely to be time-consuming and expensive, and may ultimately be unsuccessful, or may result in a remedy that is not commercially valuable. These risks are heightened in countries where laws or law enforcement practices may not protect proprietary rights as fully as in the United States. Any unauthorized use or disclosure of, or access to, our trade secrets, know-how or other proprietary information, whether accidentally or through willful misconduct, could have a material and adverse effect on our programs, our business strategy, and on our ability to compete effectively.

If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest, and our business may be adversely affected.

Failure to maintain our trademark registrations, or to obtain new trademark registrations in the future, could limit our ability to protect our trademarks and impede our marketing efforts in the countries in which we operate. We may not be able to protect our rights to trademarks and trade names which we may need to build name recognition with potential partners or customers in our markets of interest. As a means to enforce our trademark rights and prevent infringement, we may be required to file trademark claims against third parties or initiate trademark opposition proceedings. This can be expensive, particularly for a company of our size, and time-consuming, and we may not be successful. Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks.

Our pending trademark applications in the United States and in other foreign jurisdictions where we may file may not be allowed or may subsequently be opposed. Even if these applications result in registration of trademarks, third parties may challenge our use or registration of these trademarks in the future. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected.

We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties.

We employ individuals who were previously employed at other companies in the industries in which we operate, including biotechnology or diagnostic companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or willfully used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that our employees' former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims, and if we are unsuccessful, we could be required to pay substantial damages and could lose rights to important intellectual property. Even if we are successful, litigation could result in substantial costs to us and could divert the time and attention of our management and other employees.

Risks Related to Being a Public Company

We will incur significantly increased costs and devote substantial management time to reporting and other requirements as a result of operating as a public company.

As a public company, we will incur significant legal, accounting, and other expenses that we did not incur as a private company. For example, we will be subject to the reporting requirements of the Securities Exchange Act of 1934, or Exchange Act, and will be required to comply with the applicable requirements of the Sarbanes-Oxley Act and the Dodd-Frank Wall Street Reform and Consumer Protection Act, as well as rules and regulations subsequently implemented by the SEC and The Nasdaq Global Select Market, or Nasdaq, including the establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. We expect that compliance with these requirements will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. Certain members of our management and other personnel have little experience managing a public company and preparing public filings. In addition, we expect that our management and other personnel will need to divert attention from operational and other business matters to devote substantial time to these public company requirements. In particular, we expect to incur significant expenses and devote substantial management effort toward ensuring compliance with the requirements of Section 404 of the Sarbanes-Oxley Act, which will increase when we are no longer an emerging growth company, as defined by the JOBS Act. We will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. We cannot predict or estimate the amount of additional costs we may incur as a result of becoming a public company or the timing of such costs. Additional compensation costs and any future equity awards will increase our compensation expense, which would increase our general and administrative expense and could adversely affect our profitability. We also expect that operating as a public company will make it more difficult and more expensive for us to obtain director and officer liability insurance on reasonable terms. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors or our board committees or as executive officers.

We are an emerging growth company and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an emerging growth company. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption and, as a result, will not be subject to the same implementation timing for new or revised accounting standards as are required of other public companies that are not emerging growth companies, which may make comparison of our consolidated financial information to those of other public companies more difficult.

For as long as we continue to be an emerging growth company, however, we intend to take advantage of certain other exemptions from various reporting requirements that are applicable to other public

companies including, but not limited to, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile and experience decreases.

We will remain an emerging growth company until the earliest of (a) the end of the fiscal year (i) following the fifth anniversary of the closing of this offering, (ii) in which the market value of our common stock that is held by non-affiliates exceeds $700 million and (iii) in which we have total annual gross revenues of $1.07 billion or more during such fiscal year, and (b) the date on which we issue more than $1 billion in non-convertible debt in a three-year period.

We have previously identified material weaknesses in our internal control over financial reporting. If additional material weaknesses or significant deficiencies in our internal control over financial reporting are discovered or occur in the future, our consolidated financial statements may contain material misstatements and we could be required to restate our financial results, which could adversely affect our stock price and result in an inability to maintain compliance with applicable stock exchange listing requirements.

We previously concluded that there were matters that constituted material weaknesses in our internal control over financial reporting that have since been remediated. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected and corrected on a timely basis. The material weaknesses related to a lack of (i) controls designed to reconcile tests performed and recognized as revenue to billed tests and (ii) appropriately designed or effectively operating controls over the proper recording of accounts payable and accrued liabilities.

If additional material weaknesses or significant deficiencies in our internal control over financial reporting are discovered or occur in the future, our consolidated financial statements may contain material misstatements and we could be required to restate our financial results. If we are unable to successfully remediate any material weaknesses in our internal controls or if we are unable to produce accurate and timely financial statements, our stock price may be adversely affected, and we may be unable to maintain compliance with applicable stock exchange listing requirements.

Risks Related to This Offering and Ownership of Our Common Stock

An active trading market for our common stock may not develop or be sustainable, and investors may not be able to resell their shares at or above the initial public offering price.

Prior to this offering, there has been no public market for our common stock. The initial public offering price for our common stock will be determined through negotiations with the underwriters. An active trading market for our shares may never develop or be sustained following this offering. If an active market for our common stock does not develop, it may be difficult for our stockholders to sell shares purchased in this offering without depressing the market price for the shares, or at all.

The market price of our common stock is likely to be volatile, which could subject us to litigation.

The market price of our common stock is likely to be subject to wide fluctuations in response to numerous factors, many of which are beyond our control, such as those in this “Risk Factors” section and others including:

- actual or anticipated variations in our and our competitors’ operating results;

- announcements by us or our competitors of new products, product development results, significant acquisitions, strategic and commercial partnerships and relationships, joint ventures, collaborations or capital commitments;
- changes in reimbursement by current or potential payors;
- issuance of new securities analysts' reports or changed recommendations for our stock;
- periodic fluctuations in our revenue, due in part to the way in which we recognize revenue;
- actual or anticipated changes in regulatory oversight of our products;
- developments or disputes concerning our intellectual property or other proprietary rights or alleged infringement of third party's rights by our products;
- commencement of, or our involvement in, litigation or other proceedings;
- announcement or expectation of additional debt or equity financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- any major change in our management; and
- general economic conditions and slow or negative growth of our markets.

In addition, if the stock market experiences uneven investor confidence, the market price of our common stock could decline for reasons unrelated to our business, operating results or financial condition. The market price of our common stock might also decline in reaction to events that affect other companies within, or outside, our industry even if these events do not directly affect us. Some companies that have experienced volatility in the trading price of their stock have been the subject of securities class action litigation. If we are the subject of such litigation, it could result in substantial costs and a diversion of our management's attention and resources.

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

We cannot specify with any certainty the particular uses of the net proceeds that we will receive from this offering. Our management will have broad discretion in the application of the net proceeds from this offering for any of the purposes described in "Use of Proceeds," and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

Insiders have substantial control over us and will be able to influence corporate matters.

Without giving effect to any shares they may purchase in this offering, our current directors and executive officers, together with their affiliates, will beneficially own, in the aggregate, approximately 73.2% of our outstanding common stock after the completion of this offering, based on the number of shares outstanding as of June 1, 2020 on an as-converted basis. After the completion of this offering, but without giving effect to any shares they may purchase in this offering, Dr. Harry Stylli, our Chief Executive Officer and Chairman of our Board, will own 31.4% of our outstanding common stock on an as-converted basis and affiliates of Athyrium Capital Management, LP, who appointed a director to our board, will own 42.7% of our outstanding common stock on an as-converted basis. Certain of our existing stockholders, including those affiliated with members of our Board, have indicated an interest in purchasing an aggregate of up to approximately $50 million of shares of our common stock in this offering at the initial public offering price and on the same terms as the other purchasers in this offering. If such stockholders were to purchase all shares they have indicated an interest in purchasing, our current

directors, officers, together with their affiliates, would beneficially own approximately 80.3% of our outstanding common stock upon the closing of this offering (based on the assumed initial public offering price of $15.00 per share, the midpoint of the price range set forth on the cover page of this prospectus, and assuming no exercise of the underwriters' option to purchase additional shares and no exercise of outstanding options). As a result, after this offering, these stockholders will be able to exercise significant influence over all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, such as a merger or other sale of our company or its assets. They may have interests that differ from yours and may vote in a way with which you disagree and that may be adverse to your interests. This concentration of ownership could limit stockholders' ability to influence corporate matters and may have the effect of delaying, deterring or preventing a third party from acquiring control over us, depriving our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company, and could negatively impact the value and market price of our common stock.

We do not intend to pay dividends on our capital stock, so any returns will be limited to changes in the value of our common stock.

While we have paid dividends to our stockholders in the past, we currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, our ability to pay cash dividends on our capital stock may be prohibited or limited by the terms of any current or future debt financing arrangement, including our credit and security agreement with Athyrium Opportunities III Co-Invest 1 LP. Any return to stockholders may therefore be limited to the increase, if any, of the price of our common stock.

If you purchase our common stock in this offering, you will incur immediate and substantial dilution.

The initial public offering price is substantially higher than the as-converted net tangible book value per share of our common stock as of March 31, 2020. Investors purchasing common stock in this offering will pay a price per share that substantially exceeds the book value of our total tangible assets after subtracting our total liabilities. As a result, investors purchasing common stock in this offering will incur immediate dilution of approximately $15.19 per share, based on an assumed initial public offering price of $15.00 per share, the midpoint of the price range set forth on the cover of this prospectus.

This dilution is due to the substantially lower price paid by our investors who purchased shares prior to this offering as compared to the price offered to the public in this offering, and any previous exercise of stock options granted to our service providers. In addition, as of March 31, 2020, options to purchase 3,678,520 shares of our common stock with a weighted average exercise price of approximately $7.90 per share were outstanding and, as of March 31, 2020, there were 990,463 restricted stock units outstanding. The exercise of any of these options or the vesting of the restricted stock units would result in additional dilution. As a result of the dilution to investors purchasing shares in this offering, investors may receive less than the purchase price paid in this offering, if anything, in the event of our liquidation.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause the stock price of our common stock to decline.

We may issue additional securities following the completion of this offering. In the future, we may sell common stock, convertible securities, or other equity securities in one or more transactions at prices and in a manner we determine from time to time. We also expect to issue common stock to employees, directors, and consultants pursuant to our equity incentive plans. If we sell common stock, convertible securities, or other equity securities in subsequent transactions, or common stock is issued pursuant to equity incentive plans, investors may be materially diluted. New investors in such subsequent transactions could gain rights, preferences, and privileges senior to those of holders of our common stock.

Participation in this offering by our existing stockholders would reduce the available public float for our shares.

Certain of our existing stockholders, including those affiliated with members of our Board, have indicated an interest in purchasing up to an aggregate of approximately $50 million of shares of our common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, fewer or no shares of our common stock in this offering to these stockholders, or these stockholders may determine to purchase more, fewer or no shares of our common stock in this offering. To the extent these existing stockholders purchase any shares in this offering, such purchase could reduce the available public float for our shares because such stockholders may be restricted from selling the shares by restrictions under applicable securities laws. As a result, any purchase of shares by such stockholders in this offering may reduce the liquidity of our common stock relative to what it would have been had these shares been purchased by investors that were not existing stockholders.

Sales of a substantial number of shares of our common stock in the public market by our existing stockholders following this offering could cause the price of our common stock to decline.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

All of our executive officers and directors and our principal stockholders are subject to lock-up agreements with the underwriters of this offering that restrict the stockholders' ability to transfer shares of our common stock for at least 180 days from the date of this prospectus, except with the prior written consent of Piper Sandler & Co. and Wells Fargo Securities, LLC. Subject to certain limitations, approximately 35,883,293 shares of our common stock will become eligible for sale upon expiration of the 180-day lock-up period. In addition, shares issued or issuable upon exercise of options and restricted stock units vested as of the expiration of the 180-day lock-up period will be eligible for sale at that time.

All of our issued and outstanding shares of common stock will be freely tradable after the expiration date of the lock-up agreements, excluding any shares acquired in this offering by persons who may be deemed to be our affiliates as defined in Rule 144 under the Securities Act. Shares of our common stock held by our affiliates will continue to be subject to the volume and other restrictions of Rule 144 under the Securities Act. Sales of a substantial number of these shares upon expiration of the lock-up agreements could adversely affect the trading price of our common stock.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If few securities analysts commence coverage of us, or if industry analysts cease coverage of us, the trading price and volume for our common stock could be adversely affected. If one or more of the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, our common stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our common stock price and trading volume to decline.

Provisions in our eighth amended and restated certificate of incorporation and amended and restated bylaws and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the market price of our common stock.

Our eighth amended and restated certificate of incorporation and amended and restated bylaws, each to be in effect immediately prior to the completion of this offering, will contain provisions that could depress the market price of our common stock by acting to discourage, delay, or prevent a change in control of our company or changes in our management that the stockholders of our company may deem advantageous. These provisions, among other things:

- authorize the issuance of "blank check" preferred stock that our board of directors could use to implement a stockholder rights plan;
- prohibit stockholder action by written consent, which requires stockholder actions to be taken at a meeting of our stockholders, except for so long as specified current stockholders hold in excess of 50% of our outstanding common stock;
- prohibit stockholders from calling special meetings of stockholders;
- establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon by stockholders at annual stockholder meetings;
- provide the board of directors with sole authorization to establish the number of directors and fill director vacancies; and
- provide that the board of directors is expressly authorized to make, alter, or repeal our amended and restated bylaws.

In addition, Section 203 of the Delaware General Corporation Law may discourage, delay, or prevent a change in control of our company. Section 203 imposes certain restrictions on mergers, business combinations and other transactions between us and holders of 15% or more of our common stock.

For more information regarding these and other provisions, see "Description of Capital Stock."

Our eighth amended and restated certificate of incorporation will provide that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our eighth amended and restated certificate of incorporation, to be in effect immediately prior to the completion of this offering, will provide that, unless we consent in writing to the selection of an alternative forum, the sole and exclusive forum, to the fullest extent permitted by law, for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a breach of a fiduciary duty owed by any director, officer or other employee to us or our stockholders, (3) any action asserting a claim against us or any director, officer or other employee arising pursuant to the Delaware General Corporation Law, (4) any action to interpret, apply, enforce or determine the validity of our eighth amended and restated certificate of incorporation or amended and restated bylaws, or (5) any other action asserting a claim that is governed by the internal affairs doctrine, shall be the Court of Chancery of the State of Delaware (or another state court or the federal court located within the State of Delaware if the Court of Chancery does not have or declines to accept jurisdiction), in all cases subject to the court's having jurisdiction over indispensable parties named as defendants. In addition, our eighth amended and restated certificate of incorporation will provide that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act but that the forum selection provision will not apply to claims brought to enforce a duty or liability created by the Exchange Act. Although we believe these provisions benefit us by providing increased consistency in the application of Delaware law for the specified types of actions and proceedings, the provisions may have the effect of discouraging lawsuits

against us or our directors and officers. Alternatively, if a court were to find the choice of forum provision contained in our eighth amended and restated certificate of incorporation and amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, financial condition, and operating results. For example, under the Securities Act, federal courts have concurrent jurisdiction over all suits brought to enforce any duty or liability created by the Securities Act, and investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Any person or entity purchasing or otherwise acquiring any interest in our shares of capital stock shall be deemed to have notice of and consented to this exclusive forum provision, but will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains "forward-looking statements" within the meaning of the federal securities laws, which statements are subject to substantial risks and uncertainties and are based on estimates and assumptions. All statements, other than statements of historical facts included in this prospectus, including statements concerning our plans, objectives, goals, strategies, future events, future revenues or performance, financing needs, plans or intentions relating to products and markets, and business trends and other information referred to under "Prospectus Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," and "Business," are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "design," "estimate," "predict," "potential," "plan," or the negative of these terms, and similar expressions intended to identify forward-looking statements. Forward-looking statements are not historical facts, and reflect our current views with respect to future events. Given the significant uncertainties, you should not place undue reliance on these forward-looking statements.

There are a number of risks, uncertainties, and other factors that could cause our actual results to differ materially from the forward-looking statements expressed or implied in this prospectus. Such risks, uncertainties, and other factors include, among others, the following risks, uncertainties, and factors:

- the recent and ongoing COVID-19 pandemic and associated shelter-in-place orders;
- our ability to develop and commercialize molecular testing products as well as innovate in the field of precision medicine;
- the size and growth potential of the markets for our products and product candidates, and our ability to serve those markets;
- the rate and degree of market acceptance and clinical utility of our products and product candidates, if approved;
- coverage and reimbursement for our products and product candidates;
- the performance of third parties in connection with the development of our products and product candidates, including third-party suppliers;
- regulatory developments in the United States and foreign countries;
- our ability to obtain and maintain regulatory approval or clearance of our products and product candidates on expected timelines;
- our ability to improve and enhance our current products and product candidates;
- our plans to research, develop, and commercialize new products and product candidates;
- the development, regulatory approval, efficacy, and commercialization of competing products;
- the outcome of pending investigations and legal proceedings;
- the loss or retirement of key scientific or management personnel;
- our ability to develop and maintain our corporate infrastructure, including maintaining effective internal control;
- our use of the proceeds from this offering;
- our estimates regarding expenses, future revenue, capital requirements, and needs for additional financing; and

- our expectations regarding our ability to obtain and maintain intellectual property protection for our products, as well as our ability to operate our business without infringing the intellectual property rights of others.

There may be other factors that cause our actual results to differ materially from the forward-looking statements expressed or implied in this prospectus, including factors disclosed in the sections of this prospectus entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” and elsewhere. You should evaluate all forward-looking statements made in this prospectus in the context of these risks and uncertainties.

We caution you that the risks, uncertainties and other factors referred to above and elsewhere in this prospectus may not contain all of the risks, uncertainties, and other factors that may affect our future results and operations. Moreover, new risks will emerge from time to time. It is not possible for our management to predict all risks. In addition, we cannot assure you that we will realize the results, benefits, or developments that we expect or anticipate or, even if substantially realized, that they will result in the consequences or affect us or our business in the way expected.

All forward-looking statements in this prospectus apply only as of the date made and are expressly qualified in their entirety by the cautionary statements included in this prospectus. Except as required by law, we disclaim any intent to publicly update or revise any forward-looking statements to reflect subsequent events or circumstances.

INDUSTRY AND MARKET DATA

We obtained the industry, market, and competitive position data used throughout this prospectus from our own internal estimates and research, as well as from industry and general publications, and research, surveys, and studies conducted by third parties. Internal estimates are derived from publicly available information released by industry analysts and third-party sources, our internal research and our industry experience, and are based on assumptions made by us based on such data and our knowledge of the industry and market, which we believe to be reasonable. In addition, while we believe the industry, market, and competitive position data included in this prospectus is reliable and based on reasonable assumptions, we have not independently verified any third-party information, and all such data involve risks and uncertainties and are subject to change based on various factors, including those discussed in “Risk Factors.” These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

USE OF PROCEEDS

We estimate that we will receive net proceeds of approximately $89.0 million (or approximately $103.0 million if the underwriters' option to purchase additional shares is exercised in full) from the sale of the shares of common stock offered by us in this offering, based on an assumed public offering price of $15.00 per share (the midpoint of the price range set forth on the cover of this prospectus), and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each $1.00 increase (decrease) in the assumed public offering price of $15.00 per share (the midpoint of the price range set forth on the cover of this prospectus) would increase (decrease) the net proceeds to us from this offering by $6.2 million, assuming the number of shares of common stock offered by us, as set forth on the cover of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1,000,000 shares in the number of shares of common stock offered by us, as set forth on the cover of this prospectus, would increase (decrease) our net proceeds from this offering by $14.0 million, assuming the assumed public offering price remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We intend to use the net proceeds of this offering as follows:

- approximately $60.0 to 65.0 million to support our operations;
- approximately $9.0 to 11.0 million to invest in our molecular testing research and development program;
- approximately $13.0 to 15.0 million to invest in research and development with respect to our precision medicine platform; and
- the remainder for working capital and general corporate purposes.

Our expected use of proceeds from this offering represents our current intentions based on our present plans and business condition. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the proceeds to be received upon the completion of this offering or the amounts that we will actually spend on the uses set forth above. We may also use a portion of the proceeds to license, acquire, or invest in complementary businesses, technology, products, or assets. However, we have no current commitments to do so. If we receive any additional proceeds from this offering, we expect to use such proceeds on a proportional basis to the categories described above.

The amount and timing of our actual expenditures will depend on numerous factors, including the pace and results of our research and development efforts, the success and timing of our clinical trials, the timing and costs associated with our operations, including the manufacture and supply of products and product candidates, the timing of regulatory submissions, and any unforeseen cash needs. As a result, our management will have broad discretion over the use of the proceeds from this offering.

Based on our current business plans, we believe that the net proceeds from this offering allocated to research and development, together with our existing cash and cash equivalents, will be sufficient to fund the development of our molecular testing programs and our precision medicine platform into the first quarter of 2021. Such amount will not be sufficient for us to fund our precision medicine platform pipeline through regulatory approval and commercialization, and we will need to raise substantial additional capital in order to do so. To obtain the capital necessary to fund our precision medicine platform pipeline through regulatory approval and commercialization, we may need to enter into additional public or private equity offerings, debt financings or collaborations and licensing arrangements or seek out other capital sources.

Pending the use of the proceeds from this offering, we may invest the proceeds in interest-bearing, investment-grade securities, certificates of deposit, or government securities.

DIVIDEND POLICY

Our Board did not declare any dividends in 2017 or 2018. On March 6, 2019, our Board declared aggregate cash dividends of $4,500,000, which dividends were paid on March 20, 2019.

We have no present intention to pay cash dividends on our common stock or our preferred stock. Any determination to pay dividends to holders of our common stock or our preferred stock will be at the discretion of our Board and will depend on many factors, including our financial condition, results of operations, liquidity, earnings, projected capital, and other cash requirements, legal requirements, restrictions in the agreements governing any indebtedness we may enter into, business prospects and other factors that our Board deems relevant. In addition, our credit and security agreement with Athyrium Opportunities III Co-Invest 1 LP contains, and any future credit agreement may contain, restrictions on payments of cash dividends.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of March 31, 2020:

- on an actual basis;
- on a pro forma basis to give effect to the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 30,678,642 shares of common stock; and
- on a pro forma as-adjusted basis giving effect to:
  - the pro forma item described immediately above;
  - the issuance and sale of shares of our common stock in this offering, at the assumed public offering price of $15.00 per share (the midpoint of the price range set forth on the cover of this prospectus), and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us;
  - the issuance of 19,994 shares of our common stock issued subsequent to March 31, 2020;
  - the issuance of 719,398 shares of our common stock (on an as-converted basis) issuable upon the conversion of 4,444,444 shares of our Series B Preferred Stock issued subsequent to March 31, 2020; and
  - the issuance of 2,045,522 shares of our common stock pursuant to an adjustment in the conversion rate of all of our shares of Series B Preferred Stock outstanding on the date hereof that occurs when the public offering price per share of common stock is less than $16.68, based on a public offering price of $15.00 (the midpoint of the price range set forth on the cover page of this prospectus).

The pro forma information below is illustrative only and our capitalization following the completion of this offering will be adjusted based on the actual initial public offering price and other terms determined at pricing. You should read the following table in conjunction with "Use of Proceeds," "Selected Consolidated Financial Data," "Management's Discussion and Analysis of Financial Condition and Results of Operations," and our financial statements and related notes included elsewhere in this prospectus.

	As of March 31, 2020		
	Actual	Pro Forma	Pro Forma As-adjusted(1)
	(in thousands, except share and per-share amounts)		
Cash and cash equivalents	$ 11,646	$ 11,646	$ 100,646
Total indebtedness(2)	71,779	71,779	71,779
Total long-term liabilities	121,498	121,498	121,498
Stockholders' equity (deficit):			
Common stock, $0.001 par value, 300,000,000 shares authorized, 8,508,144 shares issued, and 5,033,572 shares outstanding, actual; 39,186,786 shares issued and 35,712,214 shares outstanding, pro forma; 48,638,367 shares issued and 45,163,795 shares outstanding, pro forma as-adjusted	9	39	49
Series A Preferred Stock, $0.001 par value, 4,120,000 shares authorized, 4,120,000 shares issued and outstanding, actual; no shares authorized, issued and outstanding, pro forma and pro forma as-adjusted	4	—	—
Series B Preferred Stock, $0.001 par value, 126,035,000 shares authorized, 107,901,201 shares issued and outstanding, actual; no shares authorized, issued and outstanding, pro forma and pro forma as-adjusted	108	—	—
Additional paid-in capital	299,486	299,568	388,558
Accumulated deficit	(365,630)	(365,630)	(365,630)
Treasury stock, at cost; 3,474,572 shares of common stock	(18,771)	(18,771)	(18,771)
Total stockholders' equity (deficit)	(84,794)	(84,794)	4,206
Total capitalization	$ 36,704	$ 36,704	$ 125,704

(1) Pro forma as-adjusted to give effect to the issuance and sale of shares of our common stock in this offering, at the assumed public offering price of $15.00 per share (the midpoint of the price range set forth on the cover of this prospectus), and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each $1.00 increase (decrease) in the assumed public offering price of $15.00 per share (the midpoint of the price range set forth on the cover of this prospectus) would increase (decrease) each of our pro forma as-adjusted cash and cash equivalents, additional paid-in capital, total stockholders' equity (deficit) and total capitalization by approximately $6.2 million, assuming the number of shares of common stock offered by us, as set forth on the cover of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1,000,000 shares in the number of shares of common stock offered by us would increase (decrease) each of our pro forma as-adjusted cash and cash equivalents, additional paid-in capital, total stockholders' equity (deficit) and total capitalization by approximately $14.0 million, assuming the assumed public offering price remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

(2) Total indebtedness includes mortgages payable of $3.3 million and a note payable of $68.5 million, each as of March 31, 2020.

The outstanding share information in the table above is based on 35,712,214 shares of our common stock (including shares of our preferred stock outstanding on an as-converted basis) as of March 31, 2020, and excludes:

- 3,678,520 shares of our common stock issuable upon the exercise of stock options outstanding as of March 31, 2020 under our 2011 Incentive Stock Plan, Second Amended and Restated 2012 Stock Plan, 2015 Consultant Stock Plan and 2018 Plan, at a weighted average exercise price of $7.90 per share;
- 990,463 shares of our common stock issuable upon the settlement of restricted stock units outstanding as of March 31, 2020, 83,079 of which we expect to be issued for vested restricted stock units under our 2018 Plan on the date on which any restrictions imposed by the underwriters in connection with this offering have expired;

- 114,614 restricted stock units and 230,402 options to purchase shares of our common stock granted subsequent to March 31, 2020 at a weighted-average exercise price of $12.76 per share;
- 4,707,604 shares of our common stock reserved for future issuance under our 2018 Plan, as well as any automatic increase in the number of shares of common stock reserved for future issuance under this plan;
- 510,000 shares of our common stock to be reserved for future issuance under our 2020 Employee Stock Purchase Plan, which will become effective immediately prior to the completion of this offering, as well as any automatic increase in the number of shares of common stock reserved for future issuance under this plan;
- 400,160 shares of our common stock (on an as-converted basis) issuable upon exercise of an outstanding Series B Preferred Stock Purchase Warrant at an exercise price of $13.90 per share, including 40,461 shares issuable pursuant to an adjustment in the conversion rate of all of our shares of Series B Preferred Stock outstanding as of the date hereof that occurs when the public offering price per share of common stock is less than $16.68, based on a public offering price of $15.00 (the midpoint of the price range set forth on the cover page of this prospectus); and
- 1,250,000 shares of our common stock issuable upon conversion of an unsecured convertible promissory note, based on a public offering price of $15.00 (the midpoint of the price range set forth on the cover page of this prospectus).

The number of shares outstanding after the offering will depend primarily on the price per share at which our common stock is sold in this offering and the total size of this offering. In connection with this offering and pursuant to our certificate of incorporation:

- all outstanding shares of our Series A Preferred Stock will be convertible into a number of shares of common stock as is determined by dividing $0.48543, the Series A Preferred Stock original issue price, by $0.1514, the Series A Preferred Stock conversion price;
- all outstanding shares of our Series B Preferred Stock will be convertible into a like number of shares of common stock, unless the public offering price per share of common stock is less than $16.68, in which case the conversion rate per share of Series B Preferred Stock shall be adjusted, as of immediately prior to the consummation of this offering, such that each share of our Series B Preferred Stock is convertible into a number of shares of common stock as is determined by dividing $2.25 by the product of (1) the public offering price per share of common stock and (2) 0.833;
- upon a qualified initial public offering (as defined in our existing seventh amended and restated certificate of incorporation, requiring a minimum public offering price of $13.90 in this offering), our unsecured convertible promissory note automatically converts into a number of shares of common stock calculated by dividing $15.0 million, the outstanding principal amount of the note, by the lesser of (i) $13.90 and (ii) the product of (1) the public offering price per share of common stock and (2) 0.8;
- upon an initial public offering that is not a qualified initial public offering, our unsecured convertible promissory will be convertible at the election of the holders into a number of shares of common stock as is determined by dividing $15.0 million, the outstanding principal amount of the note, by the product of (1) the public offering price per share of common stock and (2) 0.8; and
- our outstanding Series B Preferred Stock Purchase Warrant will be convertible following this offering into those shares of common stock that would be issuable upon conversion of the shares of Series B Preferred Stock subject to purchase pursuant to the Series B Preferred Stock Purchase Warrant as of the date of this offering, as described above.

DILUTION

If you invest in the shares of our common stock in this offering, your ownership interest will be immediately diluted. Dilution represents the difference between the amount per share paid by investors in this offering and the as-adjusted net tangible book value per share of our common stock immediately after this offering. The data in this section are derived from our balance sheet as of March 31, 2020. Our historical net tangible book value per share is equal to our total tangible assets less the amount of our total liabilities, divided by the sum of the number of shares of our common stock outstanding on March 31, 2020. Our historical net tangible book value as of March 31, 2020 was $(97.4) million, or $(19.35) per share of common stock.

After giving effect to our receipt of the estimated net proceeds from the sale of our common stock in this offering, based on an assumed public offering price of $15.00 per share (the midpoint of the price range set forth on the cover of this prospectus), and after deducting the estimated underwriting discounts and commissions and other estimated offering expenses payable by us, the conversion of all outstanding shares of our preferred stock as of the date hereof into 31,398,040 shares of common stock, and the issuance of 2,045,522 shares of our common stock pursuant to an adjustment in the conversion rate of all of our shares of Series B Preferred Stock outstanding on the date hereof that occurs when the public offering price per share of common stock is less than $16.68, based on a public offering price of $15.00 (the midpoint of the price range set forth on the cover page of this prospectus)), our as-adjusted net tangible book value as of March 31, 2020 would have been $(8.4) million, or $(0.19) per share of our common stock. This represents an immediate increase in net tangible book value to our existing stockholders of $19.16 per share and an immediate dilution to new investors in this offering of $15.19 per share. The following table illustrates this per share dilution:

Assumed public offering price per share		$ 15.00
Historical net tangible book value per share as of March 31, 2020	$ (19.35)	
Pro forma increase in net tangible book value per share as of March 31, 2020, after giving effect to the conversion of all preferred stock into shares of common stock	$ 16.62	
Increase in net tangible book value per share attributable to new investors	$ 2.54	
As-adjusted net tangible book value per share after this offering		$ (0.19)
Dilution per share to new investors		$ 15.19

A $1.00 increase in the assumed public offering price of $15.00 per share would increase our as-adjusted net tangible book value by $6.2 million and the as-adjusted net tangible book value per share after this offering by $0.14 per share, and the dilution per share to new investors by $0.86 per share, while a $1.00 decrease in the assumed public offering price of $15.00 per share would decrease our as-adjusted net tangible book value by $6.2 million and the as-adjusted net tangible book value per share after this offering by $0.13 per share, and the dilution per share to new investors by $0.87 per share, assuming the number of shares offered by us, as set forth on the cover of the prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase of 1,000,000 shares in the number of shares offered by us would increase our as-adjusted net tangible book value by $14.0 million, increase the as-adjusted net tangible book value per share after this offering by $0.31 per share, and decrease the dilution per share to new investors by $0.31 per share. Similarly, each decrease of 1,000,000 shares in the number of shares offered by us would decrease our as-adjusted net tangible book value by $14.0 million, decrease the as-adjusted net tangible book value per share after this offering by $0.32 per share, and increase the dilution per share to new investors by $0.32 per share.

If the underwriters fully exercise their option to purchase additional shares, our as-adjusted net tangible book value after this offering would increase by $14.0 million or $0.31 per share, and there would be an immediate dilution of approximately $14.88 per share to new investors, assuming the assumed public offering price remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The following table presents, on an as-adjusted basis, as described above, the differences between the existing stockholders and the purchasers of shares in this offering with respect to the number of shares purchased from us, the total consideration paid, and the average price paid per share at an assumed public offering price of $15.00 per share (the midpoint of the price range set forth on the cover of this prospectus):

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders	38,497,128	85.2%	$170,018,945	63.0%	$ 4.42
New investors	6,666,667	14.8	100,000,005	37.0	$ 15.00
Total	45,163,795	100.0%	$270,018,950	100.0%	

If the underwriters were to fully exercise their option to purchase 1,000,000 additional shares of our common stock from us, the percentage of shares of our common stock held by existing stockholders would be 83.4%, and the percentage of shares of our common stock held by new investors would be 16.6%.

Certain of our existing stockholders, including those affiliated with members of our Board, have indicated an interest in purchasing an aggregate of up to approximately $50 million of shares of our common stock in this offering at the initial public offering price per share and on the same terms as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares of common stock to any of these potential purchasers, and any of these potential purchasers could determine to purchase more, fewer or no shares of common stock in this offering. The underwriters will receive the same underwriting discount and commissions on these shares of common stock as they will on any other shares of common stock sold to the public in this offering.

The outstanding share information in the table above (i) is based on 35,712,214 outstanding shares of our common stock (including shares of our preferred stock outstanding on an as-converted basis) as of March 31, 2020, (ii) includes 19,994 shares of our common stock issued subsequent to March 31, 2020, (iii) includes 719,398 shares of our common stock (on an as-converted basis) issuable upon the conversion of 4,444,444 shares of our Series B Preferred Stock issued subsequent to March 31, 2020, (iv) includes 2,045,522 shares of our common stock issuable pursuant to an adjustment in the conversion rate of all of our shares of Series B Preferred Stock outstanding as of the date hereof that occurs when the public offering price per share of common stock is less than $16.68, based on a public offering price of $15.00 (the midpoint of the price range set forth on the cover page of this prospectus), and (v) excludes the following:

- 3,678,520 shares of our common stock issuable upon the exercise of stock options outstanding as of March 31, 2020 under our 2011 Incentive Stock Plan, Second Amended and Restated 2012 Stock Plan, 2015 Consultant Stock Plan and 2018 Plan, at a weighted average exercise price of $7.90 per share;
- 990,463 shares of our common stock issuable upon the settlement of restricted stock units outstanding as of March 31, 2020, 83,079 of which we expect to be issued for vested

restricted stock units under our 2018 Plan on the date on which any restrictions imposed by the underwriters in connection with this offering have expired;

- 114,614 restricted stock units and 230,402 options to purchase shares of our common stock granted subsequent to March 31, 2020 at a weighted-average exercise price of $12.76 per share;
- 4,707,604 shares of our common stock reserved for future issuance under our 2018 Plan, as well as any automatic increase in the number of shares of common stock reserved for future issuance under this plan;
- 510,000 shares of our common stock to be reserved for future issuance under our 2020 Employee Stock Purchase Plan, which will become effective immediately prior to the completion of this offering, as well as any automatic increase in the number of shares of common stock reserved for future issuance under this plan;
- 400,160 shares of our common stock (on an as-converted basis) issuable upon exercise of an outstanding Series B Preferred Stock Purchase Warrant at an exercise price of $13.90 per share, including 40,461 shares issuable pursuant to an adjustment in the conversion rate of all of our shares of Series B Preferred Stock outstanding as of the date hereof that occurs when the public offering price per share of common stock is less than $16.68, based on a public offering price of $15.00 (the midpoint of the price range set forth on the cover page of this prospectus); and
- 1,250,000 shares of our common stock issuable upon conversion of an unsecured convertible promissory note, based on a public offering price of $15.00 (the midpoint of the price range set forth on the cover page of this prospectus).

SELECTED CONSOLIDATED FINANCIAL DATA

The following tables set forth selected historical consolidated financial data as of and for the periods indicated. The historical consolidated statement of operations data for the years ended December 31, 2018 and 2019 and the consolidated balance sheet data as of December 31, 2018 and 2019 are derived from our audited consolidated financial statements included elsewhere in this prospectus. The historical consolidated statement of operations data for the three months ended March 31, 2019 and 2020 and the consolidated balance sheet data as of March 31, 2020 are derived from our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus. Our unaudited interim condensed consolidated financial statements were prepared on the same basis as our audited consolidated financial statements and, in our opinion, reflect all adjustments, consisting only of normal recurring adjustments, that are necessary for the fair statement of our unaudited interim condensed consolidated financial statements.

The historical results presented below are not necessarily indicative of the results to be expected for any future period, and our interim results are not necessarily indicative of the results to be expected for the full year or any future period. This information should be read in conjunction with "Risk Factors," "Capitalization," "Management's Discussion and Analysis of Financial Condition and Results of Operations," and our financial statements and the related notes included elsewhere in this prospectus. Our financial statements are prepared in accordance with GAAP.

	Year Ended December 31,		Three Months Ended March 31,	
	2018	2019	2019	2020
	(in thousands, except share and per share data)		(in thousands, except share and per share data) (unaudited)	
Revenue	$ 127,974	$ 143,985	$ 47,507	$ 16,828
Cost of sales	92,076	100,492	24,421	26,570
Gross profit	35,898	43,493	23,086	(9,742)
Operating expenses:				
Research and development	48,712	63,400	15,248	11,240
Selling and marketing	50,187	58,888	15,567	14,436
General and administrative	51,238	61,324	14,278	17,108
Total operating expenses	150,137	183,612	45,093	42,784
Loss from operations	(114,239)	(140,119)	(22,007)	(52,526)
Interest expense	(9,091)	(9,199)	(2,269)	(2,302)
Equity loss of equity method investee	(2,327)	—	—	—
Interest and other income, net	1,801	575	257	(20)
Loss before taxes	(123,856)	(148,743)	(24,019)	(54,848)
Income tax expense (benefit)	5,250	(706)	—	(37,696)
Net loss	$ (129,106)	$ (148,037)	$ (24,019)	$ (17,152)
Dividend paid to preferred stockholders	—	(3,652)	(3,652)	—
Stock dividend on exchange of Series A-1 for Series B Preferred Stock	—	(27,637)	—	—
Stock dividend on Series B Preferred Stock	—	(49,501)	—	—
Net loss attributable to common stockholders	$ (129,106)	$ (228,827)	$ (27,671)	$ (17,152)
Net loss per share attributable to common stockholders, basic and diluted	$ (27.72)	$ (46.87)	$ (5.88)	$ (3.43)
Weighted average number of shares outstanding, basic and diluted	4,657,337	4,882,662	4,705,641	4,993,393
Pro forma loss per share, basic and diluted (unaudited)(1)		$ (5.49)		$ (0.49)
Pro forma weighted average shares outstanding, basic and diluted (unaudited)(1)		26,961,445		35,063,069

(1) See Notes 2 and 13 to our audited consolidated financial statements and Notes 2 and 13 to our unaudited condensed consolidated financial statements included elsewhere in this prospectus for an explanation of the method used to calculate our net loss per share attributable to common stockholders, basic and diluted; pro forma net loss attributable to common stockholders, basic and diluted; and the weighted average shares used in the computation of these per share amounts.

	As of December 31, 2019	As of March 31, 2020
	(in thousands)	
Selected Balance Sheet Data:		
Cash and cash equivalents	$ 33,042	$ 11,646
Total assets	101,727	110,951
Total indebtedness(1)	72,288	71,779
Total liabilities	185,601	195,745
Preferred stock	106	112
Accumulated deficit	(348,478)	(365,630)
Total stockholders' deficit	(83,874)	(84,794)

(1) Total indebtedness includes mortgages payable of $3.3 million and a note payable of $69.0 million, each as of December 31, 2019, and mortgages payable of $3.3 million and a note payable of $68.5 million, each as of March 31, 2020.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our audited and unaudited consolidated financial statements and the related notes and other financial information included elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business, include forward-looking statements that involve risks and uncertainties. You should review the section titled "Risk Factors" for a discussion of important factors that could cause our actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a biotechnology company with an established track record of success in developing and commercializing molecular testing products as well as innovating in the field of precision medicine. We believe that we are a market-leading provider of *in vitro* molecular tests designed to improve lives by providing actionable information that helps guide patients and physicians in making critical and timely medical decisions during various life stages, such as family planning, pregnancy, or navigating a complex disease diagnosis. Our vision is to transform healthcare to become more precise and personal by improving diagnoses of disease and improving patient outcomes through localized treatment with targeted therapies. We apply a multi-omics approach, combining genomics, epigenomics, proteomics, and metabolomics, to our molecular testing products and to the development of a suite of investigational ingestible devices and drug/device combinations designed to provide precise diagnostic sampling and drug delivery solutions.

Since 2010, our molecular testing business has achieved consistent year-over-year test volume growth through our robust product portfolio and our strong commercial organization. Our internal core competencies, deep research and development pipeline and strategic acquisitions of novel technologies have fueled our innovation in women's health, supporting the development and launch of complementary molecular testing products that inform critical healthcare decision-making across a woman's lifetime.

In 2015, we launched both our Innatal Prenatal Screen, a NIPT offering, and our Preparent Carrier Test, followed by the launch of our Riscover Hereditary Cancer Test in 2017. We offer molecular tests with market-leading performance and turnaround times, supported by end-to-end workflow solutions that increase administrative efficiencies. Along with our comprehensive menu of molecular tests, we offer patients pre-test education, clear and timely results, and on-demand genetic counseling. We are committed to providing patients and physicians with empathetic communication and support during critical moments to help empower and prepare patients and their families to make critical life decisions.

We generate revenue by providing tests. Our molecular tests are provided through our certified CLIA or CAP accredited laboratory located in Ann Arbor, Michigan and we also provide anatomic and molecular pathology tests through our affiliation with Mattison Pathology, LLP, a Texas limited liability partnership doing business as Avero Diagnostics, located in Lubbock and Irving, Texas. The focus of our commercial operations is to distribute our molecular tests and our anatomic and molecular pathology tests through our dedicated direct sales force. Distribution of our tests is supported by a field operations team who provide all logistical functions in receiving clinical samples at the laboratory for analysis. During the year ended December 31, 2019, we accessioned approximately 329,000 tests, and during the three months ended March 31, 2020, we accessioned approximately 78,881 tests.

We generate revenue through providing our tests and receive payments for such tests from payors, laboratory distribution partners, and self-paying individuals. More than 95% of payments for our tests

are received through reimbursement. We receive reimbursement from several distinct channels: commercial third-party payors, laboratory distribution partners, and government health benefits programs such as Medicare and Medicaid.

We are engaged in research and development activities with respect to molecular tests and precision medicine product candidates. Our molecular test portfolio and pipeline and our precision medicine product pipeline are each powered by a combination of symbiotic technology platforms exploiting advances in genetics, epigenetics, and proteomics, fortified by an innovative bioinformatics infrastructure. Our ecosystem is designed to enable rapid development and validation of products in an integrated fashion. We intend to continue to invest in our research and development activities as a public company. As a result, we expect to incur operating losses for the foreseeable future and may need to raise additional capital in order to fund our operations. Our ability to return to profitability will depend upon achieving our revenue growth objectives and successfully manage our costs.

Factors Affecting Our Performance

We believe there are several important factors that impact our commercial performance and results of operations, including:

Report Volume

We compete in the molecular testing market based upon several factors, including (i) the strong performance and short turnaround time of our integrated tests, (ii) the quality of our sales and marketing efforts with physicians, (iii) the quality of our end-to-end customer service and support solutions, and (iv) the availability of reimbursement for our tests. Our commercial team of more than 150 individuals actively engages with physicians and their staff to emphasize the clinical need for our products, provide education on the clinical value of our products, and facilitate the ability of physicians and their staff to order our tests. The volume of tests that we accession is one of the key performance indicators that we use to evaluate our business. A test is accessioned when we receive the test samples at our laboratory, the relevant information about the desired test is entered into our systems, and the samples are routed into the appropriate process flow. The ratio of the Innatal tests and the Preparent tests that we accession is 1.2:1. As the types and categories of tests that are covered by reimbursement increase or decrease, the volume of testing may correspondingly increase or decrease, respectively. In 2019, we conducted a comprehensive review of our existing accounts and sought to eliminate accounts that did not contribute to our gross margin. Our test volumes decreased as a result of this exercise.

Beginning in March 2020, we began to observe significant declines in the volumes of our molecular tests as well as the pathology tests conducted by Avero Diagnostics due to the impact of the COVID-19 pandemic and work-from-home policies and other operational limitations mandated by federal, state and local governments as a result of the pandemic. However, we believe our business is resilient and we have observed positive signs of recovery so far. While we are implementing mitigation strategies to address these limitations, such as supporting patients and physicians virtually, there can be no assurance that the rate of decline in our testing volumes will not continue or accelerate in future periods. Our initial assessment of the impact of the COVID-19 pandemic is that our NIPT test volumes have proved more resilient than our carrier screening test volumes; however, the comparative impact may change over time.

Reimbursement

Reimbursement fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to:

- third-party payor coverage and, as we continually seek to transition to in-network coverage with commercial third-party payors, corresponding increases in our in-network covered lives;

- regulatory and medical society recommendations such CMS, ACOG, ACMG, and SMFM, that potentially lead to positive coverage determinations by commercial third-party payors and government health benefits programs for our tests;
- third-party payor medical coverage and administrative policies, including reimbursement rates published by CMS;
- delays to third-party payors' processing due to the impact of the COVID-19 pandemic and work-from-home policies and other operational limitations mandated by federal, state, and local governments as a result of the pandemic;
- future CPT code and medical procedure code changes, such as obtaining appropriate codes for our new molecular tests, including our expanded carrier screening panels, NIPT, and Exon carrier screening;
- regulatory and payor fee schedule changes for CPT codes with respect to our products;
- requirements to refund any reimbursements already received;
- the overall mix of payor class for our products sold;
- changes in physician ordering trends;
- the mix of our products sold;
- the geographic regions in which our products are sold;
- competition in our industries and any change in the competitive landscape of our industries, including potential consolidation; and
- future accounting pronouncements or changes in our accounting policies.

Gross Margin

Our gross margin is an important indicator of the operating performance of our business. Higher gross margins reflect the average selling price of our tests, as well as the operating efficiency of our laboratory operations. Reducing the costs of goods sold for our tests represents another important opportunity for innovation and is a significant area of focus for our research and development organization. We regularly evaluate our operations in order to determine whether we can reduce costs by developing new technologies, improving the efficiency of our assay and laboratory processes, modifying our processes to use materials and technologies that provide equal or greater quality at lower cost, and improving how we manage our inventory and negotiating favorable terms for our materials purchases. In 2019, we conducted a comprehensive review of our existing accounts and sought to eliminate accounts that did not contribute to our gross margin. In future periods, we expect this to have a positive impact on our gross margin; however, such an impact cannot be assured. We are currently developing our next generation Innatal Prenatal Screen (Innatal 4th Generation), an improved platform with simplified and more cost-effective assay workflow, which we believe will allow us to substantially improve the gross margin of our NIPT. We also work with partner laboratories that complement our test portfolio offering, while developing in parallel new technologies that we expect could, over time, reduce our cost structure by internalizing the production of those tests when the commercial benefits dictate such conversion.

New Product Development

Our business involves significant investment in research and development activities for the development of new products which we believe are strategic complements to our product portfolio and drive long-term revenue growth. We intend to continue investing in our pipeline of new products and technologies. We expect our investment in research and development to increase as we pursue regulatory approval of

our product candidates and as we seek to expand our pipeline of product candidates. Due to the impact of the COVID-19 pandemic and work-from-home policies and other operational limitations mandated by federal, state, and local governments as a result of the pandemic, certain of our research and development activities have been delayed and may be further delayed until such operational limitations are lifted. While we are implementing mitigation strategies, where possible, certain preclinical and clinical activities are suspended during the implementation of these policies and will necessarily incur some delay following the resumption of normal operations. In particular, the development of our preeclampsia rule-out test has been and may continue to be delayed due to shelter-in-place orders in the State of Michigan.

The achievement of key development milestones (e.g., clinical verification and validation and CLIA certification for our molecular tests and clinical studies and regulatory approval for our precision medicine product platform) is a key factor in evaluating our performance. For an overview of the key development milestones with respect to each of our precision medicine product candidates, please see the pipeline chart on page 121. For an overview of the key development milestones for our molecular tests in development, please see “Business—Our Research and Development Activities.”

Key Components of Our Results of Operations

Revenue

Substantially all of our revenue is derived from molecular laboratory tests, principally from the sale of Innatal, Preparent, and pathology molecular testing. The revenue we derive from our Innatal tests and our Preparent tests is roughly equal, although the ratio may fluctuate over time. We bill and collect from third-party payors, laboratory distribution partners, and self-paying individuals. Third-party payors include commercial third-party payors and government payors, such as Medicare and Medicaid in the United States. We bill for these tests rendered upon completion of the testing process and delivery of test results to the customer.

Due to potential future changes in insurance coverage policies, contractual rates, and other trends in the reimbursement of our tests, payments received for our tests may fluctuate significantly over time. Our revenue incorporates an estimate of variable consideration, which is adjusted for estimates of disallowed cases, discounts, and refunds. We have established an accrual for refunds of payments previously made by healthcare insurers based on historical experience and executed settlement agreements with healthcare insurers. The refunds are accounted for as reductions in revenues in the statement of operations as an element of variable consideration. Our estimate of variable consideration included in the transaction price is also impacted by our ongoing transition to in-network contracts with commercial payors. Currently, we operate primarily as an in-network provider of molecular tests and we continually seek to transition to in-network coverage with additional third-party payors, which we believe is crucial to our growth and long-term success. This transition is ongoing and we are actively negotiating with a few remaining commercial payors. We are currently contracted with payors representing an estimated approximately 127 million covered lives and will be contracted with payors representing an estimated approximately 143.5 million covered lives as of July 1, 2020.

While the negotiated fees under our in-network contracts with third-party payors are typically lower than the out-of-network list price of our tests, the percentage of tests allowed by payors traditionally increases in accordance with payors’ medical policies. While we expect the reduction in average reimbursement per test from in-network pricing to reduce our per test revenue and gross margins in the near term, in-network pricing is more predictable than out-of-network pricing, and we intend to continue to mitigate the impact by implementing a strategic focus for our most profitable accounts.

Delays to third-party payors' processing due to the impact of the COVID-19 pandemic and work-from-home policies and other operational limitations mandated by federal, state, and local governments as a result of the pandemic have and may continue to extend the typical timelines under which we are able to recognize revenue. The full impact of these delays may not be realized immediately, including within the first and second quarters of 2020, as we customarily receive payment a number of months after completion of a molecular test.

Cost of Sales

Cost of sales includes the cost of materials, direct labor of laboratory personnel, third-party laboratory testing services, equipment, and infrastructure expenses associated with processing blood and other samples, quality control analyses, shipping charges to transport samples and specimens from ordering physicians, clinics, or individuals, and allocated overhead including information technology, or IT, costs. Infrastructure expenses include allocated facility and related occupancy costs. Costs associated with the performance of molecular tests are recorded as tests are processed. We continue to implement mitigation strategies to address the work-from-home policies and other operational limitations mandated by federal, state, and local governments as a result of the COVID-19 pandemic. While largely yet to be determined, these mitigation strategies may cause increases in any or all of the aforementioned costs. The amount of cost of sales is related to our volume of accessioned tests, which is directly related to consumption of reagents and other laboratory support services. Therefore, growth in accessioned volume of tests results in increased cost of sales on an aggregate basis and potential modest reductions in cost of sales on a per test basis.

Research and Development

Research and development expenses consist primarily of costs associated with performing research and development activities to improve our tests, to reduce product costs, and to develop new products including our preeclampsia test and our precision medicine product candidates. Research and development expenses consist of personnel expenses, including salaries, bonuses, stock-based compensation expense, benefits, consulting costs, and allocated overhead costs. Research and development costs are expensed as incurred.

We plan to continue investing in research and development activities for the foreseeable future as we focus on developing innovative products, including our preeclampsia test and our precision medicine product candidates, through preclinical studies and clinical trials. We also expect our investment in research and development to increase as we pursue regulatory approval of our product candidates and as we seek to expand our pipeline of product candidates.

Due to the impact of the COVID-19 pandemic and work-from-home policies and other operational limitations mandated by federal, state, and local governments as a result of the pandemic, certain of our research and development activities have been delayed and may be further delayed until such operational limitations are lifted. While we are implementing mitigation strategies, where possible, certain preclinical and clinical activities are suspended during the implementation of these policies and will necessarily incur some delay following the resumption of normal operations.

Selling and Marketing

Selling and marketing expenses consist primarily of personnel costs, including salaries, commissions, bonuses, stock-based compensation expense, and benefits for our sales and marketing team. Selling and marketing expenses also include costs for communication, advertising, conferences, other marketing events, and allocated overhead costs. We expect selling and marketing expense to continue to increase as we increase the size of our selling and marketing function to support the growth of our business. We

continue to implement mitigation strategies to address the work-from-home policies and other operational limitations mandated by federal, state, and local governments as a result of the COVID-19 pandemic. While largely yet to be determined, these mitigation strategies include virtual meetings and mobile phlebotomy services for patients preferring not to visit a physician's office. These strategies and others may cause increases in our sales and marketing costs.

General and Administrative

General and administrative expenses consist primarily of personnel costs, including salaries, bonuses, stock-based compensation expense, and benefits, for our finance and accounting, legal, human resources, and other administrative teams. Additionally, these expenses include professional fees of audit, legal, and recruiting services. Following the listing of our common stock on Nasdaq, we expect to continue to incur additional expenses as a result of operating as a public company, including costs to comply with the rules and regulations applicable to companies listed on a U.S. securities exchange and costs related to compliance and reporting obligations pursuant to the rules and regulations of the SEC. In addition, as a public company, we expect to incur increased expenses in the areas of insurance, investor relations, and professional services. As a result, we expect the dollar amount of our general and administrative expenses to increase for the foreseeable future. We expect, however, that our general and administrative expenses will decrease as a percentage of our revenue over time, although the percentage may fluctuate from period to period depending on fluctuations in our revenue and the timing and extent of our general and administrative expenses.

Loss on Equity Method Investment

Investments over which we are deemed to exert significant influence but not control are accounted for using the equity method of accounting. For investments accounted for under the equity method of accounting, our share of income (losses) is included in income of investees in the consolidated statement of operations. Until June 2019, we owned a 20% interest in NeoSeq Ltd., a Cayman Islands exempt company, or NeoSeq, which operates a laboratory in China focused on fetal diagnostic operations for the Asia Pacific market and certain Middle Eastern countries. We evaluate our equity method investment for impairment whenever an event or change in circumstances occurs that may have a significant adverse impact on the carrying value of the investment. During 2018, NeoSeq completed a financing transaction that diluted our ownership in NeoSeq. Due to this transaction and continued losses, we recorded an impairment loss of $1.4 million in our consolidated statement of operations during the quarter ended December 31, 2018. In June 2019, we sold the NeoSeq investment to a third party.

Interest Expense

Interest expense is primarily attributable to borrowings under our Credit Agreement (as defined below). Interest expense is also attributable to our outstanding mortgages and capital lease agreements.

Interest and Other Income, Net

Interest and other income, net primarily consists of interest income earned from our cash and cash equivalents, and changes in fair value of short-term investments.

Income Tax Expense

We account for income taxes under the asset-and-liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis, and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected

to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

We recognize the effect of income tax positions only if those positions are more likely than not of being sustained. Recognized income tax positions are measured at the largest amount that is greater than 50% likely of being realized. Changes in recognition or measurement are recognized in the period in which the change in judgment occurs. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount expected to be realized. During the year ended December 31, 2018, due to losses generated in 2018 and projected future taxable losses anticipated in the future, we established a 100% valuation allowance on net deferred tax assets and as a result recorded income tax expense of $5.3 million. The tax benefit recorded during the year ended December 31, 2019 was recorded due to refunds received during 2019.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, was enacted. The CARES Act includes several significant provisions for corporations, including the usage of net operating losses, interest deductions and payroll benefits. Corporate taxpayers may carryback net operating losses, or NOLs, originating during 2018 through 2020 for up to five years. During the three months ended March 31, 2020, we recorded a discrete tax benefit of $37.7 million related to the NOL carryback provisions available under the CARES Act legislation for taxes paid in years 2013, 2014, 2015, and 2017. If any tax refund is received that is more than $5.0 million in a single year, along with other civil settlements, damages awards, and tax refunds, we have agreed to pay 65% of all such amounts received to accelerate payments to the government in connection with our proposed government settlement. See “Business—Legal Proceedings—Federal Investigation.”

Results of Operations

Comparison of Three Months Ended March 31, 2019 and 2020

	Three Months Ended March 31,	
	2019	2020
	(in thousands)	
Statements of Operations Data:	(unaudited)	
Revenue	$ 47,507	$ 16,828
Cost of sales	24,421	26,570
Gross profit (loss)	23,086	(9,742)
Operating expenses:		
Research and development	15,248	11,240
Selling and marketing	15,567	14,436
General and administrative	14,278	17,108
Total operating expenses	45,093	42,784
Loss from operations	(22,007)	(52,526)
Interest expense	(2,269)	(2,302)
Interest and other income (expense), net	257	(20)
Loss before taxes	(24,019)	(54,848)
Income tax benefit	—	(37,696)
Net loss	$(24,019)	$(17,152)

Percentage of Revenue Data:	Three Months Ended March 31, 2019 (unaudited)	2020 (unaudited)
Revenue	100%	100%
Cost of sales	51	158
Gross profit (loss)	49	(58)
Operating expenses:		
Research and development	32	67
Selling and marketing	33	86
General and administrative	30	102
Total operating expenses	95	254
Loss from operations	(46)	(312)
Interest expense	(5)	(14)
Interest and other income (expense), net	1	—
Loss before taxes	(51)	(326)
Income tax benefit	—	(224)
Net loss	(51)%	(102)%

Revenue

	Three Months Ended March 31, 2019 (in thousands) (unaudited)	2020 (in thousands) (unaudited)	Increase/ (Decrease)	% Change
Revenue	$47,507	$16,828	$(30,679)	(64.6%)

Revenue was $16.8 million for the three months ended March 31, 2020 compared to $47.5 million for the three months ended March 31, 2019, a decrease of $30.7 million, or 64.6%. During the three months ended March 31, 2020 and 2019, revenue was reduced by $13.4 million and $0.5 million, respectively, for accruals for reimbursement claims and settlements with payors. The accrual for the three months ended March 31, 2020 includes an accrual for $13.2 million related to the settlement with the DOJ and the participating State AGs.

The $30.7 million decrease in revenue was primarily due to an increase in accruals for reimbursement claims and settlements with payors of $12.9 million, which are recognized as reductions in revenue, during the three months ended March 31, 2020 compared to the three months ended March 31, 2019. The remainder of the decrease is related to rate degradation due to payor policy changes.

Cost of Sales

	Three Months Ended March 31, 2019 (in thousands) (unaudited)	2020 (in thousands) (unaudited)	Increase/ (Decrease)	% Change
Cost of sales	$24,421	$26,570	$ 2,149	8.8%

Cost of sales was $26.6 million for the three months ended March 31, 2020 compared to $24.4 million for the three months ended March 31, 2019, an increase of $2.1 million, or 8.8%.

The increase in cost of sales was primarily due to higher labor and laboratory operation expenses. Cost of sales consists primarily of cost of labor and laboratory operation expenses and is driven by the volume of accessioned tests and changes in the mix of tests accessioned. Accessioned test volume is directly related to consumption of reagents and other laboratory support services; therefore, growth in accessioned volume of tests results in increased cost of sales. As a percentage of revenue, cost of sales was 51.0% for the three months ended March 31, 2019, compared to 158.0% for the three months ended March 31, 2020. The increase was primarily due to increased salary expense as a result of increased headcount and merit increases, along with the decrease in revenue due to the accruals for reimbursement claims and settlements.

Research and Development Expenses

	Three Months ended March 31,		Increase/ (Decrease)	% Change
	2019	2020		
	(in thousands) (unaudited)			
Research and development	$15,248	$11,240	$ (4,008)	(26.3%)

Research and development expenses were $11.2 million for the three months ended March 31, 2020 compared to $15.2 million for the three months ended March 31, 2019, a decrease of $4.0 million, or 26.3%.

The decrease in research and development expenses was primarily attributable to a $4.5 million decrease in consulting costs, as well as a $0.9 million decrease in supplies costs and other expenses, partially offset by a $1.4 million increase in salaries and personnel-related costs.

The following table summarizes the changes in research and development expenses from the three months ended March 31, 2019 to the three months ended March 31, 2020, with costs broken down by program:

	Three Months Ended March 31,	
	2019	2020
	(in thousands) (unaudited)	
Molecular Testing	$ 7,752	$ 7,051
Precision Medicine	7,496	4,189
Total research and development expenses	$15,248	$11,240

Selling and Marketing Expenses

	Three Months Ended March 31,		Increase/ (Decrease)	% Change
	2019	2020		
	(in thousands) (unaudited)			
Selling and marketing	$15,567	$14,436	$ (1,131)	(7.3%)

Selling and marketing expenses were $14.4 million for the three months ended March 31, 2020 compared to $15.6 million for the three months ended March 31, 2019, a decrease of $1.1 million, or 7.3%.

The decrease in selling and marketing expenses was primarily attributable to a $1.0 million decrease in travel and entertainment costs due to reduced conferences and national meeting costs. The remainder of the decrease is associated with decreases of $0.2 million in salaries and personnel-related costs, offset by a $0.1 million increase in marketing consulting fees.

General and Administrative Expenses

	Three Months Ended March 31,		Increase/ (Decrease)	% Change
	2019	2020		
	(in thousands) (unaudited)			
General and administrative	$14,278	$17,108	$ 2,830	19.8%

General and administrative expenses were $17.1 million for the three months ended March 31, 2020 compared to $14.3 million for the three months ended March 31, 2019, an increase of $2.8 million, or 19.8%.

The increase in general and administrative expenses was primarily attributable to a $2.0 million increase in consulting and professional costs, primarily related to legal costs, a $1.0 million increase in salaries and personnel-related costs, and a $0.3 million increase in other general and administrative costs. The increase is partially offset by decreases of $0.3 million in supplies costs, and $0.2 million in fees paid for billing systems.

Interest Expense

	Three Months Ended March 31,		Increase/ (Decrease)	% Change
	2019	2020		
	(in thousands) (unaudited)			
Interest expense	$(2,269)	$(2,302)	$ 33	1.5%

Interest expense increased by $0.03 million, or 1.5%, from the three months ended March 31, 2019 to the three months ended March 31, 2020.

Interest and Other Income (Expense), Net

	Three Months Ended March 31,		Increase/ (Decrease)	% Change
	2019	2020		
	(in thousands) (unaudited)			
Interest and other income (expense), net	$ 257	$ (20)	$ (277)	(107.8)%

Interest and other income (expense), net decreased by $0.3 million from the three months ended March 31, 2019 to the three months ended March 31, 2020, primarily attributable to the sale of short-term investments during 2019.

Income Tax Benefit

	Three Months Ended March 31,		Increase/ (Decrease)	% Change
	2019	2020		
	(in thousands) (unaudited)			
Income tax benefit	$ —	$ (37,696)	$(37,696)	100.0%

Income tax benefit was $37.7 million for the three months ended March 31, 2020, while income tax benefit was zero for the three months ended March 31, 2019. The tax benefit recorded during the three months ended March 31, 2020 was recorded due to the NOL carryback provisions available under the CARES Act legislation enacted in March 2020. During the year ended December 31, 2018, due to losses generated in 2018 and projected future taxable losses anticipated in the future, we established a 100.0% valuation allowance on net deferred tax assets and as a result recorded income tax expense of $5.3 million. Due to the valuation allowance on deferred tax assets, no tax benefit was recorded for our net loss in the three months ended March 31, 2019.

Comparison of Years Ended December 31, 2018 and 2019

	Year Ended December 31,	
	2018	2019
	(in thousands)	
Statements of Operations Data:		
Revenue	$ 127,974	$ 143,985
Cost of sales	92,076	100,492
Gross profit	35,898	43,493
Operating expenses:		
Research and development	48,712	63,400
Selling and marketing	50,187	58,888
General and administrative	51,238	61,324
Total operating expenses	150,137	183,612
Loss from operations	(114,239)	(140,119)
Interest expense	(9,091)	(9,199)
Equity loss of equity method investee	(2,327)	—
Interest and other income, net	1,801	575
Loss before taxes	(123,856)	(148,743)
Income tax expense (benefit)	5,250	(706)
Net loss	$(129,106)	$(148,037)

	Year Ended December 31,	
	2018	2019
Percentage of Revenue Data:		
Revenue	100%	100%
Cost of sales	72	70
Gross profit	28	30
Operating expenses:		
Research and development	38	44
Selling and marketing	39	41
General and administrative	40	43
Total operating expenses	117	128
Loss from operations	(89)	(97)
Interest expense	(7)	(6)
Equity loss of equity method investee	(2)	—
Interest and other income, net	1	—
Loss before taxes	(97)	(103)
Income tax expense (benefit)	4	—
Net loss	(101)%	(103)%

Revenue

	Year Ended December 31,		Increase/ (Decrease)	% Change
	2018	2019		
	(in thousands)			
Revenue	$127,974	$143,985	$ 16,011	12.5%

Revenue was $144.0 million for the year ended December 31, 2019 compared to $128.0 million for the year ended December 31, 2018, an increase of $16.0 million, or 12.5%. Effective January 1, 2019, we adopted ASC 606, using the modified retrospective transition method. As a result, revenue for reporting periods beginning after January 1, 2019 are presented under ASC 606, whereas prior period amounts have not been adjusted and continue to be reported in accordance with our historical accounting policy under ASC 605. Revenue for the year ended December 31, 2019 is therefore not comparable with the same period in the prior year.

During the years ended December 31, 2019 and 2018, revenue was reduced by $39.7 million and $53.1 million, respectively, for accruals for reimbursement claims and settlements with payors. The accrual for the year ended December 31, 2019 includes an accrual for $35.8 million related to the settlement with the DOJ and the participating State AGs.

The $16.0 million increase in revenue was primarily due to a decrease in accruals for reimbursement claims and settlements with payors of $13.4 million, which are recognized as reductions in revenue, during the year ended December 31, 2019 compared to the year ended December 31, 2018. The remainder of the increase is related to increased growth in accessioned volume of tests partially offset by rate degradation due to payor policy changes.

Cost of Sales

	Year Ended December 31,		Increase/ (Decrease)	% Change
	2018	2019		
	(in thousands)			
Cost of sales	$92,076	$100,492	$ 8,416	9.1%

Cost of sales was $100.5 million for the year ended December 31, 2019 compared to $92.1 million for the year ended December 31, 2018, an increase of $8.4 million, or 9.1%.

The increase in cost of sales was primarily due to higher labor and laboratory operations expenses related to growth in accessioned volume of tests. Cost of sales consists primarily of cost of labor and laboratory operation expenses and is driven by the volume of accessioned tests and changes in the mix of tests accessioned. Accessioned test volume is directly related to consumption of reagents and other laboratory support services; therefore, growth in accessioned volume of tests results in increased cost of sales. As a percentage of revenue, cost of sales was 72% for the year ended December 31, 2018, compared to 70% for the year ended December 31, 2019. The decrease was primarily due to changes in the mix of tests accessioned between each period.

Research and Development Expenses

	Year Ended December 31,		Increase/ (Decrease)	% Change
	2018	2019		
	(in thousands)			
Research and development	$48,712	$63,400	$ 14,688	30.2%

Research and development expenses were $63.4 million for the year ended December 31, 2019 compared to $48.7 million for the year ended December 31, 2018, an increase of $14.7 million, or 30.2%.

The increase in research and development expenses was primarily attributable to a $5.8 million increase in consulting costs, as well as a $4.6 million increase in salaries and personnel-related costs, $3.9 million increase in supplies costs and other expenses.

The following table summarizes the changes in research and development expenses from the year ended December 31, 2018 to the year ended December 31, 2019, with costs broken down by program:

	Year Ended December 31,	
	2018	2019
	(in thousands)	
Molecular Testing	$23,340	$31,562
Precision Medicine	25,372	31,838
Total research and development expenses	$48,712	$63,400

Selling and Marketing Expenses

	Year Ended December 31,		Increase/ (Decrease)	% Change
	2018	2019		
	(in thousands)			
Selling and marketing	$50,187	$58,888	$ 8,701	17.3%

Selling and marketing expenses were $58.9 million for the year ended December 31, 2019 compared to $50.2 million for the year ended December 31, 2018, an increase of $8.7 million, or 17.3%.

The increase in selling and marketing expenses was primarily attributable to a $6.0 million increase in salaries and personnel-related costs. The remainder of the increase is associated with increases of $1.1 million in marketing consulting fees, $1.1 million in advertising, promotions, trade shows, and conferences, and, $0.5 million in travel and entertainment costs.

General and Administrative Expenses

	Year Ended December 31,		Increase/ (Decrease)	% Change
	2018	2019		
	(in thousands)			
General and administrative	$51,238	$61,324	$ 10,086	19.7%

General and administrative expenses were $61.3 million for the year ended December 31, 2019 compared to $51.2 million for the year ended December 31, 2018, an increase of $10.1 million, or 19.7%.

The increase in general and administrative expenses was primarily attributable to a $2.2 million increase in salaries and personnel-related costs. The remainder of the increase is associated with increases of $3.0 million in additional rent expense related to the opening of a new genetics laboratory, $2.2 million in consulting costs, $0.9 million in IT operations, $0.7 million in fees paid for billing systems, $0.3 million in facilities costs, and $0.5 million in other general and administrative costs.

Interest Expense

	Year Ended December 31,		Increase/ (Decrease)	% Change
	2018	2019		
	(in thousands)			
Interest expense	$(9,091)	$(9,199)	$ 108	1.2%

Interest expense increased by $0.1 million, or 1.2%, from the year ended December 31, 2018 to the year ended December 31, 2019.

Equity Loss of Equity Method Investee

	Year Ended December 31,		Increase/ (Decrease)	% Change
	2018	2019		
	(in thousands)			
Equity loss of equity method investee	$(2,327)	$—	$ (2,327)	(100.0)%

Equity loss of equity method investee decreased by $2.3 million from the year ended December 31, 2018 to the year ended December 31, 2019. This decrease in equity loss of equity method investee was the result of the divestiture of our investment in NeoSeq, which we sold to a third party during June 2019.

Interest and Other Income, Net

	Year Ended December 31, 2018	2019	Increase/ (Decrease)	% Change
	(in thousands)			
Interest and other income, net	$1,801	$575	$ (1,226)	(68.1)%

Interest and other income, net decreased by $1.2 million from the year ended December 31, 2018 to the year ended December 31, 2019, primarily attributable to the sale of short-term investments during 2019.

Income Tax Expense

	Year Ended December 31, 2018	2019	Increase/ (Decrease)	% Change
	(in thousands)			
Income tax expense (benefit)	$5,250	$(706)	$ (5,956)	(113.4)%

Income tax expense was $5.3 million for the year ended December 31, 2018, while income tax benefit was $0.7 million for the year ended December 31, 2019, a 113.4% decrease. During the year ended December 31, 2018, due to losses generated in 2018 and projected future taxable losses anticipated in the future, we established a 100.0% valuation allowance on net deferred tax assets and as a result recorded income tax expense of $5.3 million. The tax benefit recorded during the year ended December 31, 2019 was recorded due to refunds received during 2019.

Liquidity and Capital Resources

For the year ended December 31, 2019 and the three months ended March 31, 2020, our net losses were $148.0 million and $17.2 million, respectively. Since our inception, our primary sources of liquidity have been generated by our operations, sales of preferred stock and common stock, and cash from debt financings.

As of December 31, 2019, we had cash and cash equivalents of $33.0 million and an accumulated deficit of $348.5 million. During the year ended December 31, 2019, we had cash used in operations of $106.1 million. As of December 31, 2019, we had a $75.0 million term loan outstanding and mortgages outstanding of $3.3 million. Our primary requirements for liquidity have been to fund our working capital needs, capital expenditures, dividends, research and development, and general corporate needs, as well as to invest in or acquire companies or technologies that are synergistic with or complimentary to our business.

As of March 31, 2020, we had $11.6 million of cash and cash equivalents and a $75.0 million term loan outstanding with a private equity firm and mortgages outstanding of $3.3 million. Our accumulated deficit as of March 31, 2020 was $365.6 million. During the three months ended March 31, 2020, we had a net loss of $17.2 million and cash used in operations of $30.9 million. Our primary requirements for liquidity have been to fund our working capital needs, capital expenditures, dividends, research and development, and general corporate needs, as well as to invest in or acquire companies or technologies that are synergistic with or complimentary to our business.

Based on our planned operations, we do not expect that our current cash and cash equivalents will be sufficient to fund our operations for at least 12 months after the date that the consolidated financial statements for the three months ended March 31, 2020 are issued. We intend to raise additional capital

through equity offerings and/or debt financings. Adequate funding, if needed, may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or other operations. If any of these events occur, our ability to achieve our operational goals would be adversely affected. Our future capital requirements and the adequacy of available funds will depend on many factors, including those described in "Risk Factors." Depending on the severity and direct impact of these factors on us, we may be unable to secure additional financing to meet our operating requirements on terms favorable to us, or at all.

Credit and Security Agreements, Series B Preferred Stock, and Convertible Notes

On October 27, 2017, we entered into a new credit and security agreement, or the Credit Agreement, with a fund managed by Athyrium, as collateral agent and a lender. The Credit Agreement provided for a term loan of $75.0 million. The Credit Agreement contains customary covenants, including a requirement to maintain a minimum unrestricted cash balance at all times of at least $5.0 million. The term loan is secured by all our tangible and intangible property assets, with the exception of intellectual property. The term loan accrues interest at a rate per annum equal to 9.5% and is due October 27, 2022.

We also entered into a Series B Preferred Stock Purchase Agreement, or the 2017 Series B Stock Purchase Agreement, with the same fund managed by Athyrium, which provided for the sale of 14,164,306 shares of Series B Preferred Stock at a purchase price of $3.53 per share for an aggregate purchase price of $50.0 million. The purchase price was paid in the form of (i) cash in an amount equal to $37.5 million and (ii) the delivery of 3,489,885 shares of our Series A-2 Preferred Stock, which shares of Series A-2 Preferred Stock had been purchased from Dr. Stylli, our Chairman and Chief Executive Officer, for $12.5 million. Concurrent with such transactions, Dr. Stylli converted the remaining 624,605 shares of Series A-2 Preferred Stock that he held into 633,766 shares of our common stock and we retired all shares of Series A-2 Preferred Stock. In connection with the 2017 Series B Stock Purchase Agreement, the fund managed by Athyrium received a warrant to purchase an additional 1,416,431 shares of Series B Preferred Stock.

The total proceeds of $124.2 million were allocated to the term loan, the Series B Preferred Stock, and Series B Preferred Stock Purchase Warrant based on the relative fair values of the term loan, equity, and warrant issued. As a result, we allocated proceeds of $65.7 million to the term loan. As the proceeds allocated to the term loan are lower than the stated loan amount of $75.0 million, the resulting $9.3 million discount will be amortized to interest expense using the effective interest method over the term of the loan.

During 2018 and 2019 we recognized interest expense on the term loan of $8.7 million and $8.9 million, respectively. During both of the three months ended March 31, 2019 and 2020, we recognized interest expense on the term loan of $2.2 million.

On August 27, 2019, we entered into a Series B Preferred Stock Purchase Agreement with Athyrium Opportunities III Acquisition LP, a fund managed by Athyrium, pursuant to which we issued 9,090,910 shares of Series B Preferred Stock at $2.75 per share for an aggregate purchase price of $25.0 million. A 1.283636364-for-1 stock split for our Series B Preferred Stock shares and Series B Preferred Stock Purchase Warrant issued and outstanding previously was effected on August 27, 2019 pursuant to an amendment and restatement of our amended and restated certificate of incorporation. As a result of the stock split, we issued an additional 4,017,512 shares of Series B Preferred Stock and adjusted the Series B Preferred Stock Purchase Warrant to be a warrant to purchase 1,818,182 shares of Series B Preferred Stock.

On August 27, 2019, we executed an exchange agreement with our Series A-1 Preferred Stock holders, pursuant to which 1,500,000 outstanding shares of Series A-1 Preferred Stock were exchanged for 35,664,240 shares of Series B Preferred Stock.

On November 12, 2019, we entered into a Series B Stock Preferred Stock Purchase Agreement, or the 2019 Series B Stock Purchase Agreement, with Athyrium Opportunities III Acquisition 2 LP, a fund managed by Athyrium, pursuant to which we issued an additional 11,111,111 shares of Series B Preferred Stock at $2.25 per share for an aggregate purchase price of $25.0 million. A 1.22222222-for-1 stock split for our Series B Preferred Stock shares and Series B Preferred Stock Purchase Warrant issued and outstanding previously was effected on November 12, 2019 pursuant to an amendment and restatement of our amended and restated certificate of incorporation. The conversion price of the Series B Preferred Stock and exercise price of the outstanding Series B Preferred Stock Purchase Warrant were lowered from $2.75 to $2.25 per share (or $13.90 per share as a result of the reverse stock split effected on June 10, 2020). As a result of the stock split effected on November 12, 2019, we issued an additional 13,985,993 shares of Series B Preferred Stock and adjusted the Series B Preferred Stock Purchase Warrant to be a warrant to purchase 2,222,222 shares of Series B Preferred Stock.

On November 22, 2019, we completed an additional equity financing pursuant to the 2019 Series B Stock Purchase Agreement executed on November 12, 2019 with Beaver Creek Intermediate Fund, Ltd., an existing investor and Dr. Stylli, our Chairman and Chief Executive Officer, for an aggregate purchase price of $6.1 million. We issued an aggregate of 2,722,222 shares of Series B Preferred Stock at a purchase price of $2.25 per share.

On December 19, 2019, we completed an additional equity financing pursuant to the 2019 Series B Stock Purchase Agreement executed on November 12, 2019 with Athyrium Opportunities III Acquisition 2 LP for an aggregate purchase price of $25.0 million. We issued on aggregate of 11,111,111 shares of Series B Preferred Stock at a purchase price of $2.25 per share.

On February 28, 2020, we completed an additional equity financing pursuant to the 2019 Series B Stock Purchase Agreement executed on November 12, 2019 with Athyrium Opportunities III Acquisition 2 LP and Dr. Stylli, our Chairman and Chief Executive Officer, for an aggregate purchase price of $11.4 million. We issued an aggregate of 5,066,666 shares of Series B Preferred Stock at a purchase price of $2.25 per share.

On March 31, 2020, we entered into the First Amendment to the Credit Agreement, or the Credit Agreement Amendment, with the collateral agent and lender party thereto, providing for the payment of interest due and payable as of March 31, 2020 in shares of our Series B Preferred Stock, and further providing for the payment of interest due and payable as of June 30, 2020 in shares of our Series B Preferred Stock in the event this offering has not been consummated by such date. Pursuant to the Credit Agreement Amendment, we concurrently entered into a Series B Preferred Stock Subscription Agreement, or the Subscription Agreement, with the lender, which provided for the issuance of 967,130 shares of Series B Preferred Stock at a subscription price of $2.25 per share, as payment for interest due and payable as of March 31, 2020 and all applicable fees as set forth in the Credit Agreement Amendment. The Subscription Agreement further provided for a potential additional issuance of shares of Series B Preferred Stock as payment for the interest due and payable under the Credit Agreement as of June 30, 2020, in the event this offering has not been consummated by such date, with the amount of shares to be determined at such time.

On April 3, 2020, we entered into a Series B Preferred Stock Purchase Agreement with Athyrium Opportunities III Acquisition 2 LP, pursuant to which we issued an additional 4,444,444 shares of Series B Preferred Stock at $2.25 per share for an aggregate purchase price of $10.0 million.

On May 8, 2020, we entered into a Note Purchase Agreement with Athyrium Opportunities 2020 LP, a fund managed by Athyrium, pursuant to which we issued and sold an unsecured convertible promissory note, or the Convertible Note, with an annual interest rate of 8.0% and in an aggregate principal amount of $15.0 million. The Convertible Note has a maturity date of May 8, 2022 and, in connection with this

offering, is convertible at the option of the holder into shares of our common stock at a per share conversion price of the lesser of $13.90 and eighty percent of the public price. Based on a public offering price of $15.00 (the midpoint of the price range set forth on the cover page of this prospectus), 1,250,000 shares of our common stock will be issuable upon conversion of the Convertible Note. In connection with the issuance and sale of the Convertible Note, we entered into (i) the Second Amendment to the Credit Agreement, dated May 6, 2020, or the Second Credit Agreement Amendment, allowing for the creation or incurrence of certain indebtedness and the making of payments, in each case, in respect of the Convertible Note, among other matters, and (ii) the Second Amendment to Series B Preferred Stock Warrant, dated May 8, 2020, providing for the removal of certain restrictive exercise provisions in the Series B Preferred Stock Purchase Warrant.

Mortgages

On January 24, 2014, we executed a mortgage with Comerica Bank for $1.8 million for the purpose of acquiring a facility located in Ann Arbor, Michigan, which was previously leased by us and is used primarily for laboratory testing and research purposes. The outstanding balance was $1.4 million as of each of December 31, 2019 and March 31, 2020. The mortgage matures in 2024 and requires monthly principal and interest payments at a fixed interest rate of 2.94% plus a floating rate at LIBOR.

We also have a mortgage with American Bank of Commerce (originally executed on February 19, 2008) outstanding on Avero Diagnostic's land and building located in Lubbock, Texas, which is used primarily for laboratory testing. The outstanding balance was $1.9 million as of each of December 31, 2019 and March 31, 2020. The mortgage matures in 2029 and requires monthly principal and interest payments at an interest rate of 4.25%.

Cash Flows

Our primary uses of cash are to fund our operations and research and development as we continue to grow our business. We expect to continue to incur operating losses in future periods as our operating expenses increase to support the growth of our business. We expect that our research and development, selling and marketing, and general and administrative expenses will continue to increase as we expand our marketing efforts and increase our internal sales force to drive increased adoption of and reimbursement for our tests, continue our research and development efforts with respect to our current tests and further develop our product pipeline, including our preeclampsia test and precision medicine products under development. We expect that we will use a substantial portion of the net proceeds of this offering, in combination with our existing cash and cash equivalents, for these purposes and for the increased expenses associated with being a public company. Cash used to fund operating expenses is impacted by the timing of when we pay expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

The following table summarizes our cash flows for the periods indicated:

	Year Ended December 31,		Three Months Ended March 31,	
	2018	2019	2019	2020
	(in thousands)		(unaudited)	
Cash used in operating activities	$ (65,126)	$ (106,124)	$ (22,096)	$ (30,886)
Cash provided by (used in) investing activities	55,831	16,525	8,644	(1,094)
Cash provided by (used in) financing activities	(12,807)	73,616	(4,546)	10,584

Cash Used in Operating Activities

Net cash used in operating activities for the year ended December 31, 2018 of $65.1 million was primarily attributable to a $129.1 million net loss. This was partially offset by a $42.6 million increase in accrued expenses and other current liabilities as a result of accruals for settlement payments due to third-party payors, including accruals for settlement negotiations with UnitedHealthcare and Aetna of $27.0 million and $15.0 million, respectively, in December 2018.

Net cash used in operating activities for the year ended December 31, 2019 of $106.1 million was primarily attributable to a $148.0 million net loss. This was partially offset by a $17.8 million increase in accrued expenses and other current liabilities as well as a $9.1 million increase in other long-term liabilities primarily as a result of the accrual for settlement negotiations with the Assistant U.S. Attorney for the Southern District of New York for $35.8 million. The net loss was also partially offset by a $3.4 million increase in accounts receivable primarily as a result of the adoption of ASC 606.

Net cash used in operating activities in the three months ended March 31, 2019 of $22.1 million was primarily attributable to a $24.0 million net loss and a $4.0 million increase in prepaid expenses and other current assets, due to timing of contract renewals and prepaid deposits. This was partially offset by a $5.4 million decrease in income tax receivable for tax refunds received in 2019.

Net cash used in operating activities in the three months ended March 31, 2020 of $30.9 million was primarily attributable to a $17.2 million net loss. The net cash outflow was also attributable to a $37.7 million increase in income tax receivables due to an NOL carryback recorded under the CARES Act legislation, and a $25.4 million decrease in accrued expenses and other current liabilities related to settlement accruals for payments due to third-party payors. This decrease was partially offset by a $36.9 million increase in other long-term liabilities as a result of the accrual for settlement negotiations with the Assistant U.S. Attorney for the Southern District of New York for $49.0 million. The settlement negotiations during the three months ended March 31, 2020 resulted in an increase of $13.2 million to the total settlement accrual, and the reclassification of $36.9 million from accrued expenses and other current liabilities to other long-term liabilities.

Cash Provided by Investing Activities

Net cash provided by investing activities during the year ended December 31, 2018 of $55.8 million was primarily driven by $227.7 million from the sale of short-term investments. The cash inflow was partially offset by cash outflows of $167.0 million for purchases of short-term investments and $4.8 million for purchases of property and equipment.

Net cash provided by investing activities during the year ended December 31, 2019 of $16.5 million was primarily driven by $31.4 million from the sale of short-term investments. The cash inflow was partially offset by cash outflows of $11.2 million for purchases of short-term investments and $3.7 million for purchases of property and equipment.

Net cash provided by investing activities during the three months ended March 31, 2019 of $8.6 million was primarily driven by $20.4 million from the sale of short-term investments. The cash inflow was partially offset by cash outflows of $11.2 million for purchases of short-term investments and $0.6 million for purchases of property and equipment.

Net cash used in investing activities during the three months ended March 31, 2020 of $1.1 million was primarily for the purchase of property and equipment.

Cash (Used in) Provided by Financing Activities

Net cash used in financing activities during the year ended December 31, 2018 of $12.8 million was primarily attributable to $11.3 million in repurchase of common stock, $1.5 million in principal payments on capital lease obligations, $0.3 million in payments for contingent consideration, and $0.2 million in principal payments on mortgages payable. The cash outflows were partially offset by $0.5 million in proceeds from issuances of common stock.

Net cash provided by financing activities during the year ended December 31, 2019 of $73.6 million was primarily attributable to $79.0 million in proceeds from the issuance of Series B Preferred Stock and $0.5 million in proceeds from issuance of common stock, partially offset by $4.5 million in dividends paid, $1.0 million in principal payments on capital lease obligations, and $0.2 million in principal payments on mortgages payable, and $0.2 million in payments for deferred costs.

Net cash used in financing activities during the three months ended March 31, 2019 of $4.5 million was primarily attributable to $0.3 million in principal payments on capital lease obligations, $0.1 million in principal payments on mortgages payable, and $4.5 million in dividends paid. The cash outflows were partially offset by $0.3 million in proceeds from issuances of common stock.

Net cash provided by financing activities during the three months ended March 31, 2020 of $10.6 million was primarily attributable to $11.4 million in proceeds from the issuance of Series B Preferred Stock and $0.1 million in proceeds from the issuance of common stock, partially offset by $0.2 million in principal payments on capital lease obligations, $0.6 million in payments for deferred financing costs and $0.1 million in principal payments on mortgages payable.

Contractual Obligations and Other Commitments

See “Liquidity and Capital Resources” for a description of our contractual obligations under our Credit Agreement.

The following table summarizes our contractual obligations as of December 31, 2019:

	Payments Due by Period				
	Total	Less Than 1 Year	1 to 3 Years	3 to 5 Years	More Than 5 Years
	(in thousands)				
Long-Term Debt Obligations(1)	$ 99,288	$ 7,606	$ 88,891	$ 1,738	$ 1,053
Capital Lease Obligations(2)	1,144	773	371	—	—
Operating Lease Obligations(3)	16,562	8,167	7,489	906	—
Purchase Obligations(4)	1,000	1,000	—	—	—
Other Long-Term Liabilities(5)	36,494	24,289	12,205	—	—
Total	$ 154,488	$ 41,835	$ 108,956	$ 2,644	$ 1,053

(1) Represents amounts payable under our Credit Agreement and amounts payable under our mortgages payable with Comerica Bank and American Bank of Commerce.
(2) Represents amounts payable for capital leases, including interest and principal payments, primarily related to equipment leases.
(3) Represents amounts payable for various noncancelable operating lease agreements, primarily for office space, laboratory space, and vehicles.
(4) Represents minimum amounts payable for cancelable purchase agreement.
(5) Represents amounts payable to third-party payors pursuant to settlement agreements. Amounts exclude the settlement accrual related to an agreement in principle reached with the DOJ and State AGs on March 31, 2020. For additional information, see Note 9 to our unaudited condensed consolidated financial statements included elsewhere in this prospectus.

Off-Balance Sheet Arrangements

As of December 31, 2019, we did not have any relationships with unconsolidated organizations or financial partnerships, such as structured finance or special purpose entities, that would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risks in the ordinary course of our business.

Interest Rate Risk

Our exposure to risks related to interest rates is minimal. The interest rates for most of our indebtedness, including under our Credit Agreement and our equipment financing facility, are fixed rates. Our Ann Arbor mortgage with an initial principal amount of $1.8 million has a floating interest rate of 2.94% plus a floating rate at LIBOR. Such interest-bearing instruments carry a degree of risk; however, we have not been exposed to, nor do we anticipate being exposed to, material risks due to changes in interest rates. A hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our financial statements.

Our cash and cash equivalents consist primarily of highly liquid investments in money market funds and cash on hand and have an original maturity date of 90 days or less. The fair value of our cash and cash equivalents would not be significantly affected by either an increase or decrease in interest rates due mainly to the short-term nature of these instruments.

Foreign Currency Risk

Our operations are currently conducted primarily in the United States. As we expand internationally, our results of operations and cash flows may become subject to fluctuations due to changes in foreign currency exchange rates. In periods when the U.S. dollar declines in value as compared to the foreign currencies in which we incur expenses, our foreign-currency based expenses will increase when translated into U.S. dollars. In addition, future fluctuations in the value of the U.S. dollar may affect the price at which we sell our tests outside the United States. To date, our foreign currency risk has been minimal and we have not historically hedged our foreign currency risk; however, we may consider doing so in the future.

Critical Accounting Policies and Significant Judgments and Estimates

Our management’s discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in conformity with GAAP. The preparation of financial statements in accordance with GAAP requires management to make estimates and assumptions about future events that affect the amounts of assets and liabilities reported, disclosures about contingent assets and liabilities, and reported amounts of revenue and expenses. These estimates and assumptions are based on management’s best estimates and judgment. Management regularly evaluates its estimates and assumptions using historical experience and other factors; however, actual results could differ materially from these estimates and could have an adverse effect on our financial statements. While our significant accounting policies are more fully described in the notes to our financial statements elsewhere in this prospectus, we believe that the accounting policies discussed below are most critical to understanding and evaluating our historical and future performance.

Revenue Recognition

Revenue is primarily derived from providing molecular laboratory tests to customers. We invoice and collect from third-party payors, laboratory services intermediaries, and self-paying individuals. Third-party payors include commercial payors, such as health insurance companies, health maintenance organizations and government payors, such as Medicare and Medicaid in the United States. We bill for these tests rendered upon completion of the testing process and delivery of test results to the customer.

We adopted the new revenue recognition guidance, ASC Topic 606, *Revenue from Contracts with Customers*, or ASC 606, on January 1, 2019 using the modified retrospective transition method. The transition method was applied to all contracts that were not yet complete as of January 1, 2019. The cumulative impact of adoption was recorded as an adjustment of $23.7 million to increase the opening balance of accounts receivable and decrease accumulated deficit as of January 1, 2019. Results for reporting periods beginning after January 1, 2019 are presented under ASC 606, while prior period amounts have not been adjusted and continue to be reported in accordance with our historical accounting policy under ASC Topic 605, *Revenue Recognition*.

In accordance with ASC 606, we follow a five-step process to recognize revenue: (i) identify the contract with the customer; (ii) identify the performance obligations; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations; and (v) recognize revenue when the performance obligations are satisfied. We have evaluated our contracts with healthcare insurers, government payors, laboratory partners, and patients and identified a single performance obligation in those contracts, the delivery of a test result. We satisfy our performance obligation at a point in time upon the delivery of the test result, at which point control is transferred to the customer, and we can bill for the tests. The amount of revenue recognized reflects the amount of consideration to which we expect to be entitled, or the transaction price, and considers the effects of variable consideration, which is discussed below.

Prior to 2019, we recognized the majority of our revenue from contracts involving third-party payors upon receipt of cash due to limited historical experience and uncertainty in determining the amount of revenue and timing of collections. Effective January 1, 2019, in accordance with ASC 606, the total consideration we expect to collect from insurance carriers, clinics, and patients in exchange for the tests accessioned is recognized in the period in which our tests are performed and reported to customers.

The transaction price is an estimate and may be fixed or variable. Variable consideration includes reimbursement from healthcare insurers, government payors, and patients and is adjusted for estimates of disallowed cases, discounts, and refunds using the expected value approach. Tests billed to healthcare insurers and directly to patients can take up to six months to collect and we may be paid less than the full amount billed or not be paid at all. For insurance carriers and government payors, we utilize the expected value approach using a portfolio of relevant historical data for payors with similar reimbursement experience. The portfolio estimate is developed using historical reimbursement data from payors and patients, as well as known current reimbursement trends not reflected in the historical data. Such variable consideration is included in the transaction price only to the extent it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainties with respect to the amount are resolved. We monitor these estimates at each reporting period based on actual cash collections in order to assess whether a revision to the estimate is required. Both the initial estimate and any subsequent revision to the estimate contain uncertainty and require the use of judgment in the estimation of the transaction price and application of the constraint for variable consideration. If actual results in the future vary from our estimates, we will adjust these estimates, which would affect revenue and earnings in the period such variances become known. The consideration expected from laboratory partners is generally a fixed amount.

Stock-Based Compensation

We calculate the fair value of stock options using the Black-Scholes option pricing valuation model, which incorporates various assumptions including assumptions including the fair value of our common stock, volatility, expected life, and risk-free interest rate. Compensation related to service-based awards are recognized starting on the grant date on a straight-line basis over the vesting period, which is generally four years.

Determining the grant date fair value of options using the Black-Scholes option pricing model requires management to make assumptions and judgments. If any of the assumptions used in the Black-Scholes model change significantly, stock-based compensation for future awards may differ materially compared with the awards granted previously. The assumptions and estimates are as follows:

- *Fair value of common stock* – The fair value of each stock option grant was determined using the methods and assumptions discussed below (see "—Common Stock Valuation"). Each of these inputs is subjective and generally requires significant judgment and estimation by management.
- *Expected term* – The expected term represents the period that stock-based awards are expected to be outstanding. Our historical share option exercise information is limited due to a lack of sufficient data points and does not provide a reasonable basis upon which to estimate an expected term. The expected term for option grants is therefore determined using the simplified method. The simplified method deems the expected term to be the midpoint between the vesting date and the contractual life of the stock-based awards.
- *Expected volatility* – The expected volatility was derived from the historical stock volatilities of comparable peer public companies within our industry that are considered to be comparable to our business over a period equivalent to the expected term of the stock-based awards, since there has been no trading history of our common stock.
- *Risk free interest rate* – The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the date of grant for zero-coupon U.S. Treasury notes with maturities approximately equal to the stock-based awards' expected term.
- *Expected dividend yield* – The expected dividend yield is zero as we have no plans to make dividend payments.

The following assumptions were used for the Black-Scholes option valuation model:

	Three Months Ended March 31,	
	2019	2020
Risk-free interest rate	2.6%	0.8%-1.7%
Expected volatility	52.0%	57.0%-71.0%
Expected dividend yield	—	—
Expected term (in years)	6 Years	4.0 – 6.3 Years

Based on the assumed initial public offering price per share of $15.00, which is the midpoint of the offering price range set forth on the cover of this prospectus, the aggregate intrinsic value of our outstanding stock options as of March 31, 2020 was $13.3 million, with $10.6 million related to vested stock options.

Common Stock Valuation

The estimated fair value of the common stock underlying our stock options was determined by our board of directors, with input from management, considering our most recently available third-party valuations of common stock and our board of directors' assessment of additional objective and subjective factors that it believed were relevant, and factors that may have changed from the date of the most recent valuation through the date of the grant. The valuations of our common stock were determined in accordance with the guidelines outlined in the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. The assumptions we use in the valuation model are based on future expectations combined with management judgment. In the absence of a public trading market, our board of directors, with input from management, exercised significant judgment and considered numerous objective and subjective factors to determine the fair value of our common stock as of the date of each option grant, including the following factors:

- contemporaneous valuations performed by third-party valuation firms;
- the prices, rights, preferences, and privileges of our preferred stock relative to those of our common stock;
- the prices of preferred stock sold by us to third-party investors in arms-length transactions;
- the lack of marketability of our common stock;
- our actual operating and financial performance;
- current business conditions and projections;
- our history and the timing of the introduction of new products;
- our stage of development;
- the likelihood and timing of achieving a liquidity event, such as an initial public offering or a merger or acquisition of our business given prevailing market conditions;
- recent secondary stock transactions;
- the market performance of comparable publicly-traded companies; and
- U.S. market conditions.

For all approaches, the equity value was allocated among the various classes of our equity securities to derive a per share value of our common stock. We historically performed this allocation using the option pricing method, or OPM, which treats the securities comprising our capital structure as call options with exercise prices based on the liquidation preferences of our various series of preferred stock and the exercise prices of our options and warrants.

We performed this allocation using a probability-weighted expected return method, or PWERM. The PWERM involves the estimation of the value of our company under multiple future potential outcomes for us and estimates of the probability of each potential outcome. The per share value of our common stock determined using the PWERM is ultimately based upon probability-weighted per share values resulting from the various future scenarios, which primarily included an initial public offering or continued operation as a private company. Additionally, the PWERM was combined with the OPM to determine the value of the securities comprising our capital structure in certain of the scenarios considered in the PWERM.

After the equity value is determined and allocated to the various classes of shares, a discount for lack of marketability, or DLOM, is applied to arrive at the fair value of the common stock. A DLOM is meant to account for the lack of marketability of a stock that is not traded on public exchanges. For financial

reporting purposes, we considered the amount of time between the valuation date and the grant date of our stock options to determine whether to use the latest common stock valuation or a straight-line interpolation between the two valuation dates. This determination included an evaluation of whether the subsequent valuation indicated that any significant change in valuation had occurred between the previous valuation and the grant date.

Following this offering, we will rely on the closing price of our common stock as reported on the date of grant to determine the fair value of our common stock, as shares of our common stock will be traded in the public market.

Goodwill and Intangible Assets

Goodwill is an asset representing the future economic benefits arising from other assets acquired in a business combination that are not individually identified and separately recognized. Goodwill is not amortized but instead is tested annually for impairment at the reporting unit level, or more frequently when events or changes in circumstances indicate that fair value of the reporting unit has been reduced to less than its carrying value. We may choose to perform a qualitative assessment to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform the two-step goodwill impairment test.

If, after assessing qualitative factors, we determine it is not more likely than not that the fair value of a reporting unit is less than its carrying amount, then performing the two-step impairment test is unnecessary. If deemed necessary, a two-step test is used to identify the potential impairment and to measure the amount of goodwill impairment, if any. The first step is to compare the fair value of the reporting unit with its carrying amount, including goodwill. If the fair value of the reporting unit exceeds its carrying amount, goodwill is considered not impaired; otherwise, there is an indication that goodwill may be impaired and the amount of the loss, if any, is measured by performing step two. Under step two, the impairment loss, if any, is measured by comparing the implied fair value of the reporting unit goodwill with the carrying amount of goodwill.

Intangible assets consist of identifiable intangible assets acquired through acquisitions. Identifiable intangible assets include payor relationships, trade names, and noncompete agreements. We amortize intangible assets using the straight-line method over their useful lives. We amortize noncompete covenants using the straight-line method over the terms of the related agreements. We review for impairment of intangible assets with estimable useful lives whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. No impairment existed as of December 31, 2019 or as of March 31, 2020.

Recent Accounting Pronouncements

For more information on recently issued accounting pronouncements, see Note 2, “Summary of Significant Accounting Policies” to our consolidated financial statements.

JOBS Act Accounting Election

We are an emerging growth company, as defined in the JOBS Act. Under this act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have elected to use this extended transition period and, as a result, our financial statements may not be comparable to companies that comply with public company effective dates. We also intend to rely on other exemptions provided by the JOBS Act, including without limitation, not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002, as amended.

BUSINESS

Overview

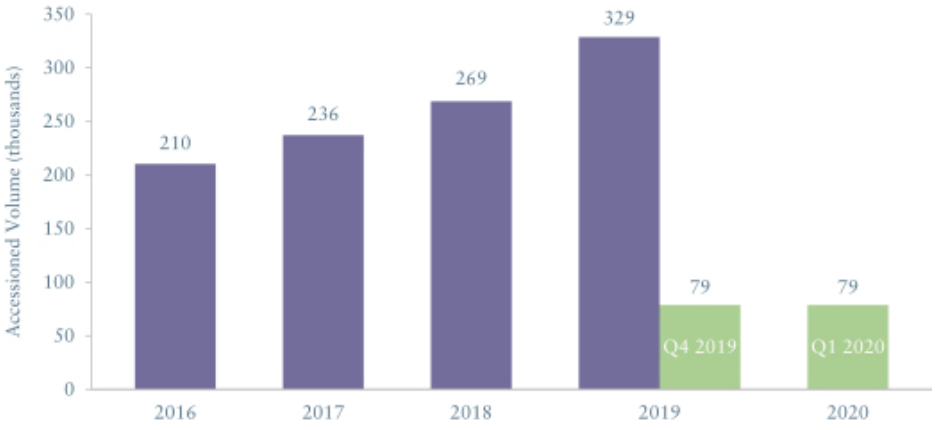
We are a biotechnology company with an established track record of success in developing and commercializing molecular testing products as well as innovating in the field of precision medicine. We believe that we are a market-leading provider of *in vitro* molecular tests designed to improve lives by providing actionable information that helps guide patients and physicians in making critical and timely medical decisions during various life stages, such as family planning, pregnancy, or navigating a complex disease diagnosis. Our vision is to transform healthcare to become more precise and personal by improving diagnoses of disease and improving patient outcomes through localized treatment with targeted therapies. We apply a multi-omics approach, combining genomics, epigenomics, proteomics, and metabolomics, to our molecular testing products and to the development of a suite of investigational ingestible devices and drug/device combinations designed to provide precise diagnostic sampling and drug delivery solutions.

Since 2010, our molecular testing business has achieved consistent year-over-year test volume growth through our robust product portfolio and our strong commercial organization. Our internal core competencies, deep research and development pipeline and strategic acquisitions of novel technologies have fueled our innovation in women's health, supporting the development and launch of complementary molecular testing products that inform critical healthcare decision-making across a woman's lifetime.

In 2015, we launched both our Innatal Prenatal Screen, a Non-Invasive Prenatal Testing, or NIPT, offering, and our Preparent Carrier Test, followed by the launch of our Riscover Hereditary Cancer Test in 2017. Our current molecular testing products collectively address a combined market of more than $2.5 billion in the United States alone. We offer molecular tests with market-leading performance and turnaround times, supported by end-to-end workflow solutions that increase administrative efficiencies. Along with our comprehensive menu of molecular tests, we offer patients pre-test education, clear and timely results, and on-demand genetic counseling. We are committed to providing patients and physicians with empathetic communication and support during critical moments to help empower and prepare patients and their families to make critical life decisions.

Since our inception, we have accessioned approximately 1.5 million tests in the United States and the growth rate of our test volume is accelerating. The figure below shows our test volume growth from 2016 through 2019, as well as the first quarter of 2020, in which quarter we observed volumes largely consistent with the fourth quarter of 2019 despite the challenges presented by the COVID-19 pandemic. We believe our business is resilient and we have observed positive signs of recovery so far.

Test Volume Growth



Our commercial team of more than 150 individuals actively engages with physicians and their staff to emphasize the clinical need for our products, educate them on clinical value, and facilitate their ability to order our molecular tests. We place special emphasis on our customers' needs and journey with their patients. We ensure they are fully equipped with all the tools they need to discuss and educate their patients about the benefits of NIPT, carrier screening, and hereditary cancer screening, and also provide the added confidence that our genetic counselors are there to support them when needed.

We continue to innovate to drive the clinical and competitive differentiation of our molecular tests. For example, our next generation Innatal Prenatal Screen (Innatal 4th Generation) is designed to provide the same highly reliable results but with a faster turnaround time and at a much lower cost to us.

We are developing a rule-out test for preeclampsia. Based on our estimates, annually, over 700,000 pregnant women in the United States experience signs and symptoms that could be attributed to preeclampsia, which can cause serious, even fatal, complications for both mother and baby. Preeclampsia is the second most common cause of maternal death worldwide and is currently diagnosed by observing risk factors and common symptoms, such as high blood pressure, rather than diagnosing the actual condition itself. This approach often leads to false positive diagnoses and provides limited clinical utility, which can each lead to unnecessary hospitalizations and medical costs. We are developing a test that we believe has the potential to address these shortcomings by ruling out the condition itself (rather than merely detecting its symptoms) through testing for certain biomarkers. We believe that identifying non-preeclamptic pregnancies would improve patient outcomes while lowering the cost burden of preeclampsia to the U.S. healthcare system, estimated to be approximately $1.03 billion for mothers and $1.15 billion for infants annually. We believe the total addressable market for our preeclampsia test is approximately $3 billion per year in the United States alone.

We believe our future success will be driven by continued capture of market share by our molecular testing business and new revenue streams resulting from our diversified product development pipeline, both within and beyond women's health. Our core expertise in complex assay development, bioinformatics, and scalable commercial laboratory operations lends itself to a variety of potential applications. We are also developing a novel pipeline of precision medicine product candidates designed to provide solutions for gastrointestinal, or GI, disorders. This pipeline includes both diagnostic applications, targeted drug delivery in the GI tract at the site of disease, and the oral delivery of biologics. We believe these product candidates, if successfully developed, have the potential to address unmet healthcare needs by more precisely identifying and treating chronic GI diseases, such as small intestinal bacterial overgrowth, or SIBO, and inflammatory bowel disease, or IBD. We are also developing an epigenetics platform designed to assess the global, regional, and site-specific methylation information of the genome at low cost that is intended to be an alternative to onerous, costly whole-genome bisulfite sequencing and enable more rapid diagnostic product development.

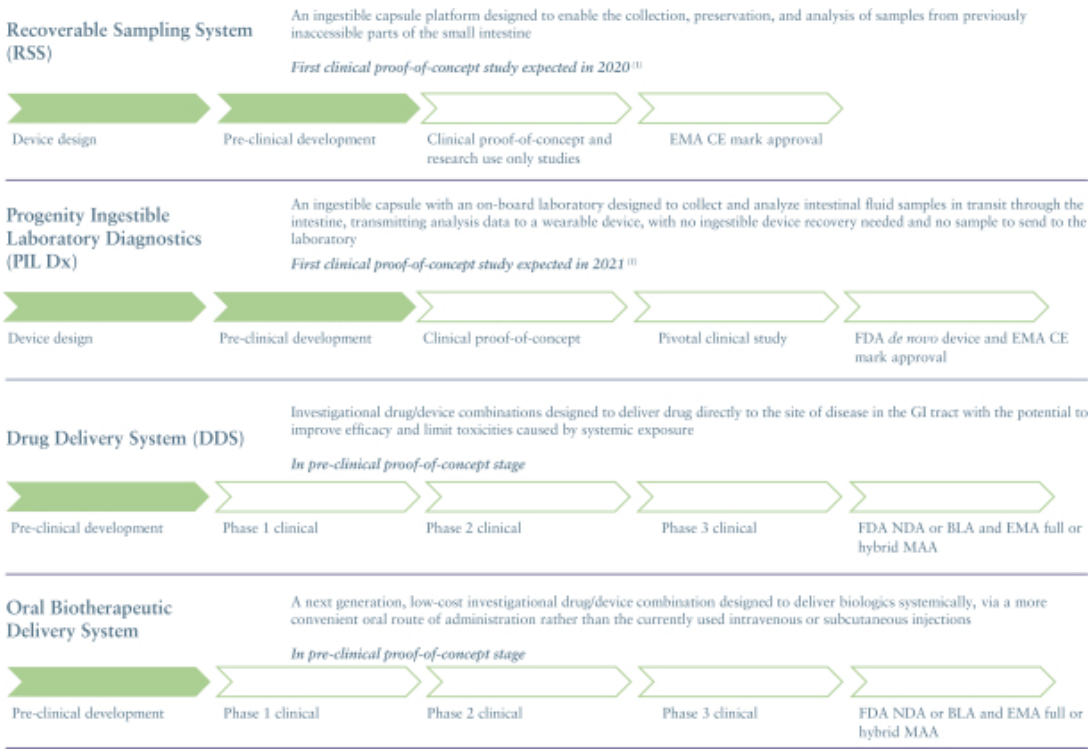
We generated revenue of $144.0 million and a net loss of $148.0 million, for the year ended December 31, 2019, compared to revenue of $128.0 million and a net loss of $129.1 million, for the year ended December 31, 2018. In the years ended December 31, 2019 and 2018, respectively, we incurred $63.4 million and $48.7 million in research and development investment costs.

Product and Product Candidate Overview

We support patients and physicians during patients' critical life decisions with our current suite of high-quality molecular tests:

Product	Description
innatal® PRENATAL SCREEN	A noninvasive prenatal test offered to women early in pregnancy to screen for risk of fetal chromosomal conditions, such as Down syndrome, trisomy 13, and trisomy 18, and sex chromosome disorders ***Commercialized in 2015***
preparent® CARRIER TEST	An expanded carrier screen that is performed on women or couples before conception or early in a pregnancy to identify if they carry certain mutations that cause genetic diseases ***Commercialized in 2015***
riscover® HEREDITARY CANCER	A hereditary cancer screen that looks for genetic mutations associated with elevated risk for certain hereditary cancers in an asymptomatic patient ***Commercialized in 2017***
resura® PRENATAL TEST FOR MONOGENIC DISEASE	A test for monogenic diseases that is the first commercially available, custom-designed solution for families at-risk for rare diseases ***Commercialized in 2019***
Preeclampsia Rule-Out Test	A test for symptomatic women suspected of developing preeclampsia during their pregnancy designed to rule out preeclampsia as the cause for the symptoms ***In Development***
Anatomic and Molecular Pathology Tests	A broad portfolio of anatomic and molecular pathology tests and specialized genetic tests we offer through Avero Diagnostics ***Acquired in 2015***

We are also developing a proprietary ingestible capsule platform designed to help diagnose and treat GI disorders at the site of disease, with the goal of addressing significant unmet needs and supporting affected patient populations by improving patient outcomes through precision medicine. Our investigational capsules are being developed for both diagnostic and therapeutic applications in disorders such as SIBO and IBD. Our precision medicine development pipeline includes:



(1) We cannot predict whether the COVID-19 pandemic or other factors will impact the timing of our clinical trials and studies. For example, see "Risk Factors—The recent and ongoing COVID-19 pandemic could materially affect our operations, as well as the business or operations of third parties with whom we conduct business. Our business could be adversely affected by the effects of other future health epidemics or pandemics in regions where we or third parties on which we rely have significant business operations."

Our Strengths

We attribute our commercial success and future growth prospects to the following:

- ***A leading molecular testing business with clinical and competitive product advantages***. Our products are built on a foundation of molecular genetic expertise, excellence in bioinformatics, and dedication to women's health and reproductive medicine. We have built a robust product portfolio through efficient in-house development, clinical laboratory partnerships, and strategic acquisitions. Our tests have achieved market-leading reliability and performance benchmarks within their respective market categories.
- ***Integrated product offering***. We offer integrated molecular tests and end-to-end support services that enable physicians to seamlessly incorporate genetic testing into their office workflow and offer the convenience of ordering multiple tests from one source. Our workflow solutions customize the experience of working with us for a range of physician practice sizes and capabilities, lowering barriers to adoption of genetic testing. We also

utilize a specialized team dedicated to integrating our systems with our healthcare providers' electronic medical record, or EMR, systems, opening bidirectional connectivity to streamline test ordering and reporting. We deliver easy-to-understand results and our customer support services provide convenient access to board-certified genetic counselors. We believe that these services collectively create substantial value and lead to customer loyalty.

- ***Breadth and depth of R&D capabilities driving breakthrough innovation***. We have built a first class research and development, or R&D, organization capable of harnessing and translating novel technologies into innovative platforms and product solutions as we strive to remain at the forefront of customer needs. Our technical expertise along the product development spectrum includes assay design, bioinformatics, and analytical and clinical validation and enables us to leverage existing knowledge to solve new challenges.
- ***Precision medicine platform targeting a large, underserved market***. We are developing an innovative and potentially scalable product platform that we believe will support the advancement of our precision medicine pipeline. This platform approach is based on an innovative capsule, which we believe could represent a paradigm shift from existing diagnostic and therapeutic approaches. We believe this platform has the potential to address significant unmet medical needs in the GI space, including the challenges in diagnosing, treating, and monitoring diseases without the repeated use of invasive procedures, such as upper GI endoscopies, colonoscopies, and biopsies.
- ***Comprehensive intellectual property portfolio***. We have retained worldwide rights to our internally-developed and acquired molecular testing and precision medicine technologies. We hold over 425 issued patents and pending patent applications that include claims that are directed to a range of molecular testing and precision medicine-related methods, systems, and compositions surrounding our suite of current and future products. In addition, we believe that our trade secrets and other know-how provide additional barriers to entry.
- ***Proven leadership with industry expertise***. Our senior management team and board of directors consist of veteran biotechnology and molecular testing professionals with deep industry experience. These individuals have extensive experience with numerous well-regarded biotechnology and diagnostic companies. Through their many years of experience, they have developed strong relationships with key thought leaders and medical societies.

Our Strategy

Our vision is to build upon our expertise and core competencies in molecular testing to transform healthcare to become more precise and personal in our existing markets as well as in new developmental fields such as ingestible diagnostics and targeted therapeutics. To realize our vision, we intend to:

- ***Expand market opportunity for our existing molecular tests***. We believe there is a significant opportunity to expand and further penetrate the markets for each of our existing molecular tests. We intend to accomplish this by working with industry groups and payors to increase payor policy coverage, educating patients, physicians, and payors on the clinical utility of our tests, and highlighting the cost efficiency and time savings provided by our tests and workflow solutions.
- ***Leverage our robust R&D capabilities to drive breakthrough innovation***. We seek to combine innovation with the technologies underlying our existing platforms to disrupt the current diagnostics and treatment paradigms. Through our robust research and development pipeline, we seek to unlock novel approaches that will drive improvement of patient outcomes in prenatal and perinatal medicine, gastroenterology, and oncology, increase the precision of medical research and diagnosis through ingestible sampling technologies, and create a new category of treatment options through proprietary drug/device combinations.

- ***Continue to expand and strengthen our direct sales force***. We believe that our specialized sales force is key to educating our customers about the clinical need for our molecular tests and our end-to-end workflow solutions. We are continuously optimizing market coverage of our highly qualified sales force and identifying new growth opportunities using a customized and targeted account profiling and messaging approach that better reflects our value proposition.
- ***Enhance our customer support services***. Our goal is to be a trusted and valued partner to our customers by delivering market-leading test performance and service to further integrate genetic testing into their workflow. We intend to expand upon our Progenity Partnerships program, our proprietary customer support services platform, to further streamline patient identification and selection for testing and enhance our customized physician and patient management initiatives. In addition, we intend to expand upon our patient management tools, which streamline and enhance the patient experience, including patient education, payor pre-authorization, easy-to-read test results, and access to genetic counselors.
- ***Develop and commercialize a disruptive precision medicine platform of GI diagnostics and therapeutics***. Our precision medicine platform is focused on addressing an unmet medical need of patients with GI disorders or related diseases. Leveraging an autonomous localization technology, we are developing a noninvasive, ingestible capsule platform, with investigational devices and drug/device combinations designed for both diagnostic and therapeutic purposes. We believe our product candidates, if successfully developed and approved or cleared, could become the first precision medicine products to diagnose and treat at the site of the disease within the GI tract. Ultimately, we intend to pursue commercialization of such product candidates ourselves or via strategic partnership.

Our Molecular Tests

Our molecular tests provide accurate, reliable, and fast test results while simplifying ordering, pre-test education, processing, testing, reporting, counseling, and billing for physicians and patients. We currently offer tests with clinical utility that enable physicians to deliver clinical decision support for, and address the medical needs of, patients and their families. We complement these tests with our proprietary suite of end-to-end workflow solutions, enabling us to educate physicians, patients, and payors on the benefits and clinical utility of genetic testing. In addition, we offer physicians the convenience of ordering multiple tests from one source, integrate our services seamlessly into their practices, and deliver easy-to-understand results and genetic counseling support.

Our Current Test Portfolio

Innatal Prenatal Aneuploidy Screen

Our Innatal Prenatal Screen, launched in 2015, is a noninvasive prenatal screening test offered to women early in pregnancy to screen for chromosome abnormalities, known as aneuploidy, such as Down syndrome, trisomy 18, and trisomy 13, and sex chromosome disorders through the analysis of cell-free DNA, or cfDNA. The test is performed using whole-genome sequencing technology and provides a high level of accuracy at or after 10 weeks of gestation.

Our Innatal Prenatal Screen provides a positive predictive value customized to the patient’s maternal age and the fetus’ gestational age in order to accurately quantify the probability that a patient with a positive screening result truly has an affected fetus. Performance of the assay is highly accurate and reliable in the commercial laboratory. As shown in Table 1 below, we recently performed a complete validation study using maternal samples with known fetal outcomes to evaluate the performance of the assay.

Table 1: Innatal Prenatal Screen Performance(1)

Disorder	Sensitivity	Specificity
Down Syndrome	99.2%	>99.9%
Trisomy 18	>99.9%	99.7%
Trisomy 13	>99.9%	>99.9%
Monosomy X	>99.9%	99.8%
XX	99.0%	99.9%
XY	99.9%	99.0%
XXX, XXY, XYY	Limited data for these less common aneuploidies preclude performance calculations	

(1) Progenity Inc. validation data on file. Clinical correlation is indicated. If definitive diagnosis is desired, chorionic villus sampling or amniocentesis is necessary.

We believe this observed level of high performance sets our Innatal Prenatal Screen apart from competing NIPT. We believe our distinguished performance is a result of our in-depth knowledge and expertise with cfDNA, allowing us to deliver a high-performing and market-leading NIPT. By selectively designing a single capture system assay that is able to query thousands of unique but related sites across the genome, we are able to reduce assay noise and boost performance. Our capture system is able to retain the ability to scan widely across the genome to retain specificity while enhancing information in key features to ensure high sensitivity, even with samples with low levels of fetal DNA.

In our validation study, our test has shown a low (approximately 1%) failure rate. Independent studies of competitive technologies have shown failure rates as much as four times higher. Failures require the drawing of another blood sample from the mother or more invasive molecular testing options. The reliability of NIPT may result in lower rates of invasive molecular testing options such as chorionic villus sampling and amniocentesis, which can cause procedure-related pregnancy losses and impose additional costs.

Market Opportunity

Numerous medical society guidelines have recognized that all pregnant women, regardless of age, should be offered screening, such as NIPT, for aneuploidy to better identify patients for whom more invasive procedures, such as amniocentesis, are recommended. We believe that guidelines will continue to develop in support of broader prenatal screening, and that provider and payor education will drive increased adoption of NIPT. We estimate that the total addressable market for NIPT is approximately $1.5 billion annually in the United States. We estimate that approximately 2 million NIPT were performed in the United States in 2018, of which an estimated 35% were on high-risk patients (those with characteristics that increase their risk of an aneuploidy pregnancy, such as advanced age of >35 years, abnormal ultrasound, family history, or positive maternal serum screen result), and 65% were on average-risk (general population) patients. We also believe that efforts at expanding payor medical coverage policy to include all patients, regardless of *a priori* risk, would help further expand the covered market to include a larger portion of the approximately four million pregnancies that occur annually in the United States.

Preparent Carrier Test

Our Preparent Carrier Test, launched in 2015, screens for carrier status of hereditary diseases prior to or early in pregnancy. Carrier screening identifies couples at-risk of having a baby with a genetic disease and allows for informed medical management decisions. Our test offers a broad menu of genetic carrier screening tests with high detection rates for a variety of genetic diseases, including cystic fibrosis, spinal muscular atrophy, and fragile X syndrome. We designed the Preparent Carrier Test to assess a couple's risk of passing down any of 200+ serious heritable diseases. This test is designed to meet the guidelines of

the American College of Obstetricians and Gynecologists, or ACOG, and the American College of Medical Genetics, or ACMG, using a combination of methods (DNA sequencing, HEXA enzyme analysis, and hemoglobin evaluation) to maximize sensitivity.

In 2017, we expanded the Preparent product portfolio with the launch of the Preparent Exon test in partnership with Baylor Genetics. The Preparent Exon test uses exon sequencing to provide the higher sensitivity desired for reproductive medicine applications. Exon sequencing evaluates all of the coding regions of each gene and can identify both known and novel changes within the genetic code. The Preparent Exon test combines full exon sequencing and select copy number variant, or CNV, analysis. CNV analysis identifies large extra or missing pieces of select genes in which this type of variation, otherwise missed by exon sequencing alone, is a common cause of disease. This test design includes analysis of up to 280+ genes for a more complete evaluation of carrier status, resulting in, on average, ³95% clinical sensitivity in the general population. Our product portfolio includes four pre-curated panels of 3, 25, 150+, and 280+ genes, designed to fit the needs of different customer segments.

Market Opportunity

ACOG recently changed its recommendations to add expanded carrier screening, or ECS, which would potentially include most of our Preparent Carrier Test panels, as an acceptable screening strategy. We estimate that the total U.S. addressable market for ECS is approximately $1.0 billion annually. We estimate that approximately 500,000 expanded carrier screens were performed in the United States in 2018. We believe significant opportunity exists to perform carrier screening in a greater proportion of the approximately four million pregnancies that occur annually in the United States, and to increase the penetration of ECS. We also believe that educating physicians and patients on the benefits of ECS, along with pursuing favorable medical policy coverage by payors, has the potential to convert traditional screening and non-screening patients to utilization of ECS.

Riscover Hereditary Cancer Test

Our Riscover Hereditary Cancer Test, launched in 2017 in partnership with Prevention Genetics, is a hereditary cancer screen that analyzes 31 genes associated with inherited risk of 12 types of cancer, including the BRCA1/2 genes for hereditary breast, ovarian, colorectal, endometrial, pancreatic, and other cancer syndromes, and the five genes associated with Lynch syndrome. Our panel was created to include the genes supported by guidelines from the National Comprehensive Cancer Network, or NCCN, and our sample workflow helps identify patients, typically those with a personal or family history of cancer, that are appropriate for testing, by following these guidelines. Our variant reporting process meets the standards of the ACMG and includes confirmation of all pathogenic variants, likely pathogenic variants, and variants of uncertain significance by a second, confirmatory method.

Patients receiving a positive Riscover test result can then consult with their physician to consider intensive screening options, lifestyle changes, drug regimens, or surgical interventions to reduce their lifetime risk of developing one of these heritable cancers. In addition, the test can also be used by asymptomatic individuals to assess familial cancer risk.

Market Opportunity

At present, we estimate there are over 82 million adults in the United States who are eligible for hereditary cancer screening in accordance with medical guidelines but that fewer than 5% of those adults have been screened. In addition, studies indicate that approximately 24% of women in OB/GYN practices meet NCCN guidelines for hereditary cancer screening, but that less than 15% of such eligible women are tested annually. We believe low penetration of this important market can be attributed to the challenges facing physicians in identifying eligible patients. For example, in a study of genetic testing for hereditary cancer published in the Journal of Clinical Oncology in 2017, the author estimated that more

than 90% of unaffected, or asymptomatic, breast cancer susceptibility gene mutation carriers have yet to be identified.

Resura Prenatal Test for Monogenic Disease

Our Resura Prenatal Test for Monogenic Disease, launched in 2019, is the first commercially available, custom-designed noninvasive prenatal test for families at risk for rare single gene disorders. The Resura test is available to families with known risk for monogenic disease, which is caused by a mutation within a single gene. Common examples of monogenic disease include cystic fibrosis, sickle cell anemia, and Tay-Sachs disease. For many of these diseases, knowing the diagnosis before birth informs critical treatment decisions upon the infant's arrival. The Resura test can be performed on disease-causing variants of all inheritance types, including recessive, dominant, and X-linked genetic mutations. Currently, testing for these genetic variants in a fetus involves undergoing invasive prenatal testing, such as amniocentesis, or waiting for postnatal diagnosis. The Resura test uses fetal cfDNA extracted from a sample of the mother's blood to test for genetic variants. The Resura test allows a patient to know with >99% accuracy whether their baby is affected, without the risks of invasive testing or waiting until after delivery. This knowledge relieves the patient of the unknown and empowers them with the information needed to prepare for their baby's birth.

Additional Products: Products of Conception, Serum Screening, and Preimplantation Testing

Our test portfolio also includes chromosomal microarray for pregnancy loss, which evaluates the genetic cause of miscarriage, maternal serum screening for chromosomal disorders, and preimplantation genetic testing for use with artificial reproductive technologies.

Services Supporting our Molecular Tests

Genetic Counseling Services

Genetic test results require interpretation and collaboration to provide the best care for the patient. Our licensed, board-certified genetic counselors are available and accessible to discuss patient test results and consult with clinicians. This service provides the clinician with support to confidently order medically appropriate testing and comprehensively counsel patients both before and after testing. We believe access to our team of board-certified genetic counselors contributes to responsible, evidence-based testing by clinicians.

Electronic Medical Record Integration

Adoption of EMRs by healthcare practices was catalyzed by HITECH, and many of our clients have EMRs in place for management of their clinical workflows. Our connectivity services are designed to integrate with multiple EMR interfaces, providing either unidirectional results delivery or bidirectional ordering and results delivery. These capabilities support the implementation of consistent clinical protocols by making orders easy and complete, and by providing results in a centralized record.

Progenity Partnerships Program

Our Progenity Partnerships program was launched in 2018 as a package of workflow solutions that are flexible and customizable for individual physician practices. The program outlines the menu of options available to support the journey of both patients and physicians with our tests and allows practices to select the options that best support their clinical workflow and patients. The program also supports regular business reviews through clinical and billing scorecards, driving client-specific discussions about test performance, billing outcomes, and emerging business needs, and is designed to ensure that our products are fully meeting the needs of each customer. We believe this support package facilitates client loyalty and cross-portfolio selling.

Our Research and Development Activities

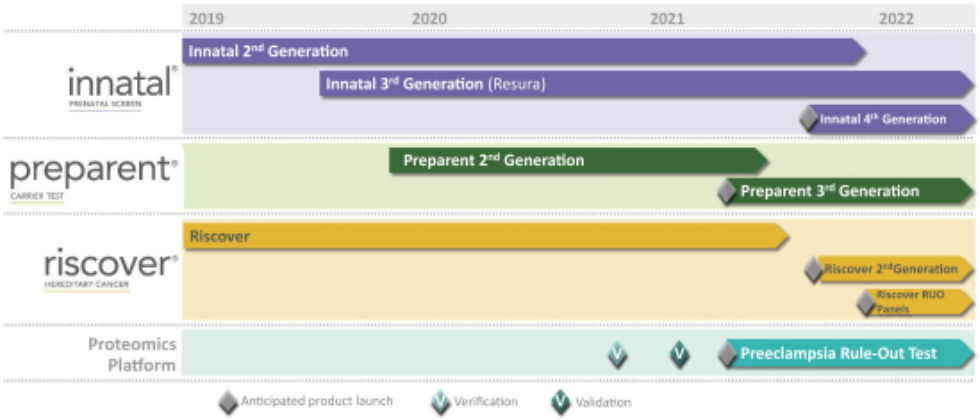
Our molecular test portfolio and pipeline and our precision medicine product pipeline are each powered by a combination of symbiotic technology platforms exploiting advances in genetics, epigenetics, and proteomics, fortified by an innovative bioinformatics infrastructure. Our ecosystem is designed to enable rapid development and validation of products in an integrated fashion.

Molecular Tests

We have developed proprietary, low-cost, high-throughput platforms for our Innatal, Preparent, and Riscover molecular testing products. Our platforms exploit proprietary developments in a number of key molecular biology applications, bioinformatic algorithms, and innovative clinical reporting. Our assay platforms are designed to deliver increased performance at lower costs compared to alternative methods and have a flexible architecture, designed to allow for rapid product development iteration cycles with best in class performance.

We are developing both Preparent 3rd Generation and Riscover 2nd Generation based on our internally developed hybridization capture platform, which platform enables efficient and uniform sequencing of genomic regions ranging from a few hundred genes to the whole human exome by selecting, integrating, and optimizing the latest advances in library preparation, probe synthesis, and laboratory automation. The resulting data is interrogated for constitutional small nucleotide variants (1-100 bp) as well as larger copy number and structural variants. We have developed, verified, and validated the platform to support current carrier testing at a subsidiary laboratory. The platform is in late stage optimization, with verification and validation contingent on laboratory software systems integration to support our proprietary variant classification software and copy counting algorithms.

Our molecular tests and tests in development include:



Next Generation Innatal Prenatal Screen (Innatal 4th Generation)

We are developing a proprietary single molecule DNA counting assay utilizing advanced optics with custom chemistry and molecular biology that we believe will represent a substantial improvement to our existing Innatal platform, with simplified and more cost-effective assay workflow resulting in the same high clinical quality and reliability but with an up to 50% reduction in turnaround time and a substantial reduction in cost of goods sold for our NIPT. We have completed the feasibility assessment for this test and are in the process of completing the optimization process. If successfully developed, we currently anticipate a commercial launch of this product by the end of 2021.

Preeclampsia Rule-Out Test

Preeclampsia is a hypertensive condition of pregnancy involving multiple pathways that usually occurs in the second half of pregnancy. The current standard of care for preeclampsia evaluations are often inconclusive and inaccurate. The only consensus treatment for preeclampsia is delivery of the baby, regardless of gestational age, which results in unnecessary hospital admissions, preterm births, and additional healthcare costs. Suspected preeclampsia before 37 weeks of gestation often results in preterm birth complications, thus a rule-out test with high negative predictive value for preeclampsia could provide the extra days and weeks of gestational development which are critical for positive infant health outcomes. While positive predictive testing is believed by some companies to be beneficial, the 2019 ACOG bulletin on gestational hypertension and preeclampsia stated that due to the relatively low positive predictive values (8% to 33%) of diagnostic tools, those tools cannot predict preeclampsia and should remain investigational. Our preeclampsia rule-out test is not diagnostic, as it is designed to rule out (exclude) the disorder and rely on a high negative predictive value, or NPV, to provide physicians and other care givers with a novel adjunctive laboratory assessment to manage patients suspected of having preeclampsia. Preeclampsia is often indistinguishable from chronic and gestational hypertension, which are treated and managed differently; and therefore must be differentiated from true preeclampsia to avoid unnecessary preterm births.

To address this problem, we are developing a proprietary proteomics platform to support novel clinical tests focused on the quantitative measurement of multiple proteins. This multi-analyte platform is designed to detect complications and diseases manifesting from multiple complex biological pathways to provide insight into disease progression and to assist in clinical management. The platform is built on automated instrumentation, which is a Class I, 510(k) exempt device commonly found in clinical laboratories, which we believe will enable expansion of the platform into multiple clinical sites. We have developed reagents, including high affinity and specific antibodies, which we believe will deliver a differentiating platform focused on performance, sensitivity, and specificity.

Through this proteomics platform, we are developing a noninvasive, high sensitivity, multi-analyte blood-based test designed to assist in the clinical assessment and medical care decision-making process of physicians who care for pregnant women presenting with signs and symptoms of preeclampsia between 28 to 37 weeks of gestational age. We believe a risk assessment test that exhibits high NPV could provide a significant improvement in the ability to manage preeclampsia by ruling out the active condition, thereby obviating the cost and risk of further diagnosis and treatment in high-cost settings. We are also developing a noninvasive test designed to predict risk of preterm birth using a similar approach. If we are able to successfully develop and integrate this platform with our proven expertise in genomics and epigenetics, we believe we will be able to provide a multi-faceted assessment of a patient’s well-being.

We believe our preeclampsia test, if successfully developed, will have the potential to impact the cadence and amount of patient visits and timing of indicated delivery, potentially saving the healthcare system money while also improving patient care for both mother and baby. We have discovered a novel biomarker for our preeclampsia test that we believe improves performance over prior tests. By designing the test to have high sensitivity and NPV rates, we expect the test, if and when offered, to be well suited to complement existing tools already part of the current standard of care, giving clinicians an additional strong, objective tool with which to better manage hypertensive disorders during pregnancy. To this end, we have completed the optimization phase of development for the preeclampsia product and have met the design specifications through our testing of over 800 subjects. In our analysis of our preeclampsia classification algorithm, we evaluated a total of 128 samples with a gestation age of between 20 and 28 weeks and a total of 394 samples with a gestation age of between 28 and 37 weeks (the intended use population). As shown in Table 2 below, we met our NPV (³ 95%) and sensitivity (³ 90%) targets and nearly met our specificity targets (³ 80%) in this analysis in the intended use population for prevalence observed at certain locations and practices with higher risk intended use populations (30%), prevalence

observed by maternal-fetal medicine providers (20%), prevalence observed by OB/GYNs (10%), and prevalence observed in the general population (2.7%).

Table 2: Preeclampsia Rule-Out Test Optimization(1)

Test Population	Sensitivity	Specificity	NPV
Intended Use Population (30.0% Prevalence)	91.0 (78.1, 96.5)	79.9 (75.0, 84.1)	95.2 (91.8, 97.5)
Intended Use Population (20.0% Prevalence)	91.0 (78.1, 96.5)	79.9 (75.0, 84.1)	97.1 (94.2, 98.8)
Intended Use Population (10.0% Prevalence)	91.0 (78.1, 96.5)	79.9 (75.0, 84.1)	98.6 (96.1, 99.4)
Intended Use Population (2.7% Prevalence)	91.0 (78.1, 96.5)	79.9 (75.0, 84.1)	99.6 (97.7, 100)

(1) Targets: NPV ³ 95.5%; Sensitivity ³ 90.0%; Specificity ³ 80.0%

We have secured the clinical verification and validation sample sets for our preeclampsia test and we are in the process of processing and analyzing these samples for verification purposes. We expect to complete verification of our preeclampsia test in the fourth quarter of 2020 and validation in the first quarter of 2021. If successfully developed, we anticipate a targeted commercial launch of this product in the second quarter of 2021. However, we cannot predict whether the COVID-19 pandemic or other factors will impact the timing of our commercial launch. For example, see “Risk Factors—The recent and ongoing COVID-19 pandemic could materially affect our operations, as well as the business or operations of third parties with whom we conduct business. Our business could be adversely affected by the effects of other future health epidemics or pandemics in regions where we or third parties on which we rely have significant business operations.” We may also explore various alternatives for future iterations of the test, including different target gestational ages.

Market Opportunity

According to the Preeclampsia Foundation, preeclampsia occurs in 5% to 8% of pregnancies in the United States and is one of the leading causes of premature birth and maternal and neonatal morbidity and mortality. Based on our estimates, annually, over 700,000 pregnant women in the United States experience signs and symptoms that could be attributed to preeclampsia. In addition, due to poor screening tools, we estimate that the number of pregnant women monitored for preeclampsia is four times greater than the number affected. An estimated 18% of maternal deaths in the United States are directly associated with preeclampsia or eclampsia. The rate of preeclampsia in the United States has increased by about 25% in the last two decades, consistent with increases in preeclampsia risk factors such as obesity, maternal age, and diabetes in the population. The only consensus treatment is early delivery of the infant, regardless of gestational age. According to a study published by the American Journal of Obstetrics and Gynecology, the annual cost burden of preeclampsia to the U.S. healthcare system is estimated to be approximately $1.03 billion for mothers and $1.15 billion for infants. We believe the total addressable market of our preeclampsia test is approximately $3 billion dollars per year in the United States alone.

Other Opportunities

In response to the COVID-19 pandemic, the Avero Diagnostics laboratory is providing molecular testing for diagnosing COVID-19. The test is run on the Hologic Panther platform using the transcription-mediated amplification version of Hologic’s SARS-CoV-2 assay, which received emergency use authorization from the FDA.

We are also developing an epigenetics platform designed to assess the global, regional, and site-specific methylation information of the genome at low cost that is intended to be an alternative to onerous, costly whole-genome bisulfite sequencing and enable more rapid diagnostic product development. Our epigenetics platform is currently a research use only discovery platform designed for the discovery of novel epigenetic signatures and variations across the human epigenome. Epigenetic signatures and variations may characterize phenotype changes and may serve as disease biomarkers if they correlate with a known clinical condition. Such biomarkers may be further developed as LDTs according to CLIA guidelines or as *in vitro* diagnostic devices, or IVDs, according to FDA regulations for diagnosis, screening, and/or monitoring of disease. We estimate the total addressable epigenetics market to be in excess of $13 billion, with particular application to nonalcoholic steatohepatitis, or NASH.

Precision Medicine for GI-Related Disorders

We are developing innovative platforms that we believe will support the advancement of our precision medicine pipeline and address the significant unmet medical needs of patients with GI-related disorders. Our approach is founded on the development of innovative technologies that are designed to diagnose and treat at the site of the disease. Using this platform, we intend to develop diagnostic and therapeutic solutions for a broad range of disorders, but our initial focus is on SIBO and inflammatory disorders such as IBD. These disorders are difficult to treat due to the challenges in diagnosing these conditions and monitoring the treatment response without the repeated use of invasive procedures such as upper GI endoscopies, colonoscopies, and biopsies. From the therapeutic perspective, the most effective approved therapies for IBDs such as ulcerative colitis and Crohn's disease, are currently potent immunomodulatory drugs such as Humira and Xeljanz. Unlike the efficacy seen with other immunological disorders such as rheumatoid arthritis and psoriasis, we believe the efficacy of these potent agents for IBD is suboptimal. This can partly be explained by the inadequate bioavailability of the drug in the GI tract when administered by traditional oral capsules or by injection or infusion, even at high doses and because of the inability to increase dosage due to dose-limiting systemic toxicity. We believe a significant opportunity exists for a device that can diagnose GI-related disorders without an endoscopy or colonoscopy and a device that can deliver drugs in a targeted manner directly to the site of disease.

To address these GI-related disorders, we are currently developing four therapeutic solutions for use with our precision medicine drug/device combinations: PGN-001, which is a GI-targeted adalimumab for use with the Oral Biotherapeutic Delivery System and DDS; PGN-300, which is a GI-targeted vedolizumab for use with DDS and potentially the Oral Biotherapeutic Delivery System; PGN-600, which is a GI-targeted tofacitinib for use with DDS; and PGN-OB2, which is a GLP-1 analog for use with the Oral Biotherapeutic Delivery System. We believe that both the Oral Biotherapeutic Delivery System and DDS will have the potential to be used in combination with other therapeutics in addition to those described above.

Our precision medicine product platform is based on our own multi-disciplinary research developed over the last five years and also in-licensed and acquired intellectual property from Medimetrics. Three of our four ingestible medical device product candidates utilize autonomous localization technology. This technology is designed to enable both diagnostic and therapeutic capsule types to autonomously determine their location within the GI tract. The autonomous localization technology is based on a proprietary LED light and photodetector sensor array that detects reflected light in the GI tract and uses a proprietary algorithm to determine anatomical locations of interest, for example, the pyloric and ileocecal transition. Of note, this technology differs from other GI tract localization technologies that rely on pH levels and other physiological factors which are not specific and are highly variable and also differs from delayed release drug delivery systems such as pH sensitive capsules and MMX technology. Our PIL Dx capsules are designed to work with a remote radio frequency, or RF, detector device that externally monitors all sensor measurements and can transmit results of GI tract testing. Our core technology is also designed to allow for precise sample collection of intestinal fluids at a predetermined

location and analysis in the GI tract in both the PIL Dx capsule and the Recoverable Sampling System capsule (described below). Additionally, certain of the capsules we have under development have temperature sensors that are designed to measure the temperature of the surrounding environment and a microchip oscillator that is designed to keep time.

Recoverable Sampling System

We are developing the Recoverable Sampling System, or RSS, to analyze and characterize the GI tract. The RSS capsule is an investigational electromechanical capsule designed to autonomously collect and preserve intestinal fluids as it transits through the GI tract for *ex-vivo* analysis. The sample chamber of the RSS capsule contains an absorbent sponge impregnated with preservative agents for a range of analytes including proteins, metabolites, and microbes. Once the capsule has been expelled, the subject would collect and ship the capsule to Progenity or another designated laboratory for sample extraction and analysis.

We believe the potential for this capsule is significant. For example, we believe it could help companies developing locally-active GI drugs to assess signals of early efficacy by measuring pharmacodynamic and associated downstream biomarkers at the site of action. The improved precision may allow for smaller clinical trial patient sizes. We believe the technology could potentially also be used for discovery of new therapeutic targets and diagnostic biomarkers. For practicing clinicians, we believe the RSS capsule, if successfully developed and cleared or approved, could be an invaluable tool to assess, in a noninvasive fashion, disease activity for inflammatory disorders like IBD and hepato-biliary disorders. In addition, recent third-party research has determined that the microbiome, which is the collective network of microorganisms that live in our GI tract, is essential for human development, immunity, and nutrition, and has led to the need for tools which can characterize the small bowel microbiome. We believe that the RSS capsule could offer researchers a simple noninvasive and yet powerful tool to characterize many diseases that have been associated with the small bowel microbiome. This could lead to advances in the understanding of many diseases which, until now, have been impractical or impossible to understand. If achieved, we expect this to lead to a new generation of more targeted therapies and diagnostics for many disorders.

In 2020, we expect to initiate the first clinical trial evaluating this technology. In preparation for our clinical trials, we have initiated manufacturing activities for clinical supply of the RSS capsule. Assuming successful results, we would expect to seek CE marking for this device in Europe and that, if CE marking is obtained, initial applications for this device would be in internal programs, partnerships, research use and academic programs.

PIL Dx—Progenity Ingestible Laboratory Diagnostics

We are developing the PIL Dx diagnostic capsule to analyze samples from specific locations of the GI tract. Once ingested, the capsule is designed to communicate wirelessly with a wearable RF receiver to report on status and other operational data. Through our core proprietary autonomous localization technology, the capsule is designed to sample intestinal fluid at a predetermined location within the GI tract for real-time analysis. An on-board fluorometric assay system would then perform prespecified analyses, which could include measurement of inflammatory cytokines, drug levels, microbes, nucleic acids and other metabolites. The sensor measurements and other data would then be transmitted to a wearable RF receiver for collection and processing. The receiver would then be returned to the clinician for data download and review.

Our most advanced investigational PIL Dx capsule is the Smart Capsule Bacterial Detection System, or SCBDS. The SCBDS capsule includes an integrated assay which is designed to measure with high sensitivity the change of a metabolically active substrate that correlates with the amount of live bacteria

in the small intestine. We believe this technology, if successfully developed and approved or cleared, has the potential to become the standard of care for diagnosing SIBO. Currently the SCBDS capsule has undergone a series of validation and verification tests of the various subsystems and evaluations of the localization algorithm. In these studies, the localization of the capsule was confirmed either by CT scan or scintigraphy. In addition, in an ongoing study, clinical samples acquired via aspiration and endoscopy are being evaluated with the SIBO assay on a standalone basis. Beyond SIBO, we believe the PIL Dx capsule, if it can be designed to measure other analytes, will have broad potential applications, such as for early tumor detection and disease characterization and subtyping, and disease activity monitoring for conditions such as IBD. We have begun testing small intestinal fluid samples collected during endoscopy with aspiration on a benchtop version of our bacterial concentration assay at three clinical sites. Samples are measured for bacterial concentration with culture and plate count. As shown in Table 3 below, the interim test results as of April 8, 2020 show a concordance between the bacterial concentration assay and the reference standard of culture and plate count for identifying 10^5 colony forming units, or CFU, per mL.

Table 3: Standalone Bacterial Concentration Assay Testing Results

Clinical Site	SIBO Assay vs TBC* (10^5 CFU per mL**)
1	13/14(93%)
2	11/12(92%)
3	12/12(100%)
Total	36/38(95%)

* Total bacterial count via culture and plate count.
** +/-.5 log.> 10^5 CFU per mL is the generally agreed definition of SIBO and agreed to by the FDA in meetings with Progenity.

In 2021, we expect to initiate the first clinical trial evaluating this technology. In preparation for our clinical trials, we have initiated manufacturing activities and are improving our manufacturing yield for clinical supply of the PIL Dx capsule. Assuming successful results, we expect to initiate a pivotal clinical study to support CE mark certification for this device in Europe and submission of an application seeking *de novo* classification in the United States. We expect to commercialize the PIL Dx capsule, if approved, through a combination of our current OB/GYN sales force, a new gastroenterology sales force, and/or partnership opportunities in the primary care market.

Market Opportunity

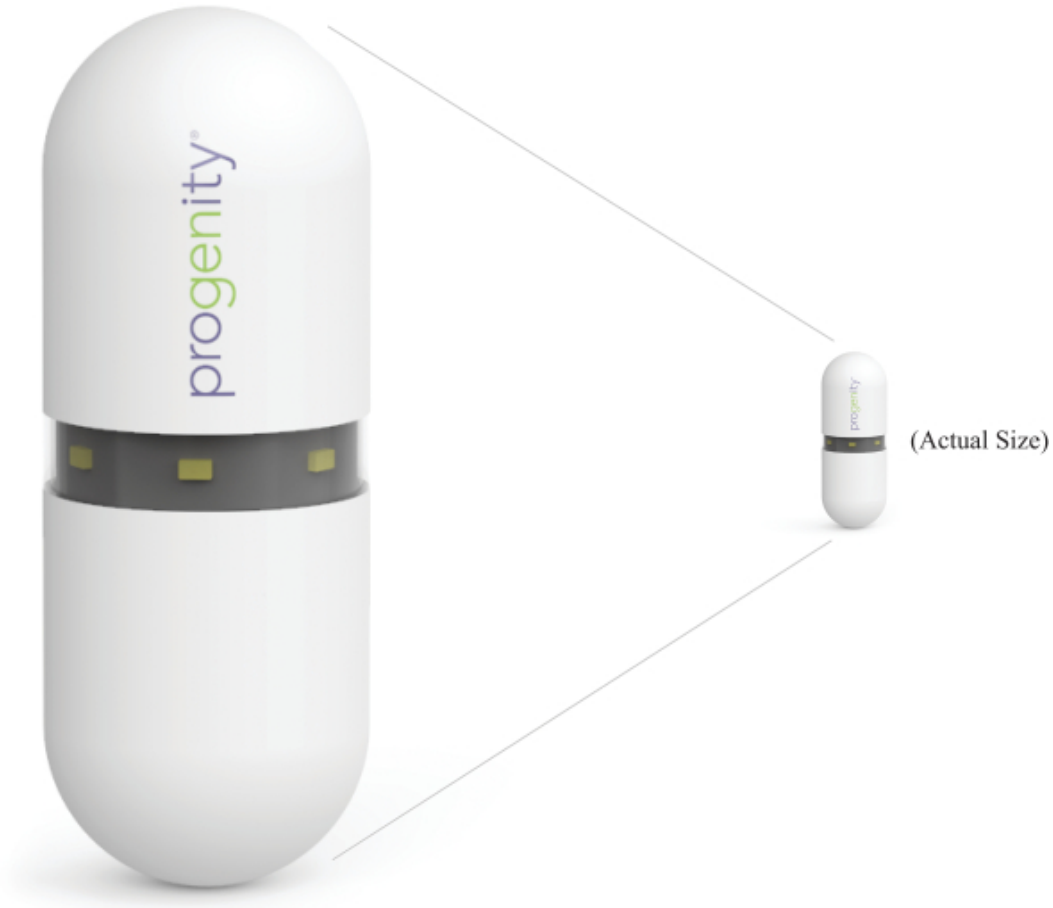
SIBO is a clinical condition associated with abnormally high bacterial counts in the small intestine that are characterized by symptoms such as bloating, abdominal pain, and diarrhea. These symptoms can be very debilitating and are believed to be caused primarily by an over production of gas by the bacteria. A reduction in the bacteria through antibiotic therapy generally alleviates the symptoms, at least temporarily. SIBO is substantially under-diagnosed and limitations exist with currently available testing methods, and as a result, patients with SIBO are poorly served. According to studies in the American Journal of Gastroenterology and the Gastroenterology Journal, there are approximately 105 million patient visits in the United States annually with symptoms that may be suggestive of SIBO. The current standard of care to diagnose SIBO is a duodenal or jejunal aspirate obtained via an invasive upper GI endoscopy which is then transported to a microbiology laboratory for culture, with results generally available several days later. There is high variability in the technique for the aspiration and culture from laboratory to laboratory, leading to inconsistent results between laboratories. This current standard of care is not only costly and time consuming, but it also requires sedation and is highly invasive, thus making our capsule technology a potentially attractive alternative. In addition, there are various breath tests which rely on the detection of hydrogen or methane as a proxy for bacterial presence in the small intestine. These breath tests suffer from lack of sensitivity and specificity which limit their effectiveness.

In addition, there are several different conditions that have similar symptoms, further complicating its diagnosis. As a result, SIBO is under-diagnosed. We believe that our SCBDS capsule, if successfully developed and cleared or approved, may fulfill an unmet medical need by accurately identifying patients that have SIBO so that physicians can treat and monitor their patients more effectively. It is estimated that SIBO may be as prevalent as up to 6% of healthy populations, up to 50% of patients on chronic proton-pump inhibitor treatment, up to 67% of patients with celiac disease, up to 88% of patients with Crohn's disease, and up to 44% of patients with diabetes. We estimate the total addressable market for the treatment of SIBO to be in excess of $36 billion.

Targeted Therapeutics

We are developing a pipeline of investigational drug/device combinations that are designed to treat disease at its site in the GI tract and achieve high concentration in the affected tissues with the potential to drive efficacy and minimize systemic exposure and toxicity.

Drug Delivery System



Our targeted therapeutics pipeline leverages our targeted drug delivery system, or DDS, capsule in an effort to deliver drugs to the site of disease in the GI tract and incorporate drug formulations designed to improve stability and uptake in the GI tract. The DDS capsule is designed to identify the ileal/ileocecal region of the GI tract using our autonomous localization technology and deliver medication to that region. The DDS capsule is an investigational, single-use ingestible device with an outer casing made of inert material and rounded for ease of swallowing. It is designed to passively deliver a precise dose of drugs that can act locally in the GI tract, thereby potentially limiting systemic absorption and the associated toxicity side effects. Candidate drugs and biologics for this form of delivery are approved drugs and biologics that predominately act in the intestinal tissues, but that we believe have limited efficacy because of systemic toxicities. Examples of such drugs include adalimumab and tofacitinib.

There is research, including research conducted by us, that suggests this may be a viable therapeutic approach. For anti-TNFs such as infliximab and adalimumab, clinical studies have shown that in patients with active IBD, the tissue TNF level far exceeded the amount of drug reaching the actively inflamed tissue, and we believe that current approaches to drug delivery are therefore inadequate to suppress the inflammatory response. Moreover, preclinical studies have shown that monoclonal antibodies, or mAbs, such as adalimumab and vedolizumab were found in inflamed colonic tissue when given directly into the lumen of the colon. We have conducted preclinical studies which indicate that these mAbs, given locally, were as efficacious as drugs given via a systemic route of administration. We believe delivering mAbs and other drugs locally at the site of inflammation will result in a higher concentration of drug in the intestinal tissues of patients with IBD, potentially leading to greater efficacy. We believe that local delivery at the site of disease will result in less systemic exposure and may require lower drug administration, potentially reducing the severe adverse event profiles seen with some of these therapeutics. We also believe that because this technology is designed to have lower systemic absorption, it may be ideal for use in combination therapy with the potential to boost efficacy without adversely affecting the active drug's safety profile.

Our lead DDS programs are in pre-clinical proof-of-concept stage. Assuming successful results, we expect to initiate Phase 1 clinical studies followed by Phase 2 studies and subsequent Phase 3 studies to support MAA filings in Europe and NDA or BLA submissions in the United States. We believe certain programs may be eligible for the 505(b)(2) pathway in the United States and/or the hybrid MAA pathway in Europe.

Our investigational drug/device combinations with the DDS capsule are initially pursuing the targeted topical delivery of certain IBD therapies. We estimate this market to be in excess of $15 billion.

Oral Biotherapeutic Delivery System

Over the past two decades, biologic drugs have become the standard of care for a variety of diseases including rheumatoid arthritis, psoriasis, diabetes, Crohn's disease, ulcerative colitis, and a range of cancers. Generally, these biologics are administered systemically via subcutaneous or intravenous injection. We are developing drug/device combinations designed to deliver biologics systemically, via a more convenient oral route of administration. Our unique approach to oral delivery of biologic drugs is through use of an ingestible capsule designed to spray a liquid drug substance past the mucosal surface into the submucosal tissues of the small intestine where it can be absorbed systemically. This ingestible capsule technology is designed to protect the drug from acids and proteolytic enzymes of the gut until it reaches the site of delivery through means other than our autonomous localization technology where it may be triggered and spray the preloaded drug substance past the intestinal barrier. The device design is simple, low-cost, and has the appearance of a typical drug capsule. We initially developed an endoscopically or surgically placed, liquid jet device for optimization and early preclinical work and have since progressed to an autonomous fully integrated prototype device for further evaluation. With the endoscopically or surgically placed device we assessed the potential bioavailability rates that may be

achieved with our device in preclinical swine studies with drugs such as human insulin, dulaglutide, and adalimumab. In these studies we have observed bioavailability of approximately 19% (n=18), 29% (n=11), and 27% (n=11), respectively. We believe this technology, if successfully developed, has broad applications beyond GI diseases and can be applied to numerous drugs that currently demand a parenteral route of administration.

In conjunction with our development of this device, we anticipate potential partnership opportunities, including with manufacturers of biologic drugs, in the parenteral protein market. We estimate this market to be in excess of $250 billion (or over $100 billion for monoclonal antibodies alone) with strong patient and physician preferences for the oral delivery of proteins as compared to subcutaneous injections.

Our current internal pipeline includes PGN-001, an oral version of adalimumab (a drug with approximately $19 billion in annual sales), and PGN-OB2, an oral version of a GLP-1 analog (a drug with a projected $15 billion market by 2025). As a result of our use of known molecules, we believe that rapid proof of concept and value inflexion with preclinical and phase 1 pharmacokinetic results is possible.
Our lead oral biotherapeutic delivery system programs are in pre-clinical proof-of-concept stage. Assuming successful results, we expect to initiate Phase 1 clinical studies followed by Phase 2 studies and subsequent Phase 3 studies to support MAA filings in Europe and NDA or BLA submissions in the United States. We believe certain programs may be eligible for the 505(b)(2) pathway in the United States and/or the hybrid MAA pathway in Europe.

Key Targeted Therapeutic Opportunities in Gastrointestinal Disease

Inflammatory Bowel Diseases

IBDs are a heterogeneous group of inflammatory disorders of the GI tract, and broadly include two major groups: Crohn's disease and ulcerative colitis. According to the Crohn's and Colitis Foundation, or CCF, there are approximately 1.6 million Americans affected by IBD. The disease typically has an onset
before 30 years of age and is a lifelong illness that can be potentially life-threatening. The body's immune system which normally protects the body from external insults like bacteria and viruses becomes dysregulated in patients with IBD and this causes the immune system to attack the body's own tissues. Although IBD has no known cause, there is strong evidence that genetics, a dysregulated immune system, the environment and the gut microbiome all play a role initially in causing the disease, and then perpetuating the inflammation.

Ulcerative Colitis

Ulcerative colitis, or UC, is characterized by inflammation and ulceration of the mucosal lining of the colon. The typical symptoms include diarrhea, bleeding and often abdominal pain. In the more severe cases, there can be large amount of blood loss, which can be life-threatening and require emergency surgery. The goal of medical treatment for all forms of IBD is to reduce the inflammation and to induce remission initially with medication, followed by the administration of maintenance medication to prevent a relapse of the disease. Treatment for UC depends on the severity of the disease, complications, and response to previous treatment. Most patients with mild to moderate UC will first be treated with aminosalicylates. For patients with moderate to severe UC who do not respond to aminosalicylates, more potent systemic therapies such as infliximab and adalimumab are used. The CCF estimates that UC may affect as many as 907,000 Americans.

Crohn's Disease

Similar to UC, Crohn's disease, or CD, is a chronic disorder that causes inflammation of the digestive tract, but unlike UC, CD may involve all layers of the intestine and can affect any part of the intestines. The symptoms of CD range from mild to severe with the most common symptoms being diarrhea,

abdominal pain, fever, and sometimes rectal bleeding. Mild symptoms may be treated with topical corticosteroids and aminosalicylates. For moderate to severe CD, the biologics described above are commonly used to treat UC. The CCF estimates as many as 780,000 Americans have CD, and states that it is most often diagnosed in adolescents and young adults between the ages of 20 and 30 years.

Other Diseases of Interest

While the abovementioned diseases are our initial focus, we believe our precision medicine platform may have broad application beyond SIBO and IBD and into other diseases where a dysbiosis of the small bowel microflora has been implicated, including irritable bowel syndrome, nonalcoholic fatty liver disease and NASH, cardiovascular diseases, and central nervous system disorders like Parkinson's disease, depression, and autism. It is well accepted that the current technology of characterizing the stool microbiome is not optimal to understand the host-microbe interaction, especially for evaluating the bacteria in the small intestine. Current technologies to assess the small intestinal microbial flora are highly invasive, imprecise, and/or impractical for larger studies; therefore, we believe that a device that has the ability to collect and characterize the bacteria, and analyze their function would dramatically advance our knowledge and understanding of the complex host-microbe interaction. We believe that our product candidates, if successfully developed, may be able to achieve these outcomes.

Another area of precision medicine research and development interest for us is the early detection or recurrence of GI tumors such as liver cancer, pancreatic cancer, and colorectal cancer, an addressable market we estimate to be approximately $4.5 billion. We believe that DNA fragments from GI tumors will be detected in intestinal fluids at higher concentrations than in the blood and therefore our products may be more sensitive than screening through a blood sample or via commercially-available diagnostic tests that analyze stool samples.

Key Features of our Precision Medicine Platform

Our platform is distinguished by several key elements:

- ***Robust discovery and development talent.*** Our multi-disciplinary precision medicine team is comprised of over 25 full-time, experienced drug discoverers, researchers, and innovators working to create solutions to improve patient outcomes. In addition to our full-time staff, our team is augmented by more than 60 contract researchers, manufacturers, and consultants. We have also added key R&D employees as part of our acquisitions, including the former Chief Scientific Officer of Medimetrics.
- ***Disciplined approach to target identification and prioritization***. We intend to target diseases with large markets and where current treatments have limited efficacy and very high morbidity, such as IBD. In addition to prioritizing diseases with high unmet need, we will look for the potential to expand the portion of the population that can be treated as our targeted therapeutics may have lower systemic toxicity, lower immunogenicity, and increase market penetration.
- ***Opportunistic approach to drug candidate selection***. Using our precision medicine platform, we are developing potentially improved versions of existing drugs with established mechanisms of action. We intend to only pursue mature and approved drugs with expiring patents that we believe are biologically suited to address the target disease. We believe this strategy of starting with an approved therapeutic is core to operating our precision medicine drug development programs in a scalable and capital efficient manner.
- ***Operational efficiency***. By starting with approved drugs with known mechanisms of action, we believe we can efficiently and cost-effectively evaluate opportunities that we believe are the most promising, and very quickly discontinue programs that do not meet performance thresholds. We believe this will enable us to develop a sustainable and scalable platform to develop multiple drug/device candidates.

- ***Rational and optimized ownership for each program***. With each product candidate, we intend to strategically evaluate the most effective and efficient means for development. When we believe we are best suited to continue a program's development, we intend to continue to fund it internally to commercialization. However, if we believe a partner is better suited to progress a specific program, we may consider entering into strategic partnerships for our programs when we believe such partnerships are economically attractive.

Laboratories

Our corporate offices are located in San Diego, California. We own and operate a certified CLIA and CAP accredited laboratory located in Ann Arbor, Michigan specializing in the molecular testing market serving women's health providers in the obstetric, gynecological, fertility, and maternal fetal medicine specialty areas in the United States. Distribution is managed by a dedicated sales force and a field operations team who support all logistical functions in receiving clinical samples to the laboratory for analysis. Through our affiliation with Mattison Pathology, LLP, a Texas limited liability partnership doing business as Avero Diagnostics, located in Lubbock and Irving, Texas, our operations have expanded to provide anatomic and molecular pathology tests in the United States.

We have a GI-focused laboratory in Irving, Texas to support our precision medicine platform. We believe that the technologies under development will provide quantitative analysis for the RSS capsule and the PIL Dx capsule, as well as for precision medicine-related studies. The team members located at the laboratory are developing and validating reagents and assays to analyze protein, nucleic acid, metabolite, and bacterial analytes. The assays will be used for a range of nonclinical and clinical studies in conditions including SIBO and IBD, and in oncology.

Avero Diagnostics

Through Avero Diagnostics, our operations have expanded to provide anatomic and molecular pathology tests in the United States. Our specialized pathology tests provide expertise in the area of women's healthcare and full-service anatomic pathology. Our expertise in pathology covers a broad spectrum of subspecialties which include gynecologic pathology, breast pathology, urologic pathology, GI pathology, molecular pathology, and dermatopathology. We currently offer histopathology, cytopathology, molecular pathology, and fluorescence in-situ hybridization tests to a network of clients located throughout the United States through Avero Diagnostics. We currently also offer genetic tests for NIPT and carrier screening through Avero Diagnostics.

Laboratory Operations and Processes

Our laboratory utilizes islands of automation and an integrated laboratory information system, or LIS, to deliver high quality results, while maximizing efficiency and agility. Samples are received by the laboratory directly from individual practices or collected by courier services via commercial shippers. Once received, sample and patient demographic information are entered into the LIS. Patient information is entered directly from physician practices (EMR orders), partner laboratories via interface to an EMR, manually from standard requisition forms, or via scanning (using an optical character recognition platform). Samples are linked to patient records via barcoded labels and distributed to testing departments or a partner laboratory.

Our islands of automation strategy utilize automated liquid handling systems to perform high complexity and repetitive tasks in a structured and reproducible manner multiplying the productivity of each staff member. Each task is verified by highly trained staff before being passed to the next step. This strategy is designed to allow optimization of staff and equipment through daily volume fluctuations while also permitting continuous process improvement and updating for new product offerings without requiring redevelopment of a fully automated process.

In-house testing first proceeds to the hematology department, if applicable, and samples are loaded onto the testing platforms. Loaded samples are automatically scanned as they are fed into the testing instruments. Preparent and Innatal samples are then delivered to the DNA extraction group. Samples are scanned while being loaded on the extraction systems, and the sample ID, plate, and plate location are captured in our LIS system, linking sample information to plate and location. Isolated DNA is split so that one isolation can be used for multiple different next generation sequencing, or NGS, and non-NGS tests, thereby reducing the need for multiple extractions and reducing labor and materials costs.

After extraction, samples are processed in batches utilizing color coded and barcoded pre-aliquoted reagent plates. Our internally prepared reagent plates reduce technologist time and improve throughput and turnaround time. Use of the color coding system and barcoding allows traceability of all reagents without requiring laborious and error prone manual recording. Continuing with automation islands, steps requiring transfer of samples as well a multi-step process are performed by internally developed automation systems. This includes amplification set-up and sample addition. Each sample plate, reagent plate, liquid handling system, thermocycler, sequencer/detection system, and performing technologist is recorded.

After amplification, library preparation and indexing samples are pooled and quantitated to allow for optimal loading on the sequencing instruments. Due to the islands of automation strategy, multiple workflows coexist on common equipment maximizing utilization while ensuring the required turnaround time. In order to ensure maximum quality during the manual steps, the materials and set-up are verified by a second trained technologist.

Once patient data is processed through the laboratory, and sent through any applicable bioinformatics pipelines, it goes to the laboratory directors for analysis and resulting. Depending on the test, analysis is performed through either a proprietary, internally-built, web-based software platform, or a commercially available desktop-based software. Laboratory directors review run-level quality metrics and positive/negative/no-template control results to confirm that each patient test run meets pre-defined criteria for reporting. Results for each patient are then carefully reviewed and the laboratory director makes the decision to either report the results, rerun the patient sample, or report the test as failed analysis. These decisions are made based on standard operating procedures and laboratory director discretion.

When laboratory director-approved results are available for a given patient report, the report is automatically generated in Progenity Report Writer, a web-based software. Laboratory directors then review each patient report and approve or edit the report as needed. Most report content is pre-programmed and automatically added to each report. Only a subset of reports require manual edits before approval and release to the ordering provider. Progenity Report Writer is also the software that the laboratory directors use to approve and release all reports generated by third-party laboratories for tests not run in our laboratories.

Our board-certified laboratory directors also work closely with the laboratory's medical science liaisons, or MSLs, who are also all board-certified genetic counselors. The MSLs are the outward facing clinical group, and they take calls from ordering providers and patients. If a clinician calls in with information that could be relevant to the analysis and reporting of their patient's test, the MSLs pass this information on to the laboratory directors. Laboratory directors also work with the MSLs any time complex results are found that require additional information from the ordering provider. MSLs also assist laboratory directors with writing custom report language for complex cases to make sure it can be easily understood by the ordering provider.

Finally, laboratory directors are responsible for ensuring compliance with CLIA regulations, applicable state-specific regulations, and recommendations from professional societies such as CAP, ACMG, and Clinical and Laboratory Standards Institute. The laboratory directors fulfill this requirement by working with the operations department to confirm that all laboratory personnel have the proper credentials and

training, procedural requirements are met, and the relevant quality metrics are monitored over time to identify any possible problems that could affect patient results.

Once complete, results are provided to clients through either an interface to an EMR, or by electronic facsimile. We staff an internal team of genetic counselors to provide additional resources to clinicians, and to speak to patients who need additional counseling. Our client service representatives serve as a final resource. These representatives support our sales team and clients in addressing challenges related to correctly populated requisitions or supplementary information necessary for clinical interpretation.

Laboratory Supplies

We are party to a supply and service agreement, as amended, or the Supply Agreement, with Illumina, pursuant to which Illumina provides us products and services that we use in our laboratory operations, including certain sequencing instruments and reagents, as well as services for the installation, maintenance, and repair of the sequencing instruments.

Pursuant to the Supply Agreement, we have agreed to exclusively use Illumina consumables and equipment for all NIPT laboratory tests that we perform during the term of the Supply Agreement, with the exception of certain reagents that are not available for purchase from Illumina. In addition, we have a minimum purchase requirement per calendar quarter for consumables. We also must maintain a service contract on each sequencing instrument that we use for our NIPT laboratory services.

During the term of the Supply Agreement, we are required to make a rolling, non-binding forecast of our expected needs for reagents and other consumables, and place purchase orders for reagents and other consumables. Illumina may not unreasonably reject conforming purchase orders. Subject to discounts that vary depending on the volume of hardware and reagents and other consumables ordered, the price for sequencing instruments and other services is based on Illumina list prices, and the price for reagents is based on contract prices that are fixed for a set period of time and may increase thereafter subject to limitations.

The initial term of the Supply Agreement continues until June 2022. We may terminate the Supply Agreement in our discretion at any time by giving 90 days' prior written notice to Illumina.

Sales and Marketing

We have a commercial team of more than 150 individuals in the United States, including a sales force of more than 140 individuals, a marketing team of 16 individuals, and a managed care team of six individuals. Our sales force promotes our products across four regions with a focus exclusively on OB/GYNs and maternal-fetal medicine providers in the women's health market and offers our full product portfolio in an effort to maximize cross-selling opportunities. We are expanding into adjacent specialty markets with sales and marketing teams targeting customers in genetic counseling and reproductive medicine, with further expansion into gastrointestinal medicine planned for 2021. We are also evaluating the expansion of our business internationally to leverage our portfolio, with our Preeclampsia test representing one potential avenue for expansion.

Engagement with our customers not only generates testing volume, but also opens access to key opinion leaders, potential clinical research partners, and decision-makers in large combined practice groups. We expect that strong relationships with key players in these markets, as we expand our women's health portfolio, will allow us to carefully address the needs, motivations, and business goals of our customers.

Our marketing strategy is focused on driving adoption of genetic testing protocols and educating healthcare professionals on the value of genetic testing for healthcare management decisions. Our marketing activities include presenting clinical research at medical conferences and scientific meetings, conducting provider education campaigns and hosting medical education events through field medical

science liaisons and sales representatives, using online advertising, social media, and public relations channels to raise product and company awareness, and developing strategic business partnerships.

Our managed care team works with the government and the commercial sector, with a focus on health systems, hospitals, and large physician groups.

Reimbursement

Laboratory tests are classified for reimbursement purposes under a coding system known as Current Procedure Terminology, or CPT, which we and our physician customers must use to bill payors and to receive payment for our molecular tests. These CPT codes are associated with the particular molecular test that we have provided to the patient. Once the AMA establishes a CPT code, CMS or its contractors may establish payment levels and coverage rules with respect to our molecular tests under Medicare and Medicaid. In addition, commercial third-party payors independently establish reimbursement rates and coverage rules for our molecular tests under their respective plans.

We currently submit for reimbursement using CPT codes that we believe are appropriate for our testing, but codes may be rejected or withdrawn and payors may seek refunds of amounts that they claim were inappropriately billed to a specified CPT code.

We generate revenue from the sales of our molecular tests and receive payments for such tests from four distinct channels: commercial third-party payors, government health benefits programs such as Medicare and Medicaid, laboratory distribution partners, and individual patients. Reimbursements from payors, including commercial third-party payors and government health benefits programs, constituted 97% of our revenue during the year ended December 31, 2019. We are currently contracted with payors representing an estimated approximately 127 million covered lives and will be contracted with payors representing an estimated approximately 143.5 million covered lives as of July 1, 2020.

Commercial Third-Party Payors

We submit claims for reimbursement and receive associated payments from commercial third-party payors. Our contracts with commercial third-party payors provide for contracted rates of reimbursement. For instances where we are not contracted with a particular commercial third-party payor, we submit claims seeking reimbursement on a non-contracted basis.

If we become an in-network provider in a commercial third-party payor health plan, we become subject to the terms of contracts entered into with such payors and we may be subject to discipline, breach of contract actions, non-renewal, or other contractual remedies for noncompliance with the requirements of these contracts (which may include reduced reimbursement rates) and we are also subject to associated state or federal laws.

We have entered into settlement agreements with commercial third-party payors in order to settle claims related to past billing and coding practices that have been discontinued, including, without limitation: Connecticut General Life Insurance Company and Cigna Health and Life Insurance Company, or Cigna, United HealthCare Services, Inc. and UnitedHealthcare Insurance Company, or United, and Aetna Health Management, Inc., or Aetna. In December 2018, we and Avero Diagnostics entered into settlement agreements with Cigna pursuant to which Avero Diagnostics agreed to pay Cigna $12 million in a series of installments and we agreed to guarantee $6 million of such payment. We and Avero Diagnostics also agreed to certain covenants regarding our billing practices. We have paid $9.5 million under such agreement to date. In September 2019, we entered into a settlement agreement with United that governs past benefit claims and a corrective action plan which governs future benefit claims that we submit for reimbursement at an arm’s length, out-of-network basis to United. The total settlement amount was $30 million, to be paid in a series of installments. We have paid $7.0 million under such agreement to date. In November 2019, we entered into a settlement agreement with Aetna, which was

amended in April 2020, pursuant to which we agreed to pay Aetna $15 million in a series of installments. We have paid $7.5 million under such agreement to date. As part of the Aetna settlement, we also entered into an in-network participation agreement with Aetna that became effective January 1, 2020. Each of these settlement agreements provides for a release of past claims by all parties.

Government Health Benefits Programs

We are enrolled and eligible to receive payment from government health benefits programs, including Medicare and Medicaid. We are a participating provider under most state Medicaid plans.

In April 2014, Congress passed the Protecting Access to Medical Care Act of 2014, or PAMA, which included substantial changes to the way in which clinical laboratory services are paid under Medicare. Under PAMA, laboratories such as us that receive the majority of their Medicare revenue from payments made under the Clinical Laboratory Fee Schedule or the Physician Fee Schedule are required to report to CMS, beginning in 2017 and every three years thereafter (or annually for "advanced diagnostic laboratory tests"), commercial third-party payor reimbursement rates and the volume of tests that they have performed for such payors. Laboratories that fail to report the required information may be subject to substantial civil monetary penalties. If we determine that our tests meet the current definition of advanced diagnostic laboratory tests, we will be required to comply with these reporting requirements on an annual basis.

For clinical diagnostic laboratory tests furnished on or after January 1, 2017, Medicare reimbursement is paid based upon the weighted median of the reported commercial third-party payor payments for the same test, as calculated using the data collected by applicable laboratories and reported to CMS during the specified data collection and reporting period. For clinical diagnostic laboratory tests that are assigned a new or substantially revised code, initial payment rates are assigned by the cross-walk or gap-fill methodology that existed under the prior law. The cross-walk methodology applies when a new test or substantially revised test is determined to be similar to an existing test, multiple existing test codes, or a portion of an existing test code, which can then be utilized to determine a payment. The gap-fill methodology applies when no comparable, existing test is available. In this case, the Medicare Administrative Contractor, or MAC, develops a local payment amount for the new test code and CMS calculates a national limitation amount after a year of payment at the local MAC rates based on the median of rates for the test code across all MACs. Initial payment rates for new advanced diagnostic laboratory tests are based on the actual list charge for the laboratory test.

The revised reimbursement methodology described above generally results in relatively lower reimbursement amounts under Medicare for clinical laboratory services than has been historically reimbursed. Any reductions to reimbursement rates resulting from the new methodology are limited to 10% per test per year in each of 2018 through 2020 and to 15% per test per year in each of 2021 through 2023. The CARES Act amended the timeline for reporting private payer payment rates and delayed by one year the payment reductions scheduled for 2021.

In addition to the CARES Act, Congress has enacted other laws in response to the COVID-19 pandemic to provide financial relief to healthcare providers and suppliers, including diagnostic laboratories, and encourage implementation of diagnostic testing and treatment for COVID-19. For instance, the Families First Coronavirus Response Act, enacted on March 18, 2020, requires certain governmental and commercial insurance plans to provide coverage of COVID-19 diagnostic testing services without imposing cost-sharing (e.g., copays, deductibles, or coinsurance) or other utilization management requirements. The CARES Act and the Paycheck Protection Program and Health Care Enhancement Act, enacted on April 24, 2020, each appropriated approximately $100 billion to provide financial relief for certain healthcare providers and to expand treatment and diagnostic testing capacity for COVID-19. The CARES Act also suspended, for the period from May 1, 2020 to December 31, 2020, the 2% Medicare payment reduction created under the sequestration required by the Budget Control Act of 2011 (as amended by the American Taxpayer Relief Act of 2012), and extended the sequester by one year, through 2030.

Laboratory Distribution Partners

We have contracted with other clinical and genetic laboratories for distribution of our products. Our reimbursement for these products comes directly from the contracted laboratory. In some instances, our distribution partners will request that we bill the payor for the provided test on their behalf. In these instances, we collect payment directly from the payor.

Individual Patients

We generally seek to collect co-payments and deductibles directly from patients in cases where we have billed the payor. For these patients, we offer a range of flexible payment plans to assist in the payment of co-payments and deductibles. We also seek to collect payment directly from patients for cash paying patients who do not have or have elected not to use medical insurance. Patients paying out of pocket are generally offered a discounted price. We are not currently promoting or offering direct-to-consumer testing products.

We are subject to applicable state and federal laws regarding who should be billed, how they should be billed, how business should be conducted, and how patient obligations regarding cost sharing should be handled.

Competition in Molecular Testing

Women's Health Molecular Testing

We compete with numerous companies that have developed and commercialized some combination of our core product portfolio: NIPT; carrier screening; and hereditary cancer screening. Our primary competitors include Invitae, Myriad Genetics (which acquired Counsyl in 2018), and Natera. Secondary competitors include Ambry Genetics, GeneDx (a subsidiary of Bio-Reference Laboratories), LabCorp, Quest Diagnostics, Roche Diagnostics, Sema4, and other commercial and academic laboratories. We expect additional competition as other established and emerging companies enter the women's health molecular testing market, including through business combinations.

We believe the principal competitive factors in our market include the following:

- test performance, including sensitivity, specificity, failure rates, and turnaround time, as demonstrated in clinical validation;
- value of product offerings, including pricing and impact on healthcare spending;
- coverage and reimbursement arrangements with third-party payors;
- convenience of testing;
- additional value-added services and digital healthcare tools;
- effectiveness of sales and marketing efforts;
- development and introduction of new, innovative products;
- key opinion leader support;
- brand awareness; and
- ease of integration with healthcare provider practices.

We believe that we compete favorably on the basis of the factors above, particularly in test performance, additional value-added services, and digital healthcare tools, value of product offerings, and effectiveness of sales and marketing efforts.

Preeclampsia

The U.S. market for preeclampsia tests currently includes certain positive or predictive tests such as the predictive Preeclampsia Screen T1 offered by NTD Labs (purchased from Perkin Elmer in 2016) and the GestAssured preeclampsia test using congo red staining offered by GestVision. We expect to offer a noninvasive biomarker test designed to rule out preeclampsia. We anticipate that our test would compete favorably by providing superior sensitivity, specificity, and high NPV to rule out preeclampsia in symptomatic women as compared to existing clinical assessment tools, including those discussed above.

Testing Services

The market for anatomic pathology and molecular testing is highly competitive. We compete with a vast network of local and regional pathology groups, national laboratories, hospital-based laboratories, and physician-owned laboratories. Competition in the industry is based on several factors including price, quality of service, accuracy of results, clinical expertise, test menu, turnaround time of test results, commercial strategy and execution, ability to retain high-quality staff, client relationships, and reputation.

Competition in Precision Medicine

The biotechnology and pharmaceutical industries are characterized by rapid technological advancement, intense competition, and a strong emphasis on intellectual property and proprietary products.

While we believe that our proprietary technology platform, knowledge, experience, and scientific expertise provide us with competitive advantages, we face substantial competition from major pharmaceutical companies, biotechnology companies, academic institutions, government agencies, and public and private research institutions. For any products that we eventually commercialize, we will not only compete with existing technologies and therapies but also with those that may become available in the future.

Given our technology's potential utility across multiple applications, we expect to face intense competition from a diverse set of competitors. Many of our competitors, either alone or with strategic partners, have significantly greater financial, technical and human resources than we do. Competitors may also possess more experience developing, obtaining regulatory approval for, and marketing novel treatments and technologies in the areas we are pursuing. These factors could give our competitors an advantage in recruiting and retaining qualified personnel, completing clinical development, securing strategic partnerships, and commercializing their products. We believe the key competitive factors that will affect the development and commercial success of our product candidates are efficacy, safety and tolerability profile, reliability, method of administration, convenience of dosing, price, and reimbursement.

Recoverable Sampling System

To our knowledge, there are no commercially available ingestible sampling devices representing an immediate competitive threat to our technology. This is, however, a nascent space, and we expect to see future competition from new entrants as companies develop potentially competitive technologies.

PIL Dx—Progenity Ingestible Laboratory Diagnostics

Although we believe that they are comparatively limited in functionality and capability, we face competition from a small number of currently marketed or in-development diagnostic devices and tests specifically targeting GI disorders, such as those from Medtronic and Commonwealth Diagnostics International. Additionally, we will similarly face competition from new entrants as advances in diagnostics and engineering bring new technologies to market.

Drug Delivery System

The current IBD market is both established and mature, comprised of a range of therapeutic agents including branded and generic small molecules, biologics, biosimilars, and involving multiple mechanisms of action as well as routes of administration. Although we believe our technology platform will provide us with a competitive advantage in its ability to enable targeted delivery of therapeutic agents (and, in particular, biologics) via oral administration, we will face competition from several companies whose current R&D efforts will likely result in the emergence of newer pharmaceuticals touting oral administration, more convenient dosing frequency, novel mechanisms of action, and improved safety profiles and drug availability. We believe that the majority of competition will come from those companies marketing or developing biologics and small molecule therapeutics, such as AbbVie, Allergan, Celgene, Eli Lilly, Galapagos, Gilead, J&J, Pfizer, Roche, Takeda, and UCB.

Oral Biotherapeutic Delivery System

We expect to face competition from a number of technologies currently marketed or being developed to enhance or facilitate the oral administration of therapeutic agents. There is a wide range of competitive technologies and mechanisms that may challenge us.

The primary categories of oral biotherapeutic technologies currently available or being developed by our competitors include:

- Functional excipients designed to enhance the solubility and/or permeability of peptides and small molecules: Emisphere Technologies and Enteris Biopharma;
- Enteric coating technologies designed to prevent gastric degradation of active pharmaceutical ingredients and facilitate GI delivery: Assembly Biosciences, Catalent, Cosmo Pharmaceuticals, Intract Pharma, Lonza, and Tillotts Pharma; and
- Ingestible devices designed for the targeted delivery of a therapeutic payload: Lyndra Therapeutics and Rani Therapeutics.

Intellectual Property

The proprietary nature of, and intellectual property protection for, our existing and future products, processes, and know-how are important to our business. Our success depends in part on our ability to obtain patent and other legal protection for our products, technology, and know-how, to operate without infringing on the proprietary rights of others, and to prevent others from infringing on our proprietary rights. We rely on a combination of patents, trade secrets, know-how, license agreements, and nondisclosure and other contractual provisions to protect our intellectual property rights. These rights cover our proprietary tests, processes, databases, information, and materials across our different businesses. We seek and maintain patent protection in the United States and internationally for our over 425 issued patents and pending patent applications, while also in-licensing technology, inventions, and improvements that we consider important to the success of our business. In addition to patent protection, we intend to use other means to protect our products, technology and know-how, including pursuing terms of marketing or data exclusivity for our products, orphan drug status (if applicable) and similar rights that are available under regulatory provisions in certain territories, including the United States and Europe. We also rely on know-how and continuing technological innovation that are protected as trade secrets to develop and maintain our competitive position.

Molecular Testing Technology Patent Portfolio

Intellectual property rights relating to the molecular testing technology include a patent portfolio consisting of 23 distinct patent families. The 23 families include a total of 55 issued patents and 36 pending applications. Of these patents and applications, the latest to expire issued U.S. patents are projected to expire in 2037 and the latest to expire U.S. patent applications, if converted to PCT or non-

provisional applications in 2020, would be projected to expire in 2040, in each case, subject to potential term extensions. Two patent families have not yet published. In general, we file our molecular testing patent applications in the United States, Europe, Canada, China, and sometimes Japan.

The 91 patents and pending applications in this portfolio include claims that are directed to a range of molecular testing-related methods, systems and compositions, including but not limited to, the following:

- detecting chromosomal abnormalities including copy number variations;
- determining allele dosages;
- determining methylation status;
- isolating and analyzing rare cells; and
- diagnosing pregnancy-associated conditions like preeclampsia and preterm birth.

In addition to the patents and applications described above, our intellectual property rights relating to the molecular testing business include know-how relating to proprietary assays, databases, and software products. Examples include the following:

- Proprietary NGS and highly multiplexed polymerase chain reaction assays and panels;
- Discovery and diagnostic algorithms;
- Laboratory, billing, and reimbursement information systems; and
- Variant classification, annotation, and reporting systems.

Precision Medicine Technology Patent Portfolio

Intellectual property rights relating to our precision medicine technology include a patent portfolio consisting of 79 distinct patent families. The 79 families include a total of 134 issued or allowed patents and 202 pending applications. Of these patents and applications, the latest to expire issued U.S. patents are projected to expire in 2037 and the latest to expire U.S. patent applications, if converted to PCT or non-provisional applications in 2020, would be projected to expire in 2040, in each case, subject to potential term extensions. Thirty of the families were acquired in connection with the acquisition of certain tangible and intangible assets relating to the business formerly operated by Medimetrics GmbH, Medimetrics Personalized Drug Delivery B.V., and Medimetrics Personalized Drug Delivery Inc. In general, we file our precision medicine patent applications in the following patent jurisdictions: the United States, Australia, China, Canada, Europe, and Japan; and sometimes in these additional jurisdictions: Brazil, Eurasia, Hong Kong, Israel, India, South Korea, Mexico, and Singapore.

The 336 patents and pending applications in this portfolio include claims that are directed to a range of gastroenterology-related methods, systems, and compositions, including but not limited to, the following:

- autonomous localization of an ingestible device in the GI tract using visible or infrared light;
- GI sampling mechanisms and compositions, including preservatives for GI analytes;
- ingestible device assays, optics and analytics for detecting and quantifying GI analytes;
- ingestible device drug delivery mechanisms and systems;
- targeted topical and systemic delivery of therapeutics, including biologics, peptides, small molecules, nucleic acids, or cells for the treatment of GI conditions;
- ingestible devices for diagnosing, treating, and aiding in the treatment of GI conditions; and
- GI-specific drug formulations and dosing regimens.

Trademarks

Our reputation and brand awareness are very important to us. Accordingly, we invest significant resources in the protection of our trademarks. We have and will continue to pursue the registration of our trademarks, including trademarks for the name Progenity, our logo, and certain of our products, in relevant jurisdictions.

Government Regulation

Regulations Related to Clinical Laboratories

Clinical Laboratory Improvement Amendments of 1988 and State Regulation

As a clinical laboratory, we are required to hold certain federal certifications under the CLIA to conduct our business. Our clinical laboratory facility located in Ann Arbor, Michigan is CLIA certified and is accredited by CAP, a CLIA-approved accrediting organization, which means that our laboratory has been certified as following CAP guidelines in operating the laboratory and in performing tests that ensure the quality of our results.

Under CLIA, a laboratory is any facility that performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, or treatment of disease or the impairment or assessment of health. CLIA requires that such laboratories obtain certification from the federal government and maintain compliance with various operational, personnel qualification, facilities administration, quality control and assurance, and proficiency testing requirements intended to ensure the accuracy, reliability, and timeliness of patient test results. CMS administers the CLIA certification program. CLIA certification is also necessary to bill state and federal healthcare programs, as well as many commercial third-party payors, for laboratory testing services.

CLIA requires that we hold a certificate that specifies the types of testing we perform and that we comply with certain standards applicable to such tests. In addition, CLIA specifies certain testing categories requiring periodic proficiency testing, and certified laboratories performing these tests must enroll in an approved proficiency testing program. To demonstrate proficiency, such laboratories must test specimens received from an outside proficiency testing organization, such as CAP, and then, submit the results back to that organization for evaluation. Failing to achieve a passing score on a proficiency test may lead to loss of certification to perform testing in the corresponding category. Furthermore, failure to comply with other proficiency testing regulations, can result in revocation of the referring laboratory's entire CLIA certification.

In addition, as a condition of CLIA certification, our laboratory is subject to survey and inspection every other year, as well as random inspections at CMS's discretion. The biannual survey is conducted by CMS, a CMS agent (typically a state agency), or, if the laboratory holds a CLIA Certificate of Accreditation, a CMS-approved accreditation organization. Because CLIA is user-fee funded, all costs of administering the program must be covered by the regulated facilities such as ours, including certification and survey costs.

Laboratories performing high-complexity testing are required to meet more stringent requirements than laboratories performing less complex tests. A high-complexity laboratory like ours that is certified under CLIA may develop, validate, and use proprietary tests referred to as LDTs. To date, the FDA has taken the position that generally it will exercise enforcement discretion and not require PMA, or pre-market notification (510(k)) for LDTs, but laboratories may voluntarily submit 510(k) or PMA applications, or *de novo* classification requests, for LDTs to obtain FDA clearance or approval following a demonstration of clinical validity. On the other hand, the CLIA program requires laboratories to demonstrate the analytical validity of any LDT used in clinical testing. All of our current products are LDTs.

CLIA provides that a state may adopt laboratory regulations that are more stringent than those under federal law, and a number of states have implemented their own more stringent laboratory regulatory

requirements. State laws may require that laboratory personnel meet certain qualifications, specify certain quality control procedures, facility requirements, or prescribe record maintenance requirements.

California Laboratory Licensing

In addition to federal certification requirements for laboratories under CLIA, licensure is required and maintained for our clinical laboratory under California law because we receive specimens for testing from California. The California licensure law establishes standards for the day-to-day operation of a clinical laboratory, including the training and skills required of personnel and quality control. In addition, California law mandates proficiency testing, which involves testing of specimens that have been specifically prepared for the laboratory.

If a clinical laboratory is out of compliance with California standards, the California Department of Public Health, Laboratory Field Services branch, may suspend, restrict, or revoke its license to operate the clinical laboratory, assess substantial civil money penalties, or impose specific corrective action plans.

New York Laboratory Licensing

Our laboratory receives specimens from New York state, and so we are required to maintain a New York clinical laboratory license, under New York laws and regulations, which establish standards for: (1) day-to-day operation of a clinical laboratory, including training and skill levels required of laboratory personnel; (2) physical requirements of a facility; (3) equipment; and (4) validation and quality control.

New York law also mandates proficiency testing for laboratories licensed under New York state law, regardless of whether or not such laboratories are located in New York. If a laboratory is out of compliance with New York statutory or regulatory standards, the New York State Department of Health may suspend, limit, revoke or annul the laboratory's New York license, censure the holder of the license or assess civil money penalties. Statutory or regulatory noncompliance may result in a laboratory's operator being found guilty of a misdemeanor under New York law. The New York State Department of Health also must approve each specific LDT before the test is offered in New York.

Other State Laboratory Licensing Laws

In addition to New York and California, other states, including Maryland, Pennsylvania, and Rhode Island, require licensing of out-of-state laboratories under certain circumstances. We have obtained licenses in these additional states and believe we are in compliance with applicable licensing laws.

Potential sanctions for violation of state statutes and regulations include significant fines, the disapproval of licensure applications and the suspension or loss of various licenses, certificates and authorizations, which could harm our business. CLIA does not preempt state laws that have established laboratory quality standards that are at least as stringent as federal law.

State Genetic Testing Laws

Many states have implemented genetic testing and privacy laws imposing specific patient consent requirements and protecting test results. In some cases, we are prohibited from conducting certain tests without a certification of patient consent by the physician ordering the test. Requirements of these laws and penalties for violations vary widely.

Federal Oversight of Laboratory Developed Tests

The laws and regulations governing the marketing of diagnostic products are evolving, extremely complex, and in many instances, there are no significant regulatory or judicial interpretations of these laws and regulations. Clinical laboratory tests are regulated under CLIA, as administered by CMS, as well as by applicable state laws In addition, pursuant to its authority under the FD&C Act, the FDA has

jurisdiction over medical devices, which include, among other things, *in vitro* diagnostic devices, or IVDs, intended for clinical purposes. LDTs are a subset of IVDs that are designed, manufactured, and used within a single laboratory. The FDA regulates, among other matters, the research, testing, manufacturing, safety, labeling, storage, recordkeeping, premarket clearance or approval, marketing and promotion and sales and distribution of medical devices, including IVDs, in the United States to ensure that such products on the domestic market are safe and effective for their intended uses. In addition, the FDA regulates the import and export of medical devices.

Although the FDA has statutory authority to assure that medical devices, including IVDs, are safe and effective for their intended uses, the FDA has historically exercised its enforcement discretion and not enforced applicable provisions of the FD&C Act and regulations with respect to LDTs. We believe our tests fall within the scope of the agency's LDT definition. As a result, we believe our molecular tests are not currently subject to the FDA's regulations and the FD&C Act provisions applicable to medical devices and IVDs.

Legislative and administrative proposals to amend FDA's oversight of LDTs have been introduced in recent years and we expect that new legislative and administrative proposals will continue to be introduced from time to time. It is possible that legislation could be enacted into law or regulations or guidance could be issued by the FDA which may result in new or increased regulatory requirements for us to continue to offer our LDTs or to develop and introduce new tests as LDTs. For example, in recent years, FDA has stated its intention to modify its enforcement discretion policy with respect to LDTs. Specifically, on July 31, 2014, the FDA notified Congress of its intent to modify, in a risk-based manner, its policy of enforcement discretion with respect to LDTs. On October 3, 2014, the FDA issued two draft guidance documents outlining a method for extending regulatory oversight to LDTs. These draft guidance documents were titled "*Framework for Regulatory Oversight of Laboratory Developed Tests*," or Framework Guidance, and "*FDA Notification and Medical Device Reporting for Laboratory Developed Tests*," or Notification Guidance. The Framework Guidance stated that FDA intended to end its policy of enforcement discretion with respect to most LDTs and apply a risk-based regulatory compliance and enforcement approach consistent with the classification of medical devices generally in Classes I through III. The Notification Guidance would have further enabled FDA to collect information regarding the LDTs currently being offered for clinical use through a notification process, as well as to enforce its regulations for reporting safety issues and collecting information on any known or suspected adverse events related to the use of an LDT. The 2014 Framework and Notification Guidances were the subject of much controversy among the device and laboratory industries, healthcare providers, the U.S. Congress, and other stakeholders, and on November 18, 2016, the FDA announced that it would not finalize either guidance document. On January 13, 2017, FDA released a document titled "*Discussion Paper on Laboratory Developed Tests*," or the Discussion Paper, which stated that the agency had declined to finalize the LDT guidances to allow for additional discussion on appropriate regulatory oversight. The Discussion Paper presented a more focused approach to LDT oversight, and stated that under the FDA's current thinking, LDTs marketed before any regulatory framework becomes effective would not be expected to comply with the requirements. The FDA has not issued any proposed rules or guidance documents relating to LDTs since January 2017.

In April 2017, Congress released a discussion draft of the Diagnostic Accuracy and Innovation Act, or DAIA, the first legislative attempt to reform the regulatory framework for LDTs and IVDs since the FDA proposed to overhaul its policy of enforcement discretion with respect to LDTs. DAIA sought to carve LDTs and certain IVDs out of the current definition of "medical devices" by codifying a new defined term, *in vitro* clinical tests, or IVCTs. IVCTs would constitute products currently regulated as IVDs and LDTs, and such products would be regulated differently from medical devices. DAIA proposed a three-tiered risk classification system with corresponding premarket review pathways for each tier. It also sought to establish jurisdictional boundaries between the FDA, CMS, and the states, with FDA oversight over development and manufacturing, CMS oversight over laboratory operations, and individual state

oversight over medical use and interpretation. In August 2018, the FDA provided technical drafting assistance on DAIA, issuing comments in the form of a revised version of the draft legislation. Unlike DAIA, the FDA's technical assistance proposed a bifurcated risk classification for IVCTs that would eliminate the middle-risk tier, subject most high-risk IVCTs to premarket approval, and exempt most low-risk IVCTs from premarket review. It would also establish a precertification program that would enable an IVCT developer to be certified by the FDA, or potentially by an FDA-accredited body, as having sufficient skill at developing IVCTs, so as to not require premarket review for each individual test marketed by a certified developer. If included in any enacted law, the FDA's recommendations would also centralize the FDA's jurisdiction, giving the FDA authority to withdraw approvals, request raw data, and take corrective action against test developers. In December 2018, legislators released a discussion draft of a new bill, the Verifying Accurate, Leading-edge IVCT Development, or VALID, Act, which largely incorporated the FDA's proposals, and in April 2019, HHS, issued technical assistance comments on the VALID Act, which largely expressed support for maintaining the FDA's jurisdiction over IVCTs and the proposed precertification program. HHS's comments reflect the most recent action on the VALID Act, which remains only a discussion draft. Even if passed by Congress and signed in to law, many of the proposals in the VALID Act, including the proposed requirements for premarket review and precertification of IVCTs, may take time to be worked out and fully implemented by the FDA, CMS and other regulatory authorities.

In addition, the FDA issued a Safety Communication on October 31, 2018 and updated it on April 4, 2019 in which the FDA advised patients and healthcare providers that claims for many genetic tests to predict a patient's response to specific medications, referred to as pharmacogenetic tests, have not been reviewed by the FDA, and may not have the scientific or clinical evidence to support this use for most medications. The FDA further noted that changing drug treatment based on the results from pharmacogenetic tests could lead to inappropriate treatment decisions and potentially serious health consequences for patients. In April 2019, the FDA issued a Warning Letter to a laboratory stating that the laboratory was required to obtain marketing authorization for certain pharmacogenetic tests that had previously been marketed as LDTs. The FDA's action reflects a heightened interest in LDTs and a particular concern with the clinical validation of high-risk tests that purport to predict a drug response that may be inconsistent with FDA-approved drug labeling.

Advertising of Laboratory Services or LDTs

Whether regulated by the FDA as a Class I or Class II device or subject to FDA's enforcement discretion as an LDT, our advertising for laboratory services and tests is subject to federal truth-in-advertising laws enforced by the Federal Trade Commission, or FTC, as well as comparable state consumer protection laws. Under the Federal Trade Commission Act, or FTC Act, the FTC is empowered, among other things, to (a) prevent unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce; (b) seek monetary redress and other relief for conduct injurious to consumers; and (c) gather and compile information and conduct investigations relating to the organization, business, practices, and management of entities engaged in commerce. The FTC has very broad enforcement authority, and failure to abide by the substantive requirements of the FTC Act and other consumer protection laws can result in administrative or judicial penalties, including civil penalties, injunctions affecting the manner in which we would be able to market services or products in the future, or criminal prosecution.

Medical Device Regulation

Pursuant to its authority under the FD&C Act, the FDA has jurisdiction over medical devices, including IVDs and other products we are currently developing. The FDA regulates, among other things, the research, design, development, pre-clinical and clinical testing, manufacturing, safety, effectiveness, packaging, labeling, storage, recordkeeping, pre-market clearance or approval, adverse event reporting, marketing, promotion, sales, distribution and import and export of medical devices. Unless an exemption

applies, each new or significantly modified medical device we seek to commercially distribute in the United States will require either a premarket notification to the FDA requesting permission for commercial distribution under Section 510(k) of the FD&C Act, also referred to as a 510(k) clearance, or FDA approval of a PMA application. Although the tests we currently market are LDTs, which are subject to FDA's enforcement discretion, we intend to develop certain product candidates, such as ingestible diagnostic products, that are subject to the FDA's premarket review requirements applicable to medical devices.

Device Classification

Under the FD&C Act, medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurances with respect to safety and effectiveness.

Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be reasonably assured by adherence to General Controls, which require compliance with the applicable portions of the FDA's QSR, facility registration and product listing, reporting of adverse events and malfunctions, and appropriate, truthful and non-misleading labeling and promotional materials. Some Class I devices also require premarket clearance by the FDA through the 510(k) premarket notification process described below. Most Class I products are exempt from the premarket notification requirements.

Class II devices are those that are subject to the General Controls, as well as Special Controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These Special Controls can include performance standards, patient registries, FDA guidance documents, and post-market surveillance. Most Class II devices are subject to premarket review and clearance by the FDA. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification process.

Class III devices include devices deemed by the FDA to pose the greatest risk such as life-supporting or life-sustaining devices, or implantable devices, in addition to those deemed novel and not substantially equivalent following the 510(k) process. The safety and effectiveness of Class III devices cannot be reasonably assured solely by the General Controls and Special Controls described above. Therefore, these devices are subject to the PMA application process, which is generally more costly and time-consuming than the 510(k) process. Through the PMA application process, the applicant must submit data and information demonstrating reasonable assurance of the safety and effectiveness of the device for its intended use to the FDA's satisfaction.

510(k) Pathway

To obtain 510(k) clearance, we must submit a premarket notification under Section 510(k) of the FD&C Act demonstrating that the proposed device is "substantially equivalent" to a predicate device. A predicate device is a legally marketed device that is not subject to premarket approval, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was found substantially equivalent through the 510(k) process. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data is sometimes required to support substantial equivalence. The FDA's 510(k) clearance pathway usually takes from three to 12 months from the date the notification is submitted, but it can take considerably longer, depending on the extent of FDA's requests for additional information and the amount of time a sponsor takes to fulfill them. After a 510(k) is submitted, the FDA determines whether to accept it for substantive review. If it

lacks necessary information for substantive review, the FDA will refuse to accept the 510(k) submission. If it is accepted for filing, the FDA begins a substantive review. By statute, the FDA is required to complete its review of a 510(k) premarket notification within 90 days of receiving the 510(k) submission. As a practical matter, clearance often takes longer, and clearance is never assured.

Although many 510(k) premarket notifications are cleared without clinical data, the FDA may require further information, including clinical data, to make a determination regarding substantial equivalence, which may significantly prolong the review process. If the FDA agrees that the device is substantially equivalent to a predicate device, it will grant clearance to commercially market the device. If the FDA determines that the device is not "substantially equivalent" to a predicate device, or if the device is automatically classified into Class III, the device sponsor must then fulfill the much more rigorous premarketing requirements of the PMA approval process, or seek reclassification of the device through the *de novo* process.

After a device receives 510(k) clearance, any modification, including modification to or deviation from design, manufacturing processes, materials, packaging and sterilization that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, may require a new 510(k) clearance or, depending on the modification, could require a PMA application. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer's determination. If the FDA requires a new 510(k) clearance or approval of a PMA application for any modifications to a previously cleared product, the applicant may be required to cease marketing or recall the modified device until clearance or approval is received. In addition, in these circumstances, the FDA can impose significant regulatory fines or penalties for failure to submit the requisite 510(k) or PMA application(s).

Medical device types that the FDA has not previously classified as Class I, II, or III are automatically classified into Class III regardless of the level of risk they pose. The Food and Drug Administration Modernization Act of 1997 established a new route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the *de novo* classification procedure.

The *de novo* classification procedure allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA application. Prior to the enactment of the Food and Drug Administration Safety and Innovation Act of 2012, or FDASIA, a medical device could only be eligible for *de novo* classification if the manufacturer first submitted a 510(k) premarket notification and received a determination from the FDA that the device was not substantially equivalent. FDASIA streamlined the *de novo* classification pathway by permitting manufacturers to request *de novo* classification directly without first submitting a 510(k) premarket notification to the FDA and receiving a not substantially equivalent determination. Under FDASIA, the FDA is required to classify the device within 120 days following receipt of the *de novo* application, though in practice the process may take significantly longer. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for Special Controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. In addition, the FDA may reject the reclassification petition if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low to moderate risk or that General Controls would be inadequate to control the risks and Special Controls cannot be developed.

PMA Pathway

We must submit a PMA if a device cannot be cleared through the 510(k) clearance or *de novo* process. A PMA application must be supported by extensive data, including, but not limited to, technical

information, preclinical data, clinical trial data, manufacturing data, and labeling, to demonstrate to the FDA's satisfaction the safety and efficacy of the device for its intended use.

Following receipt of a PMA application, the FDA conducts an administrative review to determine whether the application is sufficiently complete to permit a substantive review. If it is not, the agency will refuse to file the PMA. If it is, the FDA will accept the application for filing and begin the review. The FDA, by statute and by regulation, has 180 days to review a filed PMA application, although the review of an application more often occurs over a significantly longer period of time. During this review period, the FDA may request additional information or clarification of information already provided, and the FDA may issue a major deficiency letter to the applicant, requesting the applicant's response to deficiencies communicated by the FDA. The FDA considers a PMA or PMA supplement to have been voluntarily withdrawn if an applicant fails to respond to an FDA request for information (*e.g.*, major deficiency letter) within a total of 360 days. Before approving or denying a PMA, an FDA advisory panel may review the PMA at a public meeting and provide the FDA with the committee's recommendation on whether the FDA should approve the submission, approve it with specific conditions, or not approve it. The FDA is not bound by the recommendations of an advisory panel, but it considers such recommendations carefully when making decisions. Prior to approval of a PMA, the FDA may conduct a bioresearch monitoring inspection of the clinical trial data and clinical trial sites, and a QSR inspection of the manufacturing facility and processes. The FDA can delay, limit, or deny approval of a PMA application for many reasons, including:

- the device may not be shown safe or effective to the FDA's satisfaction;
- the data from pre-clinical studies and/or clinical trials may be found unreliable or insufficient to support approval;
- the manufacturing process or facilities may not meet applicable requirements; and
- changes in FDA approval policies or adoption of new regulations may require additional data.

If the FDA evaluation of a PMA is favorable, the FDA will issue either an approval letter, or an approvable letter, the latter of which usually contains a number of conditions that must be met in order to secure final approval of the PMA. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA approval letter authorizing commercial marketing of the device, subject to the conditions of approval and the limitations established in the approval letter. If the FDA's evaluation of a PMA application or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. The FDA also may determine that additional tests or clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and data are submitted in an amendment to the PMA, or the PMA is withdrawn and resubmitted when the data are available. The PMA process can be expensive, uncertain, and lengthy and a number of devices for which the FDA approval has been sought by other companies have never been approved by the FDA for marketing.

New PMA applications or PMA supplements may be required for modifications to the manufacturing process, equipment or facility, quality control procedures, sterilization, packaging, expiration date, labeling, device specifications, components, materials or design of a device that has been approved through the PMA process. PMA supplements often require submission of the same type of information as an initial PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the approved PMA application and may or may not require as extensive technical or clinical data or the convening of an advisory panel, depending on the nature of the proposed change.

In approving a PMA application, as a condition of approval, the FDA may also require some form of postmarket studies or postmarket surveillance, whereby the applicant follows certain patient groups for a

number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional or longer term safety and effectiveness data for the device. The FDA may require postmarket surveillance for certain devices approved under a PMA or cleared under a 510(k) notification, such as implants or life-supporting or life-sustaining devices used outside a device user facility, devices where the failure of which would be reasonably likely to have serious adverse health consequences, or devices expected to have significant use in pediatric populations. The FDA may also approve a PMA application with other post-approval conditions intended to ensure the safety and effectiveness of the device, such as, among other things, restrictions on labeling, promotion, sale, distribution, and use.

Clinical Trials

Clinical trials are almost always required to support a PMA and are sometimes required for a 510(k) premarket notification. In the United States, these trials often require submission of an application for an IDE if the investigation involves a significant risk device. Some types of studies deemed to present "non-significant risk" are deemed to have an approved IDE—without affirmative submission of an IDE application to the FDA—once certain requirements are addressed and IRB approval is obtained. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE must be approved in advance by the FDA for a specified number of patients, unless the product candidate is deemed a non-significant risk device and is eligible for more abbreviated IDE requirements. Clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and appropriate IRBs at the clinical trial sites. Submission of an IDE will not necessarily result in the ability to commence clinical trials, and although the FDA's approval of an IDE allows clinical testing to go forward for a specified number of subjects, it does not bind the FDA to accept the results of the trial as sufficient to prove the product's safety and efficacy, even if the trial meets its intended success criteria.

Future clinical trials involving our product candidates will most likely require that we obtain an IDE from the FDA prior to commencing clinical trials and that the trial be conducted under the oversight of IRBs at the clinical trial sites. All clinical trials must be conducted in accordance with the FDA's IDE regulations that govern investigational device labeling, prohibit promotion, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. Clinical trials must further comply with the FDA's GCP requirements for IRB approval and for informed consent and other human subject protections. Required records and reports are subject to inspection by the FDA. The results of clinical testing may be unfavorable, or, even if the intended safety and efficacy success criteria are achieved, may not be considered sufficient for the FDA to grant marketing approval or clearance of a product candidate.

Postmarket Requirements—U.S.

After the FDA permits a device to enter commercial distribution, numerous regulatory requirements continue to apply. These include:

- Establishment registration and device listing with the FDA;
- The FDA's QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, production, control, supplier/contractor selection, complaint handling, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- Labeling regulations, unique device identification requirements and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label uses;
- Advertising and promotion requirements;
- Restrictions on sale, distribution or use of a device;

- PMA annual reporting requirements;
- PMA approval or clearance of a 510(k) for product modifications;
- Medical device reporting, or MDR, regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur;
- Medical device correction and removal reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FD&C Act that may present a risk to health;
- Recall requirements, including a mandatory recall if there is a reasonable probability that the device would cause serious adverse health consequences or death;
- An order of repair, replacement or refund;
- Device tracking requirements; and
- Post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Additionally, once devices are commercialized, manufacturers are subject to unannounced inspections by the FDA to determine compliance with the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, device history file, and complaint files. Manufacturers are subject to periodic scheduled or unscheduled inspections by the FDA. A failure to maintain compliance with the QSR requirements could result in the shut-down of, or restrictions on, manufacturing operations and the recall or seizure of products. The discovery of previously unknown problems with products, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or approval or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls. In addition, the FDA can issue warning letters or untitled letters, impose injunctions, suspend regulatory clearance or approvals, ban certain medical devices, detain or seize adulterated or misbranded medical devices, order repair, replacement or refund of these devices, and require notification of health professionals and others with regard to medical devices that present unreasonable risks of substantial harm to the public health. The FDA may also initiate action for criminal prosecution of such violations.

There are also certain requirements of state, local, and foreign governments that must be complied with in the manufacturing and marketing of our products once we have the appropriate marketing approvals. We maintain customer complaint files, record all lot numbers of disposable products, and conduct periodic audits to assure compliance with applicable regulations. We will place special emphasis on customer training and advise all customers that device operation should be undertaken only by qualified personnel. In addition to laws and regulations in the United States, we are subject to a variety of laws and regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our product candidates.

Postmarket Requirements—EU

The regulatory review process varies from country to country and may in some cases require the submission of clinical data. Our international sales will be subject to regulatory requirements in the countries in which our product candidates are sold. These regulations will be significantly modified in the

next couple of years. For example, in May 2017, the EU Medical Devices Regulation (Regulation 2017/745) was adopted. The EU Medical Devices Regulation, or EU MDR, repeals and replaces the EU Medical Devices Directive. The EU MDR, among other things, is intended to establish a uniform, transparent, predictable, and sustainable regulatory framework across the EEA for medical devices and ensure a high level of safety and health while supporting innovation. The EU MDR will however only become applicable three years after publication (in May 2020). Once applicable, the new regulations will among other things:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities;
- improve the traceability of medical devices;
- set up a central database to provide comprehensive information on products available in the EU; and
- strengthen rules for the assessment of certain high-risk devices before they are placed on the market.

In the meantime, the current EU Medical Devices Directive continues to apply.

Drug and Biologics Regulation

Premarket Requirements—U.S.

Generally, a new drug may be marketed in the United States only if FDA has approved a NDA containing substantial evidence that the new drug is safe and effective for its intended use. A new biologic may generally only be marketed in the United States if FDA has approved a BLA containing substantial evidence that the biologic is safe, pure, and potent for its intended use. The results of preclinical studies and clinical trials, along with information regarding the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA/BLA, and FDA review and approval of the NDA/BLA is necessary prior to any commercial marketing or sale of a drug or biologic in the United States.

The process generally required by the FDA before a biologic or drug product candidate may be marketed in the United States involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's Good Laboratory Practice, or GLP, requirements, the Animal Welfare Act, and other laws and regulations, as applicable;
- submission to the FDA of an IND which must become effective before human clinical trials may begin and must be updated at least once annually;
- approval by an IRB, or ethics committee at each clinical site before the trial is initiated;
- performance of adequate and well-controlled clinical trials in accordance with the FDA's GCP requirements and other applicable regulations to establish the safety, purity and potency of the proposed biologic, and the safety and efficacy of the proposed drug for each indication;
- preparation of and submission to the FDA of a BLA or NDA after successful completion of all pivotal clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;

- a determination by the FDA within 60 days of its receipt of an NDA or BLA to file the application for substantive review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product candidate is produced to assess cGMP and to assure that the facilities, methods and controls are adequate for manufacturing of the drug or biologic according to its specifications; and
- FDA review and approval of the BLA or NDA prior to any commercial marketing or sale of the biologic or drug product in the United States.

Preclinical Testing

Before testing any compound or biologic in human subjects in the United States, we must generate extensive preclinical data. Preclinical testing generally includes laboratory evaluation of product chemistry and formulation, as well as toxicological and pharmacological studies in several animal species to assess the quality and safety of the product candidate. Certain animal studies must be performed in compliance with the FDA's GLP regulations and the U.S. Department of Agriculture's Animal Welfare Act.

IND Submission

Human clinical trials for drugs or biologics in the United States cannot commence until an IND is submitted and becomes effective. A company must submit preclinical testing results, together with manufacturing information and analytical data, to the FDA as part of the IND, and the FDA must evaluate whether there is an adequate basis for testing the drug in initial clinical studies in human volunteers. The sponsor will also include a protocol detailing, among other things, the objectives of the initial clinical trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated, if the initial clinical trial lends itself to an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to the proposed clinical studies. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before clinical studies can begin. Once human clinical trials have commenced, the FDA may stop the clinical trials by placing them on "clinical hold" because of concerns about the safety of the product candidate being tested, or for other reasons.

Clinical Trials

Clinical trials involve the administration of the drug to healthy human volunteers or to patients, under the supervision of a qualified investigator. The conduct of clinical trials is subject to extensive regulation, including compliance with the FDA's bioresearch monitoring regulations and GCP requirements, which establish standards for conducting, recording data from, and reporting the results of, clinical trials, and are intended to assure that the data and reported results are credible and accurate, and that the rights, safety, and well-being of study participants are protected. Clinical trials must be conducted under protocols that detail the study objectives, parameters for monitoring safety, and the efficacy criteria, if any, to be evaluated. Each protocol is reviewed by the FDA as part of the IND. In addition, each clinical trial must be reviewed and approved by, and conducted under the auspices of an IRB. Companies sponsoring the clinical trials, investigators, and IRBs also must comply with, as applicable, regulations and guidelines for obtaining informed consent from the study subjects, following the protocol and investigational plan, adequately monitoring the clinical trial, and timely reporting of adverse events. Foreign studies conducted under an IND must meet the same requirements that apply to studies being conducted in the United States. Data from a foreign study not conducted under an IND may be submitted in support of an NDA or BLA if the study was conducted in accordance with GCP requirements and the FDA is able to validate the data.

A study sponsor is required to publicly post certain details about clinical trials and clinical trial results on government or independent websites (such as http://clinicaltrials.gov). Human clinical trials typically are conducted in three or four sequential phases, although the phases may overlap with one another:

- Phase 1 clinical trials include the initial administration of the investigational drug or biologic to humans, typically to a small group of healthy human subjects, but occasionally to a group of patients with the targeted disease or disorder. Phase 1 clinical trials generally are intended to determine the metabolism and pharmacologic actions of the drug or biologic, the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness.
- Phase 2 clinical trials generally are controlled studies that involve a relatively small sample of the intended patient population, and are designed to develop data regarding the product candidate's effectiveness, to determine dose response and the optimal dose range, and to gather additional information relating to safety and potential adverse effects.
- Phase 3 clinical trials are conducted after preliminary evidence of effectiveness has been obtained, and are intended to gather the additional information about safety and effectiveness necessary to evaluate the drug's overall risk-benefit profile for a particular use, and to provide a basis for physician labeling. Generally, Phase 3 clinical development programs consist of expanded, large-scale studies of patients with the target disease or disorder to obtain statistical evidence of the efficacy and safety of the drug at the proposed dosing regimen, or the safety, purity, and potency of a biological product candidate.
- Phase 4 clinical trials may be conducted in some cases, including where the FDA conditions approval of an NDA or BLA for a product candidate on the sponsor's agreement to conduct additional clinical studies after approval. In other cases, a sponsor may voluntarily conduct additional clinical studies after approval to gain more information about the product candidate. Such post-approval studies are typically referred to as Phase 4 clinical trials.

A pivotal trial is a clinical study that is designed to generate substantial evidence of product candidate's safety and efficacy to meet regulatory agency requirements and serve as the basis for approval of the product candidate. Generally, pivotal trials are Phase 3 trials, but the FDA may accept results from Phase 2 trials if the trial design provides a well-controlled and reliable assessment of clinical benefit, particularly in situations where there is an unmet medical need and the results are sufficiently robust.

The sponsoring company, the FDA, or the IRB may suspend or terminate a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk. Further, success in early-stage clinical trials does not assure success in later-stage clinical trials. Data obtained from clinical activities are not always conclusive and may be subject to alternative interpretations that could delay, limit, or prevent regulatory approval. Additionally, some clinical studies are overseen by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board or data monitoring committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial. We may also suspend or terminate a clinical study based on safety or efficacy concerns, evolving business objectives and/or competitive climate.

During the development of a new drug or biologic, sponsors may seek opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA or BLA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development. For example, sponsors typically use the meetings at the end of the Phase 2 trial to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trial that they believe will support approval of the new drug or biologic.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality, and purity of the final drug. In addition, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life. While the IND is active and before approval, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or *in vitro* testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

There are also requirements governing the reporting of ongoing clinical trials and completed trial results to public registries. Sponsors of certain clinical trials of FDA regulated products are required to register and disclose specified clinical trial information, which is publicly available at www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, trial sites and investigators and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to disclose certain results of their clinical trials after completion.

NDA/BLA Submission and Review

After completing clinical testing of an investigational drug or biologic, a sponsor must prepare and submit an NDA or BLA for review and approval by the FDA. The NDA is a comprehensive, multi-volume application that includes, among other things, the results of preclinical and clinical studies, information about the drug's composition, and plans for manufacturing, packaging, and labeling the drug. For certain product candidates, such as immunotherapeutic antibodies, this information is submitted in a BLA. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of a use of the product candidate, or from a number of alternative sources, including studies initiated by investigators. Under federal law, the submission of most NDAs and BLAs is subject to an application user fee, and the sponsor of an approved NDA or BLA is also subject to annual prescription drug program fees. These fees are typically increased annually. A waiver of user fees may be obtained under certain limited circumstances.

When an NDA or BLA is submitted, the FDA conducts a preliminary review to determine whether the application is sufficiently complete to be accepted for filing. If it is not, the FDA may refuse to file the application and request additional information, in which case the application must be resubmitted with the supplemental information, and review of the application is delayed.

FDA performance goals generally provide for action on a standard NDA or an original BLA submission within 10 months of the 60-day filing date, but that goal may be extended in certain circumstances. Moreover, the review process is often significantly extended by FDA requests for additional information or clarification. Before approving a BLA or NDA, the FDA typically will inspect the facility or facilities at which the product candidate is manufactured. The FDA will not approve the application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product candidate within required specifications. Additionally, before approving a BLA or NDA, the FDA will typically inspect one or more clinical sites or investigators to assure compliance with GCP requirements. If the FDA determines that the application, clinical data, manufacturing process, or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding

the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

As part of its review, the FDA may refer an NDA or BLA to an advisory committee for evaluation and a recommendation as to whether the application should be approved. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. Although the FDA is not bound by the recommendation of an advisory committee, the agency carefully considers such recommendations when making decisions. The FDA may also determine that a REMS is necessary to ensure that the benefits of a new product candidate outweigh its risks, and the product candidate can therefore be approved. A REMS may include various elements, ranging from medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools, depending on what the FDA considers necessary for the safe use of the drug.

After review of an NDA or BLA, the FDA may decide to not approve the application and issue a Complete Response letter outlining the deficiencies in the submission. The Complete Response letter also may request additional information, including additional preclinical or clinical data. Even if such additional information and data are submitted, the FDA may decide that the NDA or BLA still does not meet the standards for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than the sponsor. Obtaining regulatory approval often takes a number of years, involves the expenditure of substantial resources, and depends on a number of factors, including the severity of the disease in question, the availability of alternative treatments, and the risks and benefits demonstrated in clinical trials. Additionally, as a condition of approval, the FDA may impose restrictions that could affect the commercial success of a drug or require post-approval commitments, including the completion within a specified time period of additional Phase 4 clinical studies.

In addition, the Pediatric Research Equity Act, or PREA, requires a sponsor to conduct pediatric clinical trials for most drugs and biologics, including for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration. Under PREA, original NDAs, BLAs, and supplements thereto must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug or biologic is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin.

Post-approval modifications to the drug or biologic product candidate, such as changes in indications, labeling, or manufacturing processes or facilities, may require a sponsor to develop additional data or conduct additional preclinical or clinical trials, to be submitted in a new or supplemental NDA or BLA, which would require FDA approval.

Expedited Development and Review Programs

The FDA has established a number of programs intended to expedite the development and review of products intended to treat serious and life-threatening diseases or conditions. First, the FDA has a Fast Track program that is designed to expedite or facilitate the process for reviewing new drug products intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation applies to the product and the specific indication for which it is being studied. For a Fast Track-designated product, the FDA may consider for review sections of the NDA or BLA on a rolling basis before the complete application is submitted.

A product, including a product with a Fast Track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis, or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug designated for priority review in an effort to facilitate the review. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to ten months for review of original BLAs and new molecular entity NDAs under its standard review goals.

In addition, a product may be eligible for accelerated approval. Drug and biologic products intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality but that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform confirmatory clinical trials after approval. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Fast Track designation, priority review, and accelerated approval do not change the standards for approval but may expedite the development or approval process.

The FDA also designates certain products as “breakthrough therapies,” if the product is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. This designation includes all of the Fast Track program features, as well as more intensive FDA interaction and guidance. The Breakthrough Therapy Designation is a distinct status from both accelerated approval and priority review, which can also be granted to the same drug if relevant criteria are met. All requests for breakthrough therapy designation will be reviewed within 60 days of receipt, and the FDA will either grant or deny the request.

Fast track designation, priority review, accelerated approval, and breakthrough therapy designation do not change the standards for approval and may not result in fast or more efficient review.

Hatch-Waxman Act

The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, establishes two abbreviated approval pathways for pharmaceutical products that are in some way follow-on or bioequivalent versions of drugs approved through the NDA process.

Generic Drugs

A generic version of an approved drug is approved by means of an abbreviated new drug application, or ANDA. An ANDA is a comprehensive submission that contains, among other things, data, and information pertaining to the active pharmaceutical ingredient, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data and quality control procedures. Premarket applications for generic drugs are termed abbreviated because they generally do not include preclinical and clinical data to demonstrate safety and effectiveness. Instead, a generic applicant must demonstrate that its product performs in the same manner as, or is bioequivalent to, the innovator drug, also referred to as a reference listed drug, or RLD. In certain situations, an applicant may obtain ANDA approval of a generic product with a strength or dosage form that differs from a referenced innovator drug pursuant to the filing and approval of an ANDA Suitability

Petition. The FDA will approve the generic product as suitable for an ANDA application if it finds that the generic product does not raise new questions of safety and effectiveness as compared to the innovator product. A product is not eligible for ANDA approval if the FDA determines that it is not bioequivalent to the referenced innovator drug, if it is intended for a different use, or if it is not subject to an approved Suitability Petition. However, such a product might be approved under an NDA, with supportive data from clinical trials.

505(b)(2) NDAs

Section 505(b)(2) of the FD&C Act provides an alternate regulatory pathway to obtain FDA approval for product candidates that represent modifications to formulations or uses of previously approved drug products. Specifically, Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely to some extent upon the FDA's findings of safety and effectiveness for an approved product that acts as the RLD and submit its own product-specific data—which may include data from preclinical studies or clinical trials conducted by or on behalf of the applicant—to address differences between the product candidate and the RLD. Unlike an ANDA, this does not excuse the sponsor from demonstrating the proposed product candidate's safety and effectiveness. Rather, the sponsor is permitted to rely to some degree on the FDA's finding that the RLD is safe and effective, and must submit its own product candidate-specific data of safety and effectiveness to an extent necessary because of the differences between the products. An NDA approved under Section 505(b)(2) may in turn serve as an RLD for subsequent applications from other sponsors.

RLD Patents

In seeking approval for a drug through an NDA, including a 505(b)(2) NDA, applicants are required to list with the FDA certain patents whose claims cover the applicant's product. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in the FDA publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the *Orange Book*. Any applicant who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a 505(b)(2) NDA referencing a drug listed in the Orange Book must certify to the FDA that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This last certification is known as a paragraph IV certification. A notice of the paragraph IV certification must be provided to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the ANDA or 505(b)(2) application refers. The applicant may also elect to submit a "section viii" statement certifying that its proposed label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the reference NDA holder and patent owners assert a patent challenge directed to one of the Orange Book listed patents within 45 days of the receipt of the paragraph IV certification notice, the FDA is prohibited from approving the application until the earlier of 30 months from the receipt of the paragraph IV certification expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the applicant. The ANDA or 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the branded reference drug has expired as described in further detail below.

Regulatory Exclusivities

The Hatch-Waxman Act provides periods of regulatory exclusivity for products that would serve as RLDs for an ANDA or 505(b)(2) application. For example, a pharmaceutical manufacturer may obtain five years of non-patent exclusivity upon NDA approval of a "new chemical entity," or NCE—which is a

drug that contains an active moiety that has not been approved by the FDA in any other NDA. An "active moiety" is defined as the molecule or ion responsible for the drug substance's physiological or pharmacologic action. During this five year exclusivity period, the FDA may not accept for filing any ANDA seeking approval of a generic version of that drug or any 505(b)(2) application for a drug with the same active moiety. An ANDA or 505(b)(2) application may be submitted after four years, however, if the sponsor of the application makes a Paragraph IV certification.

A product that is not an NCE, including a product approved through a 505(b)(2) NDA, may qualify for a three-year period of exclusivity if the NDA contains new clinical data, derived from studies conducted by or for the sponsor (other than bioavailability or bioequivalence studies), that were essential for approval. In that instance, the exclusivity period does not preclude filing or review of the ANDA or 505(b)(2) application; rather, the FDA is precluded from granting final approval to the ANDA or 505(b)(2) application until three years after approval of the RLD. Additionally, the exclusivity applies only to the conditions of approval that required submission of the clinical data. For example, if an NDA is submitted for a product candidate that is not an NCE, but that seeks approval for a new indication, and clinical data were required to demonstrate the safety or effectiveness of the product candidate for that new application, the FDA could not approve an ANDA or 505(b)(2) application for another product candidate with that active moiety for that use.

Other Exclusivities

Pediatric Exclusivity. Section 505A of the FD&C Act provides for six months of additional exclusivity or patent protection if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show that the product is effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or *Orange Book* listed patent protection that cover the drug are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve an ANDA or 505(b)(2) application owing to regulatory exclusivity or listed patents. If and when any drug or biologic product candidate is approved, we will evaluate seeking pediatric exclusivity as appropriate.

Orphan Drug Exclusivity. Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States or, if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making a drug or biologic product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan designation must be requested before submitting an NDA or BLA. After the FDA grants orphan designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug or biological product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity or inability to manufacture the product in sufficient quantities. The orphan designation of such drug or biologic also entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user fee waivers. However, competitors, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication

for which the orphan product has exclusivity. Orphan exclusivity also could block the approval of one of our product candidates for seven years if a competitor obtains approval of the same drug or biologic as defined by the FDA or if our product candidate is determined to be contained within the scope of the orphan exclusivity of the competitor's product for the same indication or disease. Orphan drug status in the European Union has similar but not identical benefits in that jurisdiction.

The Biologics Price Competition and Innovation Act

The ACA includes a subtitle called the Biologics Price Competition and Innovation Act, which authorizes the FDA to license a biological product candidate that is biosimilar to or interchangeable with an FDA-licensed biologic through an abbreviated pathway. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being addressed by the FDA.

The BPCIA establishes criteria for determining that a product candidate is biosimilar to an already-licensed biologic, or reference product, and establishes a process by which a BLA for a biosimilar product candidate is submitted, reviewed, and licensed. The BPCIA provides periods of exclusivity that protect a reference product from biosimilars competition. Under the BPCIA, the FDA may not accept a biosimilar application for review until four years after the date of first licensure of the reference product, and the biosimilar may not be licensed until at least 12 years after the reference product's approval. During this twelve year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well controlled clinical trials to demonstrate the safety, purity, and potency of their product.

Additionally, the BPCIA establishes procedures by which the biosimilar applicant provides information about its application and product candidate to the reference product sponsor, and by which information about potentially relevant patents may be shared and litigation over patents may proceed in advance of approval. The timing of final FDA approval of a biosimilar for commercial distribution depends on a variety of factors, including whether the manufacturer of the reference product is entitled to one or more statutory exclusivity periods, during which time the FDA is prohibited from approving any product candidates that are biosimilar to the branded product. The BPCIA also provides a period of exclusivity for the first biosimilar determined by the FDA to be interchangeable with the reference product. To date, the FDA has not approved an interchangeable biosimilar product, and at this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, as these substitution practices are governed by state pharmacy law.

The contours of the BPCIA continue to be defined as the statute is implemented over a period of years. This likely will be accomplished by a variety of means, including decisions related to the statute by the relevant federal courts. The FDA has to date issued various guidance documents and other materials indicating the agency's thinking regarding a number of issues implicated by the BPCIA. Additionally, the FDA's approval of a number of biosimilar applications in recent years has helped define the agency's approach to certain issues. However, the ultimate impact, implementation, and meaning of the BPCIA remains subject to significant uncertainty.

Post-Approval Regulation of Drug and Biologic Products

Once a drug or biologic is approved, it and its manufacturer will be subject to continuing regulation by the FDA. If ongoing regulatory requirements are not met or if safety problems occur after a product reaches the market, the FDA may at any time withdraw product approval or take actions that would limit or suspend marketing. Additionally, the FDA may require post-marketing studies or clinical trials if new safety information develops.

Once we are engaged in manufacturing approved drug or biologic products or their components, we must comply with applicable cGMP requirements and product-specific regulations enforced by the FDA and other regulatory agencies. Compliance with cGMP includes adhering to requirements relating to organization and training of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, quality control and quality assurance, packaging and labeling controls, holding and distribution, laboratory controls, and records and reports. The FDA regulates and inspects equipment, facilities, and processes used in manufacturing pharmaceutical or biologic products prior to approval. If, after receiving approval, a company makes a material change in manufacturing equipment, location, or process (all of which are, to some degree, incorporated in the NDA or BLA), additional regulatory review and approval may be required. The FDA also conducts regular, periodic visits to re-inspect equipment, facilities, and processes following the initial approval of a product. Failure to comply with applicable cGMP requirements and conditions of product approval may lead the FDA to seek sanctions, including fines, civil penalties, injunctions, suspension of manufacturing operations, operating restrictions, withdrawal of FDA approval, seizure, or recall of products, and criminal prosecution.

The FDA and other federal regulatory agencies closely regulate the marketing and promotion of drugs and biologics through, among other things, standards and regulations for direct-to-consumer advertising, advertising and promotion to healthcare professionals, communications regarding unapproved uses, industry-sponsored scientific and educational activities, and promotional activities involving the Internet. A product candidate cannot be promoted as safe or effective for any use before it is approved. After approval, product promotion can include only those claims relating to safety and effectiveness that are consistent with the labeling approved by the FDA. Healthcare providers are permitted to prescribe drugs and biologics for "off-label" uses—that is, uses not approved by the FDA and therefore not described in the product's labeling—because the FDA does not regulate the practice of medicine. However, FDA regulations impose stringent restrictions on manufacturers' communications regarding off-label uses. Broadly speaking, a manufacturer may not promote a drug or biologic for off-label use, but under certain conditions may engage in non-promotional, balanced, scientific communication regarding off-label uses. Failure to comply with applicable FDA requirements and restrictions in this area may subject a company to adverse publicity and enforcement action by the FDA, the DOJ, or the HHS Office of Inspector General, or OIG, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug or biological products.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- adverse publicity, fines, warning letters or holds on post-approval clinical trials;

- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

Other Requirements

In addition, if we hold approved NDAs or BLAs and/or manufacture or distribute drug or biological products, we must comply with other regulatory requirements, including registration and listing, submitting annual reports, reporting information about adverse drug experiences, and maintaining certain records. Similar, and in some cases additional, requirements exist in other countries, including the EU.

EU Requirements

We must obtain the requisite marketing authorizations from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of a product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application, or CTA, much like an IND, prior to the commencement of clinical trials. In the EU, for example, a CTA must be submitted to the national health authority of each EU Member State in which the clinical trial is to be conducted and to an independent ethics committee, much like the FDA and an IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed.

The requirements and process governing the conduct of clinical trials, product licensing, pricing, and reimbursement vary from country to country. In all cases in EU Member States, for example, the clinical trials must be conducted in accordance with GCP requirements, applicable regulatory requirements, and ethical principles that have their origin in the Declaration of Helsinki. Other EU requirements include regulations concerning marketing authorizations, pricing and reimbursement, patient rights in cross-border healthcare, advertising, and promotion, interactions with physicians, bribery, and corruption.

For other countries outside of the EU, such as countries in Eastern Europe, Central and South America, or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing, and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP requirements, applicable regulatory requirements, and ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, warning letters or untitled letters, injunctions, civil, administrative, or criminal penalties, monetary fines or imprisonment, suspension or withdrawal of regulatory approvals, suspension of ongoing clinical studies, refusal to approve pending applications or supplements to applications filed by us, suspension or the imposition of restrictions on operations, product recalls, the refusal to permit the import or export of our products or the seizure or detention of products.

Combination Products

A combination product is the combination of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are combined or mixed and produced as a single entity; packaged together in a single package or as a unit; or a drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

To determine which the FDA center or centers will review a combination product candidate submission, companies may submit a request for assignment to the FDA. Those requests may be handled formally or informally. In some cases, jurisdiction may be determined informally based on FDA experience with similar products. However, informal jurisdictional determinations are not binding on the FDA. Companies also may submit a formal Request for Designation to the FDA Office of Combination Products. The Office of Combination Products will review the request and make its jurisdictional determination within 60 days of receiving a Request for Designation.

FDA will determine which center or centers within the FDA will review the product candidate and under what legal authority the product candidate will be reviewed. Depending on how the FDA views the product candidates that are developed, the FDA may have aspects of the product candidate reviewed by the FDA's Center for Biologics Evaluation and Research, Center for Devices and Radiological Health and Center for Drug Evaluation and Research, though one center will be designated as the center with primary jurisdiction, based on the product candidate's primary mode of action. The FDA determines the primary mode of action based on the single mode of action that provides the most important therapeutic action of the combination product candidate—the mode of action expected to make the greatest contribution to the overall intended therapeutic effects of the combination product candidate. The review of such combination product candidates is often complex and time consuming, as the FDA may select the combination product candidate to be reviewed and regulated by one or multiple of the FDA centers identified above, which could affect the path to regulatory clearance or approval. Furthermore, the FDA may also require submission of separate applications to multiple centers.

We are developing certain product candidates, that are subject to regulation in the United States as combination products. We believe that the primary mode of action of these candidates is the drug or biologic component. We expect to seek approval for these candidates through submission of a BLA for biologic candidates and through submission of a NDA submitted under Section 505(b)(2) of the FD&C Act for small molecule candidates. Based on a pre-IND meeting, we do not expect that the FDA will require a separate marketing authorization for each constituent of these product candidates.

The post-market requirements that apply to the cleared or approved product will largely be aligned with the agency center determined to have primary jurisdiction over the product candidate and that provided marketing authorization, but manufacturers must also comply with certain post-market requirements with respect to the constituent parts of combination products. In April 2019, FDA published a final guidance document entitled *Compliance Policy for Combination Product Postmarketing Safety Reporting*, which is intended to assist manufacturers of combination products comply with reporting requirements applicable to such products.

After issuing marketing authorizations, the FDA has discretion in determining post-approval compliance requirements for combination products and could thus require compliance with certain cGMP requirements as well as QSR requirements for device components of a combination product. Other post-market requirements analogous to those described above for medical devices and drugs/biologics will also apply, depending on the application type and center overseeing regulation of the combination product, including:

- Post-market adverse event and Medical Device Reporting requirements;
- Labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label uses;
- Advertising and promotion requirements;
- Restrictions on sale, distribution or use of the product;
- Requirements for recalls being conducted and recall reporting;
- Product tracking requirements;

- Post-market surveillance or clinical trials; and
- Other record-keeping requirements.

HIPAA and Other Data Privacy and Security Laws

We are subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. The regulations promulgated under HIPAA, as amended by HITECH, impose privacy, security and breach reporting obligations with respect to individually identifiable health information upon "covered entities" (health plans, healthcare clearinghouses and certain healthcare providers), and their respective "business associates," individuals or entities that create, receive, maintain, or transmit PHI, in connection with providing a service for or on behalf of a covered entity. Under HIPAA, covered entities must also enter into agreements with their business associates, which require the business associates to protect any PHI provided by the covered entity against improper use or disclosure. HITECH also increased the civil and criminal penalties that may be imposed against covered entities and business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. Additionally, HITECH mandates the reporting of certain breaches of health information to HHS, affected individuals, and if the breach is large enough, the media.

HITECH makes specific HIPAA privacy and security requirements directly applicable to business associates. We are both a covered entity and a business associate of our covered entity customers. Under the terms of the business associate agreements into which we have entered, we have certain obligations regarding the use and disclosure of any PHI that may be provided to us, and we could incur significant liability if we do not meet such obligations.

HHS promulgated various requirements under HIPAA with which we must comply. HHS rules define standards for electronic transactions, which establish standards for common healthcare transactions, such as claims information, plan eligibility, payment information, and the use of electronic signatures. We must also follow standards for the privacy of individually identifiable health information, which limit use and disclosure of most written and oral communications, including those in electronic form, regarding a patient's past, present or future physical or mental health or condition or disclosing healthcare provided to the individual or payment for that healthcare, if the individual may be identified from such information. In addition, HIPAA's security standards require us to ensure the confidentiality, integrity, and availability of all electronic PHI we create, receive, maintain, or transmit, to protect against reasonably anticipated threats or hazards to the security of such information and to protect such information from unauthorized use or disclosure.

There are significant civil and criminal fines and other penalties that may be imposed for violating HIPAA. A covered entity or business associate is also liable for civil money penalties for a violation that is based on an act or omission of any of its agents, which may include a downstream business associate, as determined according to the federal common law of agency. HITECH also increased the civil and criminal penalties applicable to covered entities and business associates and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions. To the extent that we submit electronic healthcare claims and payment transactions that do not comply with the electronic data transmission standards established under HIPAA and HITECH, payments to us may be delayed or denied.

Regardless of the applicability of HIPAA or other data privacy laws or regulations, failing to take what the FTC perceives to be appropriate steps to keep consumers' personal information secure may result in the FTC bringing a claim that a company has engaged in unfair or deceptive acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, or the FTCA, 15

U.S.C. § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. In addition, state consumer protection laws, which may or may not be modeled on the FTCA, may provide state-law causes of action for allegedly unfair or deceptive practices, among other things, including causes of action for alleged data privacy violations.

Moreover, various state and non-U.S. laws and regulations, such as the CCPA and GDPR, may govern the privacy and security of health information in certain circumstances. Some of these laws and regulations are more stringent than HIPAA, and many differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation.

Healthcare Fraud and Abuse Laws

The federal Anti-Kickback Statute, or AKS, makes it a crime for a provider or supplier, including a laboratory, to knowingly and willfully offer, pay, solicit, or receive payments, directly or indirectly, in order to induce business reimbursable under any federal healthcare program. An intentional violation of the AKS may result in imprisonment for up to ten years and/or criminal fines of up to $100,000. The U.S. government may also assess civil monetary penalties under AKS and seek to exclude the provider from participation in Medicare, Medicaid, and other federal healthcare programs.

Actions that violate the federal AKS or similar laws may also involve liability under the federal False Claims Act, or FCA, which prohibits knowingly presenting or causing to be presented a false, fictitious, or fraudulent claim for payment to the U.S. government. Although the AKS and FCA apply only to federal healthcare programs, a number of states have passed substantially equivalent laws in which similar types of prohibitions are made applicable to other, non-federal health plans and third-party payors.

Federal and state law enforcement authorities scrutinize arrangements between healthcare providers and potential referral sources to ensure that the arrangements are not designed as a mechanism to induce patient care referrals and opportunities. The law enforcement authorities, the courts, and Congress have also demonstrated a willingness to look behind the formalities of a transaction to determine the underlying purpose of payments between healthcare providers and actual or potential referral sources. Generally, courts have taken a broad interpretation of the scope of the federal AKS, holding that the statute may be violated if merely one purpose of a payment arrangement is to induce future referrals.

In December 1994 and in June 2014, the OIG issued Special Fraud Alerts on arrangements for the provision of clinical laboratory services and relationships between laboratories and referring physicians. The alerts described multiple practices allegedly employed by some clinical laboratories and healthcare providers that potentially violate federal fraud and abuse laws, including the AKS. The OIG emphasized that when a purpose of such arrangements is to induce referrals for reimbursed laboratory testing, both the clinical laboratory and the healthcare provider may be liable under the AKS, and may be subject to criminal prosecution and exclusion from participation in Medicare and Medicaid.

Recognizing that the AKS is broad and may technically prohibit innocuous or beneficial arrangements for the provision of healthcare services, HHS developed a series of regulatory "safe harbors." These safe harbor provisions assure healthcare providers and other parties that they may not be prosecuted under the AKS, as long as all applicable requirements are met. Although full compliance with these provisions protects against prosecution under the AKS, the failure of a transaction or arrangement to fit squarely within a specific safe harbor does not necessarily mean that it is illegal or that the OIG will pursue prosecution under the AKS.

While we believe we are not in violation of the AKS, we cannot provide assurance that our relationships with physicians, hospitals, and other customers will not be subject to scrutiny or will survive regulatory challenge. If imposed for any reason, sanctions under the AKS could have a negative effect on our business.

In addition to the requirements that are discussed above, there are several other healthcare fraud and abuse laws that could have an impact on our business. The federal FCA prohibits a person from knowingly submitting or causing to be submitted false claims or making a false record or statement in order to secure payment by the federal government. In addition to actions initiated by the government itself, the statute's "whistleblower," or "*qui tam*," provisions authorizes actions to be brought on behalf of the federal government by a private party having knowledge of the alleged fraud, also known as a relator. Because a *qui tam* complaint is initially filed under seal, the action may be pending for some time before the defendant is even aware of the action. If the government is ultimately successful in obtaining monetary damages in the matter, or if the relator succeeds in obtaining monetary damages without the government's involvement, the relator will receive a percentage of the recovery. Violation of the FCA may result in fines of up to three times the actual damages sustained by the government, plus mandatory civil penalties of up to approximately $22,000 for each separate false claim, imprisonment, or both, and possible exclusion from government healthcare programs, including Medicare and Medicaid.

In October 2018, the Eliminating Kickbacks in Recovery Act of 2018, or EKRA, was passed as part of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (the SUPPORT Act). The EKRA creates criminal penalties for knowingly and willfully paying, offering to pay, soliciting, or receiving any remuneration (including any kickback, bribe, or rebate), whether directly or indirectly, overtly or covertly, in cash or in kind, to induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory, or in exchange for an individual using the services of that recovery home, clinical treatment facility, or laboratory, unless a specific exception applies. Unlike the federal AKS, the EKRA applies to all "health care benefit programs," including private health care programs, and is not limited to government health care programs. Most of the safe harbors available under the federal AKS are not reiterated under the EKRA's exceptions. Therefore, compliance with a federal AKS safe harbor does not guarantee protection under the EKRA. As such, the EKRA potentially expands the universe of arrangements that could be subject to enforcement under federal fraud and abuse laws. Violation of the EKRA may result in fines up to $200,000 and imprisonment up to 10 years for each occurrence. Because the EKRA is a new law, there is very little additional guidance to indicate how and to what extent it will be applied and enforced by government agencies in our industry. Our relationships with physicians, sales representatives, hospitals, or customers may be subject to scrutiny under the EKRA. If imposed for any reason, sanctions under the EKRA could have a negative effect on our business.

We are also subject to a federal law commonly known as the Stark Law, which prohibits, with certain exceptions, "self-referrals," which in our case means payments made by a laboratory to a physician in exchange for the provision of clinical laboratory services, presenting or causing to be presented claims to Medicare and Medicaid for laboratory tests referred by physicians who personally, or through a family member, have an investment interest in, or a compensation arrangement with, the clinical laboratory performing the tests. A person who attempts to circumvent the Stark Law may be fined up to approximately $165,000 for each arrangement or scheme that violates the statute. In addition, any person who presents or causes to be presented a claim to the Medicare or Medicaid programs in violation of the Stark Law is subject to civil monetary penalties up to approximately $25,000 per claim, additional fines of up to three times the amount of reimbursement claimed, and possible exclusion from government healthcare programs, including Medicare and Medicaid. Claims that violate the Stark Law may not be paid by Medicare or Medicaid, and any person collecting any amounts under such claims is obligated to refund the payment.

Various states have also enacted self-referral restrictions with which we have to comply and which differ from those imposed by the federal Stark Law.

While we have attempted to comply with the federal fraud and abuse laws, and similar laws of other states, some of our arrangements could be subject to regulatory scrutiny, and we cannot provide assurance that we will be found to be in compliance with these laws following regulatory review.

Further, in addition to the privacy and security regulations stated above, HIPAA created two federal crimes: (1) healthcare fraud and (2) false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully defrauding a healthcare benefit program, including private payors. A violation of this statute may result in fines, imprisonment, or exclusion from government healthcare programs. The false statements statute prohibits knowingly and willfully falsifying, concealing, or covering up a material fact or making a materially false, fictitious, or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items, or services. A violation of this statute may result in fines or imprisonment.

Finally, federal law prohibits any entity from offering or transferring to a Medicare or Medicaid beneficiary any remuneration that the entity knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of Medicare or Medicaid payable items or services, including waivers of copayments and deductible amounts (or any part thereof) and transfers of items or services for free or for other than fair market value. Any violation of these prohibitions may result in civil monetary penalties up to $20,000 for each wrongful act. Although we believe that our sales and marketing practices comply in all materials respects with all applicable federal and state laws and regulations, regulatory authorities may disagree. Any identified violation of applicable fraud and abuse laws could result in significant fines or our exclusion from Medicare, Medicaid, and other governmental programs, which could have a material adverse effect on our business, results of operations, financial condition, and cash flows.

Regulations Related to Our Precision Medicine Business

Due to the variety of product candidates that we are developing, we and our product candidates will be subject to a wide variety of regulations promulgated by the FDA. Specifically, our product candidates are subject to regulation by the FDA's Center for Biologics Evaluation and Research, Center for Devices and Radiological Health and Center for Drug Evaluation and Research, as well as other non-U.S. regulatory bodies (should we develop the product candidates and seek to obtain regulatory clearances or approvals to market outside of the United States).

Avero Diagnostics Relationship and the Corporate Practice of Medicine

Through one of our wholly-owned subsidiaries, we have a contractual relationship with Mattison Pathology, LLP, dba Avero Diagnostics, a professional partnership organized in Texas. We provide certain management services to Avero Diagnostics in accordance with the terms of a management services arrangement, and a separate nominee agreement provides us the right, but not the obligation, to designate persons to purchase the stock of Avero Diagnostics at any time for a nominal amount. We receive a management fee equal to the net operating income of Avero Diagnostics.

We have determined that Avero Diagnostics is a variable interest entity and that Progenity is the primary beneficiary, resulting in the consolidation of Avero Diagnostics as required by the accounting guidance for consolidation.

The laws of certain states in which we operate or may operate in the future prohibit non-physician entities from practicing medicine, exercising control over physicians or engaging in certain practices such as fee-splitting with physicians. Although we believe that we have structured our affiliation with Avero Diagnostics so that the physicians maintain exclusive authority regarding the delivery of medical care, there

can be no assurance that these laws will be interpreted in a manner consistent with our practices or that other laws or regulations will not be enacted in the future that could have a material adverse effect on our business. Regulatory authorities and other parties, including our associated physicians, may assert that, despite the management service agreement and other arrangements through which we operate, we are engaged in the prohibited corporate practice of medicine and/or that our contractual arrangement with Avero Diagnostics constitutes unlawful fee-splitting. If a corporate practice of medicine or fee-splitting law is interpreted in a manner that is inconsistent with our practices, we would be required to restructure or terminate our relationship with Avero Diagnostics to bring its activities into compliance with such law. A determination of noncompliance, the termination of or failure to successfully restructure this relationship could result in disciplinary action, penalties, damages, fines, and/or a loss of revenue, any of which could have a material adverse effect on our business, financial condition, or operating results.

Environmental Matters

Our operations require the use of hazardous materials (including biological materials), which materials subject us to a variety of federal, state, and local environmental and safety laws and regulations. Some of these laws and regulations provide for strict liability, potentially holding a party liable without regard to fault or negligence. We could be held liable for damages and fines as a result of our, or others', business operations should contamination of the environment or individual exposure to hazardous materials occur. We cannot predict how new, or changes in, laws or regulations will affect our business, operations, or the cost of compliance.

Facilities

Our headquarters are located in San Diego, California, where we lease 25,795 square feet of office space. Our lease expires in June 2023.

We own property in Ann Arbor, Michigan that we use for laboratory testing and research and such property is subject to a mortgage. We also lease approximately 26,000 square feet of office space in Ann Arbor, Michigan. Our lease expires in October 2023, and we have an option to extend it through at least October 2028.

We own property located in Lubbock, Texas that we use for the purpose of laboratory testing for Avero Diagnostics and such property is subject to a mortgage. We also lease approximately 42,000 square feet of laboratory testing and research space for Avero Diagnostics in Irving, Texas. Our lease expires in November 2022, and we have an option to extend it through November 2027.

We believe that our current facilities are adequate for our needs. We also believe we will be able to obtain additional space, as needed, on commercially reasonable terms.

Employees

As of June 1, 2020, we had 674 full-time employees. None of our employees is represented by a labor union or covered by a collective bargaining agreement with respect to his or her employment with us. We consider our relationship with our employees to be good.

Legal Proceedings

Federal Investigations

In April 2018, we received a civil investigative demand from an Assistant U.S. Attorney for the Southern District of New York and a HIPAA subpoena issued by an Assistant U.S. Attorney for the Southern District of California. In May 2018, we received a subpoena from the State of New York Medicaid Fraud Control Unit. Since that time, we have cooperated with federal civil and criminal investigations, and state civil investigations, regarding discontinued legacy billing practices for our NIPT and

microdeletion tests and the provision of alleged kickbacks or inducements to physicians and patients. The civil investigations also include inquiries about our laboratory licenses, our enrollment in state Medicaid programs, and the laboratories that performed testing for us.

On March 31, 2020, we reached an agreement on the monetary terms with the DOJ and the State of New York (with the State of New York Attorney General representing or facilitating the interests of all States participating in the settlement, which we refer to collectively as the State AGs) with respect to relevant government health benefit programs to resolve all of the government's outstanding civil and criminal investigations, including the investigations by the U.S. Attorney's Office for the Southern District of California and the U.S. Attorney's Office for the Southern District of New York, as well as the investigation by the State AGs. The terms of this agreement in principle contemplate that we will enter into a civil settlement agreement providing that we will pay $49.0 million in the aggregate over a five-year period, structured as follows: $8.0 million upon entering into the settlement; $4.0 million in December 2020; $5.0 million in December 2021; $7.0 million in December 2022; $8.0 million in December 2023; $9.0 million in December 2024; and $8.0 million in December 2025 for a release of the civil claims and that we will enter into a non-prosecution agreement to resolve all criminal allegations. Those criminal allegations pertain to discontinued legacy billing practices for our NIPT tests. The amounts payable to the government, other than the initial $8.0 million payment, will be subject to interest at a rate of 1.25% per annum, and any or all amounts may be paid earlier at the option of the company. The companion civil settlement agreement is expected to resolve all civil claims involving discontinued legacy billing practices for our NIPT and microdeletion tests as well as other allegations pertaining to the provision of potential kickbacks or inducements to physicians and patients. Other non-financial terms and conditions remain subject to negotiation. The final civil settlement materials are subject to final approval of the Assistant Attorney General at DOJ, a U.S. District Court judge in New York, and any other relevant parties, including any potential whistleblower and the State AGs. We also expect to enter into a corporate integrity agreement with the Department of Health and Human Services Office of Inspector General, which would be expected to impose additional compliance, reporting and disclosure obligations, and related costs in the future.

As of December 31, 2019, we had accrued an aggregate of $35.8 million associated with a potential settlement with the DOJ and the participating State AGs within accrued expenses and other current liabilities and as a reduction of revenue as reflected on the consolidated balance sheet of the Company as of December 31, 2019 and consolidated statement of operations for the year ended December 31, 2019. In addition, in the quarter ended March 31, 2020, we accrued an additional $13.2 million with respect to the total amount to be paid under the agreement in principle to the DOJ and the participating State AGs, and additional amounts for related costs as of and for the quarterly period ended March 31, 2020. Furthermore, in connection with recording the CARES Act Tax Benefit, we have agreed with the government that, if during calendar years 2020 through 2023, and as long as amounts payable to the government remain unpaid, we receive any civil settlement, damages awards, or tax refunds, to the extent that the amounts exceed $5.0 million in a calendar year, we will pay 65% of the amount received in such civil settlement, damages award, or tax refunds as an accelerated payment on the scheduled amounts set forth above, first as a dollar-for-dollar acceleration of the scheduled payment due in December 2025 and then as an accelerated payment of the scheduled payments due in each prior year, up to a maximum total acceleration of $24.96 million. During the three months ended March 31, 2020, we recorded a discrete tax benefit of $37.7 million for the CARES Act Tax Benefit, and if fully paid, we expect that the total accelerated payments to the government will be $24.5 million. Until the final documents are approved and signed, there can be no assurance that the amount we have accrued will be sufficient to cover our obligations relating to this matter. Our obligations could also increase, potentially materially, depending on a number of factors including whether or not the agreement in principle is finalized, the terms of the final approved agreements, the parties to the settlement, the cost of complying with the terms of the settlement, including monitoring fees related to any potential corporate integrity agreement, the costs related to the settlement, and other factors. For additional information, please see

Note 9. Commitments and Contingencies to our audited financial statements for the year ended December 31, 2019, included in this prospectus and "Risk Factors—Regulatory Risks Related to Our Business—If we or our commercial partners act in a manner that violates healthcare laws or otherwise engage in misconduct, we could face substantial penalties and our business operations and financial condition could be adversely affected."

OIG Inquiry

On October 16, 2019, we received an inquiry from the Texas Health & Human Services Commission Office of Inspector General, or the TX OIG, alleging that we did not hold the required CLIA Laboratory Certificate of Accreditation to perform, bill for, or be reimbursed by the Texas Medicaid Program for certain tests performed by us from January 1, 2015 through December 31, 2018. Although we believe that we hold and have held all required CLIA certificates and/or subcontract with third-party laboratories that hold and have held such certificates to perform all of the tests subject to the TX OIG inquiry, there can be no assurance that the TX OIG will agree with this position. We submitted a written response to the inquiry on October 23, 2019 and are awaiting a response from the TX OIG on the matter. It is not possible to predict the outcome of these matters and the timing for resolution.

MANAGEMENT

Directors, Executive Officers, and Key Employees

The following table sets forth certain information regarding our directors, executive officers, and key employees as of the date of this prospectus.

Name	Age	Position
Harry Stylli, Ph.D.	58	Chairman and Chief Executive Officer
Jeffrey D. Alter(1)(2)	57	Director
John T. Bigalke(1)(3)(5)	65	Director
Jeffrey A. Ferrell(2)(3)	45	Director
Brian L. Kotzin, M.D.(2)(4)	71	Director
Samuel R. Nussbaum, M.D.(3)(4)(5)	72	Director
Lynne Powell(1)(4)(5)	53	Director
Eric d'Esparbes	52	Chief Financial Officer
Damon Silvestry	52	Chief Operating Officer
Sami Shihabi	49	Chief Commercial Officer
Matthew Cooper, Ph.D.	47	Chief Scientific Officer
Troy Seelye	56	Chief Information Officer
Clarke Neumann, J.D.	56	General Counsel and Secretary
George Gianakopoulos	59	Senior Vice President of Sales

(1) Member of the Audit Committee.
(2) Member of the Compensation Committee.
(3) Member of the Nominating/Corporate Governance Committee.
(4) Member of the Science Committee.
(5) Member of the Special Committee.

The following is a biographical summary of the experience of our directors, executive officers, and key employees:

Harry Stylli, Ph.D. Dr. Stylli has served as the Chairman of our Board and our Chief Executive Officer since August 2018. Previously, he served as the Executive Chairman of our Board from January 2013 to August 2018 and as the Chairman of our Board from January 2011 to January 2013. He has also served as executive chairman of the board of directors at Immunis.Al (formerly OncoCell MDx), a diagnostic testing company, since April 2019. He previously served as Chief Executive Officer and chairman of the board of directors of OncoCell MDx from June 2010 to April 2019. From June 2005 to September 2009, Dr. Stylli was President, Chief Executive Officer, and a member of the board of directors of Sequenom, Inc., a molecular diagnostic testing and genetics analysis company. From December 2003 to February 2005, Dr. Stylli was President and Chief Executive Officer of Xencor, Inc., a biopharmaceutical company. From April 2002 to July 2003, Dr. Stylli served as co-founder, President and Chief Executive Officer of CovX Pharmaceuticals Inc., a biopharmaceutical company. In May 1995, he co-founded Aurora Biosciences Corp., a biotechnology company. From May 1995 to April 2001, when Aurora Biosciences Corp. was acquired by Vertex Pharmaceuticals Incorporated, he held various senior roles at Aurora Biosciences Corp. From April 2001 to June 2002, following the acquisition, Dr. Stylli served as President of Aurora Biosciences Corp. and PanVera Corporation, a biotechnology company. Dr. Stylli received his B.S. from the University of East London, his M.B.A. from Open University in the United Kingdom, and his Ph.D. from London University.

We believe Dr. Stylli is qualified to serve on our Board because of his extensive experience forming and building biotechnology companies.

Jeffrey D. Alter Mr. Alter has served as a member of our Board since January 2019. From April 2004 to June 2018, Mr. Alter served in various chief leadership positions at UnitedHealthcare, a health plan

business, including as Chief Executive Officer of its commercial group from November 2014 to June 2018, as Chief Executive Officer of its employer and individual business from January 2011 to November 2014, as Chief Executive Officer, Northeast Region from June 2008 to January 2011, as Chief Operating Officer from April 2005 to June 2008, and as Chief Financial Officer, Northeast Region from April 2004 to April 2005. Mr. Alter earned both his B.S. in Marketing and his M.B.A. in Finance from Saint John's University, New York.

We believe Mr. Alter is qualified to serve on our Board because of his extensive leadership experience in the healthcare industry and finance experience.

John T. Bigalke Mr. Bigalke has served as a member of our Board since January 2019. Mr. Bigalke has served as the Chief Executive Officer of Second Half Healthcare Advisors, a healthcare strategy firm, since its founding by Mr. Bigalke in August 2016. Prior to founding Second Half Healthcare Advisors, he served as Vice Chairman and Senior Partner, Global Health Care Practice at Deloitte USA LLP, an accounting and consulting firm, from April 2012 to August 2016 and as Vice Chairman and National Industry Leader for the Health Care and Life Science Practice at Deloitte USA LLP from June 1998 until April 2012. Mr. Bigalke has served as a member of the board of directors of Premier, Inc., a healthcare improvement company, since October 2019, as a member of the advisory board for Concord Health Partners, a healthcare focused investment firm, since December 2018, and as a director for AdventHealth, a health system company, since June 2012. He previously served as a member of the board of directors of Deloitte USA, LLP from June 2004 to May 2007. Mr. Bigalke earned his B.S. in Financial Management from Clemson University. Mr. Bigalke is a Certified Public Accountant.

We believe Mr. Bigalke is qualified to serve on our Board because of his extensive experience in the healthcare and life sciences industry and his finance and accounting experience.

Jeffrey A. Ferrell Mr. Ferrell has served as a member of our Board since June 2014. Mr. Ferrell has served as the Managing Partner of Athyrium Capital Management, LP, a life sciences focused investment and advisory company, since November 2008. Mr. Ferrell served as a director of Lpath, Inc. from April 2007 to December 2016. Prior to Lpath, Inc., Mr. Ferrell served in a number of roles at Lehman Brothers, including as Senior Vice President from December 2005 to November 2008 and as Vice President in Lehman Brothers' private equity division from December 2002 to December 2005. From June 1997 to February 2001, Mr. Ferrell was a principal at Schroder Ventures Life Sciences. Mr. Ferrell earned his A.B. in Biochemical Sciences from Harvard University.

We believe Mr. Ferrell is qualified to serve on our Board because of his extensive experience investing in and guiding early stage life sciences companies.

Brian L. Kotzin, M.D. Dr. Kotzin has served as a member of our Board since June 2019. Dr. Kotzin has served as Senior Vice President, Clinical Development at Nektar Therapeutics, a biopharmaceutical company, since April 2017. Prior to Nektar, Dr. Kotzin was at Amgen Inc., where he served as Vice President, Global Clinical Development and Head, Inflammation Therapeutic Area from July 2004 to January 2015. During his employment at Amgen Inc., he also served as Vice President, Translational Sciences and Head of Medical Sciences from February 2006 to July 2011. Before joining Amgen, Dr. Kotzin was a faculty member in the Division of Rheumatology of the Department of Medicine and Department of Immunology at the University of Colorado Health Sciences Center in Denver, Colorado from September 1981 to July 2004. During this time at the University of Colorado Health Sciences Center, he was also head of Clinical Immunology in the Department of Medicine and director of the Autoimmunity Center of Excellence from July 1998 to July 2004. He has served as a member of the board of directors of Vera Therapeutics, Inc. since April 2020, Kyverna Therapeutics, Inc. since August 2019, and Rigel Pharmaceuticals, Inc. since August 2017. Dr. Kotzin earned his medical degree from Stanford University and his B.S. in Mathematics from the University of Southern California.

We believe Dr. Kotzin is qualified to serve on our Board because of his extensive academic research experience in immunology and experience as a senior executive for life sciences companies.

Samuel R. Nussbaum, M.D. Dr. Nussbaum has served as a member of our Board since January 2019. Dr. Nussbaum has served as a Strategic Consultant for EBG Advisors, the consulting arm for Epstein Becker and Green, since January 2016. Dr. Nussbaum has also served as a Senior Advisor to Sandbox Industries, a venture fund, since January 2017, and Ontario Teachers' Pension Fund since August 2016. From January 2000 until December 2015, Dr. Nussbaum served as Executive Vice President, Clinical Health Policy, and Chief Medical Officer of Anthem, Inc., a health insurance company. Dr. Nussbaum has served as a member of the board of directors of The Able Channel, a streaming and digital health platform company, since January 2020, Atrio Health Plans, a Medicare Advantage health plan provider, since September 2019, Coherus BioSciences, Inc., a biosimilar company, since May 2018, Motus GI Holdings, Inc., a medical technology company, since March 2017, and PhyMed Healthcare Group, an anesthesia management company, since July 2016. Dr. Nussbaum is a Professor of Clinical Medicine at Washington University School of Medicine and an adjunct professor at the Olin School of Business, Washington University and serves as Senior Fellow at the University of Southern California Schaeffer Center for Health Policy and Economics. Dr. Nussbaum earned his B.A. from New York University and his M.D. from Mount Sinai School of Medicine. He trained in internal medicine at Stanford University and Massachusetts General Hospital and in endocrinology at Harvard Medical School and Massachusetts General Hospital.

We believe Dr. Nussbaum is qualified to serve on our Board because of his experience advising life sciences and healthcare companies and his extensive experience as a senior executive and board member in the pharmaceutical and healthcare industries.

Lynne Powell Ms. Powell has served as a member of our Board since February 2019. Since September 2019 and October 2019, Ms. Powell has served as Chief Executive Officer and as a member of the board of directors, respectively, of Druggability Technologies Holdings Ltd, a specialty pharmaceutical company. Prior to joining Druggability, Ms. Powell served as Senior Vice President and Chief Commercial Officer of BioCryst Pharmaceuticals, Inc., a biotherapeutics company, from January 2015 to July 2019. From January 2010 to October 2014, Ms. Powell served as Senior Vice President of North American Commercial Operations at CSL Behring, a biotherapeutics company. She earned her B.S. in Applied Biology, Pharmacology & Toxicology from the University of East London and her M.B.A. from Monash University (Australia) and Warwick University (UK).

We believe Ms. Powell is qualified to serve on our Board because of her extensive experience as a senior executive and board member in the pharmaceutical industry.

Eric d'Esparbes Mr. d'Esparbes has served as our Chief Financial Officer since May 2019. From September 2014 to August 2018, Mr. d'Esparbes served as the Chief Financial Officer of Innoviva, Inc., a biotechnology company, where he was responsible for all aspects of the finance function including financial accounting, capital planning, audit, tax, and investor relations. Mr. d'Esparbes also served as the interim Principal Executive Officer of Innoviva from February 2018 to June 2018. Prior to Innoviva, he served as Chief Financial Officer for Joule Unlimited, an energy company, from December 2010 to March 2014, Vice President of Finance for AEI, Inc., a global energy company, from February 2010 to December 2010, Chief Financial Officer of AEI Asia Limited from May 2007 to February 2010, and Chief Financial Officer for Meiya Power Company (now CNG New Energy), an energy company, from October 1999 to May 2007. Mr. d'Esparbes earned his bachelor's degree from Hautes Études Commercial in Montréal, Canada.

Damon Silvestry Mr. Silvestry has served as our Chief Operating Officer since May 2020. Previously, Mr. Silvestry served as the Senior Vice President of Operations and People at Natera, Inc., a cell-free DNA testing company, from April 2018 to May 2020, Senior Vice President of Operations from April

2016 to April 2018, and Vice President of Operations from April 2015 to April 2016. Prior to Natera, Mr. Silvestry was the Senior Vice President of Operations at Miraca Life Sciences (now known as Inform Diagnostics) from June 2011 to October 2014, an anatomic pathology provider. Prior to Miraca, Mr. Silvestry served in a number of roles at Dell, Inc., including as the Executive Director for Latin America & Canada Sales Operations, Director of Dell Americas Engineering, Senior Manager of New Product Introductions and in various leadership roles within engineering. Mr. Silvestry earned his B.S. in Industrial Engineering from Southern Illinois University and his master's degree in Manufacturing Engineering from New York University—Polytechnic School of Engineering.

Sami Shihabi Mr. Shihabi has served as our Chief Commercial Officer since October 2019. From January 2018 to October 2019, he served as our Senior Vice President of Marketing and Portfolio Strategy, where he was responsible for leading the marketing strategies for our women's health business. Previously, Mr. Shihabi was the Vice President, Head of Commercial for Prometheus Laboratories Inc., a diagnostic company, from October 2016 to January 2018, where he was responsible for leading the commercials sales, marketing, and managed care organizations. Also at Prometheus, he served as Executive Director, Global Strategic Marketing from October 2015 to October 2016. Prior to Prometheus, he served as Global Commercial and Marketing Lead at Nestlé Health Science, a health science company, from January 2014 to October 2015. Mr. Shihabi earned his B.S. in Biological Sciences from the University of California, Davis, his master's degree in Molecular Biology from Pennsylvania State University, and his M.B.A. from the University of California Irvine.

Matthew Cooper, Ph.D. Dr. Cooper has served as our Chief Scientific Officer since March 2015. Previously, Dr. Cooper was the Chief Executive Officer and founder of Carmenta Bioscience, Inc., a biotechnology company, from February 2012 until we acquired Carmenta in March 2015. Prior to Carmenta, he was founding Chief Scientific Officer at Syapse Inc., a precision medicine software platform company, from February 2010 to February 2012. Previously, he served as Head of Non-Clinical Safety Information at Hoffmann-La Roche, a healthcare company, from January 2009 to April 2010 and as Principal Research Scientist at Hoffman-La Roche from February 2006 to January 2009. He was a scientist at Biogen Idec from February 2001 to February 2006. Dr. Cooper earned his B.S. in Chemistry from the University of Tulsa, dual M.B.A.s from Columbia Business School and the Berkeley Haas School of Business, and his Ph.D. in Toxicology from the University of Kentucky College of Medicine.

Troy Seelye Mr. Seelye has served as our Chief Information Officer since March 2020. Previously, Mr. Seelye served as Chief Information Officer of Teradata Corp., a provider of data warehousing and analytics solutions, from January 2017 to March 2020. Prior to Teradata, he served in various roles at Illumina Inc., a genetic testing company, including as the Head of Global IT Operations from February 2014 to January 2017 and as the Senior Director of Global Information Systems from September 2008 to February 2014. Prior to Illumina, Mr. Seelye spent 17 years in a number of roles at Amgen Inc., including as Senior Manager, Network Infrastructure Engineering, Senior Manager, Data Center Operations, and Senior Architect, where he led global expansion across Asia and Europe. Mr. Seelye earned his B.S. from California Lutheran University.

Clarke Neumann, J.D. Mr. Neumann has served as our General Counsel and Secretary since September 2014. Previously, Mr. Neumann served as Vice President, Associate General Counsel, and Assistant Secretary of Sequenom, Inc., a molecular diagnostic testing and genetics analysis company, from October 2012 to August 2014, as Vice President and General Counsel and Assistant Secretary from May 2001 to October 2012, and as Corporate Counsel from July 1999 to May 2001. From October 1993 to May 1999, Mr. Neumann was an attorney at Lyon & Lyon, LLP, specializing in intellectual property litigation, strategic counseling, business litigation, and transactional matters. Mr. Neumann earned his B.S. in chemical engineering from Pennsylvania State University and his J.D. from Loyola Law School, Los Angeles.

George Gianakopoulos Mr. Gianakopoulos has served as our Senior Vice President of Sales since October 2019. He previously served as our Corporate Vice President of Sales from January 2018 to October 2019 and as our Vice President of Sales from September 2014 to January 2018. Prior to joining our company, Mr. Gianakopoulos served as a sales leader in the oncology division of Myriad Genetics, Inc., a diagnostics company, from June 2006 to August 2014. Mr. Gianakopoulos earned his B.S.B.A. and his M.B.A. from Indiana University.

Board Structure

Our business and affairs are managed under the direction of our Board, which currently consists of seven members. Each of our current directors will continue to serve until the election and qualification of his or her successor, or his or her earlier death, resignation or removal.

In accordance with our eighth amended and restated certificate of incorporation and amended and restated bylaws, each to be in effect immediately prior to the completion of this offering, our entire Board will stand for election at each annual meeting of stockholders. Each director will hold office for a one-year term and until the election and qualification of his or her successor. The authorized number of directors is determined from time to time solely by resolution of the Board. Our certificate of incorporation and bylaws provide sole authority to our Board to fill vacancies and any additional directorships resulting from an increase in the authorized number of directors.

Board Leadership Structure

Our Board has designated Dr. Stylli, our Chief Executive Officer, to serve as Chairman of the Board. Combining the roles of Chief Executive Officer and Chairman allows one person to drive strategy and agenda setting at the board level while maintaining responsibility for executing on that strategy as Chief Executive Officer. On May 21, 2020, our independent directors elected Jeffrey Alter as Lead Independent Director. In accordance with our Principles of Corporate Governance, in such role, Mr. Alter has responsibility for: (a) presiding at meetings of the Board at which the Chairman of the Board is not present, including executive sessions of the independent directors; (b) overseeing the process of informing the Board, including addressing timing, nature and scope of information and materials disseminated to the Board; (c) collaborating with the Chairman on the agenda and schedule for Board meetings to provide that there is sufficient time for discussion of all agenda items; (d) serving as liaison between the CEO/Chairman of the Board and the independent directors, while ensuring no impediments to direct communication; (e) being available for consultation and communication with major stockholders upon request; and (f) performing such other designated duties as the Board may determine from time to time.

Although our amended and restated bylaws do not require that we combine the Chief Executive Officer and Chairman positions, our Board believes that having the positions be combined is the appropriate leadership structure for us at this time. Our Board recognizes that, depending on the circumstances, other leadership models, such as separating the roles of Chief Executive Officer and Chairman, might be appropriate. Accordingly, our board of directors may periodically review its leadership structure. Our Board believes its administration of its risk oversight function has not affected its leadership structure.

Our independent directors will meet alone in executive session regularly throughout each year, or otherwise as called by the lead independent director. The purpose of these executive sessions is to promote open and candid discussion among independent directors.

Role of our Board in Risk Oversight

We face a number of risks, including those described under the section titled “Risk Factors” included elsewhere in this prospectus. Our board of directors believes that risk management is an important part of establishing, updating, and executing on the company’s business strategy. Our Board, as a whole and at the committee level, has oversight responsibility relating to risks that could affect the corporate strategy, business objectives, compliance, operations and the financial condition and performance of the company.

Our Board focuses its oversight on the most significant risks facing the company and on its processes to identify, prioritize, assess, manage, and mitigate those risks. Our Board and its committees receive regular reports from members of the company's senior management on areas of material risk to the company, including strategic, operational, financial, legal, and regulatory risks. While our Board has an oversight role, management is principally tasked with direct responsibility for management and assessment of risks and the implementation of processes and controls to mitigate their effects on the company.

Board Committees

Our Board has established an audit committee, or the Audit Committee, a compensation committee, or the Compensation Committee, a nominating and corporate governance committee, or the Nominating/Corporate Governance Committee, a science committee, or the Science Committee, and a special committee, or the Special Committee. We believe that the functioning of these committees complies with the requirements of the Sarbanes-Oxley Act, the rules of Nasdaq, and SEC rules and regulations that will become applicable to us upon the completion of this offering. Each committee has the responsibilities described below.

Audit Committee

The members of our Audit Committee are Messrs. Bigalke and Alter and Ms. Powell, each of whom qualifies as an independent director for audit committee purposes, as defined under the rules of the SEC and the applicable Nasdaq listing rules and has sufficient knowledge in financial and auditing matters to serve on the audit committee. Mr. Bigalke chairs the Audit Committee. Additionally, Mr. Bigalke qualifies as an "audit committee financial expert" as that term is defined in the rules and regulations established by the SEC.

The primary responsibilities of our Audit Committee are to oversee our accounting and financial reporting processes, including the audits of the financial statements, and the internal and external audit processes. The Audit Committee also oversees the system of internal control established by management. The Audit Committee oversees the independent auditors, including their independence and objectivity. The Audit Committee is empowered to retain outside legal counsel and other advisors as it deems necessary or appropriate to assist it in fulfilling its responsibilities, and to approve the fees and other retention terms of the advisors.

Compensation Committee

The members of our Compensation Committee are Messrs. Alter and Ferrell and Dr. Kotzin, each of whom qualifies as an independent director, as defined under applicable Nasdaq qualification standards, and also meets the additional, heightened independence criteria applicable to members of the Compensation Committee. Mr. Alter chairs the Compensation Committee.

The primary responsibilities of our Compensation Committee are to periodically review and approve the compensation and other benefits for our senior officers and directors. This includes reviewing and approving corporate goals and objectives relevant to the compensation of our senior officers, evaluating the performance of these officers in light of the goals and objectives, and setting the officers' compensation. Our Compensation Committee also administers and makes recommendations to the Board regarding equity incentive plans that are subject to the Board's approval and approve the grant of equity awards under the plans.

Nominating/Corporate Governance Committee

The members of our Nominating/Corporate Governance Committee are Dr. Nussbaum and Messrs. Bigalke and Ferrell, each of whom qualifies as an independent director, as defined under applicable Nasdaq qualification standards. Dr. Nussbaum chairs the Nominating/Corporate Governance Committee.

The Nominating/Corporate Governance Committee is responsible for engaging in succession planning for the Board, developing and recommending to the Board criteria for identifying and evaluating qualified director candidates, and making recommendations to the Board regarding candidates for election or reelection to the Board at each annual stockholders' meeting. In addition, the Nominating/Corporate Governance Committee is responsible for overseeing our corporate governance practices and making recommendations to the Board concerning corporate governance matters. The Nominating/Corporate Governance Committee is also responsible for making recommendations to the Board concerning the structure, composition, and functioning of the Board and its committees.

Science Committee

The members of our Science Committee are Dr. Kotzin, Dr. Nussbaum, and Ms. Powell. Dr. Kotzin chairs the Science Committee. The Science Committee is responsible for assisting our Board in ensuring that our research and development organization is optimized to support our strategic goals, and reviewing and monitoring the science, technology, processes, procedures, and infrastructure underlying our major discovery and development programs.

Special Committee

The members of our Special Committee are Mr. Bigalke, Dr. Nussbaum, and Ms. Powell. Mr. Bigalke chairs the Special Committee. The Special Committee is responsible for evaluating, overseeing, making decisions, and taking actions for and on behalf of the company with respect to the pending government investigations and any related proceedings.

Code of Conduct and Ethics

Our Board has adopted a Code of Conduct and Ethics that establishes the standards of ethical conduct applicable to all our directors, officers, and employees. It addresses, among other matters, compliance with laws and policies, conflicts of interest, corporate opportunities, regulatory reporting, external communications, confidentiality requirements, insider trading, proper use of assets, and how to report compliance concerns. We intend to disclose any amendments to the Code of Conduct and Ethics, or any waivers of its requirements, on our website to the extent required by applicable rules. Our Board is responsible for applying and interpreting our Code of Conduct and Ethics in situations where questions are presented to it.

Compensation Committee Interlocks

None of the members of our Compensation Committee has at any time during the prior three years been one of our officers or employees. None of our executive officers currently serves, or in the past fiscal year has served, as a member of our Board or Compensation Committee of any entity that has one or more executive officers serving on our Board or Compensation Committee.

Director Independence

In connection with this offering and our planned listing on Nasdaq, our Board has reviewed the independence of all directors in light of each director's (or any family member's, if applicable) affiliations with the company and members of management, as well as significant holdings of our securities. The Board uses the definition of independence under Nasdaq listing standards to assess independence of our directors. These rules establish objective tests and a subjective test for determining who is an "independent director." The subjective test states that an independent director must be a person who lacks a relationship that, in the opinion of the Board, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. The Board has not established categorical standards or guidelines to make these subjective determinations, but considers all relevant facts and circumstances. After considering the foregoing factors, our Board has determined that Messrs. Alter, Bigalke, Ferrell, Nussbaum, Dr. Kotzin,

and Ms. Powell qualify as "independent directors" as defined by Nasdaq rules. Dr. Stylli is not deemed to be independent under Nasdaq rules by virtue of his employment with the company.

Following the effectiveness of this registration statement, the members of our Audit Committee must satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act, or Rule 10A-3. In order to be considered independent for purposes of Rule 10A-3, no member of the Audit Committee may, other than in his or her capacity as a member of the Audit Committee, the Board or any other committee of the Board: (i) accept, directly or indirectly, any consulting, advisory or other compensatory fee from us or any of our subsidiaries; or (ii) directly, or indirectly through one or more intermediaries, control, be controlled by or be under common control with us or any of our subsidiaries.

Director Compensation

Outside Director Compensation Policy

We adopted a policy for compensating our non-employee directors with a combination of cash and equity, with such equity awards being subject to the terms and conditions of the 2018 Plan and the Restricted Stock Unit Agreement and Stock Option Agreement thereunder and related forms of grant notices approved by the Board.

Cash Compensation. All non-employee directors are entitled to receive a $50,000 annual cash retainer for serving as a member of the board of directors as well as the following additional annual cash retainers for their board committee service:

	Chair	Member
Audit Committee	$20,000	$ 8,000
Compensation Committee	$15,000	$ 6,000
Nominating/Corporate Governance Committee	$10,000	$ 5,000
Science Committee	$15,000	$ 6,000
Special Committee	$20,000	$12,000

Each annual cash retainer and additional annual fee is paid quarterly in advance on a prorated basis except for the special committee fees, which are paid once per year. We have reimbursed and will continue to reimburse all of our directors for their reasonable out-of-pocket expenses, including travel, food, and lodging, incurred in attending meetings of our Board and/or its committees.

Equity Compensation. During 2019, all non-employee directors, other than Jeffrey Ferrell, who elected not to receive any compensation from us for his services in 2019, received an initial equity grant which was awarded in the form of 65,812 restricted stock units and 131,625 stock options. Subject to the director's continued service, the initial equity award vests in equal annual installments over a four-year period following the date of grant. In March of 2020, after consideration of market data presented by the compensation committee's compensation consultant, Compensia, the compensation committee approved a revised policy for compensating non-employee directors with equity awards. New non-employee directors are entitled to receive an initial equity grant with a target grant date fair value of $350,000, half of which is awarded in the form of restricted stock units and half of which is awarded in the form of stock options. Subject to the director's continued service, initial equity awards will vest in equal installments over a four-year period following the date of grant. In addition, each non-employee director is entitled to receive an annual equity grant with a target grant date fair value of $150,000, half of which is awarded in the form of restricted stock units and half of which is awarded in the form of stock options. The annual equity awards will vest in full on the one-year anniversary of the date of grant subject to the director's continued service through such date.

Fiscal Year 2019 Outside Director Compensation Table

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)(1)	Option Awards ($)(1)	Total ($)
Jeffrey D. Alter	67,250	199,411	204,796	471,457
John T. Bigalke	85,092	199,411	204,796	489,299
Jeffrey A. Ferrell(2)	—	—	—	—
Brian L. Kotzin, M.D.	33,518	121,753	135,127	290,398
Samuel R. Nussbaum, M.D.	71,000	199,411	204,796	475,207
Lynne Powell	63,667	199,411	204,796	467,874

(1) Amounts shown in this column represent the aggregate grant date fair value (calculated in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718) of stock awards and stock options granted during the year. A description of the methodologies and assumptions we use to value equity awards and the manner in which we recognize the related expense are described in Note 9 to our consolidated financial statements, Stock-Based Compensation. These amounts may not correspond to the actual value eventually realized by each director because the value depends on the market value of our common stock at the time the award vests or is exercised. As of December 31, 2019, Mr. Alter held 10,652 restricted stock units and 21,305 stock options, Mr. Bigalke held 10,652 restricted stock units and 21,305 stock options, Mr. Ferrell held 0 restricted stock units and 0 stock options, Dr. Kotzin held 10,652 restricted stock units and 21,305 stock options, Dr. Nussbaum held 10,652 restricted stock units and 21,305 stock options and Ms. Powell held 10,652 restricted stock units and 21,305 stock options.

(2) Mr. Ferrell elected not to receive any compensation from us for his services in 2019.

Directors who are also employees, such as Dr. Stylli, did not and do not receive any compensation for their services as our directors. The compensation received by Dr. Stylli for his services to us as our chief executive officer is presented in the 2019 Summary Compensation Table in “Executive Compensation” below. We do not expect to compensate our employee directors for their service on our board of directors in the future.

Indemnification Agreements

We have entered into indemnification agreements with our officers and directors. The indemnification agreements and our amended and restated bylaws to be in effect immediately prior to the completion of this offering will require us to indemnify these individuals to the fullest extent permitted by Delaware law.

EXECUTIVE COMPENSATION

Our named executive officers, or NEOs, for 2019, which consist of our principal executive officer and the next two most highly-compensated executives, are:

- Dr. Harry Stylli, our Chief Executive Officer, or CEO, and Chairman of our Board;
- Matthew Cooper, our Chief Scientific Officer; and
- Sami Shihabi, our Chief Commercial Officer.

2019 Summary Compensation Table

The following table summarizes the compensation awarded to, earned by, or paid to our NEOs for 2019.

Name and Principal Position	Year	Salary ($)	Stock Awards ($)(1)	Option Awards ($)(1)	Non-Equity Incentive Plan Compensation ($)(2)	All Other Compensation ($)(3)	Total ($)
Harry Stylli, *CEO and Chairman of the Board*	2019	395,000	—	—	—	—	395,000
Matthew Cooper, *Chief Scientific Officer*	2019	382,306	228,938	257,475	—	11,400	935,806
Sami Shihabi, *Chief Commercial Officer*	2019	415,520	241,875	285,483	—	—	982,253

(1) Amounts shown in this column represent the aggregate grant date fair value (calculated in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718) of stock awards and stock options granted during the year. A description of the methodologies and assumptions we use to value equity awards and the manner in which we recognize the related expense are described in Note 9 to our consolidated financial statements, Stock-Based Compensation. These amounts may not correspond to the actual value eventually realized by each NEO because the value depends on the market value of our common stock at the time the award vests or is exercised.

(2) Each named executive officer, other than Dr. Stylli who does not currently participate in our annual incentive bonus program, had a target bonus equal to 40% of base salary. In lieu of paying cash bonuses for the fiscal year ended December 31, 2019, on March 3, 2020, the compensation committee approved granting Dr. Cooper 3,916 restricted stock units with a fair value on such date of $38,231 and 6,614 stock options with a fair value on such date of $41,787 and Mr. Shihabi 6,385 restricted stock units with a fair value on such date of $62,336 and 10,783 stock options with a fair value on such date of $68,126. The grant date for all awards was March 4, 2020. The stock options will be fully-vested as of the date of grant and the restricted stock units will vest on the one-year anniversary of the date of grant. In accordance with applicable SEC rules, the grant date fair value of each award will appear in next year's Summary Compensation Table as Stock Awards and Option Awards.

(3) Amounts shown in this column represent the value of 401(k) contributions made by the Company.

Outstanding Equity Awards at 2019 Fiscal-Year End

The following table sets forth information regarding outstanding equity awards at the end of 2019 for each of our NEOs.

		Option Awards				Stock Awards			
Name	Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)(1)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)		
Harry Stylli, Ph.D.	—	—	—	—	—	—	—	—	—
Matthew Cooper	03/30/2015(2)	36,419	—	10.75	03/30/2025	—	—	—	—
	02/24/2016(2)	9,162	398	12.54	02/24/2026	—	—	—	—
	02/23/2017(2)	17,198	7,081	13.34	02/23/2027	—	—	—	—
	02/22/2018(3)	3,710	4,383	18.84	02/22/2028	2,191(5)	$ 21,390	—	—
	04/15/2019(4)	2,967	37,094	14.21	04/15/2029	18,546(5)	$ 181,058	—	—
Sami Shihabi	01/15/2018(2)	17,451	18,968	20.51	01/15/2028	—	—	—	—
	02/22/2018(3)	1,854	2,192	18.84	02/22/2028	1,138(5)	$ 11,110	—	—
	04/15/2019(4)	2,697	25,628	14.21	04/15/2029	12,813(5)	$ 125,089	—	—
	11/15/2019(3)	337	15,849	11.30	11/15/2029	7,924(5)	$ 77,359	—	—

(1) Following the end of the fiscal year, on January 9, 2020, our Board and stockholders approved the reduction of the exercise price of each of the stock options granted on or after February 23, 2017 to $9.88 to reflect the current fair market value of our common stock on such date.
(2) These stock options vest over a four-year period, with 25% vesting on the one-year anniversary of the date of grant and then in equal monthly installments thereafter.
(3) These stock options vest in equal monthly installments over a four-year period beginning on the 15th of the month following the date of grant.
(4) 22,256 of Dr. Cooper's stock options and 12,139 of Mr. Shihabi's stock options vest in full on the four-year anniversary of the date of grant and the remainder vest in equal monthly installments over a four-year period beginning on the 15th of the month following the date of grant.
(5) Subject to continued service through each such date, 11,128 of Dr. Cooper's restricted stock units and 6,069 of Mr. Shihabi's restricted stock units granted on April 15, 2019 are currently unvested and scheduled to vest in full on the four-year anniversary of the date of grant, 2,023 of Mr. Shihabi's restricted stock units granted on February 22, 2018 vested 25% on March 15, 2019 with the remaining portion vesting in equal monthly installments thereafter over the following three years and the remainder of the named executive officers' restricted stock units vest in equal monthly installments over a four-year period beginning on the 15th of the month following the date of grant, provided that vesting will convert to equal semi-annual installments following the completion of this offering. The named executive officers are only eligible to receive the vested shares underlying the restricted stock units, however, upon the earlier of a change in control (as defined in the 2018 Plan and applicable restricted stock unit award agreement) and our initial public offering, provided that either such event must occur on or before December 31, 2038. Any restricted stock units that remain unvested upon the completion of this offering shall continue to vest on the semi-annual vesting schedule described above.

Employment Agreements

We do not have employment agreements with any of our NEOs at this time, but, in connection with Dr. Cooper's and Mr. Shihabi's commencement of employment, we extended offer letters to each of

them that provide for base salary, participation in benefit plans and eligibility to earn an annual bonus. In addition, the offer letters provided for the grant of 36,419 stock options to each NEO that vested 25% on the first anniversary of the date of grant and then in equal monthly installments thereafter for the next 36 months. Dr. Cooper's offer letter also provides for severance benefits upon a termination without cause as described in further detail below.

Incentive Compensation

Annual Incentive. During 2019, our NEOs, other than Dr. Stylli, were eligible to receive an annual incentive bonus determined as a percentage of base salary based upon the achievement of pre-established performance goals, which for 2019 included revenue, sales and managed care goals, weighted 50%, products and launch goals, weighted 20%, corporate process goals relating to compliance, marketing, and human resources, weighted 10% and precision medicine goals, weighted 20%. For 2019, the target award opportunities for Messrs. Cooper and Shihabi were 40% of base salary. Performance was measured at fiscal year-end. Following the end of the year, the compensation committee decided to award the bonuses as equity awards granted under the 2018 Plan in the form of fully-vested stock options and restricted stock units that will vest on the one-year anniversary of the grant date, provided that Dr. Cooper and Mr. Shihabi are only eligible to receive vested shares underlying the restricted stock units upon the earlier of a change in control and our initial public offering, provided that either such event must occur on or before December 31, 2038. On March 3, 2020, the compensation committee approved granting Dr. Cooper 3,916 restricted stock units with a fair value on such date of $38,231.26 and 6,614 stock options with a fair value on such date of $38,230.49 and Mr. Shihabi 6,385 restricted stock units with a fair value on such date of $62,335.70 and 10,783 stock options with a fair value on such date of $62,328.30. The grant date for all awards was March 4, 2020. In accordance with applicable SEC rules, the grant date fair value of each award will appear in next year's Summary Compensation Table as Stock Awards and Option Awards.

Equity Incentive. We maintain our 2018 Plan pursuant to which we currently grant stock option and restricted stock unit awards to eligible participants. Dr. Cooper and Mr. Shihabi received grants of stock options and restricted stock units under this plan in 2019. See the table titled "Outstanding Equity Awards at 2019 Fiscal-Year End" for more information with respect to these grants. Following the fiscal year ended December 31, 2019, Dr. Cooper and Mr. Shihabi received the stock options and restricted stock units described above under "Incentive Compensation" in lieu of cash bonuses for their performance in 2019. In addition, each named executive officer received annual equity awards under the 2018 Plan in 2020. Dr. Stylli received 239,074 restricted stock units and 478,148 stock options, Dr. Cooper received 16,186 restricted stock units and 32,372 stock options and Mr. Shihabi received 9,711 restricted stock units and 19,423 stock options. Subject to continued service through each such date, Dr. Stylli's restricted stock units vest in equal monthly installments over a four-year period from the date of grant and Dr. Cooper's and Mr. Shihabi's restricted stock units vest over a four-year period with 25% vesting on the one-year anniversary of the date of grant and then in equal monthly installments thereafter, provided that, in each case, vesting will convert to equal semi-annual installments following the completion of this offering. The named executive officers are only eligible to receive the vested shares underlying the restricted stock units upon the earlier of a change in control (as defined in the 2018 Plan and applicable restricted stock unit award agreement) and our initial public offering, provided that either such event must occur on or before December 31, 2038. Any restricted stock units that remain unvested upon the completion of this offering shall continue to vest on the semi-annual vesting schedule described above. Subject to continued service through each such date, the stock options vest in equal monthly installments over a four-year period.

Post-Employment Compensation and Change in Control Payments and Benefits

In December 2019, our Board adopted the Progenity, Inc. Severance Plan, or the Severance Plan, pursuant to which certain senior employees, including our NEOs, may become eligible to receive

compensation and benefits upon certain qualifying terminations of employment. In the event that an NEO is terminated by the company without cause or voluntarily terminates employment with good reason (with "cause" and "good reason" each as defined in the Severance Plan), in either case more than three months prior to or 13 months or more following a change in control (as defined in the Severance Plan), subject to execution of a general release of claims in favor of the company and compliance with various standard restrictive covenants (such as protection of confidential information and non-disparagement commitments), the NEO is entitled to receive: (i) continued payment of base salary (for a period of 12 months, in the case of our CEO, and for a period of nine months, in the case of the other NEOs); and (ii) payment of the before-tax cost of the NEO's premiums to continue coverage, or the Continued Coverage, for the NEO and the NEO's eligible dependents, if any, under the company's health, vision and/or dental benefit plans to the extent such NEO (and eligible dependents, if applicable) were enrolled prior to such termination (for a period of 12 months, in the case of our CEO and for a period of nine months, in the case of the other NEOs). In the event that an NEO is terminated by the company without cause or voluntarily terminates employment with good reason, in either case within the period that is three months prior to or 13 months following a change in control, subject to execution of a general release of claims in favor of the company, the NEO is entitled to receive: (i) a lump sum payment within 30 days of the change in control equal to 24 months of base salary for the CEO and 18 months of base salary for the other NEOs; (ii) a lump sum payment within 30 days of the change in control equal to the NEO's average cash incentive bonus earned for the two most recently completed fiscal years multiplied by 2, in the case of the CEO and by 1.5, in the case of the other NEOs; (iii) the Continued Coverage for a period of 24 months (or such shorter period as required by law), in the case of the CEO and 18 months, in the case of the other NEOs; and (iv) all unvested time-based equity awards will accelerate in full and all unvested performance-based equity awards that are outstanding as of the termination date will vest, if at all, based on actual performance for the portion of the performance period ending shortly prior to the occurrence of the change in control as if such partial performance period were the entire performance period.

In addition, pursuant to the offer letter agreement entered into with Dr. Cooper, upon a termination without cause (as defined in his offer letter), subject to his execution and non-revocation of a release of claims in favor of the company and compliance with various standard restrictive covenants (such as protection of confidential information), he is entitled to receive continued payment of base salary and COBRA premiums for a period of 12 months. Any payments or benefits provided to Dr. Cooper pursuant to the offer letter will reduce any payments or benefits that may become due pursuant to the Severance Plan.

Employee Benefit Plans

Equity Plans

We currently maintain our 2018 Plan, our 2011 Incentive Stock Plan, or the 2011 Plan, and our Second Amended and Restated 2012 Stock Plan, or the 2012 Plan, pursuant to which we have granted equity awards to our NEOs and certain of our other employees, and our 2015 Consultant Stock Plan, or the 2015 Plan, pursuant to which we have granted equity awards to certain eligible consultants. Awards can no longer be granted under our 2011 Plan, 2012 Plan or 2015 Plan, but there are awards that remain outstanding under each of those plans. We have also adopted our 2020 Employee Stock Purchase Plan which will become effective upon the completion of this offering as described in further detail below.

2018 Plan

Purpose. The 2018 Plan, which is the successor to and continuation of the 2012 Plan and 2015 Plan, is intended to help the company secure and retain the services of eligible award recipients, provide incentives for such persons to exert maximum efforts for the success of the company and its affiliates and provide a means by which the eligible recipients may benefit from increases in the value of our common stock.

Eligibility. Awards may be granted to employees, including officers, non-employee directors, and consultants of the company and its affiliates. Only our employees and those of our affiliates are eligible to receive incentive stock options.

Types of Awards. The 2018 Plan provides for the grant of incentive stock options within the meaning of Section 422 of the Code, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance stock awards, performance cash awards, and other stock awards.

Authorized Shares. Subject to adjustment for certain dilutive or related events, the aggregate maximum number of shares of our common stock that may be issued pursuant to stock awards under the 2018 Plan, or the Share Reserve, is 7,615,733 shares of common stock. The Share Reserve will automatically increase annually beginning on January 1, 2021 and ending with a final increase on January 1, 2030 in an amount equal to 4% of the total number of shares of capital stock outstanding on December 31st of the preceding calendar year; provided, however, that the Board may provide that there will not be a January 1st increase in the Share Reserve in a given year or that the increase will be less than 4% of the shares of capital stock outstanding on the preceding December 31st.

The Share Reserve will not be reduced if an award or any portion thereof (i) expires, is canceled, is forfeited or otherwise terminates without all of the shares covered by such award having been issued or (ii) is settled in cash. If any shares of common stock issued under an award are forfeited back to or repurchased by the company, such shares will revert to and again be made available for issuance under the 2018 Plan. Any shares retained or reacquired by the company in satisfaction of tax withholding obligations, as consideration for the exercise or purchase price of an award, or with the proceeds paid by the participant under the terms of a stock award, will also again become available for issuance under the 2018 Plan. If the company repurchases shares of common stock with stock option exercise or stock purchase proceeds, such shares will be added to the Share Reserve. For any stock award with respect to which a net number of shares of common stock are issued, whether in satisfaction of tax withholding obligations, exercise or purchase prices or otherwise, only the net number of shares will reduce the Share Reserve.

The aggregate maximum number of shares of common stock that may be issued on the exercise of incentive stock options is 7,615,733.

The aggregate dollar value of stock awards (based on the grant date fair value of such awards) granted under the 2018 Plan during any calendar year to any one non-employee director may not exceed $750,000.

Shares issued under the 2018 Plan may consist of authorized but unissued or reacquired common stock of the company, including shares repurchased by the company on the open market or otherwise or shares classified as treasury shares.

Plan Administration. Our Board has the authority to administer the 2018 Plan, including the powers to: (i) determine who will be granted awards and what type of award, when and how each award will be granted, the provisions of each award (which need not be identical), the number of shares or cash value subject to an award and the fair market value applicable to an award; (ii) construe and interpret the 2018 Plan and awards granted thereunder and establish, amend and revoke rules and regulations for administration of the 2018 Plan and awards, including the ability to correct any defect, omission or inconsistency in the 2018 Plan or any award document; (iii) settle all controversies regarding the 2018 Plan and awards granted thereunder; (iv) accelerate or extend, in whole or in part, the time during which an award may be exercised or vested or at which cash or shares may be issued; (v) suspend or terminate the 2018 Plan; (vi) amend the 2018 Plan; (vii) submit any amendment to the 2018 Plan for stockholder approval; (viii) approve forms of award documents for use under the 2018 Plan and to amend the terms of any one or more outstanding awards; (ix) generally exercise such powers and perform such acts as the

Board may deem necessary or expedient to promote the best interests of the company and that are not in conflict with the provisions of the 2018 Plan or any award documents; and (x) adopt procedures and sub-plans as are necessary or appropriate.

Subject to the provisions of the 2018 Plan, our Board may delegate all or some of the administration of the 2018 Plan to a committee of one or more directors and may delegate to one or more officers the authority to designate employees who are not officers to be recipients of options and stock appreciation rights (and, to the extent permitted by applicable law, other stock awards) and, to the extent permitted by applicable law, to determine the terms of such awards and the number of shares of common stock to be subject to such stock awards granted to such employees. Unless otherwise provided by the Board, delegation of authority by the Board to a committee or an officer will not limit the authority of the Board. All determinations, interpretations and constructions made by the Board (or another authorized committee or officer exercising powers delegated by the Board) in good faith will be final, binding and conclusive on all persons. Pursuant to the provisions of the 2018 Plan, the Board has delegated administration of the 2018 Plan to the Compensation Committee.

Stock Options. A stock option may be granted as an incentive stock option or a nonqualified stock option. The option exercise price may not be less than the fair market value of the stock subject to the option on the date the option is granted or, with respect to incentive stock options, less than 110% of the fair market value if the recipient owns stock possessing more than 10% of the total combined voting power of all classes of stock of the company or any affiliate, or a Ten Percent Stockholder (as defined in the 2018 Plan), unless the option was granted pursuant to an assumption or substitution for another option in a manner satisfying the provisions of Section 409A and, if applicable, Section 424(a) of the Code. Options will not be exercisable after the expiration of ten years from the date of grant (or five years, in the case of an incentive stock option issued to a Ten Percent Stockholder). Each award agreement will set forth the number of shares subject to each option. The purchase price of any shares acquired pursuant to an option may be payable in cash, check, bank draft, money order, net exercise or as otherwise determined by the Board and set forth in the award agreement, including through an irrevocable commitment by a broker to pay over such amount from a sale of the shares issuable under the option and the delivery of previously owned shares. The vesting schedule applicable to any option, including any performance conditions, will be as set forth in the award agreement.

Stock Appreciation Rights. A stock appreciation right, or SAR, is a right that entitles the participant to receive, in cash or shares of stock or a combination thereof, as determined by the Board, value equal to or otherwise based on the excess of (i) the fair market value of a specified number of shares at the time of exercise over (ii) the exercise price of the right, as established by the Board on the date of grant. Upon exercising a SAR, the participant is entitled to receive the amount by which the fair market value of the stock at the time of exercise exceeds the exercise price of the SAR. The exercise price of each SAR may not be less than the fair market value of the stock subject to the award on the date the SAR is granted, unless the SAR was granted pursuant to an assumption of or substitution for another option in a manner satisfying the provisions of Section 409A of the Code. SARs will not be exercisable after the expiration of ten years from the date of grant. Each award agreement will set forth the number of shares subject to the SAR. The vesting schedule applicable to any SAR, including any performance conditions, will be as set forth in the award agreement.

Provisions Applicable to Both Options and SARs

Transferability. The Board may, in its sole discretion, impose limitations on the transferability of options and SARs. Unless the Board provides otherwise, an option or SAR will not be transferable except by will or the laws of descent and distribution and will be exercisable during the lifetime of a participant only by such participant. The Board may permit transfer of an option or SAR in a manner not prohibited by applicable law. Subject to approval by the Board, an option or SAR may be transferred pursuant to the terms of a domestic relations order or similar instrument or pursuant to a beneficiary designation.

Termination of Service. Except as otherwise provided in an applicable award document or other agreement between a participant and the company or any affiliate, upon a termination for any reason other than for cause or due to death or disability, a participant may exercise his or her option or SAR (to the extent such award was exercisable as of the date of termination) for a period of three months following the termination date or, if earlier, until the expiration of the term of such award. Upon a termination due to a participant's disability, unless otherwise provided in an applicable award or other agreement, the participant may exercise his or her option or SAR (to the extent that such award was exercisable as of the date of termination) for a period of 12 months following the termination date or, if earlier, until the expiration of the term of such award. Upon a termination due to a participant's death, unless otherwise provided in an applicable award or other agreement, the participant's estate may exercise the option or SAR (to the extent such award was exercisable as of the termination date) for a period of 18 months following the termination date or, if earlier, until the expiration of the term of such award. Unless provided otherwise in an award or other agreement, an option or SAR will terminate on the date that a participant is terminated for cause and the participant will not be permitted to exercise such award.

Awards Other Than Options and SARs

Restricted Stock and Restricted Stock Units. Restricted shares are awards of shares, the grant, issuance, retention, vesting and/or transferability of which is subject during specified periods of time to such conditions (including continued employment) and terms as the Board deems appropriate. Restricted stock units, or RSUs, are an award denominated in units under which the issuance of shares (or cash payment in lieu thereof) is subject to such conditions (including continued employment) and terms as the Board deems appropriate. Each award document evidencing a grant of restricted stock or RSUs will set forth the terms and conditions of each award, including vesting and forfeiture provisions, transferability and, if applicable, right to receive dividends or dividend equivalents.

Performance Awards. A performance award is a stock or cash award that is payable contingent upon the attainment during a performance period of certain performance goals. A performance award may, but need not, require the completion of a specified period of service. The length of any performance period, the applicable performance goals, and the measurement of whether and to what degree such performance goals have been attained will be as determined by the Compensation Committee or the Board. The Compensation Committee or the Board retains the discretion to reduce or eliminate the compensation or economic benefit upon the attainment of any performance goals and to define the manner of calculating the performance criteria it selects to use for a performance period.

Other Stock Awards. The 2018 Plan permits the grant of other forms of stock awards valued in whole or in part by reference to, or otherwise based on, the common stock of the company, including the appreciation in value thereof. Subject to the provisions of the 2018 Plan, the Board has the sole and complete authority to determine the persons to whom and the times at which such other stock awards may be granted and other provisions related thereto.

Certain Adjustments. In the event of any change in the capitalization of the company, the Board will appropriately and proportionately adjust: (i) the class(es) and maximum number of securities subject to the 2018 Plan; (ii) the class(es) and maximum number of securities that may be issued pursuant to the exercise of incentive stock options; and (iii) the class(es) and number of securities or other property and value (including price per share of stock) subject to outstanding stock awards. The Board will make such adjustments, and its determination will be final, binding, and conclusive. Unless provided otherwise in an award or other agreement, in the event of a dissolution or liquidation of the company, all outstanding stock awards (other than stock awards consisting of vested and outstanding shares of company common stock not subject to a forfeiture condition or the company's right of repurchase) will terminate immediately prior to the completion of such dissolution or liquidation, and the shares of common stock subject to the company's repurchase rights or subject to forfeiture may be repurchased or reacquired by the company notwithstanding the fact that the holder of such stock award is providing continuous

service; provided, however, that the Board may, in its sole discretion, provide that some or all stock awards will become fully vested, exercisable and/or no longer subject to repurchase or forfeiture (to the extent not already expired or terminated) before the dissolution or liquidation is completed but contingent upon its completion.

Corporate Transaction. Unless provided otherwise in an award agreement or other agreement between a participant and the company or an affiliate, in the event of a Corporate Transaction (as defined in the 2018 Plan), the Board will take one or more of the following actions with respect to each outstanding award, contingent upon the closing or completion of the Corporate Transaction:

(i) arrange for the surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company) to assume or continue the award or to substitute a similar stock award for the award (including, but not limited to, an award to acquire the same consideration per share paid to the stockholders of the company pursuant to the Corporate Transaction);

(ii) arrange for the assignment of any reacquisition or repurchase rights held by the company in respect of common stock issued pursuant to the award to the surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company);

(iii) accelerate the vesting, in whole or in part, of the award (and, if applicable, the time at which the award may be exercised) to a date prior to the effective time of such Corporate Transaction as determined by the Board, with such award terminating if not exercised (if applicable) at or prior to the effective time of the Corporate Transaction, and with such accelerated vesting (and if applicable, such exercise) reversed if the Corporate Transaction does not become effective;

(iv) arrange for the lapse, in whole or in part, of any reacquisition or repurchase rights held by the company with respect to the award;

(v) cancel or arrange for the cancellation of the award, to the extent not vested or not exercised prior to the effective time of the Corporate Transaction, in exchange for such cash consideration, if any, as the Board, in its reasonable determination, may consider appropriate as an approximation of the value of the canceled award;

(vi) cancel or arrange for the cancellation of the award, to the extent not vested or not exercised prior to the effective time of the Corporate Transaction, in exchange for a payment equal to the excess, if any, of (A) the value in the Corporate Transaction of the property the participant would have received upon the exercise of the award immediately prior to the effective time of the Corporate Transaction, over (B) any exercise price payable by such holder in connection with such exercise; and

(vii) continuation of the award.

The Board need not take the same action or actions with respect to all awards or portions thereof or with respect to all participants and may take different actions with respect to the vested and unvested portions of an award.

In the absence of any affirmative determination by the Board at the time of a Corporate Transaction, each outstanding award will be assumed or an equivalent award will be substituted by such successor corporation or a parent or subsidiary of such successor corporation, referred to as a Successor Corporation, unless the Successor Corporation does not agree to assume the award or to substitute an equivalent award, in which case the vesting of such award will accelerate in its entirety (along with, if applicable, the time at which the award may be exercised) to a date prior to the effective time of such

Corporate Transaction as the Board will determine (or, if the Board does not determine such a date, to the date that is five days prior to the effective date of the Corporate Transaction), with such award terminating if not exercised (if applicable) at or prior to the effective time of the Corporate Transaction, and with such exercise reversed if the Corporate Transaction does not become effective.

Change in Control. An award may be subject to additional acceleration of vesting and exercisability upon or after a Change in Control (as defined in the 2018 Plan) as may be provided in the award agreement for such award or as may be provided in any other written agreement between the company or any affiliate and the participant, but in the absence of such provision, no such acceleration will occur.

Termination and Amendment. The Board may suspend or terminate the 2018 Plan at any time. No awards will be granted after the tenth anniversary of the date the Board adopted the 2018 Plan. No awards may be granted under the 2018 Plan while the 2018 Plan is suspended or after it is terminated.

2015 Plan

Purpose. The 2015 Plan was adopted to advance the interests of the company and our stockholders by providing an incentive to attract, retain, and reward individual consultants performing services for us and by motivating such persons to contribute to our growth and profitability. The 2015 Plan ceased to be available for the grant of awards upon the effective date of the 2018 Plan.

Eligibility. The 2015 Plan provided for awards to be granted to consultants who qualified as accredited investors at the time of grant.

Authorized Shares. The 2015 Plan ceased to be available for the grant of awards upon the effective date of the 2018 Plan, so there are no future authorized shares. As of June 1, 2020, options to purchase 102,784 shares of our common stock remained outstanding under the 2015 Plan, a sufficient number of shares remain available under the 2015 Plan to satisfy these outstanding options, and the terms of the 2015 Plan will continue to govern the outstanding awards.

Plan Administration. Our Board or a committee thereof appointed by the Board has the authority to administer the 2015 Plan, including the powers to: (i) determine the persons to whom, and the time or times at which, awards would be granted and the number of shares of common stock subject to such awards, (ii) determine the types of awards granted, (iii) determine the fair market value of our common stock, (iv) determine the terms, conditions and restrictions applicable to each award (which need not be identical) and any shares acquired pursuant thereto, including, without limitation, (a) the exercise or purchase price of shares pursuant to any award, (b) the method of payment for shares purchased pursuant to any award, (c) the method for satisfaction of any tax withholding obligation arising in connection with any award or shares acquired pursuant thereto, including by the withholding or delivery of shares of common stock, (d) the timing, terms and conditions of the exercisability or vesting of any award or shares acquired pursuant thereto, (e) the time of expiration of any award, (f) the effect of any participant's termination of service on any of the foregoing, and (g) all other terms, conditions and restrictions applicable to any award or shares acquired pursuant thereto not inconsistent with the terms of the 2015 Plan, (v) approve forms of award agreements, (vi) amend, modify, extend, cancel or renew any award or waive any restrictions or conditions applicable to any award or any shares acquired pursuant thereto, (vii) accelerate, continue, extend or defer the exercisability or vesting of any award or any shares acquired pursuant thereto, including with respect to the period following a participant's termination of service, (viii) prescribe, amend or rescind rules, guidelines and policies relating to the 2015 Plan, or adopt sub-plans or supplements to, or alternate versions of, the 2015 Plan as deemed necessary or desirable to comply with laws, tax policies, accounting principles or customs of foreign jurisdictions, and (ix) correct any defect, supply any omission or reconcile any inconsistency in the 2015 Plan or any award agreement and to make all other determinations and take such other actions with respect to the plan and outstanding awards as deemed advisable to the extent not inconsistent with the terms of the 2015 Plan or applicable law.

Stock Options. A stock option may be granted only as a nonqualified stock option. The option exercise price may not be less than the fair market value of the stock subject to the option on the date the option is granted, unless the option was granted pursuant to an assumption or substitution for another option in a manner qualifying under Section 409A of the Code. Options will not be exercisable after the expiration of ten years from the date of grant. Each award agreement sets forth the number of shares subject to each option. The purchase price of any shares acquired pursuant to an option may be payable in cash, check or cash equivalent, cashless exercise, net exercise or as otherwise determined by the Board and set forth in the award agreement, including through an irrevocable commitment by a broker to pay over such amount from a sale of the shares issuable under the option and the delivery of previously owned shares. The vesting schedule applicable to any option is as set forth in the award agreement.

Transferability. Unless otherwise provided in an award agreement, during the lifetime of the participant, an option will only be exercisable by the participant or his or her guardian or legal representative. An option may not be subject to anticipation, alienation, sale, exchange, transfer, assignment, pledge, encumbrance, or garnishment, except by transfer by will or the laws of descent and distribution.

Certain Adjustments. In the event of certain changes in the capitalization of the company, the Board will make appropriate and proportionate adjustments, including to outstanding awards and any applicable exercise price in order to prevent dilution or enlargement of participants' rights.

Change in Control. Subject to the requirements and limitations of Section 409A of the Code, if applicable, the Board may provide for any one or more of the following upon a Change in Control (as defined in the 2015 Plan): (i) accelerated vesting of outstanding awards, (ii) assumption, continuation or substitution of outstanding awards and/or (iii) cash-out of outstanding awards.

Termination and Amendment. The Board may amend, suspend, or terminate the 2015 Plan at any time, subject to stockholder approval, if applicable in the case of certain amendments. As of the effectiveness of the 2018 Plan, no awards have been or will be granted under the 2015 Plan but outstanding awards will continue to be governed by their terms.

2012 Plan

Purpose. The 2012 Plan was adopted to advance the interests of the company and our stockholders by providing an incentive to attract, retain, and reward persons performing services for us and by motivating such persons to contribute to our growth and profitability. The 2012 Plan ceased to be available for the grant of awards upon the effective date of the 2018 Plan.

Eligibility. The 2012 Plan allowed for awards to be granted to employees, consultants and non-employee directors.

Authorized Shares. The 2012 Plan ceased to be available for the grant of awards upon the effective date of the 2018 Plan, so there are no future authorized shares. As of June 1, 2020, options to purchase 1,609,920 shares of our common stock remained outstanding under the 2012 Plan, a sufficient number of shares remain available under the 2012 Plan to satisfy these outstanding options, and the terms of the 2012 Plan will continue to govern the outstanding awards.

Plan Administration. Our Board or a committee thereof appointed by the Board has the authority to administer the 2012 Plan, including the powers to: (i) determine the persons to whom, and the time or times at which, awards would be granted and the number of shares of common stock subject to such awards, (ii) determine the types of awards granted, (iii) determine the fair market value of our common stock, (iv) determine the terms, conditions and restrictions applicable to each award (which need not be

identical) and any shares acquired pursuant thereto, including, without limitation, (a) the exercise or purchase price of shares pursuant to any award, (b) the method of payment for shares purchased pursuant to any award, (c) the method for satisfaction of any tax withholding obligation arising in connection with any award or shares acquired pursuant thereto, including by the withholding or delivery of shares of common stock, (d) the timing, terms and conditions of the exercisability or vesting of any award or shares acquired pursuant thereto, (e) the time of expiration of any award, (f) the effect of any participant's termination of service on any of the foregoing, and (g) all other terms, conditions and restrictions applicable to any award or shares acquired pursuant thereto not inconsistent with the terms of the 2012 Plan, (v) approve forms of award agreements, (vi) amend, modify, extend, cancel or renew any award or waive any restrictions or conditions applicable to any award or any shares acquired pursuant thereto, (vii) accelerate, continue, extend or defer the exercisability or vesting of any award or any shares acquired pursuant thereto, including with respect to the period following a participant's termination of service, (viii) prescribe, amend or rescind rules, guidelines and policies relating to the 2012 Plan, or adopt sub-plans or supplements to, or alternate versions of, the 2012 Plan as deemed necessary or desirable to comply with laws, tax policies, accounting principles or customs of foreign jurisdictions, and (ix) correct any defect, supply any omission or reconcile any inconsistency in the 2012 Plan or any award agreement and to make all other determinations and take such other actions with respect to the plan and outstanding awards as deemed advisable to the extent not inconsistent with the terms of the 2012 Plan or applicable law.

Stock Options. A stock option may be granted as an incentive stock option or a nonqualified stock option. The option exercise price may not be less than the fair market value of the stock subject to the option on the date the option is granted or, with respect to incentive stock options, less than 110% of the fair market value if the recipient is a Ten Percent Stockholder (as defined in the 2012 Plan), unless the option was granted pursuant to an assumption or substitution for another option in a manner qualifying under Section 424(a) of the Code. Options will not be exercisable after the expiration of ten years from the date of grant (or five years, in the case of an incentive stock option issued to a Ten Percent Stockholder). Each award agreement sets forth the number of shares subject to each option. The purchase price of any shares acquired pursuant to an option may be payable in cash, check or cash equivalent, cashless exercise, net exercise or as otherwise determined by the Board and set forth in the award agreement, including through an irrevocable commitment by a broker to pay over such amount from a sale of the shares issuable under the option and the delivery of previously owned shares. The vesting schedule applicable to any option is as set forth in the award agreement.

Transferability. During the lifetime of the participant, an option will only be exercisable by the participant or his or her guardian or legal representative. An option may not be subject to anticipation, alienation, sale, exchange, transfer, assignment, pledge, encumbrance, or garnishment, except by transfer by will or the laws of descent and distribution. Notwithstanding the foregoing, the administrator, in its discretion, may provide that nonstatutory stock options may be assigned or transferred subject to certain limitations.

Certain Adjustments. In the event of certain changes in the capitalization of the company, the Board will make appropriate and proportionate adjustments, including to outstanding awards and any applicable exercise price in order to prevent dilution or enlargement of participants' rights.

Change in Control. Subject to the requirements and limitations of Section 409A of the Code, if applicable, the Board may provide for any one or more of the following upon a Change in Control (as defined in the 2012 Plan): (i) accelerated vesting of outstanding awards, (ii) assumption, continuation or substitution of outstanding awards and/or (iii) cash-out of outstanding awards.

Termination and Amendment. The Board may amend, suspend, or terminate the 2012 Plan at any time, subject to stockholder approval, if applicable in the case of certain amendments. As of the

effectiveness of the 2018 Plan, no awards have been or will be granted under the 2012 Plan but outstanding awards will continue to be governed by their terms.

2011 Plan

We ceased granting awards under the 2011 Plan following the adoption of the 2012 Plan. As of June 1, 2020, options to purchase 27,989 shares of our common stock remained outstanding under the 2011 Plan, a sufficient number of shares remain available under the 2011 Plan to satisfy these outstanding options, and the terms of the 2011 Plan, which are the same in all material respects to the terms under the 2012 Plan, will continue to govern the outstanding awards.

2020 Employee Stock Purchase Plan

Our Board adopted, subject to the consummation of this offering, the 2020 Employee Stock Purchase Plan, or 2020 ESPP, in order to enable eligible employees to purchase shares of our common stock at a discount following the date of this offering. Purchases will be accomplished by employees through participation in discrete offering periods. There are not currently any outstanding awards under the 2020 ESPP because no offering period under the 2020 ESPP has yet commenced. The 2020 ESPP, excluding any sub-plans thereunder, is intended to qualify as an employee stock purchase plan under Section 423 of the Code. The initial number of shares of our common stock reserved for issuance under the 2020 ESPP will be equal to 510,000 shares of our common stock. The number of shares of common stock reserved for issuance under the 2020 ESPP will increase automatically on January 1 of each year, for ten years, by the lesser of (i) 1% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year or (ii) 600,000 shares of our common stock, unless otherwise provided by the Board. The maximum number of shares that may be issued to any employee in a given offering period will be that number of shares of common stock that could be purchased on the first day of such offering period with $50,000, taking into consideration any discount from the offering period in accordance with the terms of the 2020 ESPP; provided, however, that the administrator of the 2020 ESPP may change this limitation at any time on a prospective basis to apply to future offering periods. In addition, no participant will have the right to purchase shares of our common stock in an amount, when aggregated with purchase rights under all of our employee stock purchase plans that are also in effect in the same calendar year, that has a fair market value of more than $25,000, determined as of the first day of the applicable offering period, for each calendar year in which that right is outstanding.

Our Compensation Committee will administer the 2020 ESPP. All of our employees who work 20 or more hours per week and for five or more months per year who are employed at the beginning of an enrollment period are generally eligible to participate in the 2020 ESPP. Employees who are 5% stockholders, or would become 5% stockholders as a result of their participation in the 2020 ESPP, cannot participate in the 2020 ESPP. Under the 2020 ESPP, eligible employees will be able to acquire shares of our common stock by accumulating funds through payroll deductions. Our eligible employees will be able to select a rate of payroll deduction between 1% and 15% of their eligible compensation. We will also have the right to amend or terminate the 2020 ESPP at any time. The 2020 ESPP will continue until terminated in accordance with the provisions therein.

The 2020 ESPP will consist of offering periods of no more than 27 months. Once established, the duration and timing of offering periods may be changed or modified by the Compensation Committee. Unless established otherwise by the Compensation Committee, the duration of an offering period will be 24 months, each offering period will consist of four (4) consecutive six (6) month purchase periods and a new offering period will commence every six (6) months following the first day of the prior offering period. For each offering period, new participants will be required to enroll in a timely manner. A participant may only participate in a single offering period at a time. Once an employee is enrolled in an offering period, participation in the next 24 month offering period that begins following the cessation of the current offering period in which the employee is participating will occur automatically unless the

participant provides timely notice to the administrator in accordance with the administrator's established procedures. Unless the Compensation Committee provides otherwise, an employee must be employed on each purchase date in order for his or her option to be exercised on such purchase date. Upon an employee's termination of employment during an offering period, the employee's outstanding option to purchase shares of common stock will immediately terminate and all sums previously collected from the employee will be refunded.

The purchase price for shares of our common stock purchased under the 2020 ESPP will be not less than 85% of the lesser of the fair market value of our common stock on (i) the first trading day of the applicable offering period and (ii) the last trading day of each six month purchase period in the applicable offering period.

If we experience any change in our capitalization without receipt of consideration by the company, the type and number of securities covered by each outstanding purchase right, the then number of authorized shares under the 2020 ESPP and the maximum number of shares that may be added to the share reserve for the 2020 ESPP in the future will be appropriately and proportionately adjusted by our Board.

If we experience a proposed liquidation or dissolution, any offering period will terminate immediately prior to the consummation of such transaction and all outstanding purchase rights will automatically terminate and the amounts of all payroll deductions will be refunded without interest to the participants. In the event of a proposed sale of all or substantially all of our assets, or our merger or consolidation or similar combination of the company with or into another entity, then in the sole discretion of our Board, (i) each purchase right will be assumed or an equivalent right substituted by the successor corporation or parent or subsidiary of such successor entity, (ii) on a date established by our Board on or before the date of consummation of such merger, consolidation, combination or sale, such date will be treated as the final purchase date of each offering period, and all outstanding purchase rights will be exercised on such date, (iii) all outstanding purchase rights will terminate and the accumulated payroll deductions will be refunded without interest to the participants, or (iv) outstanding purchase rights will continue unchanged.

The Compensation Committee may adopt rules or procedures relating to the operation and administration of the 2020 ESPP to accommodate specific requirements of local laws and jurisdictions and, if necessary, can establish sub-plans for particular foreign jurisdictions.

Our Board or Compensation Committee may terminate or suspend the 2020 ESPP at any time and may revise or amend the plan in any respect, subject to required stockholder approval.

The foregoing description of the 2020 ESPP is qualified in its entirety by reference to the complete text of the 2020 ESPP, which will be provided as an exhibit to this registration statement.

401(k) Plan

We offer our eligible full-time employees, including our NEOs, the opportunity to participate in our tax-qualified 401(k) plan. Employees can contribute 1% to 85% of their eligible earnings up to the Internal Revenue Service's annual limits on a before-tax basis, which is generally $19,500 for 2020. We provide a match of 60% of the first 10% contributed. The matches we provided to our NEOs in 2019 are reflected in the "All Other Compensation" column of the 2019 Summary Compensation Table above. The matching funds that we provide are 100% vested after the completion of one year of service.

Avero Diagnostics offers eligible full-time employees the opportunity to participate in its tax-qualified 401(k) plan. Employees can contribute 1% to 90% of their eligible earnings up to the Internal Revenue

Service's annual limits on a before-tax basis, which is generally $19,500 for 2020. Avero Diagnostics provides a match of 60% of the first 10% contributed. Avero Diagnostics funds are 100% vested after the completion of one year of service.

Other Retirement Benefits

We do not maintain any defined benefit pension plans or any nonqualified deferred compensation plans.

PRINCIPAL STOCKHOLDERS

The following table presents information regarding beneficial ownership of our equity interests as of June 1, 2020 by:

- each stockholder or group of stockholders known by us to be the beneficial owner of more than 5% of our outstanding equity interests, or our 5% and Greater Stockholders;
- each of our directors;
- our NEOs; and
- all of our directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC, and thus represents voting or investment power with respect to our securities as of June 1, 2020. Under such rules, beneficial ownership includes any shares over which the individual has sole or shared voting power or investment power as well as any shares that the individual has the right to acquire within 60 days after June 1, 2020 through the exercise of any stock option, warrants or other rights. Unless otherwise indicated below, to our knowledge and subject to applicable community property rules, the persons and entities named in the table have sole voting and sole investment power with respect to all equity interests beneficially owned, subject to community property laws where applicable. Unless otherwise indicated, the address of each individual listed in this table is 4330 La Jolla Village Drive, Suite 200, San Diego, CA 92122.

The percentage ownership information shown in the column titled “Shares Beneficially Owned Prior to the Offering” in the table below is based on 36,434,808 shares of our common stock outstanding as of June 1, 2020, assuming the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 31,398,040 shares of common stock. The percentage ownership information shown in the column titled “Shares Beneficially Owned After the Offering” in the table below is based on 45,146,997 shares of our common stock outstanding after this offering, assuming 6,666,667 shares of common stock being sold in this offering and the issuance of 2,045,522 shares of our common stock pursuant to an adjustment in the conversion rate of all of our shares of Series B Preferred Stock outstanding as of June 1, 2020 that occurs when the public offering price per share of common stock is less than $16.68, based on a public offering price of $15.00 (the midpoint of the price range set forth on the cover page of this prospectus). Shares of our common stock that a person has the right to acquire within 60 days after June 1, 2020 are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person, except with respect to the percentage ownership of all directors and executive officers as a group.
Certain of our existing stockholders, including those affiliated with members of our Board, have indicated an interest in purchasing an aggregate of up to approximately $50 million of shares of our common stock in this offering at the initial public offering price per share and on the same terms as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares of common stock to any of these potential purchasers, and any of these potential purchasers could determine to

purchase more, fewer or no shares of common stock in this offering. The following table does not reflect the purchase of any shares in this offering by these existing stockholders.

Name and Address of Beneficial Owner	Shares Beneficially Owned Prior to the Offering		Shares Beneficially Owned After the Offering(1)	
	Number	Percent	Number	Percent
5% and Greater Stockholders				
Athyrium Capital Management, LP(2)(12)	18,117,664	47.6%	19,970,016	42.7%
Named Executive Officer and Directors				
Harry Stylli, Ph.D.(3)(12)	14,186,032	38.9%	14,201,483	31.4%
Jeffrey D. Alter(4)	7,989	*	7,989	*
John T. Bigalke(5)	7,989	*	7,989	*
Jeffrey A. Ferrell(2)(12)	18,117,664	47.6%	19,970,016	42.7%
Brian L. Kotzin, M.D.(6)	7,989	*	7,989	*
Samuel R. Nussbaum, M.D.(7)	7,989	*	7,989	*
Lynne Powell(8)	7,989	*	7,989	*
Matthew Cooper(9)	91,707	*	91,437	*
Sami Shihabi(10)	50,418	*	50,040	*
All Executive Officers and Directors as a group (14 persons)(11)	32,639,814	84.9%	34,506,194	73.2%

* Represents beneficial ownership of less than one percent.

(1) Following the completion of the offering, the vesting schedule for all unvested restricted stock units will convert to equal semi-annual installments (the "Post-Offering Vesting Schedule").

(2) Consists of (a) 1,250,000 shares of common stock issuable upon the conversion of an Unsecured Convertible Promissory Note, dated as of May 8, 2020, by and between the Company and Athyrium Opportunities 2020 LP (the "Note"), with an aggregate principal amount of $15,000,000, (b) 3,786,098 shares of common stock issuable upon conversion of shares of our Series B Preferred Stock owned by Athyrium Opportunities Fund (A) LP, (c) 2,093,586 shares of common stock issuable upon conversion of shares of our Series B Preferred Stock owned by Athyrium Opportunities Fund (B) LP, (d) 6,834,284 shares of common stock issuable upon conversion of shares of our Series B Preferred Stock owned by Athyrium Opportunities III Acquisition 2 LP, (e) 3,753,536 shares of common stock issuable upon conversion of shares of our Series B Preferred Stock owned by Athyrium Opportunities III Co-Invest 1 LP, and (f) 400,160 shares of common stock issuable upon exercise of the Series B Preferred Stock Warrant (the "Warrant") owned by Athyrium Opportunities III Co-Invest 1 LP. Voting and investment power with respect to the shares of our common stock held by Athyrium Opportunities 2020 LP, Athyrium Opportunities Fund (A) LP, Athyrium Opportunities Fund (B) LP, Athyrium Opportunities III Acquisition 2 LP, and Athyrium Opportunities III Co-Invest 1 LP (collectively, the "Athyrium Entities") may be deemed to be shared by certain affiliated entities. Athyrium Opportunities Associates Co-Invest LLC is the general partner of Athyrium Opportunities III Co-Invest 1 LP, Athyrium Opportunities Associates III GP LLC is the general partner of Athyrium Opportunities Associates III LP, which is the general partner of each of Athyrium Opportunities 2020 LP and Athyrium Opportunities III Acquisition 2 LP, and Athyrium Opportunities Associates GP LLC is the general partner of Athyrium Opportunities Associates LP, which is the general partner of each of Athyrium Opportunities Fund (A) LP and Athyrium Opportunities Fund (B) LP. Jeffrey A. Ferrell, a member of our Board, is President of each of Athyrium Opportunities Associates Co-Invest LLC, Athyrium Opportunities Associates III GP LLC, and Athyrium Opportunities Associates GP LLC and in his capacity as such, may be deemed to exercise shared voting and investment power over the shares owned by the Athyrium Entities. Jeffrey A. Ferrell disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein. The business address of each of the Athyrium Entities is c/o Athyrium Capital Management, LP is 505 Fifth Avenue, Floor 18, New York, New York 10017.

(3) Consists of (a) 766,228 shares of common stock, (b) 13,394,901 shares of common stock issuable upon conversion of shares of our Series A Preferred Stock and Series B Preferred Stock, and (c) 24,903 shares of common stock underlying restricted stock units, or 19,922 based on the Post-Offering Vesting Schedule, vested as of June 1, 2020 or that will vest within 60 days after such date.

(4) Consists of (a) 2,663 shares of common stock underlying restricted stock units vested as of June 1, 2020 or that will vest within 60 days after such date and (b) 5,326 shares of common stock underlying options that are exercisable as of June 1, 2020 or will become exercisable within 60 days after such date.

(5) Consists of (a) 2,663 shares of common stock underlying restricted stock units vested as of June 1, 2020 or that will vest within 60 days after such date and (b) 5,326 shares of common stock underlying options that are exercisable as of June 1, 2020 or will become exercisable within 60 days after such date.

(6) Consists of (a) 2,663 shares of common stock underlying restricted stock units vested as of June 1, 2020 or that will vest within 60 days after such date and (b) 5,326 shares of common stock underlying options that are exercisable as of June 1, 2020 or will become exercisable within 60 days after such date.

(7) Consists of (a) 2,663 shares of common stock underlying restricted stock units vested as of June 1, 2020 or that will vest within 60 days after such date and (b) 5,326 shares of common stock underlying options that are exercisable as of June 1, 2020 or will become exercisable within 60 days after such date.

(8) Consists of (a) 2,663 shares of common stock underlying restricted stock units vested as of June 1, 2020 or that will vest within 60 days after such date and (b) 5,326 shares of common stock underlying options that are exercisable as of June 1, 2020 or will become exercisable within 60 days after such date.

(9) Consists of (a) 5,226 shares of common stock underlying restricted stock units, or 4,956 based on the Post-Offering Vesting Schedule, vested as of June 1, 2020 or that will vest within 60 days after such date and (b) 86,481 shares of common stock underlying options that are exercisable as of June 1, 2020 or will become exercisable within 60 days after such date.

(10) Consists of (a) 5,056 shares of common stock underlying restricted stock units, or 4,678 based on the Post-Offering Vesting Schedule, vested as of June 1, 2020 or that will vest within 60 days after such date and (b) 45,362 shares of common stock underlying options that are exercisable as of June 1, 2020 or will become exercisable within 60 days after such date.

(11) Consists of (a) those shares described in footnotes (2) through (10) above, (b) 6,474 shares of common stock beneficially owned by our executive officers not named in the table above, (c) 12,231 shares of common stock underlying restricted stock units, or 11,456 based on the Post-Offering Vesting Schedule, vested as of June 1, 2020 or that will vest within 60 days after such date held by our executive officers not named in the table above, and (d) 135,342 shares of common stock underlying options that are exercisable as of June 1, 2020 or will become exercisable within 60 days after such date held by our executive officers not named in the table above.

(12) The Athyrium Entities and Harry Stylli will receive 1,852,352 and 20,432 shares of common stock, respectively, immediately prior to the completion of this offering pursuant to an adjustment in the conversion rate of our Series B Preferred Stock that occurs when the public offering price per share of common stock is less than $16.68 based on a public offering price of $15.00 (the midpoint of the price range set forth on the cover page of this prospectus).

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a summary of each transaction or series of similar transactions since January 1, 2017, or any currently proposed transaction, to which we were or are a party in which:

- the amount involved exceeded or exceeds $120,000; and
- any of our directors or executive officers, any holder of 5% of any class of our voting capital stock or any member of his or her immediate family had or will have a direct or indirect material interest.

Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to such securities.

Related Party Transactions

Sales of Series B Preferred Stock

In October 2017, we entered into the Credit Agreement with Athyrium Opportunities III Co-Invest 1 LP, as collateral agent and a lender, which is a fund managed by Athyrium. Athyrium beneficially owns more than 5% of a class of our voting securities and has designated a director on our Board.

The Credit Agreement provides for a term loan of $75.0 million, which accrues interest at a rate of 9.5% and is due October 27, 2022. The term loan contains customary covenants, including a requirement that we maintain a minimum unrestricted cash balance at all times of at least $5.0 million. The term loan is secured by all of our tangible and intangible property and assets, with the exception of our intellectual property. As of December 31, 2019, $75.0 million in principal was outstanding under the term loan. Through December 31, 2019, we have paid $15.8 million in interest on the term loan.

The Credit Agreement also provided for the issuance of a warrant to purchase 1,416,431 shares of our Series B Preferred Stock at an initial exercise price of $3.53 per share. For a more detailed description of the Series B Preferred Stock Purchase Warrant, see “Description of Capital Stock—Warrant.”

A portion of the proceeds of the term loan was used to repay in full the $20.0 million of principal plus accrued and unpaid interest on a credit and security agreement we entered into in June 2013 with other funds managed by Athyrium.

On March 31, 2020, we entered into the Credit Agreement Amendment with the collateral agent and lender party thereto, providing for the payment of interest due and payable as of March 31, 2020 in shares of our Series B Preferred Stock, and further providing for the payment of interest due and payable as of June 30, 2020 in shares of our Series B Preferred Stock in the event this offering has not been consummated by such date. Pursuant to the Credit Agreement Amendment, we concurrently entered into a Series B Preferred Stock Subscription Agreement, or the Subscription Agreement, with the lender, which provided for the issuance of 967,130 shares of Series B Preferred Stock at a subscription price of $2.25 per share, as payment for interest due and payable as of March 31, 2020 and all applicable fees as set forth in the Credit Agreement Amendment. The Subscription Agreement further provided for a potential additional issuance of shares of Series B Preferred Stock as payment for the interest due and payable under the Credit Agreement as of June 30, 2020, in the event this offering has not been consummated by such date, with the amount of shares to be determined at such time.

On May 6, 2020, in connection with the issuance and sale of the Convertible Note described below, we entered into the Second Credit Agreement Amendment allowing for the creation or incurrence of certain indebtedness and the making of payments, in each case, in respect of the Convertible Note, among other matters.

In October 2017, we also completed an equity financing and issued and sold an aggregate of 14,164,306 shares of our newly created Series B Preferred Stock at a purchase price of $3.53 per share. We issued and sold the shares of Series B Preferred Stock pursuant to a stock purchase agreement entered into with Athyrium Opportunities III Co-Invest 1 LP, a fund managed by Athyrium, for an aggregate purchase price of approximately $50.0 million. Each share of our Series B Preferred Stock is convertible into one share of common stock. The purchase price was paid in the form of (i) cash in an amount equal to $37.5 million and (ii) the delivery of 3,489,885 shares of our Series A-2 Preferred Stock, which shares of Series A-2 Preferred Stock had been purchased from Dr. Stylli, our Chairman and Chief Executive Officer, for $12.5 million.

In August 2019, we completed an equity financing and issued and sold an aggregate of 9,090,910 shares of our Series B Preferred Stock at a purchase price of $2.75 per share. The shares were issued and sold pursuant to a stock purchase agreement entered into with Athyrium Opportunities III Acquisition LP, a fund managed by Athyrium, a beneficial owner of more than 5% of a class of our voting securities, for an aggregate purchase price of $25.0 million. Each share of our Series B Preferred Stock is convertible into one share of common stock. Concurrent with the issuance, we offered all holders of our Series A-1 Preferred Stock the opportunity to exchange their shares of Series A-1 Preferred Stock for Series B Preferred Stock. All holders of Series A-1 Preferred Stock exchanged all of their shares of Series A-1 Preferred Stock (an aggregate amount of 1,500,000 shares) for an aggregate of 35,664,240 shares of Series B Preferred Stock. In connection with the issuance, we amended and restated our Investors' Rights Agreement, Co-Sale Agreement, and Voting Agreement, as described in further detail below.

On November 12, 2019, we entered into a stock purchase agreement pursuant to which we issued and sold 11,111,111 shares of our Series B Preferred Stock to Athyrium Opportunities III Acquisition 2 LP, a fund managed by Athyrium, at a purchase price of $2.25 per share for an aggregate purchase price of $25.0 million. A 1.22222222-for-1 stock split for our Series B Preferred Stock shares and Series B Preferred Stock Purchase Warrant issued and outstanding was effected on November 12, 2019 pursuant to an amendment and restatement of our certificate of incorporation. The conversion price of the Series B Preferred Stock and exercise price of the outstanding Series B Preferred Stock Warrant were automatically adjusted from $2.75 to $2.25 per share (or $13.90 per share as a result of the reverse stock split effected on June 10, 2020). As a result of the stock split effected on November 12, 2019, we issued an additional 13,985,993 shares of Series B Preferred Stock and adjusted the Series B Preferred Stock to be a warrant to purchase 2,222,222 shares of Series B Preferred Stock.

On November 22, 2019, we completed an additional equity financing pursuant to a stock purchase agreement executed on November 12, 2019 with Beaver Creek Intermediate Fund, Ltd., an existing investor and Dr. Stylli, our Chairman and Chief Executive Officer, for an aggregate purchase price of $6.1 million. We issued an aggregate of 2,722,222 shares of Series B Preferred Stock at a purchase price of $2.25 per share.

On December 19, 2019, we completed an additional equity financing pursuant to a stock purchase agreement executed on November 12, 2019 with Athyrium Opportunities III Acquisition 2 LP for an aggregate purchase price of $25.0 million. We issued on aggregate of 11,111,111 shares of Series B Preferred Stock at a purchase price of $2.25 per share.

On February 28, 2020, we completed an additional equity financing pursuant to a stock purchase agreement executed on November 12, 2019 with Athyrium Opportunities III Acquisition 2 LP and Dr. Stylli, our Chairman and Chief Executive Officer, for an aggregate purchase price of $11.4 million. We issued an aggregate of 5,066,666 shares of Series B Preferred Stock at a purchase price of $2.25 per share.

On April 3, 2020, we entered into a stock purchase agreement pursuant to which we issued and sold 4,444,444 shares of our Series B Preferred Stock to Athyrium Opportunities III Acquisition 2 LP, at a purchase price of $2.25 per share for an aggregate purchase price of $10.0 million.

On May 8, 2020, we entered into a note purchase agreement with Athyrium Opportunities 2020 LP, a fund managed by Athyrium, pursuant to which we issued and sold an unsecured convertible promissory note, or the Convertible Note, with an annual interest rate of 8.0% and in an aggregate principal amount of $15.0 million. The Convertible Note has a maturity date of May 8, 2022 and, in connection with this offering, is convertible at the option of the holder into shares of our common stock at a per share conversion price of the lesser of $13.90 and eighty percent of the public price. Based on a public offering price of $15.00 (the midpoint of the price range set forth on the cover page of this prospectus), 1,250,000 shares of our common stock will be issuable upon conversion of the Convertible Note. In connection with the issuance and sale of the Convertible Note, we entered into the Second Amendment to Series B Preferred Stock Warrant, dated May 8, 2020, providing for the removal of certain restrictive exercise provisions in the Series B Preferred Stock Purchase Warrant.

Fourth Amended and Restated Investors' Rights Agreement

We are party to a fourth amended and restated investors' rights agreement, effective as of August 27, 2019, which provides certain holders of our capital stock, including Dr. Stylli and funds managed by Athyrium, with certain registration rights, including the right to demand that we file a registration statement or request that their shares be covered by a registration statement that we are otherwise filing. For a more detailed description of these registration rights, see "Description of Capital Stock—Registration Rights."

Fourth Amended and Restated Voting Agreement

We are party to a fourth amended and restated voting agreement, effective as of August 27, 2019, under which certain holders of our capital stock, including Dr. Stylli, funds managed by Athyrium, and three of our founders, which three founders are referred to as the Key Holders, have agreed to vote in a certain way on certain matters, including with respect to the election of our directors. All of our current directors were elected pursuant to the terms of this agreement. The fourth amended and restated voting agreement will terminate upon the completion of this offering.

Fourth Amended and Restated Co-Sale Agreement

We are party to a fourth amended and restated co-sale agreement, effective as of August 27, 2019, with certain holders of our capital stock, including Dr. Stylli and funds managed by Athyrium, pursuant to which we have a right of first refusal on certain transfers of our shares by the Key Holders, holders of our preferred stock have a secondary right of first refusal on such transfers, and such preferred stock holders have a right of co-sale in respect of such transfers. The fourth amended and restated co-sale agreement will terminate upon the completion of this offering.

Guarantee by Dr. Stylli

On May 21, 2020, in connection with our proposed government settlement described under "Business—Legal Proceedings—Federal Investigation," the government required a guarantee of a portion of our obligations to the government by one or more of our significant stockholders, and Dr. Stylli, our Chairman and Chief Executive Officer, agreed to provide such a guarantee, and reached an agreement in principle with the government to personally guarantee payment of our obligations to the government up to an amount of $5 million. Additional terms of the guarantee remain subject to negotiation.

Indications of Interest to Participate in this Offering

Certain of our existing stockholders, including those affiliated with members of our Board, have indicated an interest in purchasing an aggregate of up to approximately $50 million of shares of our common stock in this offering at the initial public offering price per share and on the same terms as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares of common stock to any of these potential purchasers, and any of these potential purchasers could determine to purchase more, fewer or no shares of common stock in this offering.

Related Party Transaction Policy

Prior to this offering, we did not have a formal policy regarding approval of transactions with related parties. To date, all transactions with related parties have been approved by the directors not interested in the transaction pursuant to Section 144(a)(1) of the Delaware General Corporation Law. We will adopt a related party transaction policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related person transactions. The policy will become effective upon the execution of the underwriting agreement for this offering. For purposes of our policy only, a related person transaction is a transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we and any related person are, were or will be participants in which the amount involved exceeds $100,000. A related person is any executive officer, director, or beneficial owner of more than 5% of any class of our voting securities, including any of their immediate family members and any entity owned or controlled by such persons. Transactions involving compensation for services provided to us as an employee or director, among other limited exceptions, are deemed to have standing pre-approval by the Audit Committee but may be specifically reviewed if appropriate in light of the facts and circumstances.

Under the policy, if a transaction has been identified as a related party transaction, including any transaction that was not a related party transaction when originally consummated or any transaction that was not initially identified as a related party transaction prior to consummation, our management must present information regarding the related party transaction to our Audit Committee for review, consideration and approval or ratification. The presentation must include a description of, among other matters, the material facts, the interests, direct and indirect, of the related persons, the benefits to us of the transaction and whether the transaction is on terms that are comparable to the terms available to or from, as the case may be, an unrelated third party or to or from employees generally. Under the policy, we will collect information that we deem reasonably necessary from each director, executive officer and, to the extent feasible, significant stockholder to enable us to identify any existing or potential related party transactions and to effectuate the terms of the policy. In addition, under our Code of Conduct and Ethics, our employees and directors have an affirmative responsibility to disclose any transaction or relationship that reasonably could be expected to give rise to a conflict of interest. In considering related party transactions, our Audit Committee will take into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;
- the impact on a director’s independence in the event that the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties or to or from employees generally

The policy requires that, in determining whether to approve, ratify, or reject a related party transaction, our Audit Committee consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, our best interests and those of our stockholders, as our Audit Committee determines in the good faith exercise of its discretion.

The related party transactions described above were consummated prior to our adoption of the formal, written policy described above, and, accordingly, the foregoing policies and procedures were not followed with respect to these transactions. However, we believe that the terms obtained or consideration that we paid or received, as applicable, in connection with the transactions described below were comparable to terms available or the amounts that would be paid or received, as applicable, in arms-length transactions at such time.

DESCRIPTION OF CAPITAL STOCK

General

The following is a summary of the material terms of our capital stock, as well as other material terms of our eighth amended and restated certificate of incorporation and amended and restated bylaws, as each will be in effect immediately prior to the completion of this offering, and certain provisions of Delaware law. This summary does not purport to be complete and is qualified in its entirety by the provisions of our eighth amended and restated certificate of incorporation and amended and restated bylaws, copies of which will be filed with the SEC as exhibits to the registration statement, of which this prospectus forms a part.

Upon the completion of this offering, our authorized capital stock will consist of 350,000,000 shares of common stock, $0.001 par value per share, and 10,000,000 shares of "blank check" preferred stock, $0.001 par value per share.

As of June 15, 2020, 5,053,566 shares of our common stock and 116,465,645 shares of preferred stock were outstanding and held by 114 stockholders of record. This amount does not take into account the conversion of all outstanding shares of our preferred stock into common stock upon the completion of this offering.

Common Stock

Our eighth amended and restated certificate of incorporation will authorize the issuance of up to 350,000,000 shares of our common stock. All outstanding shares of our common stock are validly issued, fully paid and nonassessable, and the shares of our common stock to be issued in connection with this offering will be validly issued, fully paid and nonassessable.

The holders of our common stock will be entitled to one vote per share on all matters submitted to a vote of stockholders, and our eighth amended and restated certificate of incorporation will not provide for cumulative voting in the election of directors. The holders of our common stock will receive ratably any dividends declared by our Board out of funds legally available therefor. In the event of our liquidation, dissolution, or winding-up, the holders of our common stock will be entitled to share ratably in all assets remaining after payment of or provision for any liabilities.

Preferred Stock

As of June 15, 2020, there were 116,465,645 shares of our preferred stock outstanding, which will convert into 33,443,562 shares of our common stock upon the completion of this offering (and includes 2,045,522 shares of our common stock issuable pursuant to an adjustment in the conversion rate of all of our shares of Series B Preferred Stock outstanding on the date hereof that occurs when the public offering price per share of common stock is less than $16.68), based on a public offering price of $15.00 (the midpoint of the price range set forth on the cover page of this prospectus).

Upon completion of this offering, all of our previously outstanding shares of preferred stock will have been converted into shares of our common stock and we will have no shares of preferred stock outstanding. Under the terms of our eighth amended and restated certificate of incorporation, our Board will have the authority, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the dividend, voting and other rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our Board may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring, or preventing a change in our control and may adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. We have no current plans to issue any shares of preferred stock.

Warrant

In connection with the Credit and Security Agreement we entered into with Athyrium Opportunities III Co-Invest 1 LP, an affiliate of Athyrium Capital Management, LP, and the other lenders party thereto, we issued to Athyrium Opportunities III Co-Invest 1 LP a warrant to purchase 1,416,431 shares of our Series B Preferred Stock at an initial exercise price of $3.53 per share. The Series B Preferred Stock Purchase Warrant provides for the adjustment of the exercise price and the number of shares issuable upon the exercise of the warrant in the event of certain stock dividends, stock splits, recapitalizations, reclassifications, consolidations and other fundamental transactions. Upon the completion of this offering, the Series B Preferred Stock Purchase Warrant will be exercisable for the number of shares of our common stock that would be issuable on conversion of the shares of our Series B Preferred Stock that could otherwise be purchased pursuant to the warrant. In addition, if the initial public offering price of the shares of our common stock sold in this offering is less than the exercise price per share of our common stock that is otherwise payable under the Series B Preferred Stock Purchase Warrant, the exercise price will be decreased to equal the initial public offering price in this offering.

On August 27, 2019, the company and Athyrium Opportunities III Co-Invest 1 LP amended the Series B Preferred Stock Purchase Warrant in connection with the share split of the Series B Preferred Stock, which share split became effective upon the filing of our fifth amended and restated certificate of incorporation. Pursuant to the first amendment, we adjusted the Series B Preferred Stock Purchase Warrant to be a warrant to purchase 1,818,182 shares of our Series B Preferred Stock at an initial exercise price of $2.75.

On November 12, 2019, the Series B Preferred Stock Purchase Warrant was adjusted pursuant to its terms in connection with the share split of the Series B Preferred Stock, which share split became effective upon the filing of the sixth amended and restated certificate of incorporation. Pursuant to the terms of the Series B Preferred Stock Purchase Warrant, we adjusted the Series B Preferred Stock Purchase Warrant to be a warrant to purchase 2,222,222 shares of our Series B Preferred Stock at an initial exercise price of $2.25 (or $13.90 per share as a result of the reverse stock split effected on June 10, 2020).

On May 8, 2020, the Series B Preferred Stock Purchase Warrant was further amended pursuant to the Second Amendment to Series B Preferred Stock Purchase Warrant, pursuant to which certain restrictive exercise provisions were removed from the Series B Preferred Stock Purchase Warrant in connection with the issuance and sale of the Convertible Note.

As of June 4, 2020, the Series B Preferred Stock Purchase Warrant is exercisable for an aggregate of 2,222,222 shares of our Series B Preferred Stock at an exercise price of $2.25 per share (or $13.90 per share as a result of the reverse stock split effected on June 10, 2020) and after the completion of this offering, it is exercisable into 400,160 shares of our common stock, including 40,461 shares issuable pursuant to an adjustment in the conversion rate of all of our shares of Series B Preferred Stock outstanding as of the date hereof that occurs when the public offering price per share of common stock is less than $16.68, based on a public offering price of $15.00 (the midpoint of the price range set forth on the cover page of this prospectus), until its expiration on October 27, 2022.

Registration Rights

We are party to a fourth amended and restated investors' rights agreement which provides that holders of 116,465,645 shares of our preferred stock and certain holders of 3,720,825 shares of our common stock have certain registration rights described below. The registration of shares of our common stock pursuant to the exercise of registration rights described below would enable holders to sell these shares without restriction under the Securities Act when the registration statement is declared effective. We will pay all expenses related to any demand, piggyback, or Form S-3 registration described below, with the exception of underwriting discounts and commissions.

The registration rights described below will expire (i) five years after the completion of this offering, (ii) with respect to any particular holder, at the time that such holder can sell all its registrable securities under Rule 144 or another similar exemption under the Securities Act without limitation during a three-month period without registration or (iii) upon termination of the fourth amended and restated investors' rights agreement.

Demand Registration Rights

At any time beginning 210 days after the effective date of the registration statement of which this prospectus forms a part, the holders of 50% or more of the registrable securities then outstanding may make a written request that we register all or a portion of their shares, subject to certain specified exceptions. Such request for registration must cover securities with an aggregate offering price, net of underwriting discounts and commissions, of at least $20,000,000. We will prepare and file a registration statement as requested, unless, in the good faith judgment of our Board, such registration would be seriously detrimental to the company and its stockholders and filing should be deferred. We may defer only once in any 12-month period, and such deferral shall not exceed 120 days after receipt of the request. In addition, we are not obligated to effect more than two of these registrations within any twelve 12-month period or if the holders' proposed registered securities may be immediately registered on Form S-3.

Piggyback Registration Rights

Subject to certain specified exceptions, if we propose to register any of our securities under the Securities Act either for our own account or for the account of other stockholders, the holders of shares having registration rights are entitled to written notice and certain "piggyback" registration rights allowing them to include their shares in our registration statement. These registration rights are subject to specified conditions and limitations, including the right of the underwriters, in their sole discretion, to limit the number of shares included in any such offering under certain circumstances, but not below 15% of the total amount of securities included in such offering, unless (i) such offering is the initial public offering or (ii) all other securities, other than our securities, are entirely excluded from the offering.

Form S-3 Registration Rights

At any time after we are qualified to file a registration statement on Form S-3, and subject to limitations and conditions, the holders of 50% or more of the registrable securities then outstanding are entitled to written notice of such registration and may make a written request that we prepare and file a registration statement on Form S-3 under the Securities Act covering their shares, so long as the aggregate price to the public, net of the underwriters' discounts and commissions, is at least $10,000,000. We will prepare and file the Form S-3 registration as requested, unless, in the good faith judgment of our board of directors, such registration would be seriously detrimental to the company and its stockholders and filing should be deferred. We may defer only once in any 12-month period, and such deferral shall not exceed 120 days after receipt of the request. In addition, we are not obligated to prepare or file any of these registration statements (i) within 180 days after the effective date of a registration statement pursuant to demand or piggyback registration rights or (ii) if two of these registrations have been completed within any 12-month period.

Our Certificate of Incorporation and Our Bylaws

Special Meetings; Action by Written Consent

Under our eighth amended and restated certificate of incorporation, only a majority of the members of our Board then in office may be able to call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Under our eighth amended and restated certificate of incorporation, stockholders will be permitted to take action by written consent with respect to any matter that can be acted upon at a meeting of our stockholders for so long as Dr. Stylli, entities affiliated with Athyrium Capital Management, LP and entities affiliated with Andrew Midler collectively own more than 50% of our issued and outstanding common stock. Such holders currently collectively own 89.3% shares of our issued and outstanding common stock on an as-converted basis and will collectively own 78.2% of our issued and outstanding common stock after giving effect to this offering but without giving effect to any shares they may purchase in this offering. In all other circumstances, our eighth amended and restated certificate of incorporation provides that stockholders may not take any action by written consent in lieu of a meeting. This limit may lengthen the amount of time required to take stockholder actions and would prevent the amendment of our amended and restated bylaws or removal of directors by our stockholders without holding a meeting of stockholders.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Our amended and restated bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors that specify certain requirements as to the timing, form, and content of a stockholder's notice. Business that may be conducted at an annual meeting of stockholders will be limited to those matters properly brought before the meeting. These provisions may make it more difficult for our stockholders to nominate directors at or bring other matters before our annual meeting.

Election and Removal of Directors

Directors will be elected by a plurality vote. Our Board will have the exclusive right to increase or decrease the size of the Board and to fill vacancies on the Board. These provisions prevent stockholders from increasing the size of our Board and filling the resulting vacancies. Directors may be removed with or without cause with the approval of the holders of a majority of our outstanding common stock.

Issuance of Undesignated Preferred Stock

Under our eighth amended and restated certificate of incorporation, our Board has the authority, without further action by the stockholders, to issue up to 10,000,000 shares of undesignated preferred stock with rights and preferences, including voting rights, designated from time to time by our Board. Depending on the rights and terms of any new series of preferred stock created, rights of existing stockholders could be negatively affected. The existence of authorized but unissued shares of preferred stock enables our Board to make it more difficult to attempt to obtain control of us by means of a merger, tender offer, proxy contest, or otherwise.

Delaware General Corporation Law Section 203

As a Delaware corporation, we are also subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which prohibits a Delaware corporation from engaging in a business combination specified in the statute with an interested stockholder (as defined in the statute) for a period of three years after the date of the transaction in which the person first becomes an interested stockholder, unless the business combination is approved in advance by a majority of the independent directors or by the holders of at least two-thirds of the outstanding disinterested shares. The application of Section 203 of the Delaware General Corporation Law could also have the effect of delaying or preventing a change of control of us.

Exclusive Forum Selection Clause

Our eighth amended and restated certificate of incorporation will provide that, unless we consent in writing to the selection of an alternative forum, the sole and exclusive forum to the fullest extent permitted by law for: (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a breach of fiduciary duty owed by any director, officer or other employee to us or our stockholders; (3) any action asserting a claim against us or any director or officer or other employee arising pursuant to the Delaware General Corporation Law; (4) any action to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or bylaws; or (5) any other action asserting a claim that is governed by the internal affairs doctrine, shall be the Court of Chancery of the State of Delaware (or another state court or the federal court located within the State of Delaware if the Court of Chancery does not have or declines to accept jurisdiction), in all cases subject to the court's having jurisdiction over indispensable parties named as defendants. In addition, our eighth amended and restated certificate of incorporation will provide that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act but the forum selection provisions will not apply to claims brought to enforce a duty or liability created by the Exchange Act. Although we believe these provisions benefit us by providing increased consistency in the application of Delaware law for the specified types of actions and proceedings, the provisions may have the effect of discouraging lawsuits against us or our directors or officers.

Transfer Agent and Registrar

American Stock Transfer and Trust Company, LLC will serve as the transfer agent and registrar for our common stock.

Listing

We have applied to list our common stock on The Nasdaq Global Select Market under the symbol "PROG."

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for shares of our common stock. Future sales of our common stock, including shares issued upon the vesting of restricted stock units or the exercise of options or warrants, in the public market after this offering, or the perception that those sales may occur, could cause the prevailing market price for our common stock to fall or impair our ability to raise equity capital in the future. As described below, only a limited number of shares of our common stock will be available for sale in the public market for a period of several months after the completion of this offering due to the contractual and legal restrictions on resale described below. Future sales of our common stock in the public market either before (to the extent permitted) or after restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price of our common stock at such time and our ability to raise equity capital at a time and price we deem appropriate.

Sale of Restricted Shares

Immediately following the completion of this offering, we will have an aggregate of 45,163,795 shares of common stock outstanding (or 46,163,795 shares if the underwriters exercise in full their option to purchase additional shares). Of these outstanding shares of our common stock, all of the shares of common stock sold in this offering (plus any shares purchased by the underwriters pursuant to the exercise of their option to purchase additional shares) will be freely tradable without restriction or further registration under the Securities Act, except that any such shares held by our affiliates, as that term is defined in Rule 144 of the Securities Act, may generally be sold only in compliance with the limitations described below. All remaining shares of our common stock held by existing stockholders immediately prior to the completion of this offering will be "restricted securities" as such term is defined in Rule 144. These restricted securities were issued and sold by us, or will be issued and sold by us, in private transactions and are eligible for public sale only if registered under the Securities Act or if they qualify for an exemption from registration under the Securities Act, including the exemptions provided by Rule 144 or Rule 701, which rules are summarized below.

Lock-Up Agreements

We and all of our directors and officers, as well as the other holders of substantially all shares of our common stock outstanding immediately prior to the completion of this offering, have agreed with the underwriters that, for a period of 180 days following the date of this prospectus, subject to certain exceptions, we and they will not, directly or indirectly, offer, pledge, announce the intention to sell, contract to sell, sell any option or contract to purchase, sell any option or contract to purchase, grant any option, right or warrant to purchase, make any short sale or otherwise transfer or dispose of any of shares of our common stock, or any options or warrants to purchase any shares of our common stock, or any securities convertible into, or exchangeable for or that represent the right to receive shares of our common stock. Piper Sandler & Co. and Wells Fargo Securities, LLC may, in their sole discretion, release all or any portion of the shares from these restrictions.

Rule 144

In general, under Rule 144, as currently in effect, once we have been subject to the public company reporting requirements of the Exchange Act for at least 90 days, a person (or persons whose shares are required to be aggregated) who is not deemed to have been one of our "affiliates" for purposes of Rule 144 at any time during the three months preceding a sale, and who has beneficially owned restricted securities within the meaning of Rule 144 for at least six months, including the holding period of any prior owner other than one of our "affiliates," is entitled to sell those shares in the public market (subject to the lock-up agreement referred to above, if applicable) without complying with the manner of sale, volume limitations or notice provisions of Rule 144, but subject to compliance with the public information requirements of Rule 144. If such a person has beneficially owned the shares proposed to be

sold for at least one year, including the holding period of any prior owner other than affiliates, then such person is entitled to sell such shares in the public market without complying with any of the requirements of Rule 144 (subject to the lock-up agreement referred to above, if applicable). In general, under Rule 144, as currently in effect, once we have been subject to the public company reporting requirements of the Exchange Act for at least 90 days, our affiliates, as defined in Rule 144, who have beneficially owned the shares proposed to be sold for at least six months are entitled to sell in the public market, upon expiration of any applicable lock-up agreements and within any three-month period, a number of those shares of our common stock that does not exceed the greater of:

- one percent of the number of shares of our common stock then outstanding, which will equal approximately 451,638 shares of our common stock immediately after this offering (calculated on the basis of the assumptions described above and assuming no exercise of the underwriters' option to purchase additional shares of our common stock); or
- the average weekly trading volume of our common stock on The Nasdaq Global Select Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Such sales under Rule 144 by our "affiliates" or persons selling shares on behalf of our "affiliates" are also subject to certain manner of sale provisions, notice requirements and to the availability of current public information about us. Notwithstanding the availability of Rule 144, the holders of substantially all of our restricted securities have entered into lock-up agreements as referenced above and their restricted securities will become eligible for sale (subject to the above limitations under Rule 144) upon the expiration of the restrictions set forth in those agreements.

Rule 701

In general, under Rule 701, as currently in effect, any of our employees, directors, officers, consultants, or advisors who acquired common stock from us in connection with a written compensatory stock or option plan or other written agreement in compliance with Rule 701 under the Securities Act before the effective date of the registration statement of which this prospectus is a part (to the extent such common stock is not subject to a lock-up agreement) is entitled to rely on Rule 701 to resell such shares beginning 90 days after we become subject to the public company reporting requirements of the Exchange Act in reliance on Rule 144, but without compliance with the holding period requirements contained in Rule 144. Accordingly, subject to any applicable lock-up agreements, beginning 90 days after we become subject to the public company reporting requirements of the Exchange Act, under Rule 701, persons who are not our affiliates, as defined in Rule 144, may resell those shares without complying with the minimum holding period or public information requirements of Rule 144, and persons who are our affiliates may resell those shares without compliance with Rule 144's minimum holding period requirements (subject to the terms of the lock-up agreements referred to above, if applicable). In addition, after the effective date of this offering, we plan to register on a Form S-8 registration statement all shares of our common stock that we may issue under our equity compensation plans. As a result, these shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates, and subject to any lock-up agreements.

Upon expiration of the 180-day lock-up period described above, all shares of our common stock will be eligible for sale under Rule 144 (including shares issued pursuant to Rule 701). We cannot estimate the timing or the number of shares that our existing stockholders and other equity holders may elect to sell under Rule 144 or pursuant to registration statements. For a description of certain registration rights granted, see "Description of Capital Stock—Registration Rights."

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following discussion is a summary of material U.S. federal income tax consequences to Non-U.S. Holders (as defined below) of the purchase, ownership, and disposition of our common stock issued pursuant to this offering. The discussion does not purport to be a complete analysis of all potential tax consequences. The consequences of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or non-U.S. tax laws, are not discussed. This discussion is based on the Code, Treasury Regulations promulgated under the Code, judicial decisions and published rulings and administrative pronouncements of the U.S. Internal Revenue Service, or IRS, in each case in effect as of the date hereof. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a Non-U.S. Holder of our common stock. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the tax consequences of the purchase, ownership, and disposition of our common stock.

This discussion is limited to Non-U.S. Holders that hold our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a Non-U.S. Holder's particular circumstances, including without limitation the impact of the alternative minimum tax or the Medicare contribution tax on net investment income. In addition, it does not address consequences relevant to Non-U.S. Holders subject to special rules, including, without limitation:

- U.S. expatriates and former citizens or long-term residents of the United States;
- persons holding our common stock as part of a hedge, straddle or other risk-reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies and other financial institutions;
- brokers, dealers or traders in securities;
- "controlled foreign corporations," "passive foreign investment companies" and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements classified as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation; and
- tax-qualified retirement plans.

If an entity or arrangement classified as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Accordingly, partnerships holding our common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

This discussion is for informational purposes only and is not tax advice. Investors should consult their tax advisors with respect to the application of the U.S. federal income tax laws to their particular situations as well as any tax consequences of the purchase, ownership and disposition of our common stock arising under the U.S. federal estate or gift tax laws or under the laws of any state, local or non-U.S. taxing jurisdiction or under any applicable income tax treaty.

Definition of a Non-U.S. Holder

For purposes of this discussion, a "Non-U.S. Holder" is any beneficial owner of our common stock that is neither a "U.S. person" nor an entity or arrangement classified as a partnership for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that: (i) is subject to the primary supervision of a U.S. court and the control of one or more "United States persons" (within the meaning of Section 7701(a)(30) of the Code); or (ii) has a valid election in effect to be treated as a U.S. person for U.S. federal income tax purposes.

Distributions

As described in the section entitled "Dividend Policy," we have no present intention to pay cash dividends on our common stock. However, if we make distributions of cash or other property on our common stock, those distributions will generally constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If the amount of such distributions exceed our current and accumulated earnings and profits, such excess will generally constitute a tax-free return of capital and will first be applied against and reduce a Non-U.S. Holder's adjusted tax basis in its common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described below under "Sale or Other Taxable Disposition."

Subject to the discussion below on effectively connected income, dividends paid to a Non-U.S. Holder of our common stock generally will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty, provided the Non-U.S. Holder furnishes the applicable withholding agent with documentation required to claim benefits under such tax treaty (generally, a valid IRS Form W-8BEN or W-8BEN-E or a suitable successor or substitute form)). A Non-U.S. Holder that does not timely furnish the required documentation, but that qualifies for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding U.S. federal withholding tax on distributions, including their eligibility for benefits under any applicable income tax treaties and the availability of a refund on any excess U.S. federal tax withheld.

If dividends paid to a Non-U.S. Holder are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (or, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such dividends are attributable), the Non-U.S. Holder will generally be exempt from the U.S. federal withholding tax described above. To claim the exemption, the Non-U.S. Holder must furnish to the applicable withholding agent a valid IRS Form W-8ECI (or a suitable successor or substitute form) certifying that the dividends are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States.

However, any such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular rates applicable to U.S. persons. A Non-U.S. Holder that is a corporation also

may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected dividends, as adjusted for certain items. Non-U.S. Holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

The foregoing discussion is subject to the discussion below under "Additional Withholding Tax on Payments Made to Foreign Accounts" and "Information Reporting and Backup Withholding."

Sale or Other Taxable Disposition

Subject to the discussion below regarding backup withholding and the Foreign Account Tax Compliance Act, or FATCA, a Non-U.S. Holder generally will not be subject to U.S. federal income or withholding tax on any gain realized upon the sale or other taxable disposition of our common stock unless:

- the gain is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (or, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such gain is attributable);
- the Non-U.S. Holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- our common stock constitutes a U.S. real property interest, or USRPI, by reason of our status as a U.S. real property holding corporation, or USRPHC, for U.S. federal income tax purposes.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular rates applicable to U.S. persons. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items.

Gain described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty), which may be offset by U.S. source capital losses of the Non-U.S. Holder (even though the individual is not considered a resident of the United States), provided the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we currently are not, and we do not anticipate becoming, a USRPHC. However, because the determination of whether we are a USRPHC depends on the fair market value of our USRPIs relative to the fair market value of our non-U.S. real property interests and our other business assets, we cannot assure you that we will not become a USRPHC in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition by a Non-U.S. Holder of our common stock will not be subject to U.S. federal income tax if our common stock is "regularly traded" on an "established securities market" (as such terms are defined by applicable Treasury Regulations), and such Non-U.S. Holder owned, actually and constructively, 5% or less of our common stock throughout the shorter of the 5-year period ending on the date of the sale or other taxable disposition or the Non-U.S. Holder's holding period. If we are determined to be a USRPHC and the foregoing exception does not apply, the Non-U.S. Holder generally will be taxed on its net gain derived from the disposition at the U.S. federal income tax rates applicable to U.S. persons. No assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rules described above.

Non-U.S. Holders should consult their tax advisors regarding potentially applicable income tax treaties that may provide for different rules.

Information Reporting and Backup Withholding

Payments of dividends on our common stock generally will not be subject to backup withholding provided the applicable withholding agent does not have actual knowledge or reason to know the Non-U.S. Holder is a U.S. person and the Non-U.S. Holder certifies its non-U.S. status by furnishing a valid IRS Form W-8BEN, W-8BEN-E, W-8ECI, W-8EXP, or other applicable IRS form, or otherwise establishes an exemption. Information returns are required to be filed with the IRS in connection with any dividends on our common stock paid to the Non-U.S. Holder, regardless of whether any tax was actually withheld. Copies of these information returns may also be made available under the provisions of an applicable treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides or is established.

Information reporting and, depending on the circumstances, backup withholding generally will apply to the proceeds of the sale or other taxable disposition of our common stock within the United States or conducted through certain U.S.-related brokers, unless the applicable withholding agent receives the certification described above and does not have actual knowledge or reason to know that the Non-U.S. Holder is a U.S. person, or the holder otherwise establishes an exemption. Proceeds of a disposition of our common stock conducted through a non-U.S. office of a non-U.S. broker that does not have certain enumerated relationships with the United States generally will not be subject to backup withholding or information reporting.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a Non-U.S. Holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

Additional Withholding Tax on Payments Made to Foreign Accounts

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code (such Sections commonly referred to as FATCA) on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends on, or (subject to the proposed Treasury Regulations discussed below) gross proceeds from the sale or other disposition of, our common stock paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless: (i) the foreign financial institution undertakes certain diligence, reporting and withholding obligations; (ii) the non-financial foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or furnishes identifying information regarding each substantial U.S. owner; or (iii) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence, reporting and withholding requirements in (i) above, it must enter into an agreement with the U.S. Treasury requiring, among other things, that it undertake to identify accounts held by certain "specified United States persons" or "United States owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to noncompliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the U.S. governing FATCA may be subject to different rules.

The U.S. Treasury recently released proposed regulations which, if finalized in their present form, would eliminate the federal withholding tax of 30% applicable to the gross proceeds of a sale or other disposition of our common stock. In its preamble to such proposed regulations, the U.S. Treasury stated that taxpayers may generally rely on the proposed regulations until final regulations are issued. There can be no assurance that final regulations would provide an exemption from the FATCA withholding tax

for gross proceeds. The FATCA withholding tax generally applies to all withholdable payments without regard to whether the beneficial owner of the payment would otherwise be entitled to an exemption from imposition of withholding tax pursuant to an applicable tax treaty with the United States or U.S. domestic law.

Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our common stock.

UNDERWRITING

Subject to the terms and conditions set forth in the underwriting agreement, dated , 2020, among us and Piper Sandler & Co. and Wells Fargo Securities, LLC, as the representatives of the underwriters named below and the joint book-running managers of this offering, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the respective number of shares of common stock shown opposite its name below:

Underwriter	Number of Shares
Piper Sandler & Co.	
Wells Fargo Securities, LLC	
Robert W. Baird & Co. Incorporated	
Raymond James & Associates, Inc.	
BTIG, LLC	
Total	6,666,667

The underwriting agreement provides that the obligations of the several underwriters are subject to certain conditions precedent such as the receipt by the underwriters of officers' certificates and legal opinions and approval of certain legal matters by their counsel. The underwriting agreement provides that the underwriters will purchase all of the shares of common stock if any of them are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated. We have agreed to indemnify the underwriters and certain of their controlling persons against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make in respect of those liabilities.

The underwriters have advised us that, following the completion of this offering, they currently intend to make a market in the common stock as permitted by applicable laws and regulations. However, the underwriters are not obligated to do so, and the underwriters may discontinue any market-making activities at any time without notice in their sole discretion. Accordingly, no assurance can be given as to the liquidity of the trading market for the common stock, that you will be able to sell any of the common stock held by you at a particular time or that the prices that you receive when you sell will be favorable.

The underwriters are offering the shares of common stock subject to their acceptance of the shares of common stock from us and subject to prior sale. The underwriters reserve the right to withdraw, cancel, or modify offers to the public and to reject orders in whole or in part. In addition, the underwriters have advised us that they do not intend to confirm sales to any account over which they exercise discretionary authority.

Certain of our existing stockholders, including those affiliated with members of our Board, have indicated an interest in purchasing an aggregate of up to approximately $50 million of shares of our common stock in this offering at the initial public offering price per share and on the same terms as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares of common stock to any of these potential purchasers, and any of these potential purchasers could determine to purchase more, fewer or no shares of common stock in this offering. The underwriters will receive the same underwriting discount and commissions on these shares of common stock as they will on any other shares of common stock sold to the public in this offering.

Commission and Expenses

The underwriters have advised us that they propose to offer the shares of common stock to the public at the initial public offering price set forth on the cover of this prospectus and to certain dealers, which may include the underwriters, at that price less a concession not in excess of $ per share of common stock. After the offering, the initial public offering price, concession, and reallowance to dealers may be reduced by the representatives. No such reduction will change the amount of proceeds to be received by us as set forth on the cover of this prospectus.

The following table shows the public offering price, the underwriting discounts, and commissions that we are to pay the underwriters and the proceeds, before expenses, to us in connection with this offering. Such amounts are shown assuming both no exercise and full exercise of the underwriters‘ option to purchase additional shares.

	Per Share		Total	
	Without Option to Purchase Additional Shares	With Option to Purchase Additional Shares	Without Option to Purchase Additional Shares	With Option to Purchase Additional Shares
Public offering price	$	$	$	$
Underwriting discount	$	$	$	$
Proceeds, before expenses, to us	$	$	$	$

We estimate expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately $4.0 million. We have agreed to reimburse the underwriters for certain of their expenses in an amount not to exceed $50,000 in the aggregate.

Determination of Offering Price

Prior to this offering, there has not been a public market for our common stock. Consequently, the initial public offering price for our common stock will be determined by negotiations between us and the representatives. Among the factors to be considered in these negotiations will be prevailing market conditions, our financial information, market valuations of other companies that we and the underwriters believe to be comparable to us, estimates of our business potential, the present state of our development, and other factors deemed relevant.

We offer no assurances that the initial public offering price will correspond to the price at which the common stock will trade in the public market subsequent to the offering or that an active trading market for the common stock will develop and continue after the offering.

Listing

We have applied to have our common stock approved for listing on The Nasdaq Global Select Market under the trading symbol “PROG.”

Stamp Taxes

If you purchase shares of common stock offered in this prospectus, you may be required to pay stamp taxes and other charges under the laws and practices of the country of purchase, in addition to the offering price listed on the cover of this prospectus.

Option to Purchase Additional Shares

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase, from time to time, in whole or in part, up to an aggregate of 1,000,000 shares from us at

the public offering price set forth on the cover of this prospectus, less underwriting discounts and commissions. If the underwriters exercise this option, each underwriter will be obligated, subject to specified conditions, to purchase a number of additional shares proportionate to that underwriter's initial purchase commitment as indicated in the table above. This option may be exercised only if the underwriters sell more shares than the total number set forth on the cover of this prospectus.

No Sales of Similar Securities

We, our officers, directors and holders of all or substantially all our outstanding capital stock and other securities have agreed, subject to specified exceptions, not to directly or indirectly:

- offer, pledge, sell, or contract to sell any shares of our common stock;
- sell any option or contract to purchase any shares of our common stock;
- purchase any option or contract to sell any shares of our common stock;
- grant any option, right, or warrant to purchase any shares of our common stock;
- make any short sale or otherwise transfer or dispose of any shares of our common stock;
- enter into any swap or other agreement that transfers, in whole or in part, the economic consequences of ownership of any shares of our common stock whether any such swap or transaction is to be settled by delivery of shares or other securities, in cash, or otherwise;
- make any demand for or exercise any right with respect to the registration of our common stock; or
- publicly announce the intention to do any of the foregoing for a period of 180 days after the date of this prospectus without the prior written consent of Piper Sandler & Co. and Wells Fargo Securities, LLC.

This restriction terminates after the close of trading of our common stock on and including the 180th day after the date of this prospectus.

Piper Sandler & Co. and Wells Fargo Securities, LLC may, in their sole discretion and at any time or from time to time before the termination of the 180-day period, release all or any portion of the securities subject to lock-up agreements. There are no existing agreements between the underwriters and any of our stockholders who will execute a lock-up agreement providing consent to the sale of shares prior to the expiration of the lock-up period.

Stabilization

The underwriters have advised us that, pursuant to Regulation M under the Exchange Act, certain persons participating in the offering may engage in short sale transactions, stabilizing transactions, syndicate covering transactions or the imposition of penalty bids in connection with this offering. These activities may have the effect of stabilizing or maintaining the market price of the common stock at a level above that which might otherwise prevail in the open market. Establishing short sales positions may involve either "covered" short sales or "naked" short sales.

"Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares of our common stock in this offering. The underwriters may close out any covered short position by either exercising their option to purchase additional shares of our common stock or purchasing shares of our common stock in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option to purchase additional shares.

"Naked" short sales are sales in excess of the option to purchase additional shares of our common stock. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the shares of our common stock in the open market after pricing that could adversely affect investors who purchase in this offering.

A stabilizing bid is a bid for the purchase of shares of common stock on behalf of the underwriters for the purpose of fixing or maintaining the price of the common stock. A syndicate covering transaction is the bid for or the purchase of shares of common stock on behalf of the underwriters to reduce a short position incurred by the underwriters in connection with the offering. Similar to other purchase transactions, the underwriter's purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. A penalty bid is an arrangement permitting the underwriters to reclaim the selling concession otherwise accruing to a syndicate member in connection with the offering if the shares of common stock originally sold by such syndicate member are purchased in a syndicate covering transaction and therefore have not been effectively placed by such syndicate member.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. The underwriters are not obligated to engage in these activities and, if commenced, any of the activities may be discontinued at any time.

The underwriters may also engage in passive market making transactions in our common stock on The Nasdaq Global Select Market in accordance with Rule 103 of Regulation M during a period before the commencement of offers or sales of shares of our common stock in this offering and extending through the completion of distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, that bid must then be lowered when specified purchase limits are exceeded.

Electronic Distribution

A prospectus in electronic format may be made available by e-mail or on the web sites or through online services maintained by one or more of the underwriters or their affiliates. In those cases, prospective investors may view offering terms online and may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of shares of common stock for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters' web sites and any information contained in any other web site maintained by any of the underwriters is not part of this prospectus, has not been approved and/or endorsed by us or the underwriters and should not be relied upon by investors.

Other Activities and Relationships

The underwriters and certain of their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing, and brokerage activities. The underwriters and certain of their respective affiliates have, from time to time, performed, and may in the future perform, various commercial and investment banking and financial advisory services for us and our affiliates, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and certain of their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or

related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments issued by us and our affiliates. If the underwriters or their respective affiliates have a lending relationship with us, they routinely hedge their credit exposure to us consistent with their customary risk management policies. The underwriters and their respective affiliates may hedge such exposure by entering into transactions which consist of either the purchase of credit default swaps or the creation of short positions in our securities or the securities of our affiliates, including potentially the common stock offered hereby. Any such short positions could adversely affect future trading prices of the common stock offered hereby. The underwriters and certain of their respective affiliates may also communicate independent investment recommendations, market color, or trading ideas and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Selling Restrictions

Notice to Prospective Investors in EEA and United Kingdom

In relation to each member state of the European Economic Area and the United Kingdom which has implemented the Prospectus Regulation (each, a "Relevant State"), no offer of shares of our common stock which are the subject of the offering contemplated by this prospectus has been or will be made to the public in that Relevant State, except that with effect from and including the Relevant Implementation Date, an offer of such shares of our common stock may be made to the public in that Relevant State:

- to any legal entity which is a "qualified investor" as defined in the Prospectus Regulation;
- to fewer than 150, natural or legal persons (other than qualified investors as defined in the Prospectus Regulation), as permitted under the Prospectus Regulation, subject to obtaining the prior consent of the representatives of the underwriters; or
- in any other circumstances falling within Article 3(2) of the Prospectus Regulation, provided that no such offer of shares of our common stock shall require the company or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 16 of the Prospectus Regulation.

For the purposes of this provision, the expression an "offer to the public" in relation to any shares of our common stock in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and the shares of our common stock to be offered so as to enable an investor to decide to purchase or subscribe the shares of our common stock, as the same may be varied in that Relevant State by any measure implementing the Prospectus Regulation in that Relevant State, and the expression "Prospectus Regulation" means Prospectus Regulation (EU) 2017/1129 (and amendments thereto, to the extent implemented in the Relevant States) and includes any relevant implementing measure in the Relevant State.

Notice to Prospective Investors in United Kingdom

In the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are "qualified investors" (as defined in the Prospectus Regulation) (i) who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, or the Order, and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as "relevant persons"). Any person in the United Kingdom that is not a relevant person should not act or rely on the information included in this document or use it as basis for taking any action. In the United Kingdom, any investment or investment activity that this document relates to may be made or taken exclusively by relevant persons. Any person in the United Kingdom that is not a relevant person should not act or rely on this document or any of its contents.

Notice to Prospective Investors in Bermuda

Securities may be offered or sold in Bermuda only in compliance with the provisions of the Investment Business Act of 2003 of Bermuda which regulates the sale of securities in Bermuda. Additionally, non-Bermudian persons (including companies) may not carry on or engage in any trade or business in Bermuda unless such persons are permitted to do so under applicable Bermuda legislation.

Notice to Prospective Investors in Australia

This prospectus is not a disclosure document for the purposes of Australia's Corporations Act 2001 (Cth) of Australia, or Corporations Act, has not been lodged with the Australian Securities & Investments Commission and is only directed to the categories of exempt persons set out below. Accordingly, if you receive this prospectus in Australia, you confirm and warrant that you are either:

- a "sophisticated investor" under section 708(8)(a) or (b) of the Corporations Act;
- a "sophisticated investor" under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant's certificate to the company which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made;
- a person associated with the company under Section 708(12) of the Corporations Act; or
- a "professional investor" within the meaning of section 708(11)(a) or (b) of the Corporations Act.

To the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor, associated person or professional investor under the Corporations Act any offer made to you under this prospectus is void and incapable of acceptance.

You warrant and agree that you will not offer any of the shares of our common stock issued to you pursuant to this prospectus for resale in Australia within 12 months of those shares of our common stock being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

Notice to Prospective Investors in Hong Kong

No shares of our common stock have been offered or sold, and no shares of our common stock may be offered or sold, in Hong Kong, by means of any document, other than to persons whose ordinary business is to buy or sell shares or debentures, whether as principal or agent; or to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap. 32) or the Securities and Futures Ordinance (Cap. 571) of Hong Kong. No document, invitation or advertisement relating to the shares of our common stock has been issued or may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted under the securities laws of Hong Kong) other than with respect to shares of our common stock which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance.

This prospectus has not been registered with the Registrar of Companies in Hong Kong. Accordingly, this prospectus may not be issued, circulated, or distributed in Hong Kong, and the shares of our

common stock may not be offered for subscription to members of the public in Hong Kong. Each person acquiring the shares of our common stock will be required, and is deemed by the acquisition of the shares of our common stock, to confirm that he is aware of the restriction on offers of the shares of our common stock described in this prospectus and the relevant offering documents and that he is not acquiring, and has not been offered any shares of our common stock in circumstances that contravene any such restrictions.

Notice to Prospective Investors in Japan

The offering has not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948 of Japan, as amended), or FIEL, and the underwriters will not offer or sell any shares of our common stock, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means, unless otherwise provided herein, any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to or for the benefit of a resident of Japan, except pursuant to an exemption from S-30 the registration requirements of, and otherwise in compliance with, the FIEL and any other applicable laws, regulations and ministerial guidelines of Japan.

Notice to Prospective Investors in Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or the invitation for subscription or purchase, of the shares of our common stock may not be issued, circulated or distributed, nor may the shares of our common stock be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (ii) to a relevant person pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA and in accordance with the conditions specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares of our common stock are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries‘ rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares of our common stock pursuant to an offer made under Section 275 of the SFA except:

- to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
- where no consideration is or will be given for the transfer;
- where the transfer is by operation of law;
- as specified in Section 276(7) of the SFA; or

- as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

Notice to Prospective Investors in Switzerland

The shares of our common stock may not be publicly offered, directly or indirectly, in Switzerland within the meaning of the Swiss Financial Services Act, or the FinSA, and will not be admitted to trading venue (exchange or multilateral trading facility) in Switzerland. None of this prospectus or any other offering or marketing material relating to the shares of our common stock constitutes a prospectus as such term is understood pursuant to the FinSA and none of this prospectus or any other offering or marketing material relating to our shares of common stock may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this prospectus nor any other offering or marketing material relating to the offering, the company, or the shares of our common stock have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with and the offer of shares of our common stock will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA (FINMA) and the offer of shares of our common stock has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares of our common stock.

Notice to Prospective Investors in Canada

(A) Resale Restrictions

The distribution of shares of our common stock in Canada is being made only in the provinces of Ontario, Quebec, Alberta, and British Columbia on a private placement basis exempt from the requirement that we prepare and file a prospectus with the securities regulatory authorities in each province where trades of these shares of our common stock are made. Any resale of the shares of our common stock in Canada must be made under applicable securities laws which may vary depending on the relevant jurisdiction, and which may require resales to be made under available statutory exemptions or under a discretionary exemption granted by the applicable Canadian securities regulatory authority. Purchasers are advised to seek legal advice prior to any resale of the shares of our common stock.

(B) Representations of Canadian Purchasers

By purchasing shares of our common stock in Canada and accepting delivery of a purchase confirmation, a purchaser is representing to us and the dealer from whom the purchase confirmation is received that:

- the purchaser is entitled under applicable provincial securities laws to purchase the shares of our common stock without the benefit of a prospectus qualified under those securities laws as it is an “accredited investor” as defined under National Instrument 45-106 — Prospectus Exemptions;
- the purchaser is a “permitted client” as defined in National Instrument 31-103 — Registration Requirements, Exemptions and Ongoing Registrant Obligations;
- where required by law, the purchaser is purchasing as principal and not as agent; and
- the purchaser has reviewed the text above under Resale Restrictions.

(C) Conflicts of Interest

Canadian purchasers are hereby notified that each of the underwriters are relying on the exemption set out in section 3A.3 or 3A.4, if applicable, of National Instrument 33-105 — Underwriting Conflicts from having to provide certain conflict of interest disclosure in this document.

(D) Statutory Rights of Action

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if the prospectus (including any amendment thereto) such as this document contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser of these securities in Canada should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

(E) Enforcement of Legal Rights

All of our directors and officers as well as the experts named herein may be located outside of Canada and, as a result, it may not be possible for Canadian purchasers to effect service of process within Canada upon us or those persons. All or a substantial portion of our assets and the assets of those persons may be located outside of Canada and, as a result, it may not be possible to satisfy a judgment against us or those persons in Canada or to enforce a judgment obtained in Canadian courts against us or those persons outside of Canada.

(F) Taxation and Eligibility for Investment

Canadian purchasers of shares of our common stock should consult their own legal and tax advisors with respect to the tax consequences of an investment in the shares of our common stock in their particular circumstances and about the eligibility of the shares of our common stock for investment by the purchaser under relevant Canadian legislation.

LEGAL MATTERS

The validity of the shares of our common stock offered by this prospectus will be passed upon for us by Gibson, Dunn & Crutcher LLP, Irvine, California. Latham & Watkins LLP is acting as counsel for the underwriters.

EXPERTS

The consolidated financial statements of Progenity, Inc. as of December 31, 2018 and December 31, 2019, and for the years then ended, have been included herein and in the registration statement in reliance upon the report of KPMG LLP, independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing. The audit report covering the December 31, 2018 and December 31, 2019 consolidated financial statements contains an explanatory paragraph that states that the Company has suffered recurring losses from operations and has an accumulated deficit that raise substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of that uncertainty. The audit report also refers to a change in the method of accounting for revenue due to the adoption of Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers (ASC 606), as amended.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of our common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement, some items of which are contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to us and our common stock, we refer you to the registration statement and its exhibits. Statements contained in this prospectus concerning the contents of any contract or any other document are not necessarily complete. If a contract or other document has been filed as an exhibit to the registration statement, please see the copy of the contract or other document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. The exhibits to the registration statement should be reviewed for the complete contents of these contracts and documents. A copy of the registration statement and its exhibits may be obtained from the SEC upon the payment of fees prescribed by it. The SEC maintains a website at *www.sec.gov* that contains reports, proxy and information statements, and other information regarding companies that file electronically with it.

Upon completion of this offering, we will become subject to the information and periodic and current reporting requirements of the Exchange Act, and in accordance therewith, will file periodic and current reports, proxy statements and other information with the SEC. The registration statement, such periodic and current reports, and other information can be obtained electronically by means of the SEC's website at *www.sec.gov.*

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors
Progenity, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Progenity, Inc. and subsidiaries (the Company) as of December 31, 2019 and 2018, the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for each of the years in the two-year period ended December 31, 2019, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2019, in conformity with U.S. generally accepted accounting principles.

Change in Accounting Principle

As discussed in Note 2 to the consolidated financial statements, the Company has changed its method of accounting for revenue as of January 1, 2019 due to the adoption of Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers (ASC 606)*, as amended.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations and has an accumulated deficit that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

We have served as the Company's auditor since 2011.

San Diego, California
March 18, 2020 except for the stock split described in Note 15, which is as of June 10, 2020

PROGENITY, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(in thousands, except share data)

	As of December 31, 2018	As of December 31, 2019	Pro Forma as of December 31, 2019 (unaudited)
ASSETS			
Current assets:			
Cash and cash equivalents	$ 49,005	$ 33,042	
Accounts receivable, net	1,952	22,189	
Short-term investments	20,200	—	
Inventory	7,616	10,937	
Income tax receivable	6,194	634	
Prepaid expenses and other current assets	3,979	7,846	
Total current assets	88,946	74,648	
Property and equipment, net	15,339	15,891	
Other assets	194	198	
Goodwill	6,219	6,219	
Other intangible assets, net	5,699	4,771	
Total assets	$ 116,397	$ 101,727	
LIABILITIES AND STOCKHOLDERS' DEFICIT			
Current liabilities:			
Accounts payable	$ 11,035	$ 15,754	
Accrued expenses and other current liabilities	65,793	83,615	
Current portion of mortgages payable	231	241	
Current portion of capital lease obligations	998	727	
Total current liabilities	78,057	100,337	
Capital lease obligations, net of current portion	893	358	
Mortgages payable, net of current portion	3,320	3,081	
Note payable to related party, net of unamortized discount of $7,705 and $6,034 as of December 31, 2018 and December 31, 2019, respectively	67,295	68,966	
Other long-term liabilities	3,800	12,859	
Total liabilities	$ 153,365	$ 185,601	
Commitments and Contingencies (Note 9)			
Stockholders' deficit:			
Common stock – $0.001 par value. 250,000,000 and 300,000,000 authorized as of December 31, 2018 and 2019, respectively; 8,112,581 and 8,451,415 shares issued as of December 31, 2018 and 2019, respectively; 4,638,009 and 4,976,843 shares outstanding as of December 31, 2018 and 2019, respectively; 38,153,400 shares issued and 34,678,828 shares outstanding as of December 31, 2019, pro forma	8	9	38
Series A and A-1 Preferred Stock – $0.001 par value. 6,120,000 and 4,120,000 shares authorized as of December 31, 2018 and 2019, respectively; 5,620,000 and 4,120,000 shares issued and outstanding as of December 31, 2018 and 2019, respectively; no shares issued and outstanding as of December 31, 2019, pro forma	6	4	—
Series B Preferred Stock – $0.001 par value. 15,580,737 and 126,035,000 shares authorized as of December 31, 2018 and 2019, respectively; 14,164,306 and 101,867,405 shares issued and outstanding as of December 31, 2018 and 2019, respectively; no shares issued and outstanding as of December 31, 2019, pro forma	14	102	—
Additional paid-in capital	124,244	283,260	283,337
Accumulated deficit	(142,469)	(348,478)	(348,478)
Treasury stock – at cost; 3,474,572 shares of common stock as of December 31, 2018 and December 31, 2019; actual and pro forma	(18,771)	(18,771)	(18,771)
Total stockholders' deficit	(36,968)	(83,874)	$ (83,874)
Total liabilities and stockholders' deficit	$ 116,397	$ 101,727	

See accompanying notes to consolidated financial statements.

PROGENITY, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share data)

	Year Ended December 31,	
	2018	2019
Revenue	$ 127,974	$ 143,985
Cost of sales	92,076	100,492
Gross profit	35,898	43,493
Operating expenses:		
Research and development	48,712	63,400
Selling and marketing	50,187	58,888
General and administrative	51,238	61,324
Total operating expenses	150,137	183,612
Loss from operations	(114,239)	(140,119)
Interest expense	(9,091)	(9,199)
Equity loss of equity method investee	(2,327)	—
Interest and other income, net	1,801	575
Loss before taxes	(123,856)	(148,743)
Income tax expense (benefit)	5,250	(706)
Net loss	$ (129,106)	$ (148,037)
Dividend paid to preferred stockholders	—	(3,652)
Stock dividend on exchange of Series A-1 for Series B Preferred Stock	—	(27,637)
Stock dividend on Series B Preferred Stock	—	(49,501)
Net loss attributable to common stockholders	$ (129,106)	$ (228,827)
Net loss per share attributable to common stockholders, basic and diluted	$ (27.72)	$ (46.87)
Weighted average number of shares outstanding, basic and diluted	4,657,337	4,882,662
Pro forma loss per share, basic and diluted (unaudited)		$ (5.49)
Pro forma weighted average shares outstanding, basic and diluted (unaudited)		26,961,445

See accompanying notes to consolidated financial statements.

PROGENITY, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(in thousands, except for share data)

	Common Stock		Series A and A-1 Preferred Stock		Series B Preferred Stock		Additional Paid-in Capital	Accumulated Deficit	Treasury Stock		Total
	Shares	Amount	Shares	Amount	Shares	Amount			Common Shares	Amount	
Balance—December 31, 2017	7,939,129	$ 8	5,620,000	$ 6	14,164,306	$ 14	$ 121,522	$ (13,363)	(2,901,109)	$ (7,505)	$ 100,682
Exercise of stock options	173,452	—	—	—	—	—	459	—	—	—	459
Stock-based compensation	—	—	—	—	—	—	2,263	—	—	—	2,263
Repurchase of common shares	—	—	—	—	—	—	—	—	(573,463)	(11,266)	(11,266)
Net loss	—	—	—	—	—	—	—	(129,106)	—	—	(129,106)
Balance—December 31, 2018	8,112,581	$ 8	5,620,000	$ 6	14,164,306	$ 14	$ 124,244	$ (142,469)	(3,474,572)	$(18,771)	$ (36,968)
Adoption of accounting standard (see Note 2)	—	—	—	—	—	—	—	23,666	—	—	23,666
Exercise of common stock options	338,834	1	—	—	—	—	550	—	—	—	551
Exchange of Series A-1 Preferred Stock to Series B Preferred Stock	—	—	(1,500,000)	(2)	35,664,240	36	27,603	(27,637)	—	—	—
Issuance of Series B Preferred Stock, net of issuance cost	—	—	—	—	34,035,354	34	79,005	—	—	—	79,039
Stock dividend on Series B Preferred Stock	—	—	—	—	18,003,505	18	49,483	(49,501)	—	—	—
Stock-based compensation	—	—	—	—	—	—	2,375	—	—	—	2,375
Dividends paid	—	—	—	—	—	—	—	(4,500)	—	—	(4,500)
Net loss	—	—	—	—	—	—	—	(148,037)	—	—	(148,037)
Balance—December 31, 2019	8,451,415	$ 9	4,120,000	$ 4	101,867,405	$ 102	$ 283,260	$ (348,478)	(3,474,572)	$(18,771)	$ (83,874)

See accompanying notes to consolidated financial statements.

PROGENITY, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,	
	2018	2019
Cash flows from operating activities:		
Net loss	$ (129,106)	$ (148,037)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	6,073	6,349
Inventory write-down	880	535
Loss on disposal of property and equipment	31	—
Equity loss of equity method investee	2,327	—
Stock-based compensation expense	2,263	2,375
Deferred taxes, net	6,245	—
Changes in operating assets and liabilities:		
Accounts receivable, net	584	3,429
Inventory	(3,475)	(3,857)
Prepaid expenses and other current assets	(1,730)	(3,867)
Income tax receivable (payable)	(854)	5,560
Other assets	(32)	(54)
Accounts payable	5,770	4,383
Accrued expenses and other liabilities	42,608	18,001
Other long-term liabilities	3,290	9,059
Net cash used in operating activities	(65,126)	(106,124)
Cash flows from investing activities:		
Purchases of property and equipment	(4,832)	(3,725)
Purchases of short-term investments	(167,011)	(11,214)
Proceeds from the sale of short-term investments	227,674	31,414
Proceeds from the sale of equity method investment	—	50
Net cash provided by investing activities	55,831	16,525
Cash flows from financing activities:		
Proceeds from issuance of common stock	459	551
Proceeds from issuance of Series B Preferred Stock and warrant, net of issuance cost	—	79,039
Repurchase of common stock	(11,266)	—
Dividends paid	—	(4,500)
Principal payments on mortgages payable	(220)	(228)
Principal payments on capital lease obligations	(1,530)	(1,047)
Payments for contingent consideration	(250)	—
Payments for deferred offering costs	—	(179)
Net cash (used in) provided by financing activities	(12,807)	73,636
Net decrease in cash and cash equivalents	$ (22,102)	$ (15,963)
Cash and cash equivalents—beginning of period	$ 71,107	$ 49,005
Cash and cash equivalents—end of period	$ 49,005	$ 33,042
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 7,618	$ 7,529
Cash paid for income taxes	211	6
Supplemental schedule of noncash investing and financing activities:		
Purchases of property and equipment in accounts payable	346	337
Capital lease obligations	706	241
Deferred offering costs incurred but not paid	—	871
Stock dividend on exchange of Series A-1 for Series B Preferred Stock	—	27,637
Stock dividend on Series B Preferred Stock	—	49,501

See accompanying notes to consolidated financial statements.

PROGENITY, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Description of Business

Progenity, Inc. and subsidiaries (the "Company" or "Progenity"), a Delaware corporation, commenced operations in 2010 with its corporate office located in San Diego, California. Progenity's primary operations include a licensed Clinical License Improvement Amendment ("CLIA") and College of American Pathologists ("CAP") certified laboratory located in Michigan specializing in the molecular testing markets serving women's health providers in the obstetric, gynecological, fertility, and maternal fetal medicine specialty areas in the United States.

The Company has expertise in the national reference laboratory, clinical genetics, laboratory molecular testing, and biotechnology markets. Distribution is managed by a dedicated women's health physician sales force and a field operations team who support all logistical functions in receiving clinical samples to the laboratory for analysis.

The Company's core business is focused on the prenatal carrier screening and noninvasive prenatal test market, targeting preconception planning, and routine pregnancy management for genetic disease risk assessment.

Through its affiliation with Mattison Pathology, LLP ("Mattison"), a Texas limited liability partnership doing business as Avero Diagnostics ("Avero"), located in Lubbock and Dallas, Texas, the Company's operations have expanded to provide anatomic and molecular pathology testing products in the United States.

Liquidity

As of December 31, 2019, the Company had cash and cash equivalents of $33.0 million and an accumulated deficit of $348.5 million. For the year ended December 31, 2019, the Company also had a net loss of $148.0 million and cash used in operations of $106.1 million. The Company's primary sources of capital have been private placements of preferred stock and incurrence of debt. As of December 31, 2019, the Company had a $75.0 million term loan outstanding with a private equity firm (see Note 7), and mortgages outstanding of $3.3 million (see Note 8). Management does not believe that the current available cash and cash equivalents will be sufficient to fund the Company's planned expenditures and meet its obligations for at least 12 months following the financial statement issuance date without raising additional funding. As a result, there is substantial doubt about the Company's ability to continue as a going concern for the twelve months following the issuance date of the consolidated financial statements for the year ended December 31, 2019.

The Company's ability to continue as a going concern is dependent upon its ability to raise additional funding. Management intends to raise additional capital through equity offerings and/or debt financings. Adequate funding, if needed, may not be available to the Company on acceptable terms, or at all. If the Company is unable to raise capital when needed or on attractive terms, it would be forced to delay, reduce, or eliminate its research and development programs or other operations. If any of these events occur, the Company's ability to achieve its operational goals would be adversely affected.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company's financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP") and include the accounts of Progenity, Inc., its wholly owned subsidiaries, and an affiliated professional partnership with Avero with respect to

which the Company currently has a specific management arrangement. The Company has determined that Avero is a variable interest entity and that the Company is the primary beneficiary resulting in the consolidation of Avero as required by the accounting guidance for consolidation. All significant intercompany balances and transactions have been eliminated in consolidation (see Note 3).

There have been no material changes in the Company's significant accounting policies, other than the adoption of Financial Accounting Standards Board ("FASB") Accounting Standards Update ("ASU") No. 2014-09 *Revenue from Contracts with Customers* ("ASC 606"), described below.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant items subject to such estimates include the estimate of variable consideration in connection with the recognition of revenue, the valuation of Series B preferred stock, the valuation of stock options, the valuation of goodwill and intangible assets, accrual for reimbursement claims and settlements, assessing future tax exposure and the realization of deferred tax assets, the useful lives, and the recoverability of property and equipment. The Company bases these estimates on historical and anticipated results, trends, and various other assumptions that the Company believes are reasonable under the circumstances, including assumptions as to future events. These estimates form the basis for making judgments about the carrying values of assets and liabilities and recorded revenues and expenses that are not readily apparent from other sources. Actual results could differ from those estimates and assumptions.

Operating Segments

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker or decision-making group in making decisions on how to allocate resources and assess performance. The Company views its operations and manages its business as one operating segment. All revenues are attributable to U.S.-based operations and all assets are held in the United States.

Revenue Recognition

Revenue is recognized in accordance with FASB Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). The Company adopted ASC 606 with an initial application date of January 1, 2019 using the modified retrospective method, as discussed under *Recent Accounting Pronouncements Adopted* below. In accordance with ASC 606, the Company follows a five-step process to recognize revenues: 1) identify the contract with the customer, 2) identify the performance obligations, 3) determine the transaction price, 4) allocate the transaction price to the performance obligations and 5) recognize revenues when the performance obligations are satisfied.

Revenue is primarily derived from providing molecular testing products, which are reimbursed through arrangements with third-party payors, laboratory distribution partners, and amounts from individual patients. Third-party payors include commercial payors, such as health insurance companies, health maintenance organizations and government health benefit programs such as Medicare and Medicaid. The Company's contracts generally contain a single performance obligation, which is the delivery of the test results, and the Company satisfies its performance obligation at a point in time upon the delivery of the results, which then triggers the billing for the product. The amount of revenue recognized reflects the

amount of consideration the Company expects to be entitled (the "transaction price") and considers the effects of variable consideration. Revenue is recognized when control of the promised product is transferred to customers, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those products.

The Company has elected to apply the following practical expedients and exemptions:

- Incremental costs incurred to obtain a contract have been expensed as incurred because the related amortization period would have been one year or less. The costs are included in selling and marketing expenses.
- No adjustments to amounts of promised consideration were made for the effects of a significant financing component because the Company expects, at contract inception, that the period between the transfer of a promised good or service and customer payment for that good or service will be one year or less.

Payor Concentration

The Company relies upon reimbursements from third-party government payors and private-payor insurance companies to collect accounts receivable. The Company's significant third-party payors and their related revenues as a percentage of total revenues and accounts receivable balances are as follows:

	Percentage of Revenue Year Ended December 31,		Percentage of Accounts Receivable(1) As of December 31,
	2018	2019	2019
United Healthcare	4.5%	30.8%	31.5%
Blue Shield of Texas	19.2%	21.3%	0.1%
Government Health Benefits Programs	23.0%	0.1%	16.7%

(1) The percentage of accounts receivable at December 31, 2018 is not presented as the majority of the Company's revenue was recorded as cash was received prior to the adoption of ASC 606 on January 1, 2019 and is therefore not comparable to the amounts at December 31, 2019.

Cost of Sales

The components of the Company's cost of sales are materials and service costs, personnel costs, including stock-based compensation expense, equipment, and infrastructure expenses associated with processing blood and other samples, quality control analyses, shipping charges to transport samples and specimens from ordering physicians, clinics or individuals, third-party laboratory testing products, and allocated overhead including rent, information technology costs, equipment depreciation, and utilities. Costs associated with performing tests are recorded when the test is processed regardless of whether and when revenues are recognized with respect to such test.

Cash and Cash Equivalents including Concentration of Credit Risk

The Company considers all highly liquid investment instruments purchased with an initial maturity of three months or less to be cash equivalents. The Company limits its exposure to credit loss by placing its cash and cash equivalents in financial institutions with high credit ratings. The Company's cash and cash equivalents may consist of deposits held with banks, money market funds, or other highly liquid investments that may at times exceed federally insured limits. Cash equivalents are financial instruments

that potentially subject the Company to concentrations of risk, to the extent of amounts recorded in the balance sheets. The Company performs evaluations of its cash equivalents and the relative credit standing of these financial institutions and limits the amount of credit exposure with any one institution. Management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held.

Accounts Receivable

Accounts receivable is recorded at the transaction price and considers the effects of variable consideration. The total consideration the Company expects to collect is an estimate and may be fixed or variable. Variable consideration includes reimbursement from third-party payors, laboratory distribution partners, and amounts from individual patients, and is adjusted for disallowed cases, discounts, and refunds using the expected value approach. The Company monitors these estimates at each reporting period based on actual cash collections in order to assess whether a revision to the estimate is required.

Investments

All investments have been classified as “available-for-sale” and are carried at fair value as determined based upon quoted market prices or pricing models for similar securities at period end. Investments with contractual maturities less than 12 months at the balance sheet date are considered short-term investments. Those investments with contractual maturities 12 months or greater at the balance sheet date are considered long-term investments. A decline in the fair value of any security below cost that is deemed other than temporary results in a charge to earnings and the corresponding establishment of a new cost basis for the security. Dividend and interest income are recognized when earned. Realized gains and losses are included in earnings and are derived using the specific identification method for determining the cost of the securities sold.

Inventory

Inventory is stated at lower of cost (first-in, first-out method) or net realizable value. Inventory consists entirely of supplies, which are consumed when the Company is providing its test reports, and therefore the Company does not maintain any work in process or finished goods inventory. The Company reviews its inventory on a regular basis for excess and obsolete inventory based on an estimate for future consumption. Write-downs or losses of inventory are generally due to technological advances or new product introductions in the Company’s laboratory testing products. The Company believes that the estimate used in calculating the inventory provision are reasonable and properly reflect the risk of excess and obsolete inventory. If laboratory operation demand is significantly less than inventory levels, inventory write-downs may be required, which could have a material adverse effect on the Company’s consolidated financial statements. Inventory write-downs amounted to $0.9 million and $0.5 million in 2018 and 2019, respectively.

Property and Equipment, Net

Property and equipment are stated at cost. Assets acquired under capital leases are stated at the present value of future minimum lease payments. Depreciation is recognized on a straight-line basis over the estimated useful lives of the related assets as follows:

Property and Equipment	Estimated Useful Life (in years)
Computers and software	3
Laboratory equipment	5
Furniture, fixtures, and office equipment	8
Building	15

Assets acquired under capital leases and leasehold improvements are amortized on a straight-line basis over the shorter of the lease term or the useful life of the asset. Land is not depreciated.

Goodwill

Goodwill is an asset representing the future economic benefits arising from other assets acquired in a business combination that are not individually identified and separately recognized. Goodwill is not amortized but instead is tested annually for impairment at the reporting unit level, or more frequently when events or changes in circumstances indicate that fair value of the reporting unit has been reduced to less than its carrying value. The Company may choose to perform a qualitative assessment to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform the two-step goodwill impairment test.

If, after assessing qualitative factors, an entity determines it is not more likely than not that the fair value of a reporting unit is less than its carrying amount, then performing the two-step impairment test is unnecessary. If deemed necessary, a two-step test is used to identify the potential impairment and to measure the amount of goodwill impairment, if any. The first step is to compare the fair value of the reporting unit with its carrying amount, including goodwill. If the fair value of the reporting unit exceeds its carrying amount, goodwill is considered not impaired; otherwise, there is an indication that goodwill may be impaired and the amount of the loss, if any, is measured by performing step two. Under step two, the impairment loss, if any, is measured by comparing the implied fair value of the reporting unit goodwill with the carrying amount of goodwill. No impairment was recorded for the years ended December 31, 2018 and 2019.

Intangible Assets

Intangible assets consist of identifiable intangible assets acquired through acquisitions. Identifiable intangible assets include payor relationships, trade names, and noncompete agreements. The Company amortizes payor relationships and trade names using the straight-line method over their useful lives. The Company amortizes noncompete covenants using the straight-line method over the terms of the related agreements. The Company reviews impairment for intangible assets with definite useful lives whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. Recoverability of these assets is measured by a comparison of the carrying amounts to the undiscounted future cash flows the assets are expected to generate. If such review indicates that the carrying amount of intangible assets is not recoverable, the carrying amount of such assets is reduced to fair value. No impairment was recorded for the years ended December 31, 2018 and 2019.

The amortization periods for the acquired intangible assets are:

Intangible Assets	Useful Life (in years)
Trade names	10
Payor relationships	10
Noncompete agreements	6

Impairment of Long-Lived Assets

The Company accounts for the impairment of long-lived assets, such as property and equipment, by reviewing these assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If circumstances require a long-lived asset or asset group to be tested for possible impairment, the Company first compares undiscounted future cash flows expected to be generated by that asset or asset group to its carrying value. If the carrying value of the long-lived asset or asset group is not recoverable on an undiscounted-cash-flow basis, an impairment is recognized to the extent that the carrying value exceeds its fair value. No impairment was recorded as of December 31, 2018 and 2019.

Repair and Maintenance

The Company incurs maintenance costs on its major equipment. Repair and maintenance costs are expensed as incurred.

Research and Development

Research and development expenses consist primarily of costs associated with performing research and development activities to improve the Company’s tests, to reduce costs, and to develop new products. Research and development expenses also consist of personnel expenses, including salaries, bonuses, stock-based compensation expense, and benefits, and allocated overhead costs. Research and development expenses are expensed as incurred.

Selling and Marketing

Selling and marketing expenses consist primarily of costs for communication, advertising, conferences, and other marketing events. Selling and marketing expenses also consist of personnel expenses, including salaries, bonuses, stock-based compensation expense, benefits, and allocated overhead costs. Selling and marketing expenses are expensed as incurred. Advertising expense for the years ended December 31, 2018 and 2019 amounted to $1.4 million and $2.2 million, respectively.

General and Administrative

General and administrative expenses consist primarily of personnel costs, including salaries, bonuses, stock-based compensation expense, and benefits, for the Company's finance and accounting, legal, human resources, and other administrative teams. Additionally, these expenses include professional fees, including audit, legal, and recruiting services. General and administrative expenses are expensed in the period incurred.

Stock-Based Compensation

The Company calculates the fair value of stock options using the Black-Scholes option valuation model, which incorporates various assumptions including volatility, expected life and risk-free interest rate. Compensation related to service-based awards are recognized starting on the grant date on a straight-line basis over the vesting period, which is generally four years.

The determination of the fair value of each stock award using this option-pricing model is affected by the Company's assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, the fair value of the common stock at the date of grant, the expected term of the awards, the expected stock price volatility over the term of the awards, risk-free interest rate, and dividend rate as follows:

Fair Value of Common Stock—Given the absence of a public trading market, the Company's board of directors considered numerous objective and subjective factors to determine the fair value of the Company's common stock at each grant date. These factors included, but were not limited to: (i) contemporaneous third-party valuations of common stock; (ii) the prices for preferred stock sold to outside investors; (iii) the rights and preferences of preferred stock relative to common stock; (iv) the lack of marketability of the Company's common stock; (v) developments in the business; and (vi) the likelihood of achieving a liquidity event, such as an initial public offering ("IPO") or sale of the business, given prevailing market conditions.

Expected Term—The expected term represents the period that the stock-based awards are expected to be outstanding. The Company determines the expected term using the simplified method. The simplified method deems the term to be the average of the time-to-vesting and the contractual life of the options. For stock options granted to non-employees, the expected term equals the remaining contractual term of the option from the vesting date.

Expected Volatility—Given the absence of a public trading market, the expected volatility was estimated by taking the average historic price volatility for industry peers, consisting of several public companies in the Company's industry that are either similar in size, stage, or financial leverage, over a period equivalent to the expected term of the awards.

Risk-Free Interest Rate—The risk-free interest rate is calculated using the average of the published interest rates of U.S. Treasury zero-coupon issues with maturities that are commensurate with the expected term.

Dividend Rate—The dividend yield assumption is zero, as the Company has no plans to make dividend payments.

Effective January 1, 2018, the Company adopted the guidance from ASU No. 2016-09, *Compensation—Stock Compensation (Topic 718).* As a result, the Company now recognizes the effect of forfeitures as they occur. Additionally, the excess tax benefits and deficiencies on share-based payment awards are recorded as deferred tax assets offset by a valuation allowance.

Net Loss Per Share

Basic and diluted net loss per share attributable to common stockholders is presented in conformity with the two-class method required for participating securities. The Company considers all series of preferred stock to be participating securities as the holders of such stock are entitled to receive non-cumulative dividends on an as-converted basis in the event that a dividend is paid on common stock. Under the two-class method, the net loss attributable to common stockholders is not allocated to the preferred stock as the holders of preferred stock do not have a contractual obligation to share in the Company's losses. Under the two-class method, net income is attributed to common stockholders and participating securities based on their participation rights.

Basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period. Net loss attributable to common stockholders is calculated by adjusting net loss with dividends to preferred stockholders, if any. As the Company has reported net losses for all periods presented, all potentially dilutive securities are antidilutive and, accordingly, basic net loss per share equals diluted net loss per share.

Equity Method Investment

Investments over which the Company is deemed to exert significant influence but not control are accounted for using the equity method of accounting. For investments accounted for under the equity method of accounting, the Company's share of income (losses) is included in equity in income of investees in the consolidated statements of operations. As of December 31, 2018, the Company owned a 20% interest in NeoSeq Ltd., a Cayman Islands exempted company ("NeoSeq"), which operated a laboratory in China focused on fetal diagnostic operations for the Asia Pacific market and certain Middle Eastern countries. The Company evaluates the equity method investment for impairment whenever an event or change in circumstances occurs that may have a significant adverse impact on the carrying value of the investment. During the year ended December 31, 2018, NeoSeq completed a financing transaction that diluted the Company's ownership in NeoSeq. Due to this transaction and continued losses, the Company recorded an other-than-temporary impairment of $1.4 million during the year ended December 31, 2018 within the equity loss of the equity method investee in the accompanying consolidated statements of operations.

On June 27, 2019, the Company sold the Neoseq investment to a third-party for an aggregate price of $0.05 million.

Income Taxes

The Company accounts for income taxes under the asset-and-liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

The Company recognizes the effect of income tax positions only if those positions are more likely than not of being sustained. Recognized income tax positions are measured at the largest amount that is greater than 50% likely of being realized. Changes in recognition or measurement are recognized in the period in which the change in judgment occurs. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount expected to be realized.

Comprehensive Loss

The Company did not have any other comprehensive income or loss for any of the periods presented, and therefore comprehensive loss was the same as the Company's net loss.

Unaudited Pro Forma Information

All outstanding shares of preferred stock will automatically convert into shares of the Company's common stock upon the closing of a qualified IPO, as defined in the Company's certificate of incorporation and as described in Note 10. The unaudited pro forma balance sheet information as December 31, 2019 has been prepared assuming the automatic conversion of the preferred stock and vested restricted stock units into shares of common stock assuming the completion of an IPO on December 31, 2019.

The unaudited pro forma net loss per share attributable to common stockholders for the year ended December 31, 2019 has been computed to give effect to the automatic conversion upon the closing of a qualified IPO of preferred stock and vested restricted stock units into common stock using the if-converted method as though such IPO had occurred as of the beginning of the period or the date of issuance, if later.

Recent Accounting Pronouncements Adopted

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* (*ASC 606*), which supersedes the revenue recognition requirements in ASC Topic 605, *Revenue Recognition* ("ASC 605"), and requires entities to recognize revenue when they transfer control of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services. The Company adopted ASC 606 as of January 1, 2019, using the modified retrospective transition method applied to those contracts which were not completed as of January 1, 2019. Results for reporting periods beginning after January 1, 2019 are presented under ASC 606, while prior period amounts have not been adjusted and continue to be reported in accordance with the Company's historical accounting policy under ASC 605.

Upon adoption, the Company recognized the cumulative effect of adopting this guidance as an adjustment to its opening accumulated deficit balance. The Company recorded a one-time increase to opening accounts receivable, net, and a reduction to opening accumulated deficit of $23.7 million as of January 1, 2019. The adjustment was primarily related to the recognition of variable consideration the Company expects to receive that was previously recognized as cash was received under ASC 605. The disclosure of revenue without the adoption of ASC 606 for the year ended December 31, 2019 includes an adjustment for the portion of the Company's revenue that was previously recognized as cash was received under ASC 605.

In accordance with the new revenue standard requirements, the disclosure of the impact of adoption on the Company's consolidated balance sheets as of January 1, 2019 and December 31, 2019 and statement of operations for the year ended December 31, 2019 was as follows (in thousands, except per share data):

	January 1, 2019		
	Under ASC 606	Adoption of ASC 606	Without Adoption of ASC 606
Accounts receivable, net of allowance	$ 25,618	$ (23,666)	$ 1,952
Accumulated deficit	(118,803)	(23,666)	(142,469)

PROGENITY, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

	As of December 31, 2019		
	Under ASC 606	Adoption of ASC 606	Without Adoption of ASC 606
Accounts receivable, net of allowance	$ 22,189	$ (19,168)	$ 3,021
Accumulated deficit	(348,478)	(19,168)	(367,646)

	Year Ended December 31, 2019		
	Revenue under ASC 606	Adoption of ASC 606	Revenue without Adoption of ASC 606(1)
Product revenues	$ 143,985	$ 5,068	$ 149,053
Total revenues	143,985	5,068	149,053
Loss from operations	(140,119)	5,068	(135,051)
Net loss	(148,037)	5,068	(142,969)
Net loss attributable to common stockholders	(228,827)	5,068	(223,759)
Net loss per share attributable to common stockholders, basic and diluted	$ (46.87)	$ 1.04	$ (45.83)

(1) Under ASC 605, revenue was not recognized until cash was received for the majority of the Company's molecular products. For the portion of the revenue that was not recognized until cash was received under ASC 605, the cash receipts during the year ended December 31, 2019 were greater than the estimated transaction price recognized as revenue as tests were performed during the same period under ASC 606.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments.* This standard is intended to address eight classification issues related to the statement of cash flows to reduce diversity in practice in how certain transactions are classified. The Company adopted the new accounting standard in fiscal year 2019 using the retrospective transition method for each period presented, which did not have a material impact on the consolidated financial statements.

Recent Accounting Pronouncements Not Yet Adopted

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which supersedes FASB ASC Topic 840, Leases (Topic 840), and provides principles for the recognition, measurement, presentation and disclosure of leases for both lessees and lessors. The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method for finance leases or on a straight-line basis over the term of the lease for operating leases. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of classification. Leases with a term of 12 months or less will be accounted for similar to existing guidance for operating leases. The Company is still assessing the impact that the new leasing standard will have on operations and financial position.

In November 2019, the FASB issued ASU No. 2019-10, *Leases (Topic 842): Effective Dates*. The new standard is effective for the Company for annual reporting periods beginning after December 15, 2020.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses*, which requires the measurement of expected credit losses for financial instruments carried at amortized cost, such as accounts receivable, held at the reporting date based on historical experience, current conditions and reasonable forecasts. The main objective of this standard is to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. In November 2018, the FASB issued ASU No. 2018-19, *Codification Improvements to Topic 326, Financing Instruments–Credit Losses*, which included an amendment of the effective date. The Company does not believe the adoption of this standard will have a significant impact on the financial statements. The standard is effective for the Company for annual reporting periods beginning after December 15, 2022.

In January 2017, the FASB issued ASU No. 2017-04, *Intangibles—Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment.* The new standard will simplify the measurement of goodwill by eliminating step two of the two-step impairment test. Step two measures a goodwill impairment loss by comparing the implied fair value of a reporting unit's goodwill with the carrying amount of that goodwill. The new guidance requires an entity to compare the fair value of a reporting unit with its carrying amount and recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value. Additionally, an entity should consider income tax effects from any tax-deductible goodwill on the carrying amount of the reporting unit when measuring the goodwill impairment loss, if applicable. The standard is effective for the Company for annual reporting periods beginning after December 15, 2021. The Company does not expect the adoption of this standard to have a material impact on its consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting.* The standard simplifies the accounting for share-based payments granted to nonemployees for goods and services and aligns most of the guidance on such payments to the nonemployees with the requirements for share-based payments granted to employees. ASU 2018-07 is effective for the Company for annual reporting periods beginning after December 15, 2019, and interim periods therein. The Company does not expect the adoption of this standard to have a material impact on its consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*, which eliminates certain disclosure requirements for fair value measurements for all entities, requires public entities to disclose certain new information and modifies some disclosure requirements. The Company does not expect the adoption of this ASU to have a material impact on its consolidated financial statements. The standard is effective for the Company for annual reporting periods beginning after December 15, 2019.

3. Variable Interest Entity

On June 8, 2015, the Company entered into a series of agreements with Avero. The Company entered into a purchase agreement to acquire certain assets from Mattison used in the operation of Avero. The purchase agreement was accounted for under the acquisition method in accordance with the provisions of ASC Topic 805, *Business Combinations*. The Company entered into a nominee agreement which provides it with the right, but not the obligation, to purchase, or to designate a person(s) to purchase, the stock of Avero at any time for a nominal amount.

The Company also entered into a management services arrangement that authorizes the Company to perform the management services in the manner that it deems reasonably appropriate to meet the

day-to-day business needs of Avero. The Company's involvement includes funding ongoing operational needs, directing activities related to contract negotiation, billing, human resources, legal and administrative matters and processes, among others. In exchange for the management services provided, the Company is entitled to receive an annual management fee equal to the net operating income of Avero. The term of the agreement with Avero is 10 years, subject to automatic renewals. The agreement can be terminated by either party with a 90-day notice before the end of the term.

Through the management services arrangement with Avero, the Company has (1) the power to direct the activities of Avero that most significantly impact its economic performance, and (2) the obligation to absorb losses that could potentially be significant or the right to receive benefits from Avero that could potentially be significant. Based on these determinations, the Company has determined that Avero is a variable interest entity and that the Company is the primary beneficiary. The Company does not own any equity interest in Avero; however, as these agreements provide the Company the controlling financial interest in Avero, the Company consolidates Avero's balances and activities within its consolidated financial statements.

In December 2018, Avero entered into a settlement agreement with Cigna (the "Cigna settlement obligation") whereby Avero agreed to pay an aggregate amount of $12.0 million with an upfront payment of $6.0 million and the remaining $6.0 million to be paid over 24 months, beginning in February 2019. The Company guaranteed the $12.0 million Cigna settlement obligation and recorded a charge of $12.0 million associated with this claim in its consolidated statement of operations as a reduction to revenue for the year ended December 31, 2018. During the years ended December 31, 2018 and 2019, the Company provided $6.0 million and $3.0 million, respectively, in financial support to Avero related to the Cigna settlement obligation (see Note 9).

The Company did not provide any additional financial support to Avero during the years ended December 31, 2018 and 2019 other than the Cigna settlement obligation and agreed upon management services.

PROGENITY, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

The following table presents the assets and liabilities of Avero which are included in the Company's consolidated balance sheets as of December 31, 2018 and 2019, in thousands. The creditors of Avero have no recourse to the general credit of the Company, with the exception of $2.1 million and $1.9 million in mortgage payable guaranteed by the Company as of December 31, 2018 and 2019, respectively (see Note 8), and $6.0 million and $3.0 million in remaining Cigna settlement obligation guaranteed by the Company as of December 31, 2018 and 2019, respectively. The assets and liabilities exclude intercompany balances that eliminate in consolidation:

	December 31, 2018	December 31, 2019
Assets of Avero that can only be used to settle obligations of Avero		
Cash and cash equivalents	$ 1,210	$ 1,837
Accounts receivable, net	1,952	4,269
Inventory	935	2,572
Income tax receivable	1,690	—
Prepaid expenses and other current assets	1,020	1,181
Property and equipment, net	5,840	5,586
Other assets	30	30
Goodwill	6,219	6,219
Other intangible assets, net	5,699	4,771
Total assets of Avero that can only be used to settle obligations of Avero	$ 24,595	$ 26,465
Liabilities of Avero		
Accounts payable	$ 1,018	$ 2,450
Accrued expenses and other current liabilities	4,620	5,630
Current portion of capital lease obligations	111	59
Current portion of mortgage payable	166	173
Capital lease obligations, net of current portion	109	50
Mortgage payable, net of current portion	1,903	1,733
Other long-term liabilities	3,686	467
Total liabilities of Avero	$ 11,613	$ 10,562

4. Revenue

Product revenue is derived from contracts with healthcare insurers, government payors, laboratory partners and patients in connection with sales of prenatal genetic, anatomic or molecular pathology tests. The Company enters into contracts with health care insurers related to tests provided to patients who have health insurance coverage. Insurance carriers are considered third-party payors on behalf of the patients, and the patients who receive genetic, anatomic or molecular pathology test products are considered the customers. Tests may be billed to insurance carriers, patients, or a combination of insurance carriers and patients. The Company also sells tests to laboratory partners and has also identified those parties as customers.

In accordance with ASC 606, a performance obligation represents a promise in a contract to transfer a distinct good or service to a customer and the consideration should be allocated to each distinct

performance obligation and recognized as revenue when, or as, the performance obligation is satisfied. The Company has evaluated its contracts with health care insurers, government payors, laboratory partners and patients and identified a single performance obligation in those contracts, the delivery of a test result. The Company satisfies its performance obligation at a point in time upon the delivery of the test result, at which point the Company can bill for its products. The amount of revenue recognized reflects the transaction price and considers the effects of variable consideration, which is discussed below.

The transaction price is an estimate and may be fixed or variable. Variable consideration includes reimbursement from healthcare insurers, government payors, and patients and is adjusted for estimates of disallowed cases, discounts, and refunds using the expected value approach. Tests billed to healthcare insurers and directly to patients can take up to six months to collect and the Company may be paid less than the full amount billed or not paid at all. For insurance carriers and government payors, management utilizes the expected value method using a portfolio of relevant historical data for payors with similar reimbursement experience. The portfolio estimate is developed using historical reimbursement data from payors and patients, as well as known current reimbursement trends not reflected in the historical data. Such variable consideration is included in the transaction price only to the extent it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainties with respect to the amount are resolved. Management monitors these estimates at each reporting period based on actual cash collections and status of settlement agreements with third-party payors, in order to assess whether a revision to the estimate is required. Both the initial estimate and any subsequent revision to the estimate contain uncertainty and require the use of judgment in the estimation of the transaction price and application of the constraint for variable consideration. If actual results in the future vary from the Company's estimates, the Company will adjust these estimates, which would affect revenue and earnings in the period such variances become known. The consideration expected from laboratory partners is generally a fixed amount.

During the year ended December 31, 2019, the Company updated its estimate of the variable consideration recognized for previously delivered performance obligations which resulted in a reduction of $16.0 million of revenue for the year ended December 31, 2019. This amount includes (i) adjustments for actual collections versus estimated variable consideration as of the beginning of the reporting period and (ii) cash collections and the related recognition of revenue in the current period for tests delivered in prior periods due to the release of the constraint on variable consideration, offset by (iii) reductions in revenue for the accrual for reimbursement claims and settlements described in Note 9, *Commitments and Contingencies*.

Once the Company satisfies its performance obligations upon delivery of a test result and bills for the product, the timing of the collection of payments may vary based on the payment practices of the third-party payor. The Company bills patients directly for co-pays and deductibles that they are responsible for and also bills patients directly in cases where the customer does not have insurance.

The Company has established an accrual for refunds of payments previously made by healthcare insurers based on historical experience and executed settlement agreements with healthcare insurers. The refunds are accounted for as reductions in revenues in the statement of operations as an element of variable consideration.

During the years ended December 31, 2018 and 2019, all revenues were with payors located in the United States.

PROGENITY, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Disaggregation of Revenues

The following table shows a further disaggregation of revenues by payor type (in thousands):

	Year Ended December 31,	
	2018	2019
Commercial Third-Party Payors	$ 94,799	$ 139,051
Government Health Benefit Programs	29,416	195
Patient/Laboratory Distribution Partners	3,759	4,739
Total revenues	$ 127,974	$ 143,985

5. Balance Sheet Components

Prepaid expenses and other current assets

Prepaid expenses and other current assets consist of the following (in thousands):

	December 31, 2018	December 31, 2019
Prepaid expenses	$ 3,375	$ 6,476
Other current assets	604	1,370
Total	$ 3,979	$ 7,846

Property and equipment, net

Property and equipment, net consists of the following (in thousands):

	December 31, 2018	December 31, 2019
Computers and software	$ 12,659	$ 13,913
Building and leasehold improvements	9,198	9,491
Laboratory equipment	4,324	5,580
Furniture, fixtures, and office equipment	1,422	1,633
Construction in progress	761	1,493
Land	1,091	1,091
Total property and equipment	29,455	33,201
Less accumulated depreciation and amortization	(14,116)	(17,310)
Property and equipment, net	$ 15,339	$ 15,891

Capital leases included in property and equipment, net consist of the following (in thousands):

	December 31, 2018	December 31, 2019
Capital leases	$ 5,114	$ 3,692
Less accumulated depreciation and amortization	(2,589)	(2,239)
Property and equipment, net	$ 2,525	$ 1,453

Depreciation expense was $3.7 million for each of the years ended December 31, 2018 and 2019.

Intangible assets, net

Intangible assets, net consist of the following (in thousands):

	December 31, 2018		
	Cost	Accumulated amortization	Net
Payor relationships	$7,230	$ (2,590)	$4,640
Trade names	1,410	(505)	905
Noncompete agreements	384	(230)	154
Intangible assets, net	$9,024	$ (3,325)	$5,699

	December 31, 2019		
	Cost	Accumulated amortization	Net
Payor relationships	$7,230	$ (3,314)	$3,916
Trade names	1,410	(646)	764
Noncompete agreements	384	(293)	91
Intangible assets, net	$9,024	$ (4,253)	$4,771

Amortization expense of intangible assets for each of the years ended December 31, 2018 and 2019 was $0.9 million.

The future amortization of intangible assets at December 31, 2019 is (in thousands):

Year Ending December 31,	
2020	$ 928
2021	891
2022	864
2023	864
Thereafter	1,224
Total future minimum amortization	$4,771

Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consist of the following (in thousands):

	December 31, 2018	December 31, 2019
Accrual for reimbursement claims and settlements	$ 46,405	$ 60,386
Commissions and bonus	6,628	6,357
Vacation and payroll benefits	4,840	5,506
Accrued professional services	3,146	5,322
Other	4,774	6,044
Total	$ 65,793	$ 83,615

Other long-term liabilities

Other long-term liabilities consist of the following (in thousands):

	December 31, 2018	December 31, 2019
Accrual for reimbursement claims and settlements—long term	$ 3,000	$ 12,205
Other	800	654
Total	$ 3,800	$ 12,859

6. Fair Value Measurements

The following table presents information about the Company's assets and liabilities that are measured at fair value on a recurring basis and indicates the fair value hierarchy of the valuation techniques utilized to determine such fair value (in thousands):

	Quoted Market Prices for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
At December 31, 2018			
Money market funds(1)	$ 10,217	$ —	$ —
Certificate of deposits(1)(2)	—	51,415	—
At December 31, 2019			
Money market funds(1)	$ 24,432	$ —	$ —

(1) Included in cash and cash equivalents in the accompanying consolidated balance sheets.
(2) Included in short-term investments in the accompanying consolidated balance sheets.

Short-term investment, which consists of a certificate of deposit with a maturity of 12 months or less, is classified as a Level 2 financial asset because it is valued using quoted market price and other observable inputs in active markets for identical securities.

There were no significant transfers between Level 1 and Level 2 during the years ended December 31, 2018 and 2019. The Company's policy is to recognize transfers between levels at the end of the reporting period.

The Company recorded a non-recurring Level 3 fair value impairment loss of $1.4 million on its investment in NeoSeq for the year ended December 31, 2018, discussed in Note 2 "Equity Method Investment." No impairment loss was recorded for the year ended December 31, 2019.

Fair Value of Financial Instruments

The carrying value of the Company's accounts receivable, income tax receivable, accounts payable, and accrued expenses and other current liabilities are considered to be representative of their respective fair values because of their short-term nature.

The carrying value of the Company's mortgages payable approximates their estimated fair value because the instruments bear interest at rates and have terms that are comparable to those available to the Company for similar loan instruments at December 31, 2018 and 2019.

The carrying value of the Company's note payable to a related party does not approximate its fair value because the instrument bears interest at a rate that is not comparable to those available to the Company for a similar loan instrument at December 31, 2018 and 2019. The carrying value and the fair value of the Company's term loan (the "2017 Term Loan") is $75.0 million and $76.7 million, respectively, at December 31, 2018 and $75.0 million and $79.8 million, respectively, at December 31, 2019. The carrying value of the 2017 Term Loan is presented on the accompanying consolidated balance sheets net of discount on the note and debt issuance cost.

7. Note Payable to Related Party

On October 27, 2017, the Company entered into a Credit and Security Agreement and a Series B Convertible Preferred Stock Purchase Agreement with a private equity firm (the "2017 Transaction"). The 2017 Transaction provided for the 2017 Term Loan, the issuance of Series B Preferred Stock (the "Series B Preferred Stock"), and the issuance of a warrant to purchase Series B Preferred Stock (the "Series B Preferred Stock Purchase Warrant"). The 2017 Term Loan accrues interest at a rate per annum equal to 9.5% and is due October 27, 2022.

The 2017 Term Loan contains customary covenants, including a requirement to maintain a minimum unrestricted cash balance at all times at least equal to $5.0 million. The Company is in compliance with the 2017 Term Loan covenants. The 2017 Term Loan is secured by all tangible and intangible property and assets of the Company, with the exception of intellectual property.

The total proceeds of $124.2 million from the 2017 Transaction were allocated to the 2017 Term Loan, Series B Preferred Stock, and the Series B Preferred Stock Purchase Warrant based on the relative fair value of the term loan, equity, and warrant issued. As a result, the Company allocated proceeds of $65.7 million to the 2017 Term Loan. As the proceeds allocated to the 2017 Term Loan are lower than the stated loan amount of $75.0 million, the resulting $9.3 million discount will be amortized as interest expense using the effective interest method over the term of the loan.

As of both December 31, 2018 and 2019, the outstanding unpaid principal under the 2017 Term Loan is $75.0 million, due in October 2022. The unamortized discount on the 2017 Term Loan was $7.7 million and $6.0 million as of December 31, 2018 and 2019, respectively.

During the years ended December 31, 2018 and 2019, the Company recognized interest expense on the 2017 Term Loan of $8.7 million and $8.9 million, inclusive of $1.5 million and $1.7 million of amortized interest expense on the discount for the years ended December 31, 2018 and 2019, respectively.

8. Mortgages Payable

On January 24, 2014, the Company executed a mortgage with Comerica Bank for $1.8 million for the purpose of acquiring property located in Ann Arbor, Michigan, which was previously leased by the Company and used for laboratory testing and research purposes. The outstanding balance as of December 31, 2018 and 2019 was $1.5 million and $1.4 million, respectively. The mortgage matures in 2024 and requires monthly principal and interest payments at a fixed interest rate of 2.94% plus a floating rate at London Interbank Offered Rate ("LIBOR").

The Company also has a mortgage with American Bank of Commerce (originally executed on February 19, 2008) outstanding on Avero's property located in Lubbock, Texas, which is used primarily for laboratory testing. The outstanding balance as of December 31, 2018 and 2019 was $2.1 million and

$1.9 million, respectively. The mortgage matures in 2029 and requires monthly principal and interest payments at an interest rate of 4.25%.

As of December 31, 2019, the minimum principal payments under the mortgages payable are as follows (in thousands):

Year Ending December 31,	Minimum Mortgages Payable Payments
2020	241
2021	253
2022	265
2023	277
2024 and thereafter	2,286
Total future minimum payments	$ 3,322
Less current portion of mortgages payable	(241)
Mortgages payable, net of current portion	$ 3,081

9. Commitments and Contingencies

Operating Leases

The Company has entered into various noncancelable operating lease agreements, primarily for office space, laboratory space, and vehicles, which expire over the next 2 to 4 years. Minimum rent payments under operating leases are recognized on a straight-line basis over the term of the lease. Rent expense for operating leases for the years ended December 31, 2018 and 2019, was $7.1 million and $8.9 million, respectively.

As of December 31, 2019, the Company's net minimum payments under the non-cancelable operating leases are as follows (in thousands):

Year Ending December 31,	Minimum Operating Lease Payments
2020	$ 8,167
2021	4,838
2022	2,652
2023 and thereafter	906
Total future minimum payments	$ 16,563

Capital Leases

The Company has entered into various capital lease agreements, primarily for equipment. The outstanding leases have a weighted average imputed interest rate of 5.62% per annum.

As of December 31, 2019, the future minimum payments under the capital leases are as follows (in thousands):

Year Ending December 31,	Minimum Capital Lease Payments
2020	$ 773
2021	324
2022 and thereafter	47
Total future minimum payments	$ 1,144
Less amount representing interest	(59)
Present value of minimum capital lease payments	1,085
Less current portion of capital lease obligations	(727)
Capital lease obligations, net of current portion	$ 358

Contingencies

The Company, in the ordinary course of its business, can be involved in lawsuits, threats of litigation, and audit and investigative demands from third parties. While management is unable to predict the exact outcome of such matters, it is management's current belief, that any potential liabilities resulting from these contingencies, individually or in the aggregate, could have a material impact on the Company's financial position and results of operations.

The regulations governing government reimbursement programs (e.g., Medicaid, Tricare, and Medicare) and commercial payor reimbursement programs are complex and subject to interpretation. As a provider of services to patients covered under government and commercial payor programs, post payment review audits, and other forms of reviews and investigations are routine. The Company believes it complies in all material respects with the statutes, regulations, and other requirements applicable to its laboratory operations.

In April 2018, the Company received a civil investigative demand from an Assistant U.S. Attorney ("AUSA") for the Southern District of New York and a Health Insurance Portability and Accountability Act ("HIPAA") subpoena issued by an AUSA for the Southern District of California. In May 2018, the Company received a subpoena from the State of New York Medicaid Fraud Control Unit. While the Company has not been served with a civil or criminal complaint, it is currently under federal civil and criminal investigations, and state civil investigations, regarding discontinued legacy billing practices for its non-invasive prenatal testing and microdeletion tests and for the provision of potential kickbacks or inducements to physicians and patients. The civil investigations also include inquiries about the Company's laboratory licenses, its enrollment in state Medicaid programs, and the laboratories that performed testing for the Company. The Company has met several times with representatives from the government entities conducting the related investigations, together as a group, to discuss the potential for a global resolution of all issues with all entities, which may include governmental entities and others that are not currently participating in such discussions. In response to proposed settlement offers from the Company, representatives from the government entities made a demand of $66.7 million to settle all issues. The Company has recorded an accrual of $35.8 million associated with a potential settlement in accrued expenses and other current liabilities as of December 31, 2019 which represents the amount offered by the Company to settle the matters and the minimum amount of the potential range of loss.

However, the Company has not yet completed negotiations, and there can be no assurance as to whether or when the parties will finalize any such negotiated resolution or what the final terms of such a resolution will be. The Company cannot provide any assurance as to the ultimate outcome or that an adverse resolution would not have a material adverse effect on the Company's business, financial condition and results of operations.

The Company cannot provide any assurance as to the ultimate outcome or that an adverse resolution would not have a material adverse effect on the Company's business, financial condition and results of operations.
On June 21, 2018, the Company received a letter from Cigna alleging damages related to contract terms. On December 5, 2018, Cigna and the Company entered into a settlement agreement whereby Avero agreed to pay an aggregate amount of $12.0 million with an upfront payment of $6.0 million and the remaining $6.0 million to be paid over 24 months. For the year ended December 31, 2018, the Company recorded a charge of $12.0 million associated with this claim in its consolidated statements of operations as a reduction to revenue. As of December 31, 2019, the remaining settlement accrual related to Cigna is $3.0 million in accrued expenses and other current liabilities.

On June 25, 2018, the Company received a letter from Aetna's external legal counsel that included various allegations relating to the Company's past practices. In November 2019, the Company and Aetna entered into a written settlement agreement for $15.0 million, to be paid in installment payments through December 2020. During the year ended December 31, 2018, the Company recorded a charge of $15.0 million associated with this claim in its consolidated statements of operations as a reduction to revenue. As of December 31, 2019, the Company's accrual consists of $10.0 million in accrued expenses and other current liabilities.

On October 18, 2018, the Company received a letter from UnitedHealth Group that included various allegations relating to the Company's past practices. On September 30, 2019, the Company entered into a settlement agreement with United HealthCare Services, Inc. and UnitedHealthcare Insurance Company ("United") in which the Company agreed to pay an aggregate amount of $30.0 million. The settlement is to be paid with an upfront payment of $2.0 million, and the remaining balance to be paid every six months starting December 31, 2019, with the first two installment payments of $5.0 million each, and $6.0 million each thereafter. During the years ended December 31, 2018 and 2019, the Company recorded a charge of $27.0 million and $3.0 million, respectively, associated with this claim in its consolidated statements of operations as a reduction to revenue to adjust the accrual to $30.0 million. As of December 31, 2019, the remaining settlement accrual related to United is $23.0 million consisting of $11.0 million in accrued expenses and other current liabilities and $12.0 million in other long-term liabilities.

10. Stockholders' Equity

Common Stock

Pursuant to the November 2019 sixth amended and restated certificate of incorporation, the Company is authorized to issue 300 million shares of common stock. Each holder of common stock is entitled to one vote per share of common stock held.

Treasury Stock

In June 2014, the Company authorized an Equity Repurchase Program for Key Employees (the "Repurchase Program"). The Repurchase Program allows the Company to repurchase for cash a

portion of common stock equity interest of certain employees, provided that (i) no more than 25% of the equity interest of any employee shall be repurchased under the Repurchase Program, (ii) the purchase price to be paid for each share of common stock shall equal the most recent appraisal valuation of the Company's common stock, and (iii) the aggregate repurchases shall not exceed the lesser of (a) equity interest representing, in the aggregate, 0.8 million shares of common stock, (b) a purchase price, in the aggregate, of more than $6.0 million, and (c) the maximum repurchases permitted under the General Corporation Law of the State of Delaware. In addition, it is the Company's practice to require individuals exercising stock options to hold the shares upon exercising for a reasonable period of time in order for the holder to be exposed to the economic risks and rewards of share ownership prior to participating in the Repurchase Program. A reasonable period of time is defined as a period of at least six months and that covers at least two common stock appraisal valuations.

On December 19, 2017, the Company extended the offer to certain key employees to repurchase up to 0.6 million shares in aggregate at a price of $21.81 per share of Company's common stock. In February 2018, the Company completed the offer and paid an aggregate of $12.5 million to repurchase 0.6 million shares of Company's common stock. At the time of repurchase, the Company's common stock was appraised at $19.65 per share which resulted in a recording of $11.3 million as treasury stock. The difference of $1.2 million was recorded as stock-based compensation expense.

Convertible Preferred Stock

As of December 31, 2018, the Company had outstanding Series A Preferred Stock, Series A-1 Preferred Stock and Series B Preferred Stock. As of December 31, 2019, the Company had outstanding Series A Preferred Stock and Series B Preferred Stock. The Company recorded the preferred stock at fair value on the dates of issuance net of issuance costs.

On August 27, 2019, the Company issued 9.1 million shares of Series B Preferred Stock at an issuance price of $2.75 per share for an aggregate consideration of $25.0 million (the "August 2019 Financing") pursuant to a Series B Preferred Stock Purchase Agreement with a private equity firm. In addition, the Company amended the Series B Preferred Stock Purchase Warrant dated October 27, 2017 to increase the Series B Preferred Stock underlying the Series B Preferred Stock Purchase Warrant from 1.4 million to 1.8 million shares and adjust the exercise price to $2.75 per share. The $25.0 million of proceeds from the August 2019 Financing are allocated among the newly issued Series B Preferred Stock shares and additional shares of Series B Preferred Stock Purchase Warrant at their relative fair values.

In connection with the August 2019 Financing, the board of directors and stockholders approved a 1.28-for-1 stock split for the Company's Series B Preferred Stock and Series B Preferred Stock Purchase Warrant issued and outstanding prior to the August 2019 Financing, which was effected on August 27, 2019 pursuant to an amendment to the amended and restated certificate of incorporation. The conversion price of the Series B Preferred Stock and exercise price of the outstanding Series B Preferred Stock Purchase Warrant was lowered from $3.53 to $2.75 per share. As a result, the Company issued 4.0 million additional shares of Series B Preferred Stock as a stock dividend to the preferred stockholders, which was recorded as a $13.1 million increase to accumulated deficit on the accompanying consolidated statements of stockholders' deficit during the year ended December 31, 2019.

On August 27, 2019, the Company entered into an Exchange Agreement with holders of Series A-1 Preferred Stock (the "Exchange Agreement") pursuant to which the outstanding 1,500,000 shares of Series A-1 Preferred Stock were exchanged for 35,664,240 shares of Series B Preferred Stock. The exchange ratio is 1.2 to 1 on as-if converted to 4,810,651 shares of common stock that the Series A-1

Preferred Stock can be converted to, based on the conversion rate of 3.2 to 1. The Company determined that such exchange was a modification to the Series A-1 Preferred Stock. Accordingly, the increase comparing the fair value of the Series B Preferred Stock with the fair value of the Series A-1 Preferred Stock represents a dividend to the preferred stockholders, which was approximately $27.6 million and recorded as an increase to accumulated deficit on the accompanying consolidated statements of stockholders' deficit during the year ended December 31, 2019.

On November 12, 2019, the Company entered into a Series B Preferred Stock Purchase Agreement (the "November Series B Preferred Stock Purchase Agreement") with a private equity firm and received $25.0 million (the "November 2019 Financing") in exchange for the issuance of 11.1 million shares of Series B Preferred Stock at $2.25 per share. In connection with the November 2019 Financing, the board of directors and stockholders approved a 1.22-for-1 stock split for the Company's Series B Preferred Stock and Series B Preferred Stock Purchase Warrant issued and outstanding prior to the November 2019 Financing. The conversion price of the Series B Preferred Stock and exercise price of the outstanding Series B Preferred Stock Purchase Warrant was lowered from $2.75 to $2.25 per share. As a result, the Company issued 14.0 million additional shares of Series B Preferred Stock and adjusted the Series B Preferred Stock Purchase Warrant to purchase up to 2.2 million shares of Series B Preferred Stock. The issuance of additional shares represented a stock dividend to the preferred stockholders, which was recorded as a $36.4 million increase to accumulated deficit on the accompanying consolidated statements of stockholders' deficit during the year ended December 31, 2019.

On November 22, 2019 the Company completed an additional equity financing pursuant to the November Series B Preferred Stock Purchase Agreement with certain existing, accredited investors for an aggregate of $6.1 million in exchange for the issuance of an aggregate of 2.7 million shares of Series B Preferred Stock at $2.25 per share.

On December 19, 2019, the Company completed an additional equity financing pursuant to the November Series B Preferred Stock Purchase Agreement with the same private equity firm as the November 2019 Financing for $25.0 million in exchange for the issuance of 11.1 million shares of Series B Preferred Stock at $2.25 per share.

The fair value of the preferred stock was estimated using a hybrid between a probability-weighted expected return method ("PWERM") and option pricing model ("OPM"), estimating the probability weighted value across multiple scenarios, while using an OPM to estimate the allocation of value within one or more of these scenarios. Under a PWERM, the value of the Company's various classes of stock was estimated based upon an analysis of future values for the Company assuming various future outcomes, including two IPO scenarios and one scenario contemplating the continued operation of the Company as a privately held enterprise. Guideline public company multiples were used to value the Company under its various scenarios. Share value for each class of stock was based upon the probability-weighted present value of expected future share values, considering each of these possible future outcomes, as well as the rights of each share class.

The significant unobservable inputs into the valuation model used to estimate the fair value of the preferred stock include the timing of potential events (primarily the IPO) and their probability of occurring, the selection of guideline public company multiples, a discount for the lack of marketability of the common stock, and the discount rate used to calculate the present value of the estimated equity value allocated to each share class.

PROGENITY, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Preferred stock outstanding as of December 31, 2018 and 2019 consisted of the following (in thousands, except share and per share data):

	December 31, 2018			
	Shares Authorized	Shares Issued and Outstanding	Per Share Price at Issuance	Aggregate Liquidation Preference
Series A	4,120,000	4,120,000	$ 0.48543	$ 2,000
Series A-1	2,000,000	1,500,000	9.00000	13,500
Series B	15,580,737	14,164,306	3.53000	50,000
Total preferred stock	21,700,737	19,784,306		$ 65,500

	December 31, 2019			
	Shares Authorized	Shares Issued and Outstanding	Per Share Price at Issuance	Aggregate Liquidation Preference
Series A	4,120,000	4,120,000	$ 0.48543	$ 2,000
Series A-1	—	—	9.00000	—
Series B	126,035,000	101,867,405	2.25000	229,202
Total preferred stock	130,155,000	105,987,405		$ 231,202

On November 12, 2019, in connection with the November 2019 Financing, the Company amended the certificate of incorporation. Following the amendment, there are no authorized or outstanding shares of Series A-1 Preferred Stock. Pursuant to the sixth amended and restated certificate of incorporation, the stockholders of preferred stock have the following rights, preferences, and privileges:

Dividend Rights

The Company cannot declare, pay or set aside any dividends on shares of common stock (other than dividends on shares of common stock payable in shares of common stock) unless the holders of the outstanding preferred stock also receive a dividend in an amount equal to the product of dividend payable on each share of common stock and the number of shares of common stock then issuable upon conversion of such share of preferred stock.

No other dividends can be declared, paid or set aside besides the aforementioned dividends to the convertible preferred stock.

Liquidation Preference

Upon a liquidation event, as defined in the amended and restated certificate of incorporation, the holders of Series A and Series B Preferred Stock are entitled to receive, prior to and in preference to any distribution of the proceeds of such liquidation to common stockholders, an amount per share equal to $0.48543 and $2.25, respectively, plus any declared but unpaid dividends on such shares. If the proceeds distributed among the holders of the preferred stock are insufficient to permit the Series A and Series B Preferred Stock holders to receive the full payment noted above, then the entire proceeds legally available for distribution shall be distributed ratably among the holders of the convertible preferred stock in proportion to the full preferential amount that each such holder is otherwise entitled to receive with the holders of Series B Preferred Stock having priority and preference to Series A Preferred Stock.

PROGENITY, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Voting Rights

The holders of each share of preferred stock have the right to one vote for each share of common stock into which such preferred stock could then be converted.

Holders of Series A Preferred Stock, or holders of Series B Preferred Stock voting together as a separate class, can vote for the number of directors that is proportionate to shares of common stock that each share of preferred stock can be converted into relative to all voting shares, provided at least 2.5 million and 40.0 million shares of Series A and Series B Preferred Stock, respectively, are outstanding, and Series B Preferred Stock constitutes at least 10% of the voting shares.

Conversion Rights

Each share of preferred stock is convertible, at the option of the holder, into fully paid and non-assessable shares of common stock determined by dividing the applicable original issue price by the applicable conversion price in effect at the time of conversion. The original issue prices of Series A and Series B Preferred Stock are $0.48543 and $2.25 per share, respectively. The initial conversion prices of Series A and Series B Preferred Stock are $0.15 and $13.90 per share, respectively.

Shares of Series A and Series B Preferred Stock will be automatically converted into fully paid shares of common stock immediately upon the earlier of: (a) the closing of the sale of shares of common stock to the public at a minimum price of $13.90 per share, subject to appropriate adjustment in the event of any stock dividend, stock split, combination, or other similar recapitalization with respect to common stock, in a firm-commitment underwritten IPO pursuant to an effective registration statement under the Securities Act of 1933, as amended, resulting in at least $50.0 million of gross cash proceeds to the Company (such IPO, a “Qualified IPO”) or (b) at the date specified by written consent, or affirmative vote, or agreement of the holders of at least 75% of Series A Preferred Stock and Series B Preferred Stock, voting as separate classes.

In the event of the consummation of a Qualified IPO, the conversion price per share of Series B Preferred Stock shall be adjusted to equal the lesser of (1) the then current conversion price per share of Series B Preferred Stock and (2) the “Price to Public” per share of common stock specified in the final prospectus with respect to the Qualified IPO (the “Public Price”).

Or in the event of the consummation of an IPO where the Public Price is less than $15.986 per share of common stock, the conversion rate per share of Series B Preferred Stock shall be adjusted, as of immediately prior to the consummation of the Qualified IPO, such that each share of Series B Preferred Stock shall be convertible into a number of shares of common stock equal to the quotient of (1) the Series B Preferred Stock original issue price divided by (2) the Public Price multiplied by 0.865.

Redemption Rights

The Company’s shares of preferred stock are not mandatorily redeemable.

A liquidation event will be deemed to occur upon certain sales and merger of the Company. Such deemed liquidation event will require consent of the majority of the outstanding Series B Preferred Stock, unless the consideration from such event will result into a minimum of $16.68 per share to Series B Preferred Stock or common stock converted into.

Common Stock

The Company reserved shares of common stock, on an as-if-converted basis, for future issuance as follows:

	December 31, 2018	December 31, 2019
Series A Preferred Stock	13,213,254	13,213,254
Series A-1 Preferred Stock	4,810,649	—
Series B Preferred Stock	2,292,700	16,488,731
Series B Preferred Stock Purchase Warrant	229,270	359,699
Restricted stock units	85,801	322,608
Outstanding options to purchase common stock	2,537,299	2,561,866
Options available for future issuance	432,388	1,717,817
Total	23,601,361	34,663,975

11. Stock-based Compensation

On February 22, 2018, the Company adopted the 2018 Equity Incentive Plan (the "2018 Plan"), with 0.7 million shares available for future grant. Upon adoption of the 2018 Plan, no new stock options are issuable under the Second Amended and Restated 2012 Stock Plan (the "2012 Plan") or the 2015 Consultant Stock Plan (the "2015 Plan"). The 2018 Plan is the successor to and continuation of the 2012 Plan, as amended, and the 2015 Plan, and is administered with either stock options or restricted stock units. The 2018 Plan also provides for other types of equity to issue awards, which at this time the Company does not plan to utilize. The 2018 Plan was amended in March 2019 (the "2018 Amended Plan") with 1.1 million shares available for future grant.

On December 5, 2019, the Company adopted the Second Amended and Restated 2018 Equity Incentive Plan (the "2018 Second Amended Plan"), which increased the shares available for future grant to 2.7 million. The Board of Directors administers the plans.

Activity under the 2012 Plan, the 2015 Plan, and the 2018 Second Amended Plan for the year ended December 31, 2019 is set forth below (in thousands, except share and per share data):

	Stock Options Outstanding	Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance at December 31, 2018	2,537,299	$ 7.21		
Awards authorized	—			
Options granted	518,631	14.08		
Options exercised	(338,834)	1.62		
Options forfeited	(131,765)	15.46		
Options expired	(23,465)	12.35		
Balance at December 31, 2019	2,561,866	$ 9.01	5.78	$ 8,705
Vested and exercisable at December 31, 2019	1,894,193	$ 6.89	4.69	$ 8,705
Vested and expected to vest at December 31, 2019	2,475,261	$ 8.81	5.66	$ 8,705

Options available for grant totaled 1,717,817 at December 31, 2019.

Determining Fair Value of Stock Options—Summary of Assumptions

The Company uses the Black-Scholes option pricing model to estimate the fair value of each option grant on the date of grant or any other measurement date. The following table sets forth the assumptions used to determine the fair value of stock options:

	Year Ended December 31, 2019
Risk-free interest rate	1.4% - 2.4%
Expected volatility	57.0% - 71.0%
Expected dividend yield	—
Expected term (in years)	6.25 years

For the years ended December 31, 2018 and 2019, the following table presents total stock-based compensation expense in each functional line item on the consolidated statements of operations (in thousands):

	Year Ended December 31,	
	2018	2019
Cost of sales	$ 731	$ 207
Research and development	682	851
Selling and marketing	940	501
General and administrative	1,150	816
Total stock-based compensation expense	$3,503	$2,375

The weighted-average grant date fair value of options granted during the years ended December 31, 2018 and 2019 was $9.82 per option and $7.35 per option, respectively. At December 31, 2018 and 2019, there was $3.6 million and $4.1 million, respectively, unrecognized compensation cost related to unvested stock options, which are expected to be recognized over a remaining weighted average vesting period of 2.57 years and 2.69 years, respectively.

PROGENITY, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

12. Income Taxes

The provision for income taxes consists of the following (in thousands):

	Year Ended December 31, 2018	Year Ended December 31, 2019
Current provision:		
Federal	$ (1,319)	$ (638)
State	324	(104)
	(995)	(742)
Deferred expense:		
Federal	5,163	36
State	1,082	—
	6,245	36
Income tax expense (benefit) from continuing operations	5,250	(706)
Net income tax provision	$ 5,250	$ (706)

The components of income tax expense relate to the following (in thousands):

	Year Ended December 31, 2018	Year Ended December 31, 2019
Income tax benefit at U.S. federal statutory rate	$ (26,010)	$ (31,236)
State income tax benefit, net of federal benefit	(3,223)	(4,538)
Meals and entertainment	306	367
Stock-based compensation	248	(87)
Federal research and development credit	(1,485)	(3,232)
Change in valuation allowance	36,473	38,514
Other	(1,059)	(494)
Total income tax expense	$ 5,250	$ (706)

PROGENITY, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Deferred income taxes reflect the net tax effects of (a) temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, and (b) operating losses and tax credit carryforwards. The tax effects of temporary differences that give rise to portions of the deferred tax assets and deferred tax liabilities as of December 31, 2018 and 2019 are presented below (in thousands):

	Year Ended December 31, 2018	Year Ended December 31, 2019
Deferred tax assets:		
Net operating losses and carryforwards	$ 18,907	$ 51,768
Reserves	9,857	17,287
Intangible assets	4,147	3,982
Accrued expenses	4,329	3,025
Other	979	194
Total deferred tax assets	38,219	76,256
Deferred tax liabilities:		
Fixed assets	(1,426)	(1,705)
Prepaid expenses	(150)	(138)
Goodwill	(170)	(205)
Adoption of ASC 606	—	(4,227)
Total deferred tax liabilities	(1,746)	(6,275)
Net deferred tax assets	36,473	69,981
Less: valuation allowance	(36,473)	(70,017)
Net deferred tax assets/liabilities	$ —	$ (36)

Due to the losses generated in 2018 and 2019 and projected future taxable losses anticipated in the future, in 2018 management decided that it is not more likely than not that the Company will realize the benefits of its deferred tax assets. As such, the Company recorded a valuation allowance of $36.5 million and $70.0 million, respectively, on its net deferred tax assets as of December 31, 2018 and 2019.

At December 31, 2019, the Company had federal and state income tax net operating loss carryforwards of approximately $173.6 million and $94.7 million, respectively. The U.S. federal net operating losses will be carried forward indefinitely and state net operating losses will begin to expire in 2038 unless previously utilized. Net operating loss carryforwards generated post the TCJA may be carried forward indefinitely, subject to the 80% taxable income limitation on the utilization of the carryforwards. In addition, the Company had federal and state research and expenditure credit carryforwards approximately of $4.7 million and $1.6 million, respectively, as of December 31, 2019. The federal research and expenditure credit will expire in 2038 if unused and the state research and expenditure credit may be carried forward indefinitely.

Pursuant to Section 382 of the Internal Revenue Code, annual use of the Company’s net operating loss carryforwards and tax credit carryforwards may be limited as a result of cumulative changes of ownership resulting in a change of control of the Company. The Company has not performed a section 382 study of its prior ownership changes, and therefore the recoverability of these carryforwards is an estimate that is subject to change upon completion of a study, or upon future changes in ownership as defined by Section 382 of the Internal Revenue Code.

PROGENITY, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

In accordance with ASC 740-10, *Income Taxes—Overall*, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more likely than not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. The Company has no uncertain tax positions at December 31, 2019.

The Company's policy is to recognize interest and penalties related to income tax matters in the provision for income taxes. At December 31, 2019, there were no interest and penalties related to uncertain tax positions.

The Company is subject to taxation in the United States and various state jurisdictions. The tax years 2014 through 2017 remain open to examination by the major taxing jurisdictions to which the Company is subject.

13. Net Loss Per Share

Net loss per share is computed by dividing net loss attributable to common stockholders for the period by the weighted average number of common shares outstanding during the period. Diluted loss per share reflects the additional dilution from potential issuances of common stock, such as stock issuable pursuant to the exercise of stock options, as well as from the possible conversion of the Company's preferred stock and exercise of the outstanding warrant. The treasury stock and if-converted methods are used to calculate the potential dilutive effect of these common stock equivalents. However, potentially dilutive shares are excluded from the computation of diluted loss per share when their effect is antidilutive. Due to the Company reporting a net loss attributable to common stockholders for all periods presented, all potentially dilutive securities were antidilutive and have been excluded from the computation of diluted loss per share.

The table below provides potentially dilutive securities in equivalent common shares not included in the Company's calculation of diluted loss per share because to do so would be antidilutive:

	Year Ended December 31,	
	2018	2019
Series A Preferred Stock	13,213,254	13,213,254
Series A-1 Preferred Stock	4,810,649	—
Series B Preferred Stock	2,292,700	16,488,731
Series B Preferred Stock Purchase Warrant	229,270	359,699
Options to purchase common stock	2,537,299	2,561,866
Restricted stock units	85,801	322,608
Total	23,168,973	32,946,158

PROGENITY, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

The Company has presented basic and diluted net loss per share, which has been computed to give effect to the conversion of all shares of preferred stock and restricted stock units into shares of common stock as if such conversion had occurred as of the beginning of the period presented. The following table sets forth the computation of the Company's basic and diluted net loss per common share (unaudited) (in thousands, except share and per share data):

	Year Ended December 31, 2019 (unaudited)
Numerator:	
Net loss used in computing net loss per share, basic and diluted	$ (228,827)
Pro forma adjustments to remove dividend paid to preferred stockholders	3,652
Pro forma adjustments to remove stock dividend on exchange of Series A-1 for Series B Preferred Stock	27,637
Pro forma adjustments to remove stock dividend on Series B Preferred Stock	49,501
Net loss used in computing pro forma net loss per share, basic and diluted	$ (148,037)
Denominator:	
Shares used in computing net loss per share, basic and diluted	4,882,662
Pro forma adjustments to reflect assumed conversion of preferred stock	22,032,758
Pro forma adjustments to reflect assumed conversion of vested restricted stock units	46,025
Shares used in computing pro forma net loss per share, basic and diluted	26,961,445
Pro forma basic and diluted net loss per share	$ (5.49)

Diluted loss per share does not include outstanding stock options, restricted stock units, and the outstanding Series B Preferred Stock Purchase Warrant since the effect would be antidilutive due to the net loss attributable to common stockholders for the period.

14. Employee Benefit Plan

The Company has a qualified 401(k) employee savings plan for the benefit of its employees (the "plan"). Substantially all employees are eligible to participate in the plan. Under the plan, employees can contribute and defer taxes on compensation contributed. The Company has the option to make discretionary profit-sharing contributions to the plan. The Company made employer contributions to the plan of $1.9 million and $2.5 million for the years ended December 31, 2018 and 2019, respectively.

15. Subsequent Events

The Company has evaluated subsequent events from the balance sheet date through March 18, 2020, the date the consolidated financial statements were available to be issued, except for the reverse stock split discussed below.
In February 2020, we issued and sold an aggregate of 5,066,666 shares of our Series B Preferred Stock at a purchase price of $2.25 per share to existing investors in exchange for aggregate consideration of approximately $11.4 million in cash.

On June 10, 2020 the Company amended its certificate of incorporation to reflect a 6.178-for-1 reverse stock split of the Company's common stock. The par values and the number of authorized shares of common stock were not adjusted as a result of the reverse stock split. All issued and outstanding shares

of common stock and related per share amounts contained in the accompanying consolidated financial statements have been retroactively adjusted to reflect this reverse stock split for all periods presented. The reverse stock split resulted in an adjustment to the respective Series A and B preferred stock conversion prices to reflect a proportional decrease in the number of shares of common stock to be issued upon conversion.

16. Events (Unaudited) Subsequent to the Date of Report of the Independent Registered Public Accounting Firm

On March 31, 2020, in connection with an amendment to our existing credit agreement, which provides for the payment of interest due and payable as of March 31, 2020 and June 30, 2020 in shares of our Series B Preferred Stock, we issued an aggregate of 967,130 shares of our Series B Preferred Stock at a subscription price of $2.25 per share to existing investors as payment for interest due and payable as of March 31, 2020 and all applicable fees.

On April 3, 2020, we issued and sold an aggregate of 4,444,444 shares of our Series B Preferred Stock at a purchase price of $2.25 per share to existing investors in exchange for aggregate consideration of approximately $10.0 million in cash.

In April 2018, we received a civil investigative demand from an Assistant U.S. Attorney for the Southern District of New York and a HIPAA subpoena issued by an Assistant U.S. Attorney for the Southern District of California. In May 2018, we received a subpoena from the State of New York Medicaid Fraud Control Unit. Since that time, we have cooperated with federal civil and criminal investigations, and state civil investigations, regarding discontinued legacy billing practices for our NIPT and microdeletion tests and the provision of alleged kickbacks or inducements to physicians and patients. The civil investigations also include inquiries about our laboratory licenses, our enrollment in state Medicaid programs, and the laboratories that performed testing for us.

On March 31, 2020, we reached an agreement on the monetary terms with the Department of Justice (the “DOJ”) and the State of New York (with the State of New York Attorney General representing or facilitating the interests of all States participating in the settlement (collectively, the “State AGs”)) with respect to relevant government health benefit programs to resolve all of the government’s outstanding civil and criminal investigations, including the investigations by the U.S. Attorney’s Office for the Southern District of California and the U.S. Attorney’s Office for the Southern District of New York, as well as the investigation by the State AGs. The terms of this agreement in principle contemplate that we will enter into a civil settlement agreement providing that we will pay $8.0 million upon entering into the settlement, $4.0 million in December 2020, $5.0 million in December 2021, $7.0 million in December 2022, $8.0 million in December 2023, $9.0 million in December 2024, and $8.0 million in December 2025 (all of which, other than the initial $8.0 million payment, will also be subject to interest at a rate of 1.25% per annum) for a release of the civil claims and that we will enter into a non-prosecution agreement to resolve all criminal allegations. Those criminal allegations pertain to discontinued legacy billing practices for our NIPT tests. The companion civil settlement agreement is expected to resolve all civil claims involving discontinued legacy billing practices for our NIPT and microdeletion tests as well as other allegations pertaining to the provision of potential kickbacks or inducements to physicians and patients. Other non-financial terms and conditions remain subject to negotiation. The final civil settlement materials are subject to final approval of the Assistant Attorney General at DOJ, a U.S. District Court judge in New York, and any other relevant parties, including any potential whistleblower and the State AGs. We also expect to enter into a corporate integrity agreement with the Department of Health and Human Services Office of Inspector General, which would be expected to impose additional

compliance, reporting and disclosure obligations, and related costs in the future. The agreement in principle does not cover other potential claims by a potential whistleblower(s), if any, of a nature not covered by the government settlement.

As of December 31, 2019, we had accrued an aggregate of $35.8 million associated with a potential settlement with the DOJ and the participating State AGs within accrued expenses and other current liabilities and as a reduction of revenue as reflected on the consolidated balance sheet of the Company as of December 31, 2019 and consolidated statement of operations for the year ended December 31, 2019. In addition, in the quarter ended March 31, 2020, we expect to accrue an additional $13.2 million with respect to the total amount to be paid under the agreement in principle to the DOJ and the participating State AGs, and additional amounts for any related costs as of and for the quarterly period ended March 31, 2020. Until the final documents are approved and signed, there can be no assurance that the amount we have accrued will be sufficient to cover our obligations relating to this matter. Our obligations could also increase depending on a number of factors, potentially materially, including whether or not the agreement in principle is finalized, the terms of the final approved agreements, the parties to the settlement, the cost of complying with the terms of the settlement, including monitoring fees related to any potential corporate integrity agreement, the costs related to the settlement, and other factors.

PROGENITY, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share data)

	As of December 31, 2019	As of March 31, 2020 (unaudited)	Pro Forma as of March 31, 2020 (unaudited)
ASSETS			
Current assets:			
Cash and cash equivalents	$ 33,042	$ 11,646	
Accounts receivable, net	22,189	15,639	
Inventory	10,937	9,980	
Income tax receivable	634	38,296	
Prepaid expenses and other current assets	7,846	8,207	
Total current assets	74,648	83,768	
Property and equipment, net	15,891	16,226	
Other assets	198	199	
Goodwill	6,219	6,219	
Other intangible assets, net	4,771	4,539	
Total assets	$ 101,727	$ 110,951	
LIABILITIES AND STOCKHOLDERS' DEFICIT			
Current liabilities:			
Accounts payable	$ 15,754	$ 16,963	
Accrued expenses and other current liabilities	83,615	56,410	
Current portion of mortgages payable	241	244	
Current portion of capital lease obligations	727	630	
Total current liabilities	100,337	74,247	
Capital lease obligations, net of current portion	358	240	
Mortgages payable, net of current portion	3,081	3,016	
Note payable to related party, net of unamortized discount of $6,034 and $6,481 as of December 31, 2019 and March 31, 2020, respectively	68,966	68,519	
Other long-term liabilities	12,859	49,723	
Total liabilities	$ 185,601	$ 195,745	
Commitments and Contingencies (Note 9)			
Stockholders' deficit:			
Common stock – $0.001 par value. 300,000,000 shares authorized as of December 31, 2019 and March 31, 2020; 8,451,415 and 8,508,144 shares issued as of December 31, 2019 and March 31, 2020, respectively; 4,976,843 and 5,033,572 shares outstanding as of December 31, 2019 and March 31, 2020, respectively; 39,186,786 shares issued and 35,712,214 shares outstanding as of March 31, 2020, pro forma	9	9	39
Series A Preferred Stock – $0.001 par value. 4,120,000 shares authorized as of December 31, 2019 and March 31, 2020; 4,120,000 shares issued and outstanding as of December 31, 2019 and March 31, 2020; no shares issued and outstanding as of March 31, 2020, pro forma	4	4	—
Series B Preferred Stock – $0.001 par value. 126,035,000 shares authorized as of December 31, 2019 and March 31, 2020; 101,867,405 and 107,901,201 shares issued and outstanding as of December 31, 2019 and March 31, 2020, respectively; no shares issued and outstanding as of March 31, 2020, pro forma	102	108	—
Additional paid-in capital	283,260	299,486	299,568
Accumulated deficit	(348,478)	(365,630)	(365,630)
Treasury stock – at cost; 3,474,572 shares of common stock as of December 31, 2019 and March 31, 2020; actual and pro forma	(18,771)	(18,771)	(18,771)
Total stockholders' deficit	(83,874)	(84,794)	$ (84,794)
Total liabilities and stockholders' deficit	$ 101,727	$ 110,951	

See accompanying notes to condensed consolidated financial statements.

PROGENITY, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(UNAUDITED)
(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2019	2020
Revenue	$ 47,507	$ 16,828
Cost of sales	24,421	26,570
Gross profit (loss)	23,086	(9,742)
Operating expenses:		
Research and development	15,248	11,240
Selling and marketing	15,567	14,436
General and administrative	14,278	17,108
Total operating expenses	45,093	42,784
Loss from operations	(22,007)	(52,526)
Interest expense	(2,269)	(2,302)
Interest and other income (expense), net	257	(20)
Loss before taxes	(24,019)	(54,848)
Income tax benefit	—	(37,696)
Net loss	$ (24,019)	$ (17,152)
Dividend paid to preferred stockholders	(3,652)	—
Net loss attributable to common stockholders	$ (27,671)	$ (17,152)
Net loss per share attributable to common stockholders, basic and diluted	$ (5.88)	$ (3.43)
Weighted average number of shares outstanding, basic and diluted	4,705,641	4,993,393
Pro forma loss per share, basic and diluted		$ (0.49)
Pro forma weighted average shares outstanding, basic and diluted		35,063,069

See accompanying notes to condensed consolidated financial statements.

PROGENITY, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT
(UNAUDITED)
(in thousands, except for share data)

	Common Stock		Series A and A-1 Preferred Stock		Series B Preferred Stock		Additional Paid-in Capital	Accumulated Deficit	Treasury Stock		Total
	Shares	Amount	Shares	Amount	Shares	Amount			Common Shares	Amount	
Balance—December 31, 2018	8,112,581	$ 8	5,620,000	$ 6	14,164,306	$ 14	$ 124,244	$ (142,469)	(3,474,572)	$(18,771)	$(36,968)
Adoption of accounting standard (see Note 2)	—	—	—	—	—	—	—	23,666	—	—	23,666
Exercise of common stock options	268,549	—	—	—	—	—	322	—	—	—	322
Stock-based compensation	—	—	—	—	—	—	555	—	—	—	555
Dividends paid	—	—	—	—	—	—	—	(4,500)	—	—	(4,500)
Net loss	—	—	—	—	—	—	—	(24,019)	—	—	(24,019)
Balance—March 31, 2019	8,381,130	$ 8	5,620,000	$ 6	14,164,306	$ 14	$ 125,121	$ (147,322)	(3,474,572)	$(18,771)	$(40,944)
Balance—December 31, 2019	8,451,415	$ 9	4,120,000	$ 4	101,867,405	$ 102	$ 283,260	$ (348,478)	(3,474,572)	$(18,771)	$(83,874)
Exercise of common stock options	56,729	—	—	—	—	—	103	—	—	—	103
Issuance of Series B Preferred Stock, net of issuance cost	—	—	—	—	6,033,796	6	14,066	—	—	—	14,072
Stock-based compensation	—	—	—	—	—	—	2,057	—	—	—	2,057
Net loss	—	—	—	—	—	—	—	(17,152)	—	—	(17,152)
Balance—March 31, 2020	8,508,144	$ 9	4,120,000	$ 4	107,901,201	$ 108	$ 299,486	$ (365,630)	(3,474,572)	$(18,771)	$(84,794)

See accompanying notes to condensed consolidated financial statements.

PROGENITY, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(UNAUDITED)
(in thousands)

	Three Months Ended March 31,	
	2019	2020
Cash flows from operating activities:		
Net loss	$(24,019)	$(17,152)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	1,553	1,701
Inventory write-down/(release)	57	(27)
Loss on disposal of property and equipment	—	18
Stock-based compensation expense	555	2,057
Changes in operating assets and liabilities:		
Accounts receivable, net	(873)	6,550
Inventory	(1,128)	984
Prepaid expenses and other current assets	(4,028)	460
Income tax receivable	5,427	(37,662)
Other assets	(62)	—
Accounts payable	539	727
Accrued expenses and other liabilities	(46)	(25,405)
Other long-term liabilities	(71)	36,863
Net cash used in operating activities	(22,096)	(30,886)
Cash flows from investing activities:		
Purchases of property and equipment	(591)	(1,094)
Purchases of short-term investments	(11,214)	—
Proceeds from the sale of short-term investments	20,449	—
Net cash provided by (used in) investing activities	8,644	(1,094)
Cash flows from financing activities**:**		
Proceeds from issuance of common stock	322	103
Proceeds from issuance of Series B Preferred Stock, net of issuance cost	—	11,374
Dividends paid	(4,500)	—
Principal payments on mortgages payable	(56)	(62)
Principal payments on capital lease obligations	(312)	(215)
Payments for deferred offering costs	—	(616)
Net cash (used in) provided by financing activities	(4,546)	10,584
Net decrease in cash and cash equivalents	$(17,998)	$(21,396)
Cash and cash equivalents—beginning of period	$ 49,005	$ 33,042
Cash and cash equivalents—end of period	$ 31,007	$ 11,646
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 1,876	$ 51
Cash paid for income taxes	6	5
Supplemental schedule of noncash investing and financing activities:		
Issuance of stock options in settlement of accrued bonuses	—	754
Issuance of preferred stock in settlement of interest payable	—	1,801
Issuance of preferred stock for settlement of deferred issuance costs	—	897
Purchases of property and equipment in accounts payable	615	278
Capital lease obligations	76	—
Deferred offering costs incurred but not paid	—	682

See accompanying notes to condensed consolidated financial statements.

PROGENITY, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Description of Business

Progenity, Inc. and subsidiaries (the "Company" or "Progenity"), a Delaware corporation, commenced operations in 2010 with its corporate office located in San Diego, California. Progenity's primary operations include a licensed Clinical License Improvement Amendment and College of American Pathologists certified laboratory located in Michigan specializing in the molecular testing markets serving women's health providers in the obstetric, gynecological, fertility, and maternal fetal medicine specialty areas in the United States.

The Company has expertise in the national reference laboratory, clinical genetics, laboratory molecular testing, and biotechnology markets. Distribution is managed by a dedicated women's health physician sales force and a field operations team who support all logistical functions in receiving clinical samples to the laboratory for analysis.

The Company's core business is focused on the prenatal carrier screening and noninvasive prenatal test market, targeting preconception planning, and routine pregnancy management for genetic disease risk assessment.

Through its affiliation with Mattison Pathology, LLP ("Mattison"), a Texas limited liability partnership doing business as Avero Diagnostics ("Avero"), located in Lubbock and Dallas, Texas, the Company's operations have expanded to provide anatomic and molecular pathology testing products in the United States.

Liquidity

As of March 31, 2020, the Company had cash and cash equivalents of $11.6 million and an accumulated deficit of $365.6 million. For the three months ended March 31, 2020, the Company also had a net loss of $17.2 million and cash used in operations of $30.9 million. The Company's primary sources of capital have been private placements of preferred stock and incurrence of debt. As of March 31, 2020, the Company had a $75.0 million term loan outstanding with a private equity firm (see Note 7), and mortgages outstanding of $3.3 million (see Note 8). Management does not believe that the current available cash and cash equivalents will be sufficient to fund the Company's planned expenditures and meet its obligations for at least 12 months following the financial statement issuance date without raising additional funding. As a result, there is substantial doubt about the Company's ability to continue as a going concern for the twelve months following the issuance date of the condensed consolidated financial statements for the three months ended March 31, 2020.

The Company's ability to continue as a going concern is dependent upon its ability to raise additional funding. Management intends to raise additional capital through equity offerings and/or debt financings. Adequate funding, if needed, may not be available to the Company on acceptable terms, or at all. If the Company is unable to raise capital when needed or on attractive terms, it would be forced to delay, reduce, or eliminate its research and development programs or other operations. If any of these events occur, the Company's ability to achieve its operational goals would be adversely affected.

Uncertainties Related to the COVID-19 Pandemic

In March 2020, the World Health Organization declared the novel coronavirus disease ("COVID-19") a pandemic. The Company could be negatively affected by the widespread outbreak of an illness or any other communicable disease, or any other public health crisis that results in economic and trade

disruptions, including the disruption of global supply chains. The COVID-19 pandemic has negatively impacted the global economy, disrupted global supply chains and created significant volatility and disruption of financial markets. The Company has been materially and negatively affected by the COVID-19 pandemic; however, the extent of the impact of the COVID-19 pandemic on the Company's operational and financial performance, including its ability to execute its business strategies and initiatives in the expected time frame, will depend on future developments, including the duration and spread of the pandemic and related restrictions on travel and transports, all of which are uncertain and cannot be predicted. An extended period of global supply chain and economic disruption could materially affect the Company's business, results of operations, access to sources of liquidity and financial condition.

The estimates used for, but not limited to, determining the amount to be collected for accounts receivable, fair value of long-lived assets, and fair value of goodwill could be impacted by the pandemic. While the full impact of COVID-19 is unknown at this time, the Company has made appropriate estimates based on the facts and circumstances available as of the reporting date. These estimates may change as new events occur and additional information is obtained.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company's financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP") and include the accounts of Progenity, Inc., its wholly owned subsidiaries, and an affiliated professional partnership with Avero with respect to which the Company currently has a specific management arrangement. The Company has determined that Avero is a variable interest entity and that the Company is the primary beneficiary resulting in the consolidation of Avero as required by the accounting guidance for consolidation. All significant intercompany balances and transactions have been eliminated in consolidation (see Note 3).

Unaudited Interim Financial Information

The accompanying balance sheet as of March 31, 2020, the statements of operations, the statements of stockholders' deficit and statements of cash flows for the three months ended March 31, 2019 and 2020 are unaudited. The unaudited interim financial statements have been prepared on the same basis as the audited annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of March 31, 2020 and the results of its operations and its cash flows for the three months ended March 31, 2019 and 2020. The financial data and other information disclosed in these notes related to the three months ended March 31, 2019 and 2020 are also unaudited. The results for the three months ended March 31, 2020 are not necessarily indicative of results to be expected for the year ending December 31, 2020, any other interim periods, or any future year or period. The balance sheet as of December 31, 2019 included herein was derived from the audited financial statements as of that date. Certain disclosures have been condensed or omitted from the interim financial statements. These financial statements should be read in conjunction with the Company's audited financial statements included elsewhere in this prospectus.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of

contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant items subject to such estimates include the estimate of variable consideration in connection with the recognition of revenue, the valuation of Series B preferred stock, the valuation of stock options, the valuation of goodwill and intangible assets, accrual for reimbursement claims and settlements, assessing future tax exposure and the realization of deferred tax assets, the useful lives, and the recoverability of property and equipment. The Company bases these estimates on historical and anticipated results, trends, and various other assumptions that the Company believes are reasonable under the circumstances, including assumptions as to future events. These estimates form the basis for making judgments about the carrying values of assets and liabilities and recorded revenues and expenses that are not readily apparent from other sources. Actual results could differ from those estimates and assumptions.

Operating Segments

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker or decision-making group in making decisions on how to allocate resources and assess performance. The Company views its operations and manages its business as one operating segment. All revenues are attributable to U.S.-based operations and all assets are held in the United States.

Revenue Recognition

Revenue is recognized in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). In accordance with ASC 606, the Company follows a five-step process to recognize revenues: 1) identify the contract with the customer, 2) identify the performance obligations, 3) determine the transaction price, 4) allocate the transaction price to the performance obligations and 5) recognize revenues when the performance obligations are satisfied.

Revenue is primarily derived from providing molecular testing products, which are reimbursed through arrangements with third-party payors, laboratory distribution partners, and amounts from individual patients. Third-party payors include commercial payors, such as health insurance companies, health maintenance organizations and government health benefit programs such as Medicare and Medicaid. The Company's contracts generally contain a single performance obligation, which is the delivery of the test results, and the Company satisfies its performance obligation at a point in time upon the delivery of the results, which then triggers the billing for the product. The amount of revenue recognized reflects the amount of consideration the Company expects to be entitled (the "transaction price") and considers the effects of variable consideration. Revenue is recognized when control of the promised product is transferred to customers, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those products.

The Company applies the following practical expedients and exemptions:

- Incremental costs incurred to obtain a contract have been expensed as incurred because the related amortization period would have been one year or less. The costs are included in selling and marketing expenses.
- No adjustments to amounts of promised consideration were made for the effects of a significant financing component because the Company expects, at contract inception, that the period between the transfer of a promised good or service and customer payment for that good or service will be one year or less.

PROGENITY, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Payor Concentration

The Company relies upon reimbursements from third-party government payors and private-payor insurance companies to collect accounts receivable. The Company's significant third-party payors and their related revenues as a percentage of total revenues and accounts receivable balances are as follows:

	Percentage of Revenue(1) Three Months Ended March 31,		Percentage of Accounts Receivable(1)	
	2019	2020	As of December 31, 2019	As of March 31, 2020
United Healthcare	20.7%	4.0%	31.5%	19.3%
Blue Shield of Texas	16.6%	42.5%	0.1%	15.6%
Government Health Benefits Programs	18.2%	-39.0%	16.7%	14.7%
Aetna	7.6%	12.0%	6.0%	3.5%

(1) The negative amounts presented in the percentage of revenue and accounts receivable are due to accruals for reimbursement claims and settlements included in the estimates of variable consideration recorded during the three months ended March 31, 2020. Revenue and accounts receivable recognized consider the effects of variable consideration, and include adjustments for estimates of disallowed cases, discounts, and refunds. The variable consideration includes reductions in revenue for the accrual for reimbursement claims and settlements, as described in Note 4, *Revenue*.

Accounts Receivable

Accounts receivable is recorded at the transaction price and considers the effects of variable consideration. The total consideration the Company expects to collect is an estimate and may be fixed or variable. Variable consideration includes reimbursement from third-party payors, laboratory distribution partners, and amounts from individual patients, and is adjusted for disallowed cases, discounts, and refunds using the expected value approach. The Company monitors these estimates at each reporting period based on actual cash collections in order to assess whether a revision to the estimate is required.

Net Loss Per Share

Basic and diluted net loss per share attributable to common stockholders is presented in conformity with the two-class method required for participating securities. The Company considers all series of preferred stock to be participating securities as the holders of such stock are entitled to receive non-cumulative dividends on an as-converted basis in the event that a dividend is paid on common stock. Under the two-class method, the net loss attributable to common stockholders is not allocated to the preferred stock as the holders of preferred stock do not have a contractual obligation to share in the Company's losses. Under the two-class method, net income is attributed to common stockholders and participating securities based on their participation rights.

Basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period. Net loss attributable to common stockholders is calculated by adjusting net loss with dividends to preferred stockholders, if any. As the Company has reported net losses for all

periods presented, all potentially dilutive securities are antidilutive and, accordingly, basic net loss per share equals diluted net loss per share.

Comprehensive Loss

The Company did not have any other comprehensive income or loss for any of the periods presented, and therefore comprehensive loss was the same as the Company's net loss.

Deferred Offering Costs

Deferred offering costs consist primarily of legal fees, which are direct and incremental fees related to the Company's planned initial public offering (the "IPO"). The deferred offering costs will be offset against the IPO proceeds upon the consummation of the IPO. In the event that the IPO is not consummated, the deferred offering costs will be expensed. There were $1.1 million of deferred offering costs as of December 31, 2019. As of March 31, 2020, the Company had incurred $1.9 million in deferred offering costs, which are included in prepaid expenses and other current assets on the balance sheet.

Unaudited Pro Forma Information

All outstanding shares of preferred stock will automatically convert into shares of the Company's common stock upon the closing of a qualified IPO, as defined in the Company's certificate of incorporation and as described in Note 10. The unaudited pro forma balance sheet information as March 31, 2020 has been prepared assuming the automatic conversion of the preferred stock and vested restricted stock units into shares of common stock assuming the completion of a qualified IPO on March 31, 2020.

The unaudited pro forma net loss per share attributable to common stockholders for the three months ended March 31, 2020 has been computed to give effect to the automatic conversion upon the closing of a qualified IPO of preferred stock and vested restricted stock units into common stock using the if-converted method as though such IPO had occurred as of the beginning of the period or the date of issuance, if later.

Recent Accounting Pronouncements Adopted

In June 2018, the FASB issued Accounting Standards Update ("ASU") No. 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*. The standard simplifies the accounting for share-based payments granted to nonemployees for goods and services and aligns most of the guidance on such payments to the nonemployees with the requirements for share-based payments granted to employees. The Company adopted the new accounting standard in fiscal year 2020 using the retrospective transition method for each period presented, which did not have a material impact on the condensed consolidated financial statements.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* which removes certain exceptions to the general principles of Topic 740, Accounting for Income Taxes ("ASC 740") and is intended to improve consistency and simplify GAAP in several other areas of ASC 740 by clarifying and amending existing guidance. The Company early adopted ASU No. 2019-12 for the quarter ended March 31, 2020, which did not have a material impact on the condensed consolidated financial statements.

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In March 2020, the FASB issued ASU No. 2020-04, *Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting*, which provides optional expedients and exceptions for GAAP to contracts, hedging relationships, and other transactions affected by reference rate reform if certain criteria are met. The amendments apply only to contracts, hedging relationships, and other transactions that reference the London Interbank Offered Rate ("LIBOR") or another reference rate expected to be discontinued because of reference rate reform. The amendments are effective for all entities as of March 12, 2020 through December 31, 2022. The adoption of the new accounting standard did not have a material impact on the condensed consolidated financial statements.

Recent Accounting Pronouncements Not Yet Adopted

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which supersedes FASB ASC Topic 840, *Leases (Topic 840)*, and provides principles for the recognition, measurement, presentation and disclosure of leases for both lessees and lessors. The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method for finance leases or on a straight-line basis over the term of the lease for operating leases. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of classification. Leases with a term of 12 months or less will be accounted for similar to existing guidance for operating leases. The Company is still assessing the impact that the new leasing standard will have on operations and financial position.

In November 2019, the FASB issued ASU No. 2019-10, *Leases (Topic 842): Effective Dates*. The new standard is effective for the Company for annual reporting periods beginning after December 15, 2020.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses*, which requires the measurement of expected credit losses for financial instruments carried at amortized cost, such as accounts receivable, held at the reporting date based on historical experience, current conditions and reasonable forecasts. The main objective of this standard is to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. In November 2018, the FASB issued ASU No. 2018-19, *Codification Improvements to Topic 326, Financing Instruments–Credit Losses*, which included an amendment of the effective date. The Company does not believe the adoption of this standard will have a significant impact on the financial statements. The standard is effective for the Company for annual reporting periods beginning after December 15, 2022.

In January 2017, the FASB issued ASU No. 2017-04, *Intangibles—Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment.* The new standard will simplify the measurement of goodwill by eliminating step two of the two-step impairment test. Step two measures a goodwill impairment loss by comparing the implied fair value of a reporting unit's goodwill with the carrying amount of that goodwill. The new guidance requires an entity to compare the fair value of a reporting unit with its carrying amount and recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value. Additionally, an entity should consider income tax effects from any tax-deductible goodwill on the carrying amount of the reporting unit when measuring the goodwill impairment loss, if applicable. The standard is effective for the Company for annual reporting periods beginning after December 15, 2021. The Company does not expect the adoption of this standard to have a material impact on its consolidated financial statements.

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In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*, which eliminates certain disclosure requirements for fair value measurements for all entities, requires public entities to disclose certain new information and modifies some disclosure requirements. The Company does not expect the adoption of this ASU to have a material impact on its consolidated financial statements. The standard is effective for the Company for annual reporting periods beginning after December 15, 2019.

3. Variable Interest Entity

On June 8, 2015, the Company entered into a series of agreements with Avero. The Company entered into a purchase agreement to acquire certain assets from Mattison used in the operation of Avero. The purchase agreement was accounted for under the acquisition method in accordance with the provisions of ASC Topic 805, *Business Combinations*. The Company entered into a nominee agreement which provides it with the right, but not the obligation, to purchase, or to designate a person(s) to purchase, the stock of Avero at any time for a nominal amount.

The Company also entered into a management services arrangement that authorizes the Company to perform the management services in the manner that it deems reasonably appropriate to meet the day-to-day business needs of Avero. The Company's involvement includes funding ongoing operational needs, directing activities related to contract negotiation, billing, human resources, legal and administrative matters and processes, among others. In exchange for the management services provided, the Company is entitled to receive an annual management fee equal to the net operating income of Avero. The term of the agreement with Avero is 10 years, subject to automatic renewals. The agreement can be terminated by either party with a 90-day notice before the end of the term.

Through the management services arrangement with Avero, the Company has (1) the power to direct the activities of Avero that most significantly impact its economic performance, and (2) the obligation to absorb losses that could potentially be significant or the right to receive benefits from Avero that could potentially be significant. Based on these determinations, the Company has determined that Avero is a variable interest entity and that the Company is the primary beneficiary. The Company does not own any equity interest in Avero; however, as these agreements provide the Company the controlling financial interest in Avero, the Company consolidates Avero's balances and activities within its consolidated financial statements.

In December 2018, Avero entered into a settlement agreement with Cigna (the "Cigna settlement obligation") whereby Avero agreed to pay an aggregate amount of $12.0 million with an upfront payment of $6.0 million and the remaining $6.0 million to be paid over 24 months, beginning in February 2019. The Company guaranteed the $12.0 million Cigna settlement obligation and recorded a charge of $12.0 million associated with this claim in its consolidated statement of operations as a reduction to revenue for the year ended December 31, 2018. During each of the three months ended March 31, 2019 and 2020, the Company provided $0.8 million in financial support to Avero related to the Cigna settlement obligation (see Note 9).

The Company did not provide any additional financial support to Avero during the three months ended March 31, 2019 and 2020 other than the Cigna settlement obligation and agreed upon management services.

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The following table presents the assets and liabilities of Avero which are included in the Company's condensed consolidated balance sheets as of December 31, 2019 and March 31, 2020, in thousands. The creditors of Avero have no recourse to the general credit of the Company, with the exception of $1.9 million in mortgage payable guaranteed by the Company as of each of December 31, 2019 and March 31, 2020 (see Note 8), and $3.0 million and $2.3 million in remaining Cigna settlement obligation guaranteed by the Company as of December 31, 2019 and March 31, 2020, respectively. The assets and liabilities exclude intercompany balances that eliminate in consolidation:

	December 31, 2019	March 31, 2020
Assets of Avero that can only be used to settle obligations of Avero		
Cash and cash equivalents	$ 1,837	$ 1,490
Accounts receivable, net	4,269	3,124
Inventory	2,572	2,099
Prepaid expenses and other current assets	1,181	1,397
Property and equipment, net	5,586	5,470
Other assets	30	30
Goodwill	6,219	6,219
Other intangible assets, net	4,771	4,539
Total assets of Avero that can only be used to settle obligations of Avero	$ 26,465	$ 24,368
Liabilities of Avero		
Accounts payable	$ 2,450	$ 2,123
Accrued expenses and other current liabilities	5,630	5,137
Current portion of capital lease obligations	59	48
Current portion of mortgage payable	173	175
Capital lease obligations, net of current portion	50	39
Mortgage payable, net of current portion	1,733	1,686
Other long-term liabilities	467	408
Total liabilities of Avero	$ 10,562	$ 9,616

4. Revenue

Product revenue is derived from contracts with healthcare insurers, government payors, laboratory partners and patients in connection with sales of prenatal genetic, anatomic or molecular pathology tests. The Company enters into contracts with health care insurers related to tests provided to patients who have health insurance coverage. Insurance carriers are considered third-party payors on behalf of the patients, and the patients who receive genetic, anatomic or molecular pathology test products are considered the customers. Tests may be billed to insurance carriers, patients, or a combination of insurance carriers and patients. The Company also sells tests to laboratory partners and has also identified those parties as customers.

In accordance with ASC 606, a performance obligation represents a promise in a contract to transfer a distinct good or service to a customer and the consideration should be allocated to each distinct

performance obligation and recognized as revenue when, or as, the performance obligation is satisfied. The Company has evaluated its contracts with health care insurers, government payors, laboratory partners and patients and identified a single performance obligation in those contracts, the delivery of a test result. The Company satisfies its performance obligation at a point in time upon the delivery of the test result, at which point the Company can bill for its products. The amount of revenue recognized reflects the transaction price and considers the effects of variable consideration, which is discussed below.

The transaction price is an estimate and may be fixed or variable. Variable consideration includes reimbursement from healthcare insurers, government payors, and patients and is adjusted for estimates of disallowed cases, discounts, and refunds using the expected value approach. Tests billed to healthcare insurers and directly to patients can take up to six months to collect and the Company may be paid less than the full amount billed or not paid at all. For insurance carriers and government payors, management utilizes the expected value method using a portfolio of relevant historical data for payors with similar reimbursement experience. The portfolio estimate is developed using historical reimbursement data from payors and patients, as well as known current reimbursement trends not reflected in the historical data. Such variable consideration is included in the transaction price only to the extent it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainties with respect to the amount are resolved. Management monitors these estimates at each reporting period based on actual cash collections and status of settlement agreements with third-party payors, in order to assess whether a revision to the estimate is required. Both the initial estimate and any subsequent revision to the estimate contain uncertainty and require the use of judgment in the estimation of the transaction price and application of the constraint for variable consideration. If actual results in the future vary from the Company’s estimates, the Company will adjust these estimates, which would affect revenue and earnings in the period such variances become known. The consideration expected from laboratory partners is generally a fixed amount.

During the three months ended March 31, 2020, the Company updated its estimate of the variable consideration recognized for previously delivered performance obligations which resulted in a reduction of $12.8 million of revenue for the three months ended March 31, 2020. This amount includes (i) adjustments for actual collections versus estimated variable consideration as of the beginning of the reporting period and (ii) cash collections and the related recognition of revenue in the current period for tests delivered in prior periods due to the release of the constraint on variable consideration, offset by (iii) reductions in revenue for the accrual for reimbursement claims and settlements described in Note 9, *Commitments and Contingencies*.

Once the Company satisfies its performance obligations upon delivery of a test result and bills for the product, the timing of the collection of payments may vary based on the payment practices of the third-party payor. The Company bills patients directly for co-pays and deductibles that they are responsible for and also bills patients directly in cases where the customer does not have insurance.

The Company has established an accrual for refunds of payments previously made by healthcare insurers based on historical experience and executed settlement agreements with healthcare insurers. The refunds are accounted for as reductions in revenues in the statement of operations as an element of variable consideration.

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Disaggregation of Revenues

The following table shows a further disaggregation of revenues by payor type (in thousands):

	Three Months Ended March 31,	
	2019	2020
Commercial Third-Party Payors	$37,753	$21,562
Government Health Benefit Programs	8,635	(6,143)
Patient/Laboratory Distribution Partners	1,119	1,409
Total revenues	$47,507	$16,828

5. Balance Sheet Components

Prepaid expenses and other current assets

Prepaid expenses and other current assets consist of the following (in thousands):

	December 31, 2019	March 31, 2020
Prepaid expenses	$ 6,476	$ 6,314
Other current assets	1,370	1,893
Total	$ 7,846	$ 8,207

Property and equipment, net

Property and equipment, net consists of the following (in thousands):

	December 31, 2019	March 31, 2020
Computers and software	$ 13,913	$ 13,652
Building and leasehold improvements	9,491	9,498
Laboratory equipment	5,580	6,276
Furniture, fixtures, and office equipment	1,633	1,646
Construction in progress	1,493	1,419
Land	1,091	1,091
Total property and equipment	33,201	33,582
Less accumulated depreciation and amortization	(17,310)	(17,356)
Property and equipment, net	$ 15,891	$ 16,226

Capital leases included in property and equipment, net consist of the following (in thousands):

	December 31, 2019	March 31, 2020
Capital leases	$ 3,692	$ 3,692
Less accumulated depreciation and amortization	(2,239)	(2,456)
Property and equipment, net	$ 1,453	$ 1,236

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Depreciation expense was $1.0 million and $1.1 million for the three months ended March 31, 2019 and 2020, respectively.

Intangible assets, net

Intangible assets, net consist of the following (in thousands):

	December 31, 2019		
	Cost	Accumulated amortization	Net
Payor relationships	$7,230	$ (3,314)	$3,916
Trade names	1,410	(646)	764
Noncompete agreements	384	(293)	91
Intangible assets, net	$9,024	$ (4,253)	$4,771

	March 31, 2020		
	Cost	Accumulated amortization	Net
Payor relationships	$7,230	$ (3,494)	$3,736
Trade names	1,410	(682)	728
Noncompete agreements	384	(309)	75
Intangible assets, net	$9,024	$ (4,485)	$4,539

Amortization expense of intangible assets for each of the three months ended March 31, 2019 and 2020 was $0.2 million.

The future amortization of intangible assets at March 31, 2020 is (in thousands):

Year Ending December 31,	
2020 (remaining nine months)	$ 696
2021	891
2022	864
2023	864
2024	864
Thereafter	360
Total future minimum amortization	$ 4,539

Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consist of the following (in thousands):

	December 31, 2019	March 31, 2020
Accrual for reimbursement claims and settlements	$ 60,386	$ 33,560
Commissions and bonus	6,357	6,185
Vacation and payroll benefits	5,506	8,751
Accrued professional services	5,322	3,206
Other	6,044	4,708
Total	$ 83,615	$ 56,410

Other long-term liabilities

Other long-term liabilities consist of the following (in thousands):

	December 31, 2019	March 31, 2020
Accrual for reimbursement claims and settlements—long term	$ 12,205	$ 49,137
Other	654	586
Total	$ 12,859	$ 49,723

6. Fair Value Measurements

The following table presents information about the Company's assets and liabilities that are measured at fair value on a recurring basis and indicates the fair value hierarchy of the valuation techniques utilized to determine such fair value (in thousands):

	Quoted Market Prices for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
At December 31, 2019			
Money market funds(1)	$ 24,432	$ —	$ —
At March 31, 2020			
Money market funds(1)	$ 1,563	$ —	$ —

(1) Included in cash and cash equivalents in the accompanying condensed consolidated balance sheets.

There were no significant transfers between Level 1 and Level 2 during the three months ended March 31, 2019 and 2020. The Company's policy is to recognize transfers between levels at the end of the reporting period.

Fair Value of Financial Instruments

The carrying value of the Company's accounts receivable, income tax receivable, accounts payable, and accrued expenses and other current liabilities are considered to be representative of their respective fair values because of their short-term nature.

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The carrying value of the Company's mortgages payable approximates their estimated fair value because the instruments bear interest at rates and have terms that are comparable to those available to the Company for similar loan instruments at December 31, 2019 and March 31, 2020.

The carrying value of the Company's note payable to a related party does not approximate its fair value because the instrument bears interest at a rate that is not comparable to those available to the Company for a similar loan instrument at December 31, 2019 and March 31, 2020. The carrying value and the fair value of the Company's term loan (the "2017 Term Loan") is $75.0 million and $79.8 million, respectively, at December 31, 2019 and $75.0 million and $76.5 million, respectively, at March 31, 2020. The carrying value of the 2017 Term Loan is presented on the accompanying condensed consolidated balance sheets net of discount on the note and debt issuance cost.

7. Related Party Transactions

On October 27, 2017, the Company entered into a Credit and Security Agreement and a Series B Convertible Preferred Stock Purchase Agreement with a private equity firm (the "2017 Transaction"). The 2017 Transaction provided for the 2017 Term Loan, the issuance of Series B Preferred Stock (the "Series B Preferred Stock"), and the issuance of a warrant to purchase Series B Preferred Stock (the "Series B Preferred Stock Purchase Warrant"). The 2017 Term Loan accrues interest at a rate per annum equal to 9.5% and is due October 27, 2022.

The 2017 Term Loan contains customary covenants, including a requirement to maintain a minimum unrestricted cash balance at all times at least equal to $5.0 million. The Company is in compliance with the 2017 Term Loan covenants. The 2017 Term Loan is secured by all tangible and intangible property and assets of the Company, with the exception of intellectual property.

The total proceeds of $124.2 million from the 2017 Transaction were allocated to the 2017 Term Loan, Series B Preferred Stock, and the Series B Preferred Stock Purchase Warrant based on the relative fair value of the term loan, equity, and warrant issued. As a result, the Company allocated proceeds of $65.7 million to the 2017 Term Loan. As the proceeds allocated to the 2017 Term Loan are lower than the stated loan amount of $75.0 million, the resulting $9.3 million discount will be amortized as interest expense using the effective interest method over the term of the loan.

As of both December 31, 2019 and March 31, 2020, the outstanding unpaid principal under the 2017 Term Loan is $75.0 million, due in October 2022. The unamortized discount on the 2017 Term Loan was $6.0 million and $6.5 million as of December 31, 2019 and March 31, 2020, respectively.

During the three months ended March 31, 2019 and 2020, the Company recognized interest expense on the 2017 Term Loan of $2.2 million and $2.2 million, inclusive of $0.4 million and $0.4 million of amortized interest expense on the discount for the three months ended March 31, 2019 and 2020, respectively.

On March 31, 2020, the Company entered into the First Amendment to the Credit Agreement (the "Credit Agreement Amendment"), with the collateral agent and lender party thereto, providing for the payment of interest due and payable as of March 31, 2020 in shares of Series B Preferred Stock, and further providing for the payment of interest due and payable as of June 30, 2020 in shares of our Series B Preferred Stock in the event the IPO has not been consummated by such date. Pursuant to the Credit Agreement Amendment, the Company concurrently entered into a Series B Preferred Stock Subscription Agreement (the "Subscription Agreement"), with the lender, which provided for the

issuance of 967,130 shares of Series B Preferred Stock at a subscription price of $2.25 per share, as payment for interest due and payable as of March 31, 2020 and all applicable fees as set forth in the Credit Agreement Amendment. The Subscription Agreement further provided for a potential additional issuance of shares of Series B Preferred Stock as payment for the interest due and payable under the Credit Agreement as of June 30, 2020, in the event the IPO has not been consummated by such date, with the amount of shares to be determined at such time.

8. Mortgages Payable

On January 24, 2014, the Company executed a mortgage with Comerica Bank for $1.8 million for the purpose of acquiring property located in Ann Arbor, Michigan, which was previously leased by the Company and used for laboratory testing and research purposes. The outstanding balance as of each of December 31, 2019 and March 31, 2020 was $1.4 million. The mortgage matures in 2024 and requires monthly principal and interest payments at a fixed interest rate of 2.94% plus a floating rate at LIBOR.

The Company also has a mortgage with American Bank of Commerce (originally executed on February 19, 2008) outstanding on Avero's property located in Lubbock, Texas, which is used primarily for laboratory testing. The outstanding balance as of each of December 31, 2019 and March 31, 2020 was $1.9 million. The mortgage matures in 2029 and requires monthly principal and interest payments at an interest rate of 4.25%.

As of March 31, 2020, the minimum principal payments under the mortgages payable are as follows (in thousands):

Year Ending December 31,	Minimum Mortgages Payable Payments
2020 (remaining nine months)	182
2021	253
2022	265
2023	277
2024	1,323
Thereafter	960
Total future minimum payments	$ 3,260
Less current portion of mortgages payable	(244)
Mortgages payable, net of current portion	$ 3,016

9. Commitments and Contingencies

Operating Leases

The Company has entered into various noncancelable operating lease agreements, primarily for office space, laboratory space, and vehicles, which expire over the next 2 to 4 years. Minimum rent payments under operating leases are recognized on a straight-line basis over the term of the lease. Rent expense for operating leases for the three months ended March 31, 2019 and 2020, was $2.0 million and $2.1 million, respectively.

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As of March 31, 2020, the Company's net minimum payments under the non-cancelable operating leases are as follows (in thousands):

Year Ending December 31,	Minimum Operating Lease Payments
2020 (remaining nine months)	$ 6,224
2021	5,087
2022	2,798
2023	963
2024 and thereafter	35
Total future minimum payments	$ 15,107

Capital Leases

The Company has entered into various capital lease agreements, primarily for equipment. The outstanding leases have a weighted average imputed interest rate of 5.97% per annum.

As of March 31, 2020, the future minimum payments under the capital leases are as follows (in thousands):

Year Ending December 31,	Minimum Capital Lease Payments
2020 (remaining nine months)	$ 542
2021	324
2022 and thereafter	47
Total future minimum payments	$ 913
Less amount representing interest	(43)
Present value of minimum capital lease payments	870
Less current portion of capital lease obligations	(630)
Capital lease obligations, net of current portion	$ 240

Contingencies

The Company, in the ordinary course of its business, can be involved in lawsuits, threats of litigation, and audit and investigative demands from third parties. While management is unable to predict the exact outcome of such matters, it is management's current belief, that any potential liabilities resulting from these contingencies, individually or in the aggregate, could have a material impact on the Company's financial position and results of operations.

The regulations governing government reimbursement programs (e.g., Medicaid, Tricare, and Medicare) and commercial payor reimbursement programs are complex and subject to interpretation. As a provider of services to patients covered under government and commercial payor programs, post payment review audits, and other forms of reviews and investigations are routine. The Company believes it complies in all material respects with the statutes, regulations, and other requirements applicable to its laboratory operations.

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In April 2018, the Company received a civil investigative demand from an Assistant U.S. Attorney ("AUSA") for the Southern District of New York and a Health Insurance Portability and Accountability Act subpoena issued by an AUSA for the Southern District of California. In May 2018, the Company received a subpoena from the State of New York Medicaid Fraud Control Unit. Since that time, the Company has cooperated with federal civil and criminal investigations, and state civil investigations, regarding discontinued legacy billing practices for its non-invasive prenatal testing and microdeletion tests and the provision of alleged kickbacks or inducements to physicians and patients. The civil investigations also include inquiries about the Company's laboratory licenses, its enrollment in state Medicaid programs, and the laboratories that performed testing for the Company.

On March 31, 2020, the Company reached an agreement on the monetary terms with the U.S. Department of Justice (the "DOJ") and the State of New York (with the State of New York Attorney General representing or facilitating the interests of all States participating in the settlement (collectively, the "State AGs")) with respect to relevant government health benefit programs to resolve all of the government's outstanding civil and criminal investigations, including the investigations by the U.S. Attorney's Office for the Southern District of California and the U.S. Attorney's Office for the Southern District of New York, as well as the investigation by the State AGs. The terms of this agreement in principle contemplate that the Company will enter into a civil settlement agreement providing that the Company will pay $49.0 million in the aggregate over a five-year period, structured as follows: $8.0 million upon entering into the settlement; $4.0 million in December 2020; $5.0 million in December 2021; $7.0 million in December 2022; $8.0 million in December 2023; $9.0 million in December 2024; and $8.0 million in December 2025 for a release of the civil claims and that the Company will enter into a non-prosecution agreement to resolve all criminal allegations. Those criminal allegations pertain to discontinued legacy billing practices for the Company's NIPT tests. The amounts payable to the government, other than the initial $8.0 million payment, will be subject to interest at a rate of 1.25% per annum, and any or all amounts may be paid earlier at the option of the Company. The companion civil settlement agreement is expected to resolve all civil claims involving discontinued legacy billing practices for the Company's NIPT and microdeletion tests as well as other allegations pertaining to the provision of potential kickbacks or inducements to physicians and patients. Other non-financial terms and conditions remain subject to negotiation. The final civil settlement materials are subject to final approval of the Assistant Attorney General at DOJ, a U.S. District Court judge in New York, and any other relevant parties, including any potential whistleblower and the State AGs. The Company also expects to enter into a corporate integrity agreement with the Department of Health and Human Services Office of Inspector General, which would be expected to impose additional compliance, reporting and disclosure obligations, and related costs in the future.

As of December 31, 2019, the Company had accrued an aggregate of $35.8 million associated with a potential settlement with the DOJ and the participating State AGs within accrued expenses and other current liabilities and as a reduction of revenue as reflected on the consolidated balance sheet of the Company as of December 31, 2019 and consolidated statement of operations for the year ended December 31, 2019. In addition, in the quarter ended March 31, 2020, the Company accrued an additional $13.2 million with respect to the total amount to be paid under the agreement in principle to the DOJ and the participating State AGs, and additional amounts for related costs as of and for the quarterly period ended March 31, 2020. Furthermore, in connection with recording a discrete tax benefit of $37.7 million related to the net operating loss ("NOL") carryback provisions available under the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") legislation, the Company has agreed with the government that, if during calendar years 2020 through 2023, and as long as amounts payable to the government remain unpaid, it receives any civil settlement, damages awards, or tax refunds, to the extent that the amounts exceed $5.0 million in a calendar year, the Company will pay 65% of the amount received in such civil settlement, damages award, or tax refunds as an accelerated

payment on the scheduled amounts set forth above, first as a dollar-for-dollar acceleration of the scheduled payment due in December 2025 and then as an accelerated payment of the scheduled payments due in each prior year, up to a maximum total acceleration of $24.96 million. During the three months ended March 31, 2020, we recorded a discrete tax benefit of $37.7 million related to the NOL carryback provisions available under the CARES Act legislation, and if fully paid, the Company expects that the total accelerated payments to the government will be $24.5 million. As of March 31, 2020, the Company's accrual consists of $12.0 million in accrued expenses and other current liabilities and $37.0 million in other long-term liabilities. Until the final documents are approved and signed, there can be no assurance that the amount the Company has accrued will be sufficient to cover its obligations relating to this matter. The Company's obligations could also increase, potentially materially, depending on a number of factors including whether or not the agreement in principle is finalized, the terms of the final approved agreements, the parties to the settlement, the cost of complying with the terms of the settlement, including monitoring fees related to any potential corporate integrity agreement, the costs related to the settlement, and other factors.

On June 21, 2018, the Company received a letter from Cigna alleging damages related to contract terms. On December 5, 2018, Cigna and the Company entered into a settlement agreement whereby Avero agreed to pay an aggregate amount of $12.0 million with an upfront payment of $6.0 million and the remaining $6.0 million to be paid over 24 months. For the year ended December 31, 2018, the Company recorded a charge of $12.0 million associated with this claim in its consolidated statements of operations as a reduction to revenue. As of March 31, 2020, the remaining settlement accrual related to Cigna is $2.3 million in accrued expenses and other current liabilities.

On June 25, 2018, the Company received a letter from Aetna's external legal counsel that included various allegations relating to the Company's past practices. In November 2019, the Company and Aetna entered into a written settlement agreement for $15.0 million, to be paid in installment payments through December 2020. During the year ended December 31, 2018, the Company recorded a charge of $15.0 million associated with this claim in its consolidated statements of operations as a reduction to revenue. As of March 31, 2020, the Company's accrual consists of $7.5 million in accrued expenses and other current liabilities.

On October 18, 2018, the Company received a letter from UnitedHealth Group that included various allegations relating to the Company's past practices. On September 30, 2019, the Company entered into a settlement agreement with United HealthCare Services, Inc. and UnitedHealthcare Insurance Company ("United") in which the Company agreed to pay an aggregate amount of $30.0 million. The settlement is to be paid with an upfront payment of $2.0 million, and the remaining balance to be paid every six months starting December 31, 2019, with the first two installment payments of $5.0 million each, and $6.0 million each thereafter. As of March 31, 2020, the remaining settlement accrual related to United is $23.0 million consisting of $11.0 million in accrued expenses and other current liabilities and $12.0 million in other long-term liabilities.

10. Stockholders' Equity

Common Stock

Pursuant to the November 2019 sixth amended and restated certificate of incorporation, the Company is authorized to issue 300 million shares of common stock. Each holder of common stock is entitled to one vote per share of common stock held.

PROGENITY, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Treasury Stock

In June 2014, the Company authorized an Equity Repurchase Program for Key Employees (the "Repurchase Program"). The Repurchase Program allows the Company to repurchase for cash a portion of common stock equity interest of certain employees, provided that (i) no more than 25% of the equity interest of any employee shall be repurchased under the Repurchase Program, (ii) the purchase price to be paid for each share of common stock shall equal the most recent appraisal valuation of the Company's common stock, and (iii) the aggregate repurchases shall not exceed the lesser of (a) equity interest representing, in the aggregate, 0.8 million shares of common stock, (b) a purchase price, in the aggregate, of more than $6.0 million, and (c) the maximum repurchases permitted under the General Corporation Law of the State of Delaware. In addition, it is the Company's practice to require individuals exercising stock options to hold the shares upon exercising for a reasonable period of time in order for the holder to be exposed to the economic risks and rewards of share ownership prior to participating in the Repurchase Program. A reasonable period of time is defined as a period of at least six months and that covers at least two common stock appraisal valuations.

Convertible Preferred Stock

As of December 31, 2019 and March 31, 2020, the Company had outstanding Series A Preferred Stock and Series B Preferred Stock. The Company recorded the preferred stock at fair value on the dates of issuance net of issuance costs.

On August 27, 2019, the Company issued 9.1 million shares of Series B Preferred Stock at an issuance price of $2.75 per share for an aggregate consideration of $25.0 million (the "August 2019 Financing") pursuant to a Series B Preferred Stock Purchase Agreement with a private equity firm. In addition, the Company amended the Series B Preferred Stock Purchase Warrant dated October 27, 2017 to increase the Series B Preferred Stock underlying the Series B Preferred Stock Purchase Warrant from 1.4 million to 1.8 million shares and adjust the exercise price to $2.75 per share. The $25.0 million of proceeds from the August 2019 Financing are allocated among the newly issued Series B Preferred Stock shares and additional shares of Series B Preferred Stock Purchase Warrant at their relative fair values.

In connection with the August 2019 Financing, the board of directors and stockholders approved a 1.28-for-1 stock split for the Company's Series B Preferred Stock and Series B Preferred Stock Purchase Warrant issued and outstanding prior to the August 2019 Financing, which was effected on August 27, 2019 pursuant to an amendment to the amended and restated certificate of incorporation. The conversion price of the Series B Preferred Stock and exercise price of the outstanding Series B Preferred Stock Purchase Warrant was lowered from $3.53 to $2.75 per share. As a result, the Company issued 4.0 million additional shares of Series B Preferred Stock as a stock dividend to the preferred stockholders, which was recorded as a $13.1 million increase to accumulated deficit on the accompanying consolidated statements of stockholders' deficit during the year ended December 31, 2019.

On August 27, 2019, the Company entered into an Exchange Agreement with holders of Series A-1 Preferred Stock (the "Exchange Agreement") pursuant to which the outstanding 1,500,000 shares of Series A-1 Preferred Stock were exchanged for 35,664,240 shares of Series B Preferred Stock. The exchange ratio is 1.2 to 1 on as-if converted to 4,810,651 shares of common stock that the Series A-1 Preferred Stock can be converted to, based on the conversion rate of 3.2 to 1. The Company determined that such exchange was a modification to the Series A-1 Preferred Stock. Accordingly, the increase comparing the fair value of the Series B Preferred Stock with the fair value of the Series A-1 Preferred Stock represents a dividend to the preferred stockholders, which was approximately $27.6 million and recorded as an increase to accumulated deficit on the accompanying consolidated statements of stockholders' deficit during the year ended December 31, 2019.

PROGENITY, INC. AND SUBSIDIARIES
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On November 12, 2019, the Company entered into a Series B Preferred Stock Purchase Agreement (the "November Series B Preferred Stock Purchase Agreement") with a private equity firm and received $25.0 million (the "November 2019 Financing") in exchange for the issuance of 11.1 million shares of Series B Preferred Stock at $2.25 per share. In connection with the November 2019 Financing, the board of directors and stockholders approved a 1.22-for-1 stock split for the Company's Series B Preferred Stock and Series B Preferred Stock Purchase Warrant issued and outstanding prior to the November 2019 Financing. The conversion price of the Series B Preferred Stock and exercise price of the outstanding Series B Preferred Stock Purchase Warrant was lowered from $2.75 to $2.25 per share. As a result, the Company issued 14.0 million additional shares of Series B Preferred Stock and adjusted the Series B Preferred Stock Purchase Warrant to purchase up to 2.2 million shares of Series B Preferred Stock. The issuance of additional shares represented a stock dividend to the preferred stockholders, which was recorded as a $36.4 million increase to accumulated deficit on the accompanying consolidated statements of stockholders' deficit during the year ended December 31, 2019.

On November 22, 2019 the Company completed an additional equity financing pursuant to the November Series B Preferred Stock Purchase Agreement with certain existing, accredited investors for an aggregate of $6.1 million in exchange for the issuance of an aggregate of 2.7 million shares of Series B Preferred Stock at $2.25 per share.

On December 19, 2019, the Company completed an additional equity financing pursuant to the November Series B Preferred Stock Purchase Agreement with the same private equity firm as the November 2019 Financing for $25.0 million in exchange for the issuance of 11.1 million shares of Series B Preferred Stock at $2.25 per share.

In February 2020, the Company issued and sold an aggregate of 5,066,666 shares of Series B Preferred Stock at a purchase price of $2.25 per share to existing investors in exchange for aggregate consideration of approximately $11.4 million.

On March 31, 2020, in connection with the Credit Agreement Amendment, which provides for the payment of interest due and payable as of March 31, 2020 and June 30, 2020 (only in the event the IPO has not been consummated by such date) in shares of Series B Preferred Stock, the Company issued an aggregate of 967,130 shares of Series B Preferred Stock at a subscription price of $2.25 per share to existing investors as payment for interest due and payable as of March 31, 2020 and all applicable fees.

The fair value of the preferred stock was estimated using a hybrid between a probability-weighted expected return method ("PWERM") and option pricing model ("OPM"), estimating the probability weighted value across multiple scenarios, while using an OPM to estimate the allocation of value within one or more of these scenarios. Under a PWERM, the value of the Company's various classes of stock was estimated based upon an analysis of future values for the Company assuming various future outcomes, including two IPO scenarios and one scenario contemplating the continued operation of the Company as a privately held enterprise. Guideline public company multiples were used to value the Company under its various scenarios. Share value for each class of stock was based upon the probability-weighted present value of expected future share values, considering each of these possible future outcomes, as well as the rights of each share class.

The significant unobservable inputs into the valuation model used to estimate the fair value of the preferred stock include the timing of potential events (primarily the IPO) and their probability of occurring, the selection of guideline public company multiples, a discount for the lack of marketability of the common stock, and the discount rate used to calculate the present value of the estimated equity value allocated to each share class.

PROGENITY, INC. AND SUBSIDIARIES
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Preferred stock outstanding as of December 31, 2019 and March 31, 2020 consisted of the following (in thousands, except share and per share data):

	December 31, 2019			
	Shares Authorized	Shares Issued and Outstanding	Per Share Price at Issuance	Aggregate Liquidation Preference
Series A	4,120,000	4,120,000	$ 0.48543	$ 2,000
Series B	126,035,000	101,867,405	2.25000	229,202
Total preferred stock	130,155,000	105,987,405		$ 231,202

	March 31, 2020			
	Shares Authorized	Shares Issued and Outstanding	Per Share Price at Issuance	Aggregate Liquidation Preference
Series A	4,120,000	4,120,000	$ 0.48543	$ 2,000
Series B	126,035,000	107,901,201	2.25000	242,778
Total preferred stock	130,155,000	112,021,201		$ 244,778

On November 12, 2019, in connection with the November 2019 Financing, the Company amended the certificate of incorporation. Following the amendment, there are no authorized or outstanding shares of Series A-1 Preferred Stock. Pursuant to the sixth amended and restated certificate of incorporation, the stockholders of preferred stock have the following rights, preferences, and privileges:

Dividend Rights

The Company cannot declare, pay or set aside any dividends on shares of common stock (other than dividends on shares of common stock payable in shares of common stock) unless the holders of the outstanding preferred stock also receive a dividend in an amount equal to the product of dividend payable on each share of common stock and the number of shares of common stock then issuable upon conversion of such share of preferred stock.

No other dividends can be declared, paid or set aside besides the aforementioned dividends to the convertible preferred stock.

Liquidation Preference

Upon a liquidation event, as defined in the amended and restated certificate of incorporation, the holders of Series A and Series B Preferred Stock are entitled to receive, prior to and in preference to any distribution of the proceeds of such liquidation to common stockholders, an amount per share equal to $0.48543 and $2.25, respectively, plus any declared but unpaid dividends on such shares. If the proceeds distributed among the holders of the preferred stock are insufficient to permit the Series A and Series B Preferred Stock holders to receive the full payment noted above, then the entire proceeds legally available for distribution shall be distributed ratably among the holders of the convertible preferred stock in proportion to the full preferential amount that each such holder is otherwise entitled to receive with the holders of Series B Preferred Stock having priority and preference to Series A Preferred Stock.

PROGENITY, INC. AND SUBSIDIARIES
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Voting Rights

The holders of each share of preferred stock have the right to one vote for each share of common stock into which such preferred stock could then be converted.

Holders of Series A Preferred Stock, or holders of Series B Preferred Stock voting together as a separate class, can vote for the number of directors that is proportionate to shares of common stock that each share of preferred stock can be converted into relative to all voting shares, provided at least 2.5 million and 40.0 million shares of Series A and Series B Preferred Stock, respectively, are outstanding, and Series B Preferred Stock constitutes at least 10% of the voting shares.

Conversion Rights

Each share of preferred stock is convertible, at the option of the holder, into fully paid and non-assessable shares of common stock determined by dividing the applicable original issue price by the applicable conversion price in effect at the time of conversion. The original issue prices of Series A and Series B Preferred Stock are $0.48543 and $2.25 per share, respectively. The initial conversion prices of Series A and Series B Preferred Stock are $0.15 and $13.90 per share, respectively.

Shares of Series A and Series B Preferred Stock will be automatically converted into fully paid shares of common stock immediately upon the earlier of: (a) the closing of the sale of shares of common stock to the public at a minimum price of $13.90 per share, subject to appropriate adjustment in the event of any stock dividend, stock split, combination, or other similar recapitalization with respect to common stock, in a firm-commitment underwritten IPO pursuant to an effective registration statement under the Securities Act of 1933, as amended, resulting in at least $50.0 million of gross cash proceeds to the Company (such IPO, a “Qualified IPO”) or (b) at the date specified by written consent, or affirmative vote, or agreement of the holders of at least 75% of Series A Preferred Stock and Series B Preferred Stock, voting as separate classes.

In the event of the consummation of a Qualified IPO, the conversion price per share of Series B Preferred Stock shall be adjusted to equal the lesser of (1) the then current conversion price per share of Series B Preferred Stock and (2) the “Price to Public” per share of common stock specified in the final prospectus with respect to the Qualified IPO (the “Public Price”).

Or in the event of the consummation of an IPO where the Public Price is less than $15.986 per share of common stock, the conversion rate per share of Series B Preferred Stock shall be adjusted, as of immediately prior to the consummation of the Qualified IPO, such that each share of Series B Preferred Stock shall be convertible into a number of shares of common stock equal to the quotient of (1) the Series B Preferred Stock original issue price divided by (2) the Public Price multiplied by 0.865.

Redemption Rights

The Company’s shares of preferred stock are not mandatorily redeemable.

A liquidation event will be deemed to occur upon certain sales and merger of the Company. Such deemed liquidation event will require consent of the majority of the outstanding Series B Preferred Stock, unless the consideration from such event will result into a minimum of $16.68 per share to Series B Preferred Stock or common stock converted into.

PROGENITY, INC. AND SUBSIDIARIES
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Common Stock

The Company reserved shares of common stock, on an as-if-converted basis, for future issuance as follows:

	December 31, 2019	March 31, 2020
Series A Preferred Stock	13,213,254	13,213,254
Series B Preferred Stock	16,488,731	17,465,388
Series B Preferred Stock Purchase Warrant	359,699	359,699
Restricted stock units	322,608	990,463
Outstanding options to purchase common stock	2,561,866	3,678,520
Options available for future issuance	1,717,817	4,707,604
Total	34,663,975	40,414,928

11. Stock-based Compensation

On February 22, 2018, the Company adopted the 2018 Equity Incentive Plan (the “2018 Plan”), with 0.7 million shares available for future grant. Upon adoption of the 2018 Plan, no new stock options are issuable under the Second Amended and Restated 2012 Stock Plan (the “2012 Plan”) or the 2015 Consultant Stock Plan (the “2015 Plan”). The 2018 Plan is the successor to and continuation of the 2012 Plan, as amended, and the 2015 Plan, and is administered with either stock options or restricted stock units. The 2018 Plan also provides for other types of equity to issue awards, which at this time the Company does not plan to utilize. The 2018 Plan was amended in March 2019 with 1.1 million shares available for future grant.

On December 5, 2019, the Company adopted the Second Amended and Restated 2018 Equity Incentive Plan, which increased the shares available for future grant to 2.7 million. On March 4, 2020, the Board of Directors adopted the Third Amended and Restated 2018 Equity Incentive Plan (the “2018 Third Amended Plan”), which increased the shares available for future grant to 7.6 million and was approved by stockholders on March 5, 2020. The Board of Directors administers the plans.

In January 2020, the Board of Directors approved the modification of the exercise price (the “modification”) of all outstanding stock options under the existing incentive plans. As a result of the modification, $0.3 million was recognized as stock-based compensation expense for the vested options for the three months ended March 31, 2020. Additional stock-based compensation expense of $0.6 million will be recognized over the remaining vesting period for the unvested stock options.

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Activity under the 2012 Plan, the 2015 Plan, and the 2018 Third Amended Plan for the three months ended March 31, 2020 is set forth below (in thousands, except share and per share data):

	Stock Options Outstanding	Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance at December 31, 2019	2,561,866	$ 9.01		
Awards authorized	—			
Options granted	1,289,699	9.77		
Options exercised	(56,729)	1.81		
Options forfeited	(20,674)	9.92		
Options expired	(95,642)	13.46		
Balance at March 31, 2020	3,678,520	$ 7.90	7.07	$ 13,340
Vested and exercisable at March 31, 2020	1,937,378	$ 6.16	4.90	$ 10,643
Vested and expected to vest March 31, 2020	3,405,118	$ 7.78	6.87	$ 12,913

Options available for grant totaled 4,707,604 at March 31, 2020.

Determining Fair Value of Stock Options—Summary of Assumptions

The Company uses the Black-Scholes option pricing model to estimate the fair value of each option grant on the date of grant or any other measurement date. The following table sets forth the assumptions used to determine the fair value of stock options:

	Three Months Ended March 31, 2020
Risk-free interest rate	0.8% – 1.7%
Expected volatility	57.0% – 71.0%
Expected dividend yield	—
Expected term (in years)	4.0 – 6.3 years

For the three months March 31, 2019 and 2020, the following table presents total stock-based compensation expense in each functional line item on the consolidated statements of operations (in thousands):

	Three Months Ended March 31,	
	2019	2020
Cost of sales	$ 49	$ 228
Research and development	176	662
Selling and marketing	122	373
General and administrative	208	794
Total stock-based compensation expense	$ 555	$ 2,057

PROGENITY, INC. AND SUBSIDIARIES
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The weighted-average grant date fair value of options granted during the three months ended March 31, 2019 and 2020 was $9.64 per option and $6.29 per option, respectively. At December 31, 2019 and March 31, 2020, there was $4.1 million and $9.5 million, respectively, unrecognized compensation cost related to unvested stock options, which are expected to be recognized over a remaining weighted average vesting period of 2.69 years and 3.31 years, respectively.

12. Income Taxes

The Company calculates the interim income tax provision in accordance with ASC Topic 270, *Interim Reporting*, and Topic 740, *Accounting for Income Taxes*. At the end of each interim period, management estimates the annual effective tax rate and applies such rate to the ordinary quarterly earnings to calculate income tax expense related to ordinary income. Due to the full valuation allowance, the Company has a zero effective tax rate for the three months ended March 31, 2020. The tax effects of items significant, unusual and infrequent in nature are discretely calculated and recognized in the period in which they occur.

The Company's net operating loss ("NOL") carryforwards and research and expenditure credit carryforwards may be subject to an annual limitation under Section 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code"), and similar state provisions if the Company experiences one or more ownership changes which would limit the amount of NOL and tax credit carryforwards that can be utilized to offset future taxable income and tax, respectively. In general, an ownership change as defined by Section 382 and 383 of the Code, results from transactions increasing ownership of certain stockholders or public groups in the stock of the corporation by more than 50 percentage points over a three-year period. Due to the existence of the valuation allowance, limitations created by ownership changes will not impact the Company's effective tax rate.

On March 27, 2020, the CARES Act was enacted. The CARES Act includes several significant provisions for corporations, including the usage of NOLs, interest deductions and payroll benefits. Corporate taxpayers may carryback NOLs originating during 2018 through 2020 for up to five years. During the three months ended March 31, 2020, we recorded a discrete tax benefit of $37.7 million related to the NOL carryback provisions available under the CARES Act legislation for taxes paid in years 2013, 2014, 2015, and 2017. If any tax refund is received that is more than $5.0 million in a single year, along with other civil settlements, damages awards, and tax refunds, we have agreed to pay 65% of all such amounts received to accelerate payments to the government in connection with our proposed government settlement (see Note 9).

13. Net Loss Per Share

Net loss per share is computed by dividing net loss attributable to common stockholders for the period by the weighted average number of common shares outstanding during the period. Diluted loss per share reflects the additional dilution from potential issuances of common stock, such as stock issuable pursuant to the exercise of stock options, as well as from the possible conversion of the Company's preferred stock and exercise of the outstanding warrant. The treasury stock and if-converted methods are used to calculate the potential dilutive effect of these common stock equivalents. However, potentially dilutive shares are excluded from the computation of diluted loss per share when their effect is antidilutive. Due to the Company reporting a net loss attributable to common stockholders for all periods presented, all potentially dilutive securities were antidilutive and have been excluded from the computation of diluted loss per share.

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The table below provides potentially dilutive securities in equivalent common shares not included in the Company's calculation of diluted loss per share because to do so would be antidilutive:

	Three Months Ended March 31,	
	2019	2020
Series A Preferred Stock	13,213,254	13,213,254
Series A-1 Preferred Stock	4,810,649	—
Series B Preferred Stock	2,292,700	17,465,388
Series B Preferred Stock Purchase Warrant	229,270	359,699
Options to purchase common stock	2,368,177	3,678,520
Restricted stock units	161,006	990,463
Total	23,075,056	35,707,324

The Company has presented basic and diluted net loss per share, which has been computed to give effect to the conversion of all shares of preferred stock and restricted stock units into shares of common stock as if such conversion had occurred as of the beginning of the period presented. The following table sets forth the computation of the Company's basic and diluted net loss per common share (unaudited) (in thousands, except share and per share data):

	Three Months Ended March 31, 2020
Numerator:	
Net loss used in computing pro forma net loss per share, basic and diluted	$ (17,152)
Denominator:	
Shares used in computing net loss per share, basic and diluted	4,993,393
Pro forma adjustments to reflect assumed conversion of preferred stock	29,992,097
Pro forma adjustments to reflect assumed conversion of vested restricted stock units	77,579
Shares used in computing pro forma net loss per share, basic and diluted	35,063,069
Pro forma basic and diluted net loss per share	$ (0.49)

Diluted loss per share does not include outstanding stock options, restricted stock units, and the outstanding Series B Preferred Stock Purchase Warrant since the effect would be antidilutive due to the net loss attributable to common stockholders for the period.

14. Subsequent Events

The Company has evaluated subsequent events from the balance sheet date through May 27, 2020, the date the consolidated financial statements were available to be issued, except for the reverse stock split discussed below.

PROGENITY, INC. AND SUBSIDIARIES
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On April 3, 2020, the Company issued and sold an aggregate of 4,444,444 shares of its Series B Preferred Stock at a purchase price of $2.25 per share to existing investors in exchange for aggregate consideration of approximately $10.0 million in cash.
On May 8, 2020, the Company entered into an unsecured convertible promissory note (the "Note") with an existing investor pursuant to a note purchase agreement, in an aggregate principal amount of $15.0 million, with an annual interest rate of 8.0% and a maturity date of May 8, 2022. The Note is convertible into (i) common stock upon an initial public offering at the lesser of the conversion price then in effect and a conversion price equal to 80% of the public offering price (or, if not a "qualified IPO" as defined in the Company's certificate of incorporation, at the election of a majority of the holders), (ii) on the maturity date or at the election of a majority of the holders, Series B preferred stock at an initial conversion price of $13.90 per share subject to certain adjustments, or (iii) at the election of a majority of the holders, shares of another class of equity securities issued by the Company in a future financing at 80% of the price per share of such class of equity securities issued in such offering. Interest under the Note is not generally payable except that if the Note is not converted pursuant to its terms on or prior to the maturity date and there are not sufficient authorized and unissued shares of Series B preferred stock for issuance upon the conversion of the Note on the maturity date, then the Company is required to pay all outstanding principal and any accrued and unpaid interest under the Note in cash. If the holders of the Note have not elected to convert the Note prior to, or in connection with, any sale transaction or a liquidation, dissolution or winding up of the Company, either voluntary or involuntary, then, upon any such sale transaction or liquidation, dissolution or winding up of the Company, the Company is required to pay in cash the outstanding principal balance of the Note, together with accrued and unpaid interest thereon, plus a make whole premium of 50% of the aggregate principal amount (less accrued and unpaid interest).

On June 10, 2020 the Company amended its certificate of incorporation to reflect a 6.178-for-1 reverse stock split of the Company's common stock. The par values and the number of authorized shares of common stock were not adjusted as a result of the reverse stock split. All issued and outstanding shares of common stock and related per share amounts contained in the accompanying consolidated financial statements have been retroactively adjusted to reflect this reverse stock split for all periods presented. The reverse stock split resulted in an adjustment to the respective Series A and B preferred stock conversion prices to reflect a proportional decrease in the number of shares of common stock to be issued upon conversion.

We are a biotechnology company with a track record of success in developing and commercializing molecular testing products as well as innovating in precision medicine.

CONSISTENT GROWTH

Focus on women's health to date

Robust product portfolio

~1.5 million tests performed

MULTI-OMIC APPROACH

Genomics

Epigenomics

Proteomics

Metabolomics

BREAKTHROUGH INNOVATION

GI precision medicine platform technology

Pursuing Dx and Rx opportunities

420+ Patents

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Shares

PROGENITY, INC.

Common Stock

PROSPECTUS

Until , 2020 all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

Piper Sandler

Wells Fargo Securities

Baird

Raymond James

BTIG

, 2020

PART II

INFORMATION NOT REQUIRED IN THE PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth the various expenses, other than underwriting discounts and commissions, payable by the registrant in connection with the sale of common stock being registered. All of the amounts shown are estimated except the Securities and Exchange Commission registration fee and the FINRA filing fee.

	Amount To Be Paid
SEC registration fee	$ 15,923
FINRA filing fee	15,500
Nasdaq listing fee	210,000
Printing and engraving expenses	675,250
Legal fees and expenses	1,500,000
Accounting fees and expenses	1,425,000
Transfer agent and registrar fees	6,000
Miscellaneous fees and expenses	152,327
Total	$ 4,000,000

Item 14. Indemnification of Directors and Officers.

The company is a Delaware corporation. Section 145(a) of the Delaware General Corporation Law, or the DGCL, provides that a Delaware corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, other than an action by or in the right of the corporation, by reason of the fact that such person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with such action, suit or proceeding if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful.

Section 145(b) of the DGCL provides that a Delaware corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that such person acted in any of the capacities set forth above, against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit if the person acted in good faith and in a manner the person reasonably believed to be in, or not opposed to, the best interests of the corporation, except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation, unless and only to the extent that the Court of Chancery or the court in which such action or suit was brought shall determine, upon application, that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the court shall deem proper.

Further subsections of DGCL Section 145 provide that:

(1) to the extent a present or former director or officer of a corporation has been successful on the merits or otherwise in the defense of any action, suit or proceeding referred to in subsections (i) and (ii) of Section 145 or in the defense of any claim, issue or matter therein, such person shall be indemnified against expenses, including attorneys' fees, actually and reasonably incurred by such person in connection therewith;

(2) the indemnification and advancement of expenses provided for pursuant to Section 145 shall not be deemed exclusive of any other rights to which those seeking indemnification or advancement of expenses may be entitled under any bylaw, agreement, vote of stockholders or disinterested directors or otherwise; and

(3) the corporation shall have the power to purchase and maintain insurance of behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against any liability asserted against such person and incurred by such person in any such capacity, or arising out of such person's status as such, whether or not the corporation would have the power to indemnify such person against such liability under Section 145.

As used in this Item 14, the term "proceeding" means any threatened, pending or completed action, suit or proceeding, whether or not by or in the right of the company, and whether civil, criminal, administrative, investigative or otherwise.

Section 145 of the DGCL makes provision for the indemnification of officers and directors in terms sufficiently broad to indemnify officers and directors of the company under certain circumstances from liabilities (including reimbursement for expenses incurred) arising under the Securities Act. The company's organizational documents provide, in effect, that, to the fullest extent and under the circumstances permitted by Section 145 of the DGCL, the company will indemnify any and all of its officers and directors. Before the completion of this offering, the company intends to enter into indemnification agreements with its officers and directors. The company may, in its discretion, similarly indemnify its employees and agents. The company's certificate of incorporation also relieves its directors from monetary damages to the company or its stockholders for breach of such director's fiduciary duty as a director to the fullest extent permitted by the DGCL. Under Section 102(b)(7) of the DGCL, a corporation may relieve its directors from personal liability to such corporation or its stockholders for monetary damages for any breach of their fiduciary duty as directors except (i) for a breach of the duty of loyalty, (ii) for failure to act in good faith, (iii) for intentional misconduct or knowing violation of law, (iv) for willful or negligent violations of certain provisions in the DGCL imposing certain requirements with respect to stock repurchases, redemptions and dividends or (v) for any transactions from which the director derived an improper personal benefit.

The company has purchased insurance policies that, within the limits and subject to the terms and conditions thereof, cover certain expenses and liabilities that may be incurred by directors and officers in connection with proceedings that may be brought against them as a result of an act or omission committed or suffered while acting as a director or officer of the company.

The form of Underwriting Agreement, to be entered into in connection with this offering and to be attached as Exhibit 1.1 hereto, provides for the indemnification by the underwriters of us and our officers and directors for certain liabilities, including liabilities arising under the Securities Act, and affords certain rights of contribution with respect thereto.

Item 15. Recent Sales of Unregistered Securities.

Since January 1, 2017, we have made the following sales of unregistered securities:

Issuances of Capital Stock

In October 2017, we issued and sold 14,164,306 shares of our Series B Preferred Stock at a purchase price of $3.53 per share to an investor in exchange for aggregate consideration of $50.0 million, composed of $37.5 million in cash and 3,489,885 shares of our Series A-2 Preferred Stock, which shares were valued in the aggregate at $12.5 million.

In August 2019, we issued and sold 9,090,910 shares of our Series B Preferred Stock at a purchase price of $2.75 per share to an existing investor in exchange for aggregate consideration of $25.0 million in cash. Concurrent with the issuance, we offered all holders of our Series A-1 Preferred Stock the opportunity to exchange their shares of Series A-1 Preferred Stock for Series B Preferred Stock. All holders of Series A-1 Preferred Stock exchanged all of their shares of Series A-1 Preferred Stock (an aggregate amount of 1,500,000 shares) for an aggregate of 35,664,240 shares of Series B Preferred Stock.

In November 2019, we issued and sold an aggregate of 13,833,333 shares of our Series B Preferred Stock at a purchase price of $2.25 per share to existing investors in exchange for aggregate consideration of approximately $31.1 million in cash.

In December 2019, we issued and sold an aggregate of 11,111,111 shares of our Series B Preferred Stock at a purchase price of $2.25 per share to an existing investor in exchange for aggregate consideration of approximately $25.0 million in cash.

In February 2020, we issued and sold an aggregate of 5,066,666 shares of our Series B Preferred Stock at a purchase price of $2.25 per share to existing investors in exchange for aggregate consideration of approximately $11.4 million in cash.

In March 2020, in connection with an amendment to our existing credit agreement, which provides for the payment of interest due and payable as of March 31, 2020 and June 30, 2020 in shares of our Series B Preferred Stock, we issued an aggregate of 967,130 shares of our Series B Preferred Stock at a subscription price of $2.25 per share to existing investors as payment for interest due and payable as of March 31, 2020 and all applicable fees.

In April 2020, we issued and sold an aggregate of 4,444,444 shares of our Series B Preferred Stock at a purchase price of $2.25 per share to existing investors in exchange for aggregate consideration of approximately $10.0 million in cash.

In May 2020, we issued and sold an unsecured convertible promissory note, or the Convertible Note, to an existing investor with an aggregate principal amount of $15.0 million. The Convertible Note accrues interest at a rate of 8.0% per annum and is convertible at the option of the holder at any time prior to the maturity date of May 8, 2022 into (i) shares of our Series B Preferred Stock at an initial conversion price of $13.90 per share, subject to certain adjustments, or (ii) shares of another class of equity securities of the Company issued pursuant to an equity financing at a 20% discount to the share price paid by the purchasers of such equity securities in such financing. The Convertible Note will automatically convert into shares of our Common Stock upon an initial public offering at a 20% discount to the public offering price per share (or, if not a “qualified IPO” as defined in the Company’s certificate of incorporation, at the election of a majority of the holders). Interest under the Convertible Note is not generally payable except that if the Convertible Note is not converted pursuant to its terms on or prior to the maturity date and there are not sufficient authorized and unissued shares of Series B preferred stock for issuance upon the conversion of the Convertible Note on the maturity date, then the Company is required to pay all outstanding principal and any accrued and unpaid interest under the

Convertible Note in cash. If the holders of the Note have not elected to convert the Convertible Note prior to, or in connection with, any sale transaction or a liquidation, dissolution or winding up of the Company, either voluntary or involuntary, then, upon any such sale transaction or liquidation, dissolution or winding up of the Company, the Company is required to pay in cash the outstanding principal balance of the Note, together with accrued and unpaid interest thereon, plus a make whole premium of 50% of the aggregate principal amount (less accrued and unpaid interest).

The offers, sales, and issuances of the securities listed in this Item 15 under the subheading "Issuances of Capital Stock" were deemed to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act or Rule 506 of Regulation D promulgated thereunder as transactions by an issuer not involving a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was an accredited investor within the meaning of Rule 501 of Regulation D under the Securities Act.

Grants of Stock Options

Since January 1, 2017, we have granted 1,120,778 restricted stock units and stock options to purchase an aggregate of 2,684,792 shares of our common stock at a weighted average exercise price of $10.58 to employees, directors, and non-employee service providers.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering. The offers, sales and issuances of the securities listed in this Item 15 under the subheading "Issuances of Capital Stock" were deemed to be exempt from registration under the Securities Act in reliance on Rule 701 promulgated under the Securities Act as offers and sales of securities pursuant to certain compensatory benefit plans and contracts relating to compensation in compliance with Rule 701 or Rule 175.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits

Exhibit Number	Description of Exhibit
1.1	Form of Underwriting Agreement.
3.1	Seventh Amended and Restated Certificate of Incorporation of the registrant, as amended, as currently in effect.
3.2	Form of Eighth Amended and Restated Certificate of Incorporation of the registrant, to be in effect upon completion of this offering.
3.3**	Bylaws of the registrant, as currently in effect.
3.4	Form of Amended and Restated Bylaws of the registrant, to be in effect upon completion of this offering.
4.1**	Form of common stock certificate of the registrant.
4.2**	Series B Preferred Stock Purchase Warrant.
4.3**	First Amendment to Series B Preferred Stock Purchase Warrant.
4.4**	Second Amendment to Series B Preferred Stock Purchase Warrant.
4.5**	Fourth Amended and Restated Investors' Rights Agreement, dated as of August 27, 2019, by and among Progenity, Inc. and certain of its stockholders.
5.1	Opinion of Gibson, Dunn & Crutcher LLP.

Exhibit Number	Description of Exhibit
10.1**	Form of Indemnification Agreement for directors and executive officers.
10.2**+	2011 Incentive Stock Plan.
10.3**+	Second Amended and Restated 2012 Stock Plan.
10.4**+	2015 Consultant Stock Plan.
10.5+	Third Amended and Restated 2018 Equity Incentive Plan.
10.6+	2020 Employee Stock Purchase Plan.
10.7**+	Offer Letter by and between Progenity, Inc. and Eric d'Esparbes, dated as of May 1, 2019.
10.8**+	Offer Letter by and between Progenity, Inc. and Sami Shihabi, dated as of December 13, 2017.
10.9**+	Offer Letter by and between Progenity, Inc. and Matt Cooper, dated as of March 20, 2015.
10.10**+	Offer Letter by and between Progenity, Inc. and Clarke Neumann, dated as of August 26, 2014.
10.11**+	Offer Letter by and between Progenity, Inc. and George Gianakopoulos, dated as of August 29, 2014.
10.12**+	Offer Letter by and between Progenity, Inc. and Troy Seelye, dated as of January 19, 2020.
10.13**+	Offer Letter by and between Progenity, Inc. and Damon Silvestry, dated as of March 8, 2020.
10.14**+	Severance Plan.
10.15**#	Supply & Service Agreement by and between Progenity, Inc. and Illumina, Inc., dated as of November 26, 2014, as amended.
10.16**#	Settlement Agreement by and between Progenity, Inc. and Aetna Health Management, Inc., dated as of November 11, 2019.
10.17**#	Amendment to Settlement Agreement by and between Progenity, Inc. and Aetna Health Management, Inc., dated as of April 29, 2020.
10.18**#	Confidential Settlement Agreement and Mutual Release by and among Progenity, Inc., United HealthCare Services, Inc. and UnitedHealthcare Insurance Company, dated as of September 30, 2019.
10.19**#	Settlement and General Release Agreement by and among Progenity, Inc., Connecticut General Life Insurance Company and Cigna Health and Life Insurance Company, dated as of December 5, 2018.
10.20**#	Settlement and General Release Agreement by and among Mattison Pathology, LLP d/b/a Avero Diagnostics, Connecticut General Life Insurance Company and Cigna Health and Life Insurance Company, dated as of December 5, 2018.
10.21**	Credit and Security Agreement by and among Progenity, Inc., as borrower, Athyrium Opportunities III Co-Invest 1 LP, as a lender and collateral agent, and the other lenders party thereto, dated as of October 27, 2017.
10.22**	First Amendment to Credit and Security Agreement by and among Progenity, Inc., as borrower, Athyrium Opportunities III Co-Invest 1 LP, as a lender and collateral agent, and the other lenders party thereto, dated as of March 31, 2020.
10.23**	Second Amendment to Credit and Security Agreement by and among Progenity, Inc., as borrower, Athyrium Opportunities III Co-Invest 1 LP, as a lender and collateral agent, and the other lenders party thereto, dated as of May 6, 2020.
21.1**	List of subsidiaries.

Exhibit Number	Description of Exhibit
23.1	Consent of Independent Registered Public Accounting Firm.
23.2	Consent of Gibson, Dunn & Crutcher LLP (see Exhibit 5.1).
24.1**	Power of Attorney.

** Previously filed.
+ Indicates management contract or compensatory plan.
# Certain confidential portions of this exhibit were omitted by means of marking such portions with asterisks because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

(b) No financial statement schedules are provided because the information called for is not required or is shown in the financial statements or the notes thereto.

Item 17. Undertakings.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance on Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be a part of this registration statement as of the time it was declared effective.

(2) For purposes of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

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SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of San Diego, State of California, on the 15th day of June, 2020.

Progenity, Inc.

By: **/s/ Dr. Harry Stylli**
Dr. Harry Stylli
Chairman and Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates set forth opposite their names.

Signature	Title	Date
/s/ Dr. Harry Stylli **Dr. Harry Stylli**	Chairman and Chief Executive Officer (principal executive officer)	June 15, 2020
/s/ Eric d'Esparbes **Eric d'Esparbes**	Chief Financial Officer (principal financial and accounting officer)	June 15, 2020
* **Jeffrey Alter**	Director	June 15, 2020
* **John Bigalke**	Director	June 15, 2020
* **Jeffrey Ferrell**	Director	June 15, 2020
* **Dr. Brian L. Kotzin**	Director	June 15, 2020
* **Dr. Samuel Nussbaum**	Director	June 15, 2020
* **Lynne Powell**	Director	June 15, 2020

*By: /s/ Eric d'Esparbes
Eric d'Esparbes
Attorney-in-fact

Exhibit 1.1

[●] Shares

Progenity, Inc.

Common Stock

PURCHASE AGREEMENT

[●], 2020

PIPER SANDLER & CO.
WELLS FARGO SECURITIES, LLC
As Representatives of the several
Underwriters named in Schedule I hereto

c/o Piper Sandler & Co.
800 Nicollet Mall, Suite 800
Minneapolis, MN 55402

c/o Wells Fargo Securities, LLC
500 West 33rd Street, 14th Floor
New York, NY 10001

Ladies and Gentlemen:

Progenity, Inc., a Delaware corporation (the ***"Company"***), proposes to sell to the several Underwriters named in Schedule I hereto (the ***"Underwriters"***) an aggregate of [●] shares (the ***"Firm Shares"***) of Common Stock, $0.001 par value per share (the ***"Common Stock"***), of the Company. The Firm Shares consist of [●] authorized but unissued shares of Common Stock to be issued and sold by the Company. The Company has also granted to the several Underwriters an option to purchase up to [●] additional shares of Common Stock on the terms and for the purposes set forth in Section 3 hereof (the ***"Option Shares"***). The Firm Shares and any Option Shares purchased pursuant to this Purchase Agreement are herein collectively called the ***"Securities."***

The Company hereby confirms its agreement with respect to the sale of the Securities to the several Underwriters, for whom Piper Sandler & Co. and Wells Fargo Securities, LLC are acting as representatives (the ***"Representatives"***).

1. ***Registration Statement and Prospectus***. A registration statement on Form S-1 (File No. 333-238738) with respect to the Securities, including a preliminary form of prospectus, has been prepared by the Company in conformity with the requirements of the Securities Act of 1933, as amended (the ***"Act"***), and the rules and regulations (the ***"Rules and Regulations"***) of the Securities and Exchange Commission (the ***"Commission"***) thereunder and has been filed with the Commission. Such registration statement, including the amendments, exhibits and schedules thereto, as of the time it became effective, including the Rule 430A Information (as defined below), is referred to herein as the ***"Registration Statement."*** The Company will prepare and file a prospectus pursuant to

Rule 424(b) of the Rules and Regulations that discloses the information previously omitted from the prospectus in the Registration Statement in reliance upon Rule 430A of the Rules and Regulations, which information will be deemed retroactively to be a part of the Registration Statement in accordance with Rule 430A of the Rules and Regulations (***"Rule 430A Information"***). If the Company has elected to rely upon Rule 462(b) of the Rules and Regulations to increase the size of the offering registered under the Act, the Company will prepare and file with the Commission a registration statement with respect to such increase pursuant to Rule 462(b) of the Rules and Regulations (such registration statement, including the contents of the Registration Statement incorporated by reference therein is the ***"Rule 462(b) Registration Statement"***). References herein to the ***"Registration Statement"*** will be deemed to include any such Rule 462(b) Registration Statement at and after the time of filing of the Rule 462(b) Registration Statement. ***"Preliminary Prospectus"*** means any prospectus included in the Registration Statement prior to the effective time of the Registration Statement, any prospectus filed with the Commission pursuant to Rule 424(a) under the Rules and Regulations and each prospectus that omits Rule 430A Information used after the effective time of the Registration Statement. ***"Prospectus"*** means the prospectus that discloses the public offering price and other final terms of the Securities and the offering and otherwise satisfies Section 10(a) of the Act. All references in this Agreement to the Registration Statement, any Preliminary Prospectus, the Prospectus or any amendment or supplement to any of the foregoing, is deemed to include the copy filed with the Commission pursuant to its Electronic Data Gathering, Analysis and Retrieval system or any successor system thereto.

2. ***Representations and Warranties of the Company***.

(a) *Representations and Warranties of the Company*. The Company represents and warrants to, and agrees with, the several Underwriters as follows:

(i) *Registration Statement and Prospectuses*. The Registration Statement and any post-effective amendment thereto has become effective under the Act. No stop order suspending the effectiveness of the Registration Statement or any post-effective amendment thereto has been issued by the Commission, and no proceeding for that purpose has been initiated or, to the Company's knowledge, threatened by the Commission. No order preventing or suspending the use of any Preliminary Prospectus or the Prospectus (or any supplement thereto) has been issued by the Commission and no proceeding for that purpose has been initiated or, to the Company's knowledge, threatened by the Commission. As of the time each part of the Registration Statement (or any post-effective amendment thereto) became or becomes effective, such part conformed or will conform in all material respects to the requirements of the Act and the Rules and Regulations. Upon the filing or first use within the meaning of the Rules and Regulations, each Preliminary Prospectus and the Prospectus (or any supplement to either) conformed or will conform in all material respects to the requirements of the Act and the Rules and Regulations.

(ii) *Accurate Disclosure*. Each Preliminary Prospectus, at the time of filing thereof or the time of first use within the meaning of the Rules and Regulations, did not contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading. Neither the Registration Statement nor any

amendment thereto, at the effective time of each part thereof, at the First Closing Date (as defined below) or at the Second Closing Date (as defined below), contained, contains or will contain an untrue statement of a material fact or omitted, omits or will omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. As of the Time of Sale (as defined below), neither (A) the Time of Sale Disclosure Package (as defined below) nor (B) any issuer free writing prospectus (as defined below), when considered together with the Time of Sale Disclosure Package, included an untrue statement of a material fact or omitted to state a material fact necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. Neither the Prospectus nor any supplement thereto at the time of any filing with the Commission pursuant to Rule 424(b) of the Rules and Regulations, at the First Closing Date or at the Second Closing Date, as applicable, included, includes or will include an untrue statement of a material fact or omitted, omits or will omit to state a material fact necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. The representations and warranties in this Section 2(a)(ii) shall not apply to statements in or omissions from any Preliminary Prospectus, the Registration Statement (or any amendment thereto), the Time of Sale Disclosure Package or the Prospectus (or any supplement thereto) made in reliance upon, and in conformity with, written information furnished to the Company by you, or by any Underwriter through you, specifically for use in the preparation of such document, it being understood and agreed that the only such information furnished by any Underwriter consists of the information described as such in Section 6(e).

Each reference to an ***"issuer free writing prospectus"*** herein means an issuer free writing prospectus as defined in Rule 433 of the Rules and Regulations.

"Time of Sale Disclosure Package" means the Preliminary Prospectus dated [ ], 2020, any free writing prospectus set forth on Schedule IV and the information on Schedule V, all considered together.

Each reference to a ***"free writing prospectus"*** herein means a free writing prospectus as defined in Rule 405 of the Rules and Regulations.

"Time of Sale" means [●]:00 [a/p].m. (Eastern time) on the date of this Agreement.

(iii) *Issuer Free Writing Prospectuses*.

(A) Each issuer free writing prospectus, as of its issue date and at all subsequent times through the completion of the public offer and sale of the Securities or until any earlier date that the Company notified or notifies the Representatives as described in Section 4(a)(iii)(B), did not, does not and will not include any information that conflicted, conflicts or will conflict with the information contained in the Registration Statement, any Preliminary Prospectus or the Prospectus. The foregoing sentence does not apply to statements in or omissions from any issuer free writing prospectus based upon and in conformity with written information furnished to the Company by you or by any Underwriter through you specifically for use therein; it being understood and agreed that the only such information furnished by any Underwriter consists of the information described as such in Section 6(e).

(B) At the time of filing the Registration Statement and any post-effective amendment thereto, and at the date hereof, the Company was not and is not an "ineligible issuer," as defined in Rule 405 of the Rules and Regulations, without taking account of any determination by the Commission pursuant to Rule 405 of the Rules and Regulations that it is not necessary that the Company be considered an ineligible issuer.

(C) Each issuer free writing prospectus satisfied, as of its issue date and at all subsequent times through the completion of the public offer and sale of the Securities, all other conditions to use thereof as set forth in Rules 164 and 433 under the Act.

(iv) *Emerging Growth Company*. From the time of initial confidential submission of the Registration Statement to the Commission (or, if earlier, the first date on which the Company engaged directly or through any person authorized to act on its behalf in any Testing-the-Waters Communication (as defined below)) through the date hereof, the Company has been and is an "emerging growth company," as defined in Section 2(a) of the Act (an ***"Emerging Growth Company"***). ***"Testing-the-Waters Communication"*** means any oral or written communication with potential investors undertaken in reliance on Section 5(d) of the Act.

(v) *Testing-the-Waters Materials*. The Company (i) has not alone engaged in any Testing-the-Waters Communications, other than Testing-the-Waters Communications with the prior consent of the Representatives with entities that are qualified institutional buyers within the meaning of Rule 144A under the Act or institutions that are accredited investors within the meaning of Rule 501 under the Act and (ii) has not authorized anyone other than the Representatives to engage in Testing-the-Waters Communications. The Company reconfirms that the Representatives have been authorized to act on its behalf in undertaking Testing-the-Waters Communications. The Company has not distributed any Written Testing-the-Waters Communications (as defined below) other than those listed on Schedule VI hereto. ***"Written Testing-the-Waters Communication"*** means any Testing-the-Waters Communication that is a written communication within the meaning of Rule 405 under the Act. Any individual Written Testing-the-Waters Communication does not conflict

with the information contained in the Registration Statement or the Time of Sale Disclosure Package, complied in all material respects with the Act, and when taken together with the Time of Sale Disclosure Package as of the Time of Sale, did not contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(vi) *No Other Offering Materials*. The Company has not distributed and will not distribute any prospectus or other offering material in connection with the offering and sale of the Securities other than any Preliminary Prospectus, the Time of Sale Disclosure Package, the Prospectus or other materials permitted by the Act to be distributed by the Company; *provided*, *however,* that, except as set forth on Schedule IV, the Company has not made and will not make any offer relating to the Securities that would constitute a free writing prospectus, except in accordance with the provisions of Section 4(a)(xiii) of this Agreement and, except as set forth on Schedule VI, the Company has not made and will not make any communication relating to the Securities that would constitute a Testing-the-Waters Communication, except in accordance with the provisions of Section 2(a)(v) of this Agreement.

(vii) *Financial Statements*. The financial statements of the Company, together with the related notes, set forth in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus comply in all material respects with the requirements of the Act and fairly present the financial condition of the Company and its consolidated subsidiaries as of the dates indicated and the results of operations and changes in cash flows for the periods therein specified in conformity with generally accepted accounting principles in the United States ("***GAAP***") consistently applied throughout the periods involved; the supporting schedules included in the Registration Statement present fairly the information required to be stated therein; all non-GAAP financial information, if any, included in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus complies in all material respects with the requirements of Regulation G and Item 10 of Regulation S-K under the Act; and, except as disclosed in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus, there are no material off-balance sheet arrangements (as defined in Regulation S-K under the Act, Item 303(a)(4)(ii)) or any other relationships with unconsolidated entities or other persons, that are reasonably likely to have a material effect on the Company's financial condition, results of operations, liquidity, capital expenditures, capital resources or significant components of revenue or expenses. No other financial statements or schedules are required to be included in the Registration Statement, the Time of Sale Disclosure Package or the Prospectus. To the Company's knowledge, KPMG LLP, which has expressed its opinion with respect to the financial statements and schedules filed as a part of the Registration Statement and included in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus, is (A) an independent public accounting firm within the meaning of the Act and the Rules and Regulations, (B) a registered public accounting firm (as defined in Section 2(a)(12) of the Sarbanes-Oxley Act of 2002 (the ***"Sarbanes-Oxley Act"***)) and (C) not in violation of the auditor independence requirements of the Sarbanes-Oxley Act.

(viii) *Organization and Good Standing*. Each of the Company and its subsidiaries, including, without limitation, the entities set forth on Schedule II hereto (collectively, the "***Subsidiaries***"), has been duly organized and is validly existing and in good standing under the laws of its jurisdiction of incorporation or organization. Each of the Company and the Subsidiaries has full power and authority to own its properties and conduct its business as currently being carried on and as described in the Registration Statement, the Time of Sale Disclosure Package and Prospectus, and is duly qualified to do business and in good standing in each jurisdiction in which it owns or leases real property or in which the conduct of its business makes such qualification necessary and in which the failure to so qualify would have a material adverse effect upon the business, prospects, management, properties, operations, condition (financial or otherwise) or results of operations of the Company and the Subsidiaries, taken as a whole (***"Material Adverse Effect"***).

(ix) *Absence of Certain Events*. Except as contemplated in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus, subsequent to the respective dates as of which information is given in the Time of Sale Disclosure Package, neither the Company nor any of the Subsidiaries has incurred any material liabilities or obligations, direct or contingent, or entered into any material transactions, or declared or paid any dividends or made any distribution of any kind with respect to its capital stock; and there has not been any change in the capital stock (other than a change in the number of outstanding shares of Common Stock due to the issuance of shares upon the exercise of outstanding options or warrants or conversion of convertible securities described as outstanding in, and the grant of options and awards under existing equity incentive plans described in, the Registration Statement, the Time of Sale Disclosure Package or the Prospectus), or any material change in the short-term or long-term debt (other than as a result of the conversion of convertible securities), or any issuance of options, warrants, convertible securities or other rights to purchase the capital stock, of the Company or any of the Subsidiaries, or any material adverse change in the general affairs, condition (financial or otherwise), business, prospects, management, properties, operations or results of operations of the Company and the Subsidiaries, taken as a whole (***"Material Adverse Change"***), or any development which could reasonably be expected to result in any Material Adverse Change.

(x) *Absence of Proceedings*. Except as set forth in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus, there is not pending or, to the knowledge of the Company, threatened or contemplated, any action, suit or proceeding (A) to which the Company or any of the Subsidiaries is a party or (B) which has as the subject thereof any officer or director of the Company or any Subsidiary, any employee benefit plan sponsored by the Company or any Subsidiary or any property or assets owned or leased by the Company or any Subsidiary before or by any court or Governmental Authority (as defined below), or any arbitrator, which, individually or in the aggregate, could reasonably be expected to result in any Material Adverse Change, or would materially and adversely affect the ability of the Company to perform its obligations under this Agreement or which are otherwise material in the context of the sale of the Securities. There are no current or, to the knowledge of the Company, pending, legal, governmental or regulatory actions, suits or proceedings (x) to which the Company or any of the Subsidiaries is subject or (y) which has as the subject thereof any officer or director of the Company or any Subsidiary, any employee

plan sponsored by the Company or any Subsidiary or any property or assets owned or leased by the Company or any Subsidiary, that are required to be described in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus by the Act or by the Rules and Regulations and that have not been so described.

(xi) *Authorization; No Conflicts; Authority*. This Agreement has been duly authorized, executed and delivered by the Company, and constitutes a valid, legal and binding obligation of the Company, enforceable in accordance with its terms, except as rights to indemnity hereunder may be limited by federal or state securities laws and except as such enforceability may be limited by bankruptcy, insolvency, reorganization or similar laws affecting the rights of creditors generally and subject to general principles of equity. The execution, delivery and performance of this Agreement and the consummation of the transactions herein contemplated will not (A) conflict with or result in a breach or violation of any of the terms or provisions of, or constitute a default under, or result in the creation or imposition of any lien, charge or encumbrance upon any property or assets of the Company or any of the Subsidiaries pursuant to any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which the Company or any of the Subsidiaries is a party or by which the Company or any of the Subsidiaries is bound or to which any of the property or assets of the Company or any of the Subsidiaries is subject, (B) result in any violation of the provisions of the Company's charter or by-laws or (C) result in the violation of any law or statute or any judgment, order, rule, regulation or decree of any court or arbitrator or federal, state, local or foreign governmental agency or regulatory authority having jurisdiction over the Company or any of the Subsidiaries or any of their properties or assets (each, a ***"Governmental Authority"***), except in the case of clause (A) as would not reasonably be expected to result in a Material Adverse Effect. No consent, approval, authorization or order of, or registration or filing with any Governmental Authority is required for the execution, delivery and performance of this Agreement or for the consummation of the transactions contemplated hereby, including the issuance or sale of the Securities by the Company, except such as may be required under the Act, the rules of the Financial Industry Regulatory Authority, Inc. (***"FINRA"***) or state securities or blue sky laws; and the Company has full power and authority to enter into this Agreement and to consummate the transactions contemplated hereby, including the authorization, issuance and sale of the Securities as contemplated by this Agreement.

(xii) *Capitalization; the Securities; Registration Rights*. All of the issued and outstanding shares of capital stock of the Company, including the outstanding shares of Common Stock, have been duly authorized and validly issued, are fully paid and nonassessable, have been issued in compliance with all applicable federal and state and foreign securities laws, were not issued in violation of or subject to any preemptive rights or other rights to subscribe for or purchase securities that have not been waived in writing (a copy of which has been delivered to counsel to the Representatives), and the holders thereof are not subject to personal liability by reason of being such holders; the Securities which may be sold hereunder by the Company have been duly authorized and, when issued, delivered and paid for in accordance with the terms of this Agreement, will be validly issued and fully paid and nonassessable, and the holders thereof will not be subject to personal liability by reason of being such holders; and the capital stock of the Company, including the Common

Stock, conforms in all material respects to the description thereof in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus. Except as otherwise stated in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus, (A) there are no preemptive rights or other rights to subscribe for or to purchase, or any restriction upon the voting or transfer of, any shares of Common Stock pursuant to the Company's charter, by-laws or any agreement or other instrument to which the Company or any of the Subsidiaries is a party or by which the Company or any of the Subsidiaries is bound, (B) neither the filing of the Registration Statement nor the offering or sale of the Securities as contemplated by this Agreement gives rise to any rights for or relating to the registration of any shares of Common Stock or other securities of the Company (collectively ***"Registration Rights"***) that have not been validly waived and (C) any person to whom the Company has granted Registration Rights has agreed not to exercise or has otherwise waived such rights until after expiration of the Lock-Up Period (as defined below). All of the issued and outstanding shares of capital stock of each of the Subsidiaries have been duly and validly authorized and issued and are fully paid and nonassessable, and, except as otherwise described in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus, the Company owns of record and beneficially, free and clear of any security interests, claims, liens, proxies, equities or other encumbrances, all of the issued and outstanding shares of such stock. The Company has an authorized and outstanding capitalization as set forth in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus under the caption "Capitalization." The Common Stock (including the Securities) conforms in all material respects to the description thereof contained in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus.

(xiii) *Stock Options*. Except as described in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus, there are no options, warrants, agreements, contracts or other rights in existence to purchase or acquire from the Company or any Subsidiary any shares of the capital stock of the Company or any Subsidiary. The description of the Company's stock option, stock bonus and other stock plans or arrangements (the ***"Company Stock Plans"***), and the options (the ***"Options"***) or other rights granted thereunder, set forth in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus accurately and fairly presents the information required to be shown with respect to such plans, arrangements, options and rights. Each grant of an Option (A) was duly authorized no later than the date on which the grant of such Option was by its terms to be effective by all necessary corporate action, including, as applicable, approval by the board of directors of the Company (or a duly constituted and authorized committee thereof) and any required stockholder approval by the necessary number of votes or written consents, and the award agreement governing such grant (if any) was duly executed and delivered by each party thereto and (B) was made in accordance with the terms of the applicable Company Stock Plan, and all applicable laws and regulatory rules or requirements, including all applicable federal securities laws.

(xiv) *Compliance with Laws*. The Company and each of the Subsidiaries holds, and is operating in compliance in all material respects with, all franchises, grants, authorizations, approvals, clearances, exemptions, registrations, licenses, permits, easements, consents, certificates and orders of any Governmental Authority or self-regulatory

body required for the conduct of its business ("***Permits***") and all such Permits are valid and in full force and effect; and neither the Company nor any of the Subsidiaries has received notice of any revocation or modification of any such Permits or has reason to believe that any such Permit will not be renewed in the ordinary course; and the Company and each of the Subsidiaries is in compliance in all material respects with all applicable federal, state, local and foreign laws, regulations, orders and decrees.

(xv) *Ownership of Assets*. The Company and the Subsidiaries have good and marketable title to all property (whether real or personal) described in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus as being owned by them, in each case free and clear of all liens, claims, security interests, other encumbrances or defects except such as would not reasonably be expected to result in a Material Adverse Effect or as are described in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus. The property held under lease by the Company and the Subsidiaries is held by them under valid, subsisting and enforceable leases with only such exceptions with respect to any particular lease as do not interfere in any material respect with the conduct of the business of the Company or the Subsidiaries.

(xvi) *Intellectual Property*. The Company and each of the Subsidiaries owns, possesses, or can acquire or license on reasonable terms, all Intellectual Property necessary for the conduct of the Company's and the Subsidiaries' businesses as now conducted and as proposed to be conducted as described in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus to be conducted, except as such failure to own, possess, acquire or license would not result in a Material Adverse Effect. Furthermore, (A) to the knowledge of the Company, there is no infringement, misappropriation or violation by third parties of any such Intellectual Property except as such infringement, misappropriation or violation would not result in a Material Adverse Effect; (B) there is no pending or, to the knowledge of the Company, threatened, action, suit, proceeding or claim by others challenging the Company's or any of the Subsidiaries' rights in or to any such Intellectual Property, and the Company is unaware of any facts which would form a reasonable basis for any such claim; (C) the Intellectual Property owned by the Company and the Subsidiaries, and to the knowledge of the Company, the Intellectual Property licensed to the Company and the Subsidiaries, has not been adjudged invalid or unenforceable, in whole or in part, and there is no pending or, to the knowledge of the Company, threatened action, suit, proceeding or claim by others challenging the validity or scope of any such Intellectual Property, and the Company is not aware of any facts which would form a reasonable basis for any such claim; (D) there is no prior, pending or, to the knowledge of the Company, threatened action, suit, proceeding or claim by others that the Company or any of the Subsidiaries infringes, misappropriates or otherwise violates any Intellectual Property or other proprietary rights of others, neither the Company or any of the Subsidiaries has received any written notice of such claim and the Company is not aware of any other fact which would form a reasonable basis for any such claim; and (E) to the Company's knowledge, no employee of the Company or any of the Subsidiaries is in or has ever been in violation of any term of any employment contract, patent disclosure agreement, invention assignment agreement, non-competition agreement, non-solicitation agreement, nondisclosure agreement or any restrictive covenant to or with a former employer where the basis of such violation relates to

such employee's employment with the Company or any of the Subsidiaries or actions undertaken by the employee while employed with the Company or any of the Subsidiaries. ***"Intellectual Property"*** shall mean all patents, patent applications, trade and service marks, trade and service mark registrations, trade names, copyrights, licenses, inventions, trade secrets, Internet domain names, technology, know-how and other intellectual property in the United States and foreign jurisdictions.

(xvii) *Health Care Authorizations*. The Company and each of the Subsidiaries has submitted and possesses, or qualifies for applicable exemptions to, such valid and current material registrations, listings, approvals, clearances, licenses, certificates, authorizations, accreditations, provider or supplier numbers, or permits and supplements or amendments thereto issued or required by the appropriate state, federal or foreign regulatory agencies or bodies necessary to conduct their business, including, without limitation, all such material registrations, listings, approvals, clearances, licenses, certificates, authorizations, accreditations, exemptions, provider or supplier numbers, or permits and supplements or amendments thereto required by the United States Food and Drug Administration (the "***FDA***"), the United States Department of Health and Human Services ("***HHS***"), the United States Centers for Medicare & Medicaid Services ("***CMS***"), the European Medicines Agency (the "***EMA***"), Health Canada or any other state, federal or foreign agencies or bodies engaged in the regulation of medical devices (including diagnostic products, such as laboratory developed tests), drugs, biologics or biohazardous materials (the "***Regulatory Agencies***") (collectively, "***Regulatory Licenses***"), and except as disclosed in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus: (i) the Company, each of its Subsidiaries and Mattison Pathology, LLP d/b/a Avero Diagnostics ("***Managed Practice***") has fulfilled and performed all of its obligations with respect to each Regulatory License and, to the Company's knowledge, no event has occurred which allows, or after notice or lapse of time would allow, revocation or termination thereof or results in any other material impairment of the rights of the holder of any Regulatory License, and (ii) none of the Company, any of the Subsidiaries or the Managed Practice has received any notice of proceedings relating to the revocation or modification of, or non-compliance with, any such Regulatory License, the lack of which would not, individually or in the aggregate, have a Material Adverse Effect.

(xviii) *Clinical Trials*. The studies, tests and preclinical and clinical trials conducted by or on behalf of, or sponsored by, the Company or the Subsidiaries, or in which the Company or the Subsidiaries have participated, that are described in the Registration Statement, the Time of Sale Disclosure Package or the Prospectus, or the results of which are referred to in the Registration Statement, the Time of Sale Disclosure Package or the Prospectus, were and, if still pending, are being conducted in all material respects in accordance with the protocols, procedures and controls established for each such study, test or preclinical or clinical trial and pursuant to, where applicable, accepted professional and scientific standards for products or product candidates comparable to those being developed by the Company or the Subsidiaries and all applicable statutes, rules and regulations of the Regulatory Agencies to which they are subject, including without limitation the Health Care Laws, including 21 C.F.R. Parts 50, 54, 56, 58, 312 and 812; the descriptions of the results of such studies, tests and trials contained in the Registration

Statement, the Time of Sale Disclosure Package or the Prospectus do not contain any misstatement of a material fact or omit a material fact necessary to make such statements not misleading; the Company has no knowledge of any studies, tests or trials not described in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus the results of which reasonably call into question in any material respect the results of the studies, tests and trials described in the Registration Statement, the Time of Sale Disclosure Package or Prospectus; and neither the Company nor any of the Subsidiaries has received any notices or other correspondence from the FDA, the EMA, Health Canada or any other foreign, state or local governmental body exercising comparable authority or any Institutional Review Board or comparable authority requiring or threatening the termination, suspension or material modification of any studies, tests or preclinical or clinical trials conducted by or on behalf of, or sponsored by, the Company or in which the Company has participated, and, to the Company's knowledge, there are no reasonable grounds for the same. Except as disclosed in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus, there has not been any violation of law or regulation by the Company or the Subsidiaries in their respective product development efforts, submissions or reports to any regulatory authority that could reasonably be expected to require investigation, corrective action or enforcement action.

(xix) *Compliance with Health Care Laws*. Except as disclosed in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus, the Company, the Subsidiaries, the Managed Practice and, to the Company's knowledge, their respective directors, employees and agents (while acting in such capacity) are in material compliance with all health care laws applicable to the Company and the Subsidiaries, or any of their products or activities, including, but not limited to, the federal Anti-Kickback Statute (42 U.S.C. Section 1320a-7b(b)), the Civil Monetary Penalties Law (42 U.S.C. Section 1320a-7a), the civil False Claims Act (31 U.S.C. Section 3729 et seq.), the criminal False Claims Law (42 U.S.C. Section 1320a-7b(a)), the Stark law (42 U.S.C. Section 1395nn), the Physician Payments Sunshine Act (42 U.S.C. § 1320a-7h), the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. Section 1320d et seq.) as amended by the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. Section 17921 et seq.) ("***HIPAA***"), all criminal laws relating to healthcare fraud and abuse, including but not limited to 18 U.S.C. sections 286 and 287, the healthcare fraud criminal provisions under HIPAA, the exclusion laws (42 U.S.C. Section 1320a-7), the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Section 301 et seq.), the Controlled Substances Act (21 U.S.C. Section 801 et seq.), the Public Health Service Act (42 U.S.C. Section 201 et seq.), the Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Section 263a), Medicare (Title XVIII of the Social Security Act), Medicaid (Title XIX of the Social Security Act), TRICARE (10 U.S.C. Sections 1071 et seq.), any state corporate practice or fee-splitting prohibitions, and any state or federal anti-markup or comparable laws or regulations, the regulations promulgated pursuant to such laws, and any other state, federal or foreign law, accreditation standards, regulation, memorandum, opinion letter or other issuance which imposes requirements on the manufacturing, development, testing, labeling, advertising, marketing or distribution of drugs, biologics and medical devices (including diagnostic products and laboratory developed tests), kickbacks, patient or program charges, recordkeeping, claims process, documentation requirements, medical necessity, referrals, the hiring of employees or acquisition of

services or supplies from those who have been excluded from government health care programs, quality, safety, privacy, security, licensure, accreditation or any other aspect of providing health care, clinical laboratory or diagnostics products or services (collectively, "***Health Care Laws***"). None of the Company, the Subsidiaries, the Managed Practice or any of its respective officers, directors, employees or, to the Company's knowledge, agents, have engaged in activities which are, as applicable, cause for false claims liability, civil penalties, or mandatory or permissive exclusion from Medicare, Medicaid, TRICARE or any other state or federal healthcare program (collectively, the "***Programs***"). Except as disclosed in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus, none of the Company, any of the Subsidiaries or the Managed Practice has received any notification, correspondence or any other written or, to the Company's knowledge, oral communication, including notification of any pending or threatened claim, suit, proceeding, hearing, enforcement, investigation, arbitration or other action ("***Action***") from any governmental authority, including, without limitation, the FDA, the EMA, Health Canada, the United States Federal Trade Commission, the United States Drug Enforcement Administration, CMS, HHS's Office of Inspector General, the United States Department of Justice and state Attorneys General or similar agencies of potential or actual non-compliance by, or liability of, the Company, the Subsidiaries or the Managed Practice under any Health Care Laws, except, with respect to any of the foregoing, such as would not, individually or in the aggregate, be material to the Company, its Subsidiaries or the Managed Practice. Except as disclosed in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus, to the Company's knowledge, there are no facts or circumstances that would reasonably be expected to give rise to material liability of the Company, the Subsidiaries or the Managed Practice under any Health Care Laws. None of the Company, any of its Subsidiaries or the Managed Practice is a party to, and has any ongoing reporting obligations pursuant to any corporate integrity agreement, deferred prosecution agreement, monitoring agreement, consent decree, settlement order, plan of correction or similar agreement imposed by any governmental or regulatory authority. Additionally, none of the Company, its Subsidiaries, the Managed Practice or any of its respective employees, officers or directors, nor to the Company's knowledge, any of its agents, has been excluded, suspended or debarred from participation in any Program or human clinical research or, to the knowledge of the Company, is subject to a governmental inquiry, investigation, proceeding, or other similar Action that could reasonably be expected to result in debarment, suspension, or exclusion. The statements with respect to Health Care Laws and the Company's, the Subsidiaries' and the Managed Practice's compliance therewith included in the Preliminary Prospectus, in the Time of Sale Disclosure Package and in the Prospectus fairly summarize the matters therein described.

(xx) *Third-Party Payor Programs*. Each of the Company, its Subsidiaries and the Managed Practice meets all Program requirements and conditions of participation and are a party to valid participation or other agreements required for payment by such Programs and other third-party payor programs in which the Company is a participant. There are no material suspensions, offsets, overpayments or recoupments of any Program or material third-party payor payments being sought, requested or claimed, or to the Company's knowledge, threatened against the Company, any Subsidiary or the Managed Practice. Except as disclosed in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus, as of the date of this Agreement, none of the

Company, any Subsidiary or the Managed Practice has received any notice of denial of payment, recoupment, or overpayment from any Program or other third-party payor in excess of Five Hundred Thousand Dollars ($500,000). There is no Action pending or received or, to the Company's knowledge, threatened, against the Company, any Subsidiary or the Managed Practice which relates to a violation of any legal requirement pertaining to the Programs or other third-party payor requirement which could result in the imposition of material penalties, termination or the exclusion by the Company or its Subsidiary from participation in any Program or other third-party payor program in which the Company is a participant.

(xxi) *Cybersecurity.* The Company's, its Subsidiaries' and the Managed Practice's information technology assets and equipment, computers, systems, networks, hardware, software, websites, applications, and databases (collectively, "***IT Systems***") are adequate for, and operate and perform in all material respects as required in connection with the operation of the business of the Company, its Subsidiaries and the Managed Practice as currently conducted, free and clear of all material bugs, errors, defects, Trojan horses, time bombs, malware and other corruptants. The Company, its Subsidiaries and the Managed Practice have implemented and maintained commercially reasonable physical, technical and administrative controls, policies, procedures, and safeguards to maintain and protect their material confidential information and the integrity, continuous operation, redundancy and security of all IT Systems and data, including "Personal Data," used in connection with their businesses. "***Personal Data***" means (i) a natural person's name, street address, telephone number, e-mail address, photograph, social security number or tax identification number, driver's license number, passport number, credit card number, bank information, or customer or account number; (ii) any information which would qualify as "personally identifying information" under the Federal Trade Commission Act, as amended; (iii) "personal data" as defined by GDPR (as defined below); (iv) any information which would qualify as "protected health information" under the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act (collectively, "***HIPAA***"); and (v) any other piece of information that allows the identification of such natural person, or his or her family, or permits the collection or analysis of any data related to an identified person's health or sexual orientation. There have been no breaches, violations, outages or unauthorized uses of or accesses to same, except for those that have been remedied without material cost or liability or the duty to notify any other person, nor any incidents under internal review or investigations relating to the same. The Company, its Subsidiaries and the Managed Practice are presently in material compliance with all applicable laws or statutes and all judgments, orders, rules and regulations of any court or arbitrator or governmental or regulatory authority, internal policies and contractual obligations relating to the privacy and security of IT Systems and Personal Data and to the protection of such IT Systems and Personal Data from unauthorized use, access, misappropriation or modification.

(xxii) *Compliance with Data Privacy Laws*. The Company, its Subsidiaries and the Managed Practice are, and at all prior times were, in material compliance with all applicable state and federal data privacy and security laws and

regulations, including without limitation HIPAA, and the Company, its Subsidiaries and the Managed Practice have taken commercially reasonable actions to prepare to comply with, and currently are in compliance with, the European Union General Data Protection Regulation ("***GDPR***") (EU 2016/679) (collectively, the "***Privacy Laws***"). To ensure compliance with the Privacy Laws, the Company, its Subsidiaries and the Managed Practice have in place, comply with, and take appropriate steps reasonably designed to ensure compliance in all material respects with their policies and procedures relating to data privacy and security and the collection, storage, use, disclosure, handling, and analysis of Personal Data (the "***Policies***"). The Company, its Subsidiaries and the Managed Practice have at all times made all disclosures to users or customers required by applicable laws and regulatory rules or requirements, and none of such disclosures made or contained in any Policy have, to the knowledge of the Company, been inaccurate or in violation of any applicable laws and regulatory rules or requirements in any material respect. The Company further certifies that neither it nor any Subsidiary or the Managed Practice: (i) has received notice of any actual or potential liability under or relating to, or actual or potential violation of, any of the Privacy Laws, and has no knowledge of any event or condition that would reasonably be expected to result in any such notice; (ii) is currently conducting or paying for, in whole or in part, any investigation, remediation, or other corrective action pursuant to any Privacy Law; or (iii) is a party to any order, decree, or agreement that imposes any obligation or liability under any Privacy Law.

(xxiii) *Post-Market Reporting Obligations*. The Company and the Subsidiaries are in compliance in all material respects with all applicable regulatory post-market reporting obligations, including, without limitation, the FDA's adverse event reporting requirements at 21 CFR Parts 310, 314, 600, and 803, and, to the extent applicable, the respective counterparts thereof promulgated by governmental authorities in countries outside the United States.

(xxiv) *No Shutdowns or Prohibitions*. Neither the Company nor any of the Subsidiaries has had any product, clinical laboratory or manufacturing site (whether Company-owned or that of a third party manufacturer) subject to a governmental authority (including FDA) shutdown or import or export prohibition, nor received any FDA Form 483 or other governmental authority notice of inspectional observations, "warning letters," "untitled letters," requests to make changes to the Company's products, processes or operations, or similar correspondence or notice from the FDA or other governmental authority alleging or asserting material noncompliance with any applicable Health Care Laws. To the Company's knowledge, neither the FDA nor any other governmental authority is considering such action.

(xxv) *No Safety Notices*. (A) Except as disclosed in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus, there have been no recalls, field notifications, field corrections, market withdrawals or replacements, warnings, "dear doctor" letters, investigator notices, safety alerts or other notice of action relating to an alleged lack of safety, efficacy, or regulatory compliance of the Company or the Subsidiaries' products ("***Safety Notices***") and (B) to the Company's knowledge, there are no facts that would be reasonably likely to result in (1) a Safety Notice with respect to the Company or any of the Subsidiaries' products or services, (2) a change

in labeling of any of the Company's or the Subsidiaries' respective products or services, or (3) a termination or suspension of marketing or testing of any of the Company's or the Subsidiaries' respective products or services.

(xxvi) *No Violations or Defaults*. (A) Neither the Company nor any of the Subsidiaries is in violation of its respective charter, by-laws or other organizational documents, or in breach of or otherwise in default, and (B) except as would not reasonably be expected to result in a Material Adverse Effect, no event has occurred which, with notice or lapse of time or both, would constitute such a default in the performance of any material obligation, agreement or condition contained in any bond, debenture, note, indenture, loan agreement or any other material contract, lease or other instrument to which it is subject or by which any of them may be bound, or to which any of the material property or assets of the Company or any of the Subsidiaries is subject.

(xxvii) *Taxes*. The Company and the Subsidiaries have timely filed all federal, state, local and foreign income and franchise tax returns required to be filed or have properly requested extensions thereof (except as such failure to timely file such tax returns would not result in a Material Adverse Effect) and are not in default in the payment of any taxes which were payable pursuant to said returns or any assessments with respect thereto, other than any which the Company or any of the Subsidiaries is contesting in good faith. There is no pending dispute with any taxing authority relating to any of such returns, and the Company has no knowledge of any proposed liability for any tax to be imposed upon the properties or assets of the Company or any of the Subsidiaries for which there is not an adequate reserve reflected in the Company's financial statements included in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus.

(xxviii) *Exchange Listing and Exchange Act Registration*. The Securities have been approved for listing on the Nasdaq Global Select Market upon official notice of issuance and, on the date the Registration Statement became effective, the Company's Registration Statement on Form 8-A or other applicable form under the Securities Exchange Act of 1934, as amended (the ***"Exchange Act"***), became effective. Except as previously disclosed to counsel for the Underwriters or as set forth in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus, there are no affiliations with members of FINRA among the Company's officers or directors or, to the knowledge of the Company, any five percent or greater stockholders of the Company or any beneficial owner of the Company's unregistered equity securities that were acquired during the 180-day period immediately preceding the initial filing date of the Registration Statement.

(xxix) *Ownership of Other Entities*. Other than the Subsidiaries listed in Schedule II to this Agreement, the Company, directly or indirectly, owns no capital stock or other equity or ownership or proprietary interest in any corporation, partnership, association, trust or other entity.

(xxx) *Internal Controls*. The Company and the Subsidiaries maintain a system of internal accounting controls sufficient to provide reasonable assurances that (A) transactions are executed in accordance with management's general or specific

authorization; (B) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain accountability for assets; (C) access to assets is permitted only in accordance with management's general or specific authorization; and (D) the recorded accountability for assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences. Except as disclosed in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus, the Company's internal control over financial reporting is effective and none of the Company, its board of directors and audit committee is aware of any "significant deficiencies" or "material weaknesses" (each as defined by the Public Company Accounting Oversight Board) in its internal control over financial reporting, or any fraud, whether or not material, that involves management or other employees of the Company or the Subsidiaries who have a significant role in the Company's internal controls; and since the end of the latest audited fiscal year, there has been no change in the Company's internal control over financial reporting (whether or not remediated) that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting. The Company's board of directors has, subject to the exceptions, cure periods and the phase-in periods specified in the applicable stock exchange rules (***"Exchange Rules"***), validly appointed an audit committee to oversee internal accounting controls whose composition satisfies the applicable requirements of the Exchange Rules and the Company's board of directors and/or the audit committee has adopted a charter that satisfies the requirements of the Exchange Rules in respect of the audit committee.

(xxxi) *No Brokers or Finders*. Other than as contemplated by this Agreement, the Company has not incurred and will not incur any liability for any finder's or broker's fee or agent's commission in connection with the execution and delivery of this Agreement or the consummation of the transactions contemplated hereby.

(xxxii) *Insurance*. The Company and each of the Subsidiaries carries, or is covered by, insurance from reputable insurers in such amounts and covering such risks as the Company reasonably believes is adequate for the conduct of its business and the value of its properties and the properties of the Subsidiaries and as is customary for companies engaged in similar businesses in similar industries; all policies of insurance and any fidelity or surety bonds insuring the Company or any of the Subsidiaries or its business, assets, employees, officers and directors are in full force and effect; the Company and the Subsidiaries are in compliance with the terms of such policies and instruments in all material respects; there are no claims by the Company or any of the Subsidiaries under any such policy or instrument as to which any insurance company is denying liability or defending under a reservation of rights clause; neither the Company nor any of the Subsidiaries has been refused any insurance coverage sought or applied for; and neither the Company nor any of the Subsidiaries has reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business at a cost that would not have a Material Adverse Effect.

(xxxiii) *Investment Company Act*. The Company is not and, after giving effect to the offering and sale of the Securities, will not be an "investment company," as such term is defined in the Investment Company Act of 1940, as amended.

(xxxiv) *Sarbanes-Oxley Act*. The Company is in compliance with all applicable provisions of the Sarbanes-Oxley Act and the rules and regulations of the Commission thereunder.

(xxxv) *Disclosure Controls*. The Company has established and maintains disclosure controls and procedures (as defined in Rules 13a-14 and 15d-14 under the Exchange Act) and such controls and procedures are effective in ensuring that material information relating to the Company, including the Subsidiaries, is made known to the principal executive officer and the principal financial officer. The Company has utilized such controls and procedures in preparing and evaluating the disclosures in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus.

(xxxvi) *Anti-Bribery and Anti-Money Laundering Laws*. Each of the Company, the Subsidiaries, any of their respective officers, directors, affiliates and employees, and, to the Company's knowledge, any of their respective agents has not violated, its participation in the offering will not violate, and the Company and each of the Subsidiaries has instituted and maintains policies and procedures designed to ensure continued compliance with, each of the following laws: (A) anti-bribery laws, including but not limited to, any applicable law, rule or regulation of any locality, including but not limited to any law, rule or regulation promulgated to implement the OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions, signed December 17, 1997, including the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.K. Bribery Act 2010, or any other law, rule or regulation of similar purposes and scope or (B) anti-money laundering laws, including but not limited to, applicable federal, state, international, foreign or other laws, regulations or government guidance regarding anti-money laundering, including, without limitation, Title 18 U.S. Code section 1956 and 1957, the Patriot Act, the Bank Secrecy Act and international anti-money laundering principles or procedures by an intergovernmental group or organization, such as the Financial Action Task Force on Money Laundering, of which the United States is a member and with which designation the United States representative to the group or organization continues to concur, all as amended, and any Executive order, directive or regulation pursuant to the authority of any of the foregoing, or any orders or licenses issued thereunder.

(xxxvii) *OFAC*.

(A) Neither the Company nor any of the Subsidiaries, nor any or their directors, officers or employees, nor, to the Company's knowledge, any agent, affiliate or representative of the Company or the Subsidiaries, is an individual or entity that is, or is owned or controlled by an individual or entity that is:

(1) the subject of any sanctions administered or enforced by the U.S. Department of Treasury's Office of Foreign Assets Control, the

United Nations Security Council, the European Union, Her Majesty's Treasury, or other relevant sanctions authority (collectively, ***"Sanctions"***), nor

(2) located, organized or resident in a country or territory that is the subject of Sanctions (including, without limitation, Burma/Myanmar, Cuba, Iran, Libya, North Korea and Syria).

(B) Neither the Company nor any of the Subsidiaries will, directly or indirectly, use the proceeds of the offering, or lend, contribute or otherwise make available such proceeds to any Subsidiary, joint venture partner or other individual or entity:

(1) to fund or facilitate any activities or business of or with any individual or entity or in any country or territory that, at the time of such funding or facilitation, is the subject of Sanctions; or

(2) in any other manner that will result in a violation of Sanctions by any individual or entity (including any individual or entity participating in the offering, whether as underwriter, advisor, investor or otherwise).

(C) For the past five years, neither the Company nor any of the Subsidiaries has knowingly engaged in, and is not now knowingly engaged in, any dealings or transactions with any individual or entity, or in any country or territory, that at the time of the dealing or transaction is or was the subject of Sanctions.

(xxxviii) *Compliance with Environmental Laws*. Except as disclosed in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus, neither the Company nor any of the Subsidiaries is in violation of any statute, any rule, regulation, decision or order of any Governmental Authority or any court, domestic or foreign, relating to the use, disposal or release of hazardous or toxic substances or relating to the protection or restoration of the environment or human exposure to hazardous or toxic substances (collectively, ***"Environmental Laws"***), owns or operates any real property contaminated with any substance that is subject to any Environmental Laws, is liable for any off-site disposal or contamination pursuant to any Environmental Laws, or is subject to any claim relating to any Environmental Laws, which violation, contamination, liability or claim would individually or in the aggregate, have a Material Adverse Effect; and the Company is not aware of any pending investigation which might lead to such a claim. Neither the Company nor any of the Subsidiaries anticipates incurring any material capital expenditures relating to compliance with Environmental Laws.

(xxxix) *Compliance with Occupational Laws*. The Company and each of the Subsidiaries (A) is in compliance, in all material respects, with any and all applicable foreign, federal, state and local laws, rules, regulations, treaties, statutes and codes promulgated by any and all Governmental Authorities (including pursuant to the

Occupational Health and Safety Act) relating to the protection of human health and safety in the workplace (***"Occupational Laws"***); (B) has received all material permits, licenses or other approvals required of it under applicable Occupational Laws to conduct its business as currently conducted; and (C) is in compliance, in all material respects, with all terms and conditions of such permit, license or approval. No action, proceeding, revocation proceeding, writ, injunction or claim is pending or, to the Company's knowledge, threatened against the Company or any of the Subsidiaries relating to Occupational Laws, and the Company does not have knowledge of any facts, circumstances or developments relating to its operations or cost accounting practices that could reasonably be expected to form the basis for or give rise to such actions, suits, investigations or proceedings.

(xl) *ERISA and Employee Benefits Matters*. (A) To the knowledge of the Company, no "prohibited transaction" as defined under Section 406 of ERISA or Section 4975 of the Code and not exempt under ERISA Section 408 and the regulations and published interpretations thereunder has occurred with respect to any Employee Benefit Plan. At no time has the Company or any ERISA Affiliate maintained, sponsored, participated in, contributed to or has or had any liability or obligation in respect of any Employee Benefit Plan subject to Part 3 of Subtitle B of Title I of ERISA, Title IV of ERISA, or Section 412 of the Code or any "multiemployer plan" as defined in Section 3(37) of ERISA or any multiple employer plan for which the Company or any ERISA Affiliate has incurred or would reasonably be expected to incur liability under Section 4063 or 4064 of ERISA. No Employee Benefit Plan provides or promises, or at any time provided or promised, retiree health, life insurance, or other retiree welfare benefits except as may be required by the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended, or similar state law. Each Employee Benefit Plan is and has been operated in material compliance with its terms and all applicable laws, including but not limited to ERISA and the Code and, to the knowledge of the Company, no event has occurred (including a "reportable event" as such term is defined in Section 4043 of ERISA) and no condition exists that would subject the Company or any ERISA Affiliate to any material tax, fine, lien, penalty or liability imposed by ERISA, the Code or other applicable law. Each Employee Benefit Plan intended to be qualified under Code Section 401(a) is so qualified and has a favorable determination or opinion letter from the Internal Revenue Service upon which it can rely, and any such determination or opinion letter remains in effect and has not been revoked; to the knowledge of the Company, nothing has occurred since the date of any such determination or opinion letter that is reasonably likely to adversely affect such qualification; (B) with respect to each Foreign Benefit Plan, such Foreign Benefit Plan (1) if intended to qualify for special tax treatment, meets, in all material respects, the requirements for such treatment, and (2) if required to be funded, is funded to the extent required by applicable law, and with respect to all other Foreign Benefit Plans, adequate reserves therefor have been established on the accounting statements of the applicable Company or Subsidiary; (C) the Company does not have any obligations under any collective bargaining agreement with any union and no organization efforts are underway with respect to Company employees. As used in this Agreement, ***"Code"*** means the Internal Revenue Code of 1986, as amended; ***"Employee Benefit Plan"*** means any "employee benefit plan" within the meaning of Section 3(3) of ERISA, including, without limitation, all stock purchase, stock option, stock-based severance,

employment, change-in-control, medical, disability, fringe benefit, bonus, incentive, deferred compensation, employee loan and all other employee benefit plans, agreements, programs, policies or other arrangements, whether or not subject to ERISA, under which (x) any current or former employee, director or independent contractor of the Company or the Subsidiaries has any present or future right to benefits and which are contributed to, sponsored by or maintained by the Company or any of the Subsidiaries or (y) the Company or any of the Subsidiaries has had or has any present or future obligation or liability; ***"ERISA"*** means the Employee Retirement Income Security Act of 1974, as amended; ***"ERISA Affiliate"*** means any member of the company's controlled group as defined in Code Section 414(b), (c), (m) or (o); and ***"Foreign Benefit Plan"*** means any Employee Benefit Plan established, maintained or contributed to outside of the United States or which covers any employee working or residing outside of the United States.

(xli) *Business Arrangements*. Except as disclosed in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus, neither the Company nor any of the Subsidiaries has granted rights to develop, manufacture, produce, assemble, distribute, license, market or sell its products to any other person and is not bound by any agreement that affects the exclusive right of the Company or such Subsidiary to develop, manufacture, produce, assemble, distribute, license, market or sell its products.

(xlii) *Labor Matters*. No labor problem or dispute with the employees of the Company or any of the Subsidiaries exists or, to the knowledge of the Company, is threatened or imminent, and the Company is not aware of any existing or imminent labor disturbance by the employees of any of its or the Subsidiaries' principal suppliers, contractors or customers, that could have a Material Adverse Effect.

(xliii) *Restrictions on Subsidiary Payments to the Company*. No Subsidiary is currently prohibited, directly or indirectly, from paying any dividends to the Company, from making any other distribution on such Subsidiary's capital stock, from repaying to the Company any loans or advances to such Subsidiary from the Company or from transferring any of such Subsidiary's property or assets to the Company or any other Subsidiary, except as described in or contemplated by the Registration Statement, the Time of Sale Disclosure Package and the Prospectus.

(xliv) *Disclosure of Legal Matters*. There are no statutes, regulations, legal or governmental proceedings or contracts or other documents required to be described in the Time of Sale Disclosure Package or in the Prospectus or included as exhibits to the Registration Statement that are not described or included as required.

(xlv) *Statistical Information*. Any third-party statistical and market-related data included in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus are based on or derived from sources that the Company believes to be reliable and accurate in all material respects.

(xlvi) *Forward-looking Statements*. No forward-looking statement (within the meaning of Section 27A of the Act and Section 21E of the Exchange Act) contained in the Registration Statement, the Time of Sale Disclosure Package or the Prospectus has been made or reaffirmed without a reasonable basis or has been disclosed other than in good faith.

(xlvii) *FinCEN Matters*. All of the beneficial ownership information provided to the Underwriters or to counsel for the Underwriters by the Company or its counsel in compliance with the control and beneficial ownership certification requirements of the Financial Crimes Enforcement Network within the U.S. Department of the Treasury (***"FinCEN"***) is true, complete, correct and compliant with the rules, regulations and requirements of FinCEN.

(b) *Effect of Certificates*. Any certificate signed by any officer of the Company and delivered to you or to counsel for the Underwriters shall be deemed a representation and warranty by the Company to each Underwriter as to the matters covered thereby.

3. ***Purchase, Sale and Delivery of Securities***.

(a) *Firm Shares*. On the basis of the representations, warranties and agreements herein contained, but subject to the terms and conditions herein set forth, the Company agrees to issue and sell the Firm Shares to the several Underwriters, and each Underwriter agrees, severally and not jointly, to purchase from the Company the number of Firm Shares set forth opposite the name of such Underwriter in Schedule I hereto. The purchase price for each Firm Share shall be $[●] per share. The obligation of each Underwriter to the Company shall be to purchase from the Company that number of Firm Shares (to be adjusted by the Representatives to avoid fractional shares) which represents the same proportion of the number of Firm Shares to be sold by the Company pursuant to this Agreement as the number of Firm Shares set forth opposite the name of such Underwriter in Schedule I hereto represents to the total number of Firm Shares to be purchased by all Underwriters pursuant to this Agreement. In making this Agreement, each Underwriter is contracting severally and not jointly; except as provided in paragraph (d) of this Section 3 and in Section 8 hereof, the agreement of each Underwriter is to purchase only the respective number of Firm Shares specified in Schedule I.

(b) *Option Shares*. On the basis of the representations, warranties and agreements herein contained, but subject to the terms and conditions herein set forth, the Company, with respect to [●] Option Shares, hereby grants to the several Underwriters an option to purchase all or any portion of the Option Shares at the same purchase price as the Firm Shares, for use solely in covering any over-allotments made by the Underwriters in the sale and distribution of the Firm Shares. The option granted hereunder may be exercised in whole or in part at any time (but not more than once) within 30 days after the effective date of this Agreement upon notice (confirmed in writing) by the Representatives to the Company setting forth the aggregate number of Option Shares as to which the several Underwriters are exercising the option and the date and time, as determined by you, when the Option Shares are to be delivered, but in no event earlier than the First Closing Date (as defined below) nor earlier than the second business day or later than the tenth business day after the date on which the option shall have been exercised. If the option is exercised, the number of Option

Shares to be purchased by each Underwriter shall be the same percentage of the total number of Option Shares to be purchased by the several Underwriters as the number of Firm Shares to be purchased by such Underwriter is of the total number of Firm Shares to be purchased by the several Underwriters, as adjusted by the Representatives in such manner as the Representatives deem advisable to avoid fractional shares. No Option Shares shall be sold and delivered unless the Firm Shares previously have been, or simultaneously are, sold and delivered.

(c) *Payment and Delivery*.

(i) The Securities to be purchased by each Underwriter hereunder, in book-entry form in such authorized denominations and registered in such names as Piper Sandler & Co. may request upon at least 48 hours' prior notice to the Company, shall be delivered by or on behalf of the Company to Piper Sandler & Co., through the facilities of the Depository Trust Company (***"DTC"***), for the accounts of the several Underwriters, with any transfer taxes payable in connection with the transfer of the Securities to the Underwriters duly paid, against payment by or on behalf of such Underwriter of the purchase price therefor by wire transfer of Federal (same-day) funds to the account specified by the Company to Piper Sandler & Co. at least 48 hours in advance. The time and date of such delivery and payment shall be, with respect to the Firm Shares, 9:30 a.m., New York City time, on [●], 2020 or such other time and date as Piper Sandler & Co. and the Company may agree upon in writing, and, with respect to the Option Shares, 9:30 a.m., New York City time, on the date specified by Piper Sandler & Co. in each written notice given by Piper Sandler & Co. of the Underwriters' election to purchase such Option Shares, or such other time and date as Piper Sandler & Co. and the Company may agree upon in writing. Such time and date for delivery of the Firm Shares is herein called the ***"First Closing Date,"*** each such time and date for delivery of the Option Shares, if not the First Closing Date, is herein called a ***"Second Closing Date,"*** and each such time and date for delivery is herein called a ***"Closing."***

(ii) The documents to be delivered at each Closing by or on behalf of the parties hereto pursuant to Section 5 hereof, including the cross receipt for the Securities and any additional documents requested by the Underwriters pursuant to Section 5(j) hereof, will be delivered at the offices of Piper Sandler & Co., U.S. Bancorp Center, 800 Nicollet Mall, Minneapolis, Minnesota (the ***"Closing Location"***), and the Securities will be delivered to Piper Sandler & Co., through the facilities of the DTC, for the accounts of the several Underwriters, all at such Closing. A meeting will be held at the Closing Location at 9:30 a.m., New York City time, on the New York Business Day next preceding such Closing, at which meeting the final drafts of the documents to be delivered pursuant to the preceding sentence will be available for review by the parties hereto. For the purposes of this Section 3, ***"New York Business Day"*** shall mean each Monday, Tuesday, Wednesday, Thursday and Friday which is not a day on which banking institutions in New York City are generally authorized or obligated by law or executive order to close.

(iii) In the event that the Firm Shares (and Option Shares, if elected by the Representatives) are not delivered to the Representatives by 2:30 p.m., New York City time, on the First Closing Date (and the Second Closing Date, if elected by the Representatives), the Company will return payment of the full purchase price to Piper Sandler & Co.'s agent,

Pershing LLC, via same day funds by 4:30 p.m., New York City time. The Company shall remain liable to Pershing LLC for the full amount of the purchase price and any costs associated with recovering the purchase price until the full amount has been received by Pershing LLC.

(d) *Purchase by Representatives on Behalf of Underwriters*. It is understood that you, individually and not as Representatives of the several Underwriters, may (but shall not be obligated to) make payment to the Company, on behalf of any Underwriter for the Securities to be purchased by such Underwriter. Any such payment by you shall not relieve any such Underwriter of any of its obligations hereunder. Nothing herein contained shall constitute any of the Underwriters an unincorporated association or partner with the Company.

4. ***Covenants***.

(a) *Covenants of the Company*. The Company covenants and agrees with the several Underwriters as follows:

(i) *Required Filings*. The Company will prepare and file a Prospectus with the Commission containing the Rule 430A Information omitted from the Preliminary Prospectus within the time period required by, and otherwise in accordance with the provisions of, Rules 424(b) and 430A of the Rules and Regulations. If the Company has elected to rely upon Rule 462(b) of the Rules and Regulations to increase the size of the offering registered under the Act and the Rule 462(b) Registration Statement has not yet been filed and become effective, the Company will prepare and file the Rule 462 Registration Statement with the Commission within the time period required by, and otherwise in accordance with the provisions of, Rule 462(b) and the Act. The Company will prepare and file with the Commission, promptly upon your request, any amendments or supplements to the Registration Statement or Prospectus that, in your opinion, may be necessary or advisable in connection with the distribution of the Securities by the Underwriters; and the Company will furnish the Representatives and counsel for the Underwriters a copy of any proposed amendment or supplement to the Registration Statement or Prospectus and will not file any amendment or supplement to the Registration Statement or Prospectus to which you shall reasonably object by notice to the Company after having been furnished a copy a reasonable time prior to the filing.

(ii) *Notification of Certain Commission Actions*. The Company will advise you, promptly after it shall receive notice or obtain knowledge thereof, of the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement, or any post-effective amendment thereto or preventing or suspending the use of any Preliminary Prospectus, the Time of Sale Disclosure Package, the Prospectus or any issuer free writing prospectus, of the suspension of the qualification of the Securities for offering or sale in any jurisdiction, or of the initiation or threatening of any proceeding for any such purpose; and the Company will promptly use its reasonable best efforts to prevent the issuance of any stop order or to obtain its withdrawal if such a stop order should be issued.

(iii) *Continued Compliance with Securities Laws*.

(A) Within the time during which a prospectus (assuming the absence of Rule 172 of the Rules and Regulations) relating to the Securities is required to be delivered under the Act by any Underwriter or dealer, the Company will comply with all requirements imposed upon it by the Act, as now and hereafter amended, and by the Rules and Regulations, as from time to time in force, so far as necessary to permit the continuance of sales of or dealings in the Securities as contemplated by the provisions hereof, the Time of Sale Disclosure Package and the Prospectus. If during such period any event occurs as a result of which the Prospectus (or if the Prospectus is not yet available to prospective purchasers, the Time of Sale Disclosure Package) would include an untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances then existing, not misleading, or if during such period it is necessary to amend the Registration Statement or supplement the Prospectus (or if the Prospectus is not yet available to prospective investors, the Time of Sale Disclosure Package) to comply with the Act, the Company promptly will (1) notify you of such untrue statement or omission, (2) amend the Registration Statement or supplement the Prospectus (or, if the Prospectus is not yet available to prospective purchasers, the Time of Sale Disclosure Package) (at the expense of the Company) so as to correct such statement or omission or effect such compliance, and (3) notify you when any amendment to the Registration Statement is filed or becomes effective or when any supplement to the Prospectus (or, if the Prospectus is not yet available to prospective purchasers, the Time of Sale Disclosure Package) is filed.

(B) If at any time following issuance of an issuer free writing prospectus or Written Testing-the-Waters Communication there occurred or occurs an event or development as a result of which such issuer free writing prospectus or Written Testing-the-Waters Communication conflicted or would conflict with the information contained in the Registration Statement, any Preliminary Prospectus or the Prospectus relating to the Securities or included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances prevailing at that subsequent time, not misleading, the Company (1) has promptly notified or promptly will notify the Representatives of such conflict, untrue statement or omission, (2) has promptly amended or will promptly amend or supplement, at its own expense, such issuer free writing prospectus or Written Testing-the-Waters Communication to eliminate or correct such conflict, untrue statement or omission and (3) has notified or promptly will notify you when such amendment or supplement was or is filed with the Commission to the extent required to be filed by the Rules and Regulations.

(iv) *Blue Sky Qualifications*. The Company shall take or cause to be taken all necessary action to qualify the Securities for sale under the securities laws of such domestic United States or foreign jurisdictions as you reasonably designate and to continue such qualifications in effect so long as required for the distribution of the

Securities, except that the Company shall not be required in connection therewith to qualify as a foreign corporation or to execute a general consent to service of process in any state.

(v) *Provision of Documents*. The Company will furnish, at its own expense, to the Underwriters and counsel for the Underwriters copies of the Registration Statement, and to the Underwriters and any dealer each Preliminary Prospectus, the Time of Sale Disclosure Package, the Prospectus, any issuer free writing prospectus and all amendments and supplements to such documents, in each case as soon as available and in such quantities as you may from time to time reasonably request.

(vi) *Rule 158*. The Company will make generally available to its security holders as soon as practicable, but in no event later than 15 months after the end of the Company's current fiscal quarter, an earnings statement (which need not be audited) covering a 12-month period beginning after the effective date of the Registration Statement (which, for purposes of this paragraph, will be deemed to be the effective date of the Rule 462(b) Registration Statement, if applicable) that shall satisfy the provisions of Section 11(a) of the Act and Rule 158 of the Rules and Regulations.

(vii) *Payment and Reimbursement of Expenses*. The Company, whether or not the transactions contemplated hereunder are consummated or this Agreement is terminated, will pay or cause to be paid (A) all expenses (including transfer taxes allocated to the respective transferees) incurred by the Company in connection with the delivery to the Underwriters of the Securities, (B) all expenses and fees (including, without limitation, fees and expenses of the Company's accountants and counsel but, except as otherwise provided below, not including fees of the Underwriters' counsel) in connection with the preparation, printing, filing, delivery, and shipping of the Registration Statement (including the financial statements therein and all amendments, schedules, and exhibits thereto), the Securities, each Preliminary Prospectus, the Time of Sale Disclosure Package, the Prospectus, any issuer free writing prospectus and any amendment thereof or supplement thereto, and the printing, delivery, and shipping of this Agreement and other underwriting documents, including Blue Sky Memoranda (covering the states and other applicable jurisdictions), (C) all filing fees and reasonable and documented fees and disbursements of the Underwriters' counsel incurred in connection with the qualification of the Securities for offering and sale by the Underwriters or by dealers under the securities or blue sky laws of the states and other jurisdictions which you shall designate, (D) the fees and expenses of the Company's transfer agent or registrar, (E) the filing fees and reasonable and documented fees and disbursements of Underwriters' counsel incident to any required review and approval by FINRA of the terms of the sale of the Securities, (F) Nasdaq Global Select Market listing fees, if any, (G) the cost and expenses of the Company relating to investor presentations or any "road show" undertaken in connection with marketing of the Securities, including, without limitation, expenses associated with the preparation or dissemination of any electronic road show, expenses associated with the production of road show slides and graphics, fees and expenses of any consultants engaged in connection with the road show presentations with the prior approval of the Company, travel and lodging expenses of the representatives and officers of the Company and any such consultants, and one half of the cost of any aircraft chartered in connection with the road show, and (H) all other costs and expenses of the Company incident

to the performance of its obligations hereunder that are not otherwise specifically provided for herein. If this Agreement is terminated by the Representatives pursuant to Section 9 hereof or if the sale of the Securities provided for herein is not consummated by reason of any failure, refusal or inability on the part of the Company to perform any agreement on its part to be performed, or because any other condition of the Underwriters' obligations hereunder required to be fulfilled by the Company is not fulfilled, the Company will reimburse the several Underwriters for all reasonable out-of-pocket accountable disbursements (including but not limited to reasonable fees and disbursements of counsel, printing expenses, travel expenses, postage, facsimile and telephone charges) incurred by the Underwriters in connection with their investigation, preparing to market and marketing of the Securities or in contemplation of performing their obligations hereunder; provided, however, that the total fees and disbursement of Underwriters' counsel pursuant to (C) and (E) above shall not exceed $50,000 in the aggregate. The Underwriters shall pay one half of the cost of any aircraft chartered in connection with the road show and except as otherwise explicitly provided for in this Section 4(vii), the Underwriters shall pay all of their own expenses, including expenses incurred in connection with any road show and any travel and lodging expenses incurred in connection with drafting sessions.

(viii) *Use of Proceeds*. The Company will apply the net proceeds from the sale of the Securities to be sold by it hereunder for the purposes set forth in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus and will file such reports with the Commission with respect to the sale of the Securities and the application of the proceeds therefrom as may be required in accordance with Rule 463 of the Rules and Regulations.

(ix) *Company Lock Up*. The Company will not, without the prior written consent of Piper Sandler & Co. and Wells Fargo Securities, LLC, from the date of execution of this Agreement and continuing to and including the date 180 days after the date of the Prospectus (the ***"Lock-Up Period"***), (A) offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise transfer or dispose of, directly or indirectly, any shares of Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock or (B) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the Common Stock, whether any such transaction described in clause (A) or (B) above is to be settled by delivery of Common Stock or such other securities, in cash or otherwise, except (i) to the Underwriters pursuant to this Agreement, (ii) for issuances and grants to directors, officers, employees and consultants of the Company pursuant to the Company Stock Plans, (iii) for issuances pursuant to the exercise (including any net exercise or exercise by delivery of already-owned shares of Common Stock) of outstanding options or warrants or conversion of convertible securities described as outstanding in the Registration Statement, the Time of Sale Disclosure Package or the Prospectus, (iv) for issuances of common stock or securities convertible into or exercisable for shares of common stock in connection with any acquisition, collaboration, partnership, joint venture, strategic alliance, licensing or other strategic transaction or any debt financing transaction, so long as the purpose of such issuance is not primarily for capital raising; provided, that

in the case of this clause (iv), such issuances shall not be greater than 10% of the total outstanding shares of common stock outstanding immediately after the completion of this offering, (v) any shares of Common Stock issued or options to purchase shares of Common Stock granted pursuant to any non-employee director compensation plan or dividend reinvestment plan referred to in the Registration Statement, the Time of Sale Disclosure Package or the Prospectus or (vi) the filing by the Company of a registration statement with the Commission on Form S-8 or a successor form thereto with respect to the registration of securities to be offered under any plans or programs in effect on the date hereof and referred to in clauses (ii) and (v) above; provided further, that each recipient of shares of Common Stock, or securities exchangeable or exercisable for or convertible into common stock, shall be contractually prohibited from selling, offering, disposing of or otherwise transferring any such shares or securities during the remainder of the Lock-Up Period. The Company agrees not to accelerate the vesting of any option or warrant or the lapse of any repurchase right prior to the expiration of the Lock-Up Period.

(x) *Stockholder Lock-Ups*. The Company has caused to be delivered to you prior to the date of this Agreement a letter, in the form of Exhibit A hereto (the ***"Lock-Up Agreement"***), from each individual or entity listed on Schedule III. The Company will enforce the terms of each Lock-Up Agreement and issue stop-transfer instructions to its transfer agent and registrar for the Common Stock with respect to any transaction or contemplated transaction that would constitute a breach of or default under the applicable Lock-Up Agreement. If the Representatives, in their sole discretion, agree to release or waive the restrictions of any Lock-Up Agreement between an officer or director of the Company and the Representatives and provide the Company with notice of the impending release or waiver at least three business days before the effective date of such release or waiver, the Company agrees to announce the impending release or waiver by means of a press release substantially in the form of Exhibit B hereto, issued through a major news service, at least two business days before the effective date of the release or waiver.

(xi) *No Market Stabilization or Manipulation*. The Company has not taken and will not take, directly or indirectly, any action designed to or which would reasonably be expected to cause or result in, or which has constituted, the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Securities, and has not effected any sales of Common Stock which are required to be disclosed in response to Item 701 of Regulation S-K under the Act which have not been so disclosed in the Registration Statement.

(xii) *SEC Reports*. The Company will file on a timely basis with the Commission such periodic and special reports as required by the Rules and Regulations.

(xiii) *Free Writing Prospectuses*. The Company represents and agrees that, unless it obtains the prior written consent of Piper Sandler & Co., and each Underwriter severally represents and agrees that, unless it obtains the prior written consent of the Company and Piper Sandler & Co., it has not made and will not make any offer relating to the Securities that would constitute an issuer free writing prospectus or that would otherwise constitute a free writing prospectus required to be filed with the

Commission; provided that the prior written consent of the parties hereto shall be deemed to have been given in respect of the free writing prospectuses included in Schedule IV. Any such free writing prospectus consented to by the Company and Piper Sandler & Co. is hereinafter referred to as a ***"Permitted Free Writing Prospectus."*** The Company represents that it has treated or agrees that it will treat each Permitted Free Writing Prospectus as an issuer free writing prospectus, and has complied and will comply with the requirements of Rules 164 and 433 of the Rules and Regulations applicable to any Permitted Free Writing Prospectus. The Company represents that it has satisfied and agrees that it will satisfy the conditions in Rule 433 to avoid a requirement to file with the Commission any electronic road show. Each Underwriter severally represents and agrees that, (A) unless it obtains the prior written consent of the Company and Piper Sandler & Co., it has not distributed, and will not distribute any Written Testing-the-Waters Communication other than those listed on Schedule VI, and (B) any Testing-the-Waters Communication undertaken by it was with entities that are qualified institutional buyers with the meaning of Rule 144A under the Act or institutions that are accredited investors within the meaning of Rule 501 under the Act.

(xiv) *Emerging Growth Company*. The Company will promptly notify the Representatives if the Company ceases to be an Emerging Growth Company at any time prior to the later of (A) completion of the distribution of Securities within the meaning of the Act and (B) completion of the 180-day restricted period referenced to in Section 4(a)(ix) hereof.

5. ***Conditions of Underwriters' Obligations***. The obligations of the several Underwriters hereunder are subject to the accuracy, as of the date hereof and at each of the First Closing Date and the Second Closing Date (as if made at such Closing Date), of and compliance with all representations, warranties and agreements of the Company contained herein, to the performance by the Company of its obligations hereunder and to the following additional conditions:

(a) *Required Filings; Absence of Certain Commission Actions*. All filings required by Rules 424, 430A and 433 of the Rules and Regulations shall have been timely made (without reliance on Rule 424(b)(8) or Rule 164(b)); no stop order suspending the effectiveness of the Registration Statement or any part thereof or any amendment thereof, nor suspending or preventing the use of the Time of Sale Disclosure Package, the Prospectus or any issuer free writing prospectus shall have been issued; no proceedings for the issuance of such an order shall have been initiated or, to the knowledge of the Company, threatened; and any request of the Commission for additional information (to be included in the Registration Statement, the Time of Sale Disclosure Package, the Prospectus, any issuer free writing prospectus or otherwise) shall have been complied with to your satisfaction.

(b) *Continued Compliance with Securities Laws*. No Underwriter shall have advised the Company that (i) the Registration Statement or any amendment thereof or supplement thereto contains an untrue statement of a material fact which, in your opinion, is material or omits to state a material fact which, in your opinion, is required to be stated therein or necessary to make the statements therein not misleading, or (ii) the Time of Sale Disclosure Package or the Prospectus, or any amendment thereof or supplement thereto, or any issuer free writing prospectus

contains an untrue statement of fact which, in your opinion, is material, or omits to state a fact which, in your opinion, is material and is required to be stated therein, or necessary to make the statements therein, in light of the circumstances under which they are made, not misleading.

(c) *Absence of Certain Events*. Except as contemplated in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus, subsequent to the respective dates as of which information is given in the Time of Sale Disclosure Package and in the Prospectus, neither the Company nor any of the Subsidiaries shall have incurred any material liabilities or obligations, direct or contingent, or entered into any material transactions, or declared or paid any dividends or made any distribution of any kind with respect to its capital stock; and there shall not have been any change in the capital stock (other than a change in the number of outstanding shares of Common Stock due to the issuance of shares upon the exercise of outstanding options or warrants or conversion of convertible securities), or any material change in the short-term or long-term debt of the Company (other than as a result of the conversion of convertible securities), or any issuance of options, warrants, convertible securities or other rights to purchase the capital stock of the Company or any of the Subsidiaries, or any Material Adverse Change or any development involving a prospective Material Adverse Change (whether or not arising in the ordinary course of business), that, in your judgment, makes it impractical or inadvisable to offer or deliver the Securities on the terms and in the manner contemplated in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus.

(d) *No Downgrade*. On or after the Time of Sale, (i) no downgrading shall have occurred in the rating accorded the Company's debt securities or preferred stock by any "nationally recognized statistical organization," as that term is defined by the Commission for purposes of Rule 436(g)(2) under the Act, and (ii) no such organization shall have publicly announced that it has under surveillance or review, with possible negative implications, its rating of any of the Company's debt securities or preferred stock.

(e) *Opinion of Company Counsel*. On each Closing Date, there shall have been furnished to you, as Representatives of the several Underwriters, the opinion of each of (i) Gibson, Dunn & Crutcher LLP, corporate counsel for the Company, (ii) Casimir Jones S.C., intellectual property counsel for the Company, and (iii) Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., healthcare regulatory counsel for the Company, each dated such Closing Date and addressed to you, in each case in form and substance reasonably satisfactory to you.

(f) *Opinion of Underwriters' Counsel*. On each Closing Date, there shall have been furnished to you, as Representatives of the several Underwriters, such opinion or opinions from Latham & Watkins LLP, counsel for the several Underwriters, dated such Closing Date and addressed to you, with respect to the formation of the Company, the validity of the Securities, the Registration Statement, the Time of Sale Disclosure Package or the Prospectus and other related matters as you reasonably may request, and such counsel shall have received such papers and information as they request to enable them to pass upon such matters.

(g) *Comfort Letter*. On the date hereof, on the effective date of any post-effective amendment to the Registration Statement filed after the date hereof and on each Closing

Date you, as Representatives of the several Underwriters, shall have received a letter of KPMG LLP, dated such date and addressed to you, in form and substance reasonably satisfactory to you.

(h) *Officers' Certificate*. On each Closing Date, there shall have been furnished to you, as Representatives of the Underwriters, a certificate, dated such Closing Date and addressed to you, signed by the chief executive officer and by the chief financial officer of the Company, to the effect that:

(i) The representations and warranties of the Company in this Agreement are true and correct as if made at and as of such Closing Date, and the Company has complied with all the agreements and satisfied all the conditions on its part to be performed or satisfied at or prior to such Closing Date; and

(ii) No stop order or other order suspending the effectiveness of the Registration Statement or any part thereof or any amendment thereof or the qualification of the Securities for offering or sale, nor suspending or preventing the use of the Time of Sale Disclosure Package, the Prospectus or any issuer free writing prospectus, has been issued, and no proceeding for that purpose has been instituted or, to the best of their knowledge, is contemplated by the Commission or any state or regulatory body.

(i) *Lock-Up Agreement*. The Underwriters shall have received all of the Lock-Up Agreements referenced in Section 4 and the Lock-Up Agreements shall remain in full force and effect.

(j) *Other Documents*. The Company shall have furnished to you and counsel for the Underwriters such additional documents, certificates and evidence as you or they may have reasonably requested.

(k) *FINRA No Objections*. FINRA shall have raised no objection to the fairness and reasonableness of the underwriting terms and arrangements.

(l) *Exchange Listing*. The Securities to be delivered on such Closing Date will have been approved for listing on the Nasdaq Global Select Market, subject to official notice of issuance.

All such opinions, certificates, letters and other documents will be in compliance with the provisions hereof only if they are reasonably satisfactory in form and substance to you and counsel for the Underwriters. The Company will furnish you with such conformed copies of such opinions, certificates, letters and other documents as you shall reasonably request.

6. ***Indemnification and Contribution***.

(a) *Indemnification by the Company*. The Company agrees to indemnify and hold harmless each Underwriter, its affiliates, directors and officers and each person, if any, who controls such Underwriter within the meaning of Section 15 of the Act or Section 20 of the Exchange Act, from and against any losses, claims, damages or liabilities, joint or several, to which such

Underwriter may become subject, under the Act or otherwise (including in settlement of any litigation if such settlement is effected with the written consent of the Company), insofar as such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon: (i) an untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, including the 430A Information and any other information deemed to be a part of the Registration Statement at the time of effectiveness and at any subsequent time pursuant to the Rules and Regulations, if applicable, any Preliminary Prospectus, the Time of Sale Disclosure Package, the Prospectus, or any amendment or supplement thereto, any issuer free writing prospectus, any issuer information that the Company has filed or is required to file pursuant to Rule 433(d) of the Rules and Regulations, or any Written Testing-the-Waters Communication, or any road show as defined in Rule 433(h) under the Act (a ***"road show"***), (ii) the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, or (iii) any investigation or proceeding by any governmental authority, commenced or threatened (whether or not any Underwriter is a target of or party to such investigation or proceeding); and the Company will reimburse each Underwriter for any legal or other expenses reasonably incurred by it in connection with investigating or defending against such loss, claim, damage, liability or action as such expenses are incurred; *provided, however,* that the Company will not be liable in any such case to the extent that any such loss, claim, damage, liability or action arises out of or is based upon an untrue statement or alleged untrue statement or omission or alleged omission made in reliance upon and in conformity with written information furnished to the Company by you, or by any Underwriter through you, specifically for use in the preparation thereof; it being understood and agreed that the only information furnished by an Underwriter consists of the information described as such in Section 6(e).

(b) *Indemnification by the Underwriters*. Each Underwriter will, severally and not jointly, indemnify and hold harmless the Company, its affiliates, directors and officers and each person, if any, who controls the Company within the meaning of Section 15 of the Act and Section 20 of the Exchange Act, from and against any losses, claims, damages or liabilities to which the Company may become subject, under the Act or otherwise (including in settlement of any litigation, if such settlement is effected with the written consent of such Underwriter), insofar as such losses, claims, damages or liabilities (or actions in respect thereof) (i) arise out of or are based upon an untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, any Preliminary Prospectus, the Time of Sale Disclosure Package, the Prospectus, or any amendment or supplement thereto, any issuer free writing prospectus, any issuer information that the Company has filed or is required to file pursuant to Rule 433(d) of the Rules and Regulations, or any Written Testing-the-Waters Communication, or any road show, or (ii) arise out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, in each case to the extent, but only to the extent, that such untrue statement or alleged untrue statement or omission or alleged omission was made in reliance upon or in conformity with written information furnished to the Company by you, or by such Underwriter through you, specifically for use in the preparation thereof (it being understood and agreed that the only information furnished by an Underwriter consists of the information described as such in Section 6(e)), and will reimburse the Company for any legal or other expenses reasonably incurred by the Company in connection with investigating or defending against any such loss, claim, damage, liability or action as such expenses are incurred.

(c) *Notice and Procedures*. Promptly after receipt by an indemnified party under subsection (a) or (b) above of notice of the commencement of any action, such indemnified party shall, if a claim in respect thereof is to be made against the indemnifying party under such subsection, notify the indemnifying party in writing of the commencement thereof; but the omission to so notify the indemnifying party shall not relieve the indemnifying party from any liability that it may have to any indemnified party except to the extent such indemnifying party has been materially prejudiced by such failure (through the forfeiture of substantive rights or defenses). In case any such action shall be brought against any indemnified party, and it shall notify the indemnifying party of the commencement thereof, the indemnifying party shall be entitled to participate in, and, to the extent that it shall wish, jointly with any other indemnifying party similarly notified, to assume the defense thereof, with counsel reasonably satisfactory to such indemnified party, and after notice from the indemnifying party to such indemnified party of the indemnifying party's election so to assume the defense thereof, the indemnifying party shall not be liable to such indemnified party under such subsection for any legal or other expenses subsequently incurred by such indemnified party in connection with the defense thereof other than reasonable costs of investigation; provided, however, that if, in the sole judgment of the Representatives, it is advisable for the Underwriters to be represented as a group by separate counsel, the Representatives shall have the right to employ a single counsel (in addition to local counsel) to represent the Representatives and all Underwriters who may be subject to liability arising from any claim in respect of which indemnity may be sought by the Underwriters under subsection (a) of this Section 6, in which event the reasonable fees and expenses of such separate counsel shall be borne by the indemnifying party or parties and reimbursed to the Underwriters as incurred. An indemnifying party shall not be obligated under any settlement agreement relating to any action under this Section 6 to which it has not agreed in writing. In addition, no indemnifying party shall, without the prior written consent of the indemnified party (which consent shall not be unreasonably withheld or delayed) effect any settlement of any pending or threatened proceeding unless such settlement includes an unconditional release of such indemnified party for all liability on claims that are the subject matter of such proceeding and does not include a statement as to, or an admission of, fault, culpability or a failure to act by or on behalf of an indemnified party. Notwithstanding the foregoing, if at any time an indemnified party shall have requested an indemnifying party to reimburse the indemnified party for fees and expenses of counsel pursuant to this Section 6(c), such indemnifying party agrees that it shall be liable for any settlement effected without its written consent if (i) such settlement is entered into more than 45 days after receipt by such indemnifying party of the aforesaid request and (ii) such indemnifying party shall not have reimbursed such indemnified party in accordance with such request prior to the date of such settlement.

(d) *Contribution; Limitations on Liability; Non-Exclusive Remedy*. If the indemnification provided for in this Section 6 is unavailable or insufficient to hold harmless an indemnified party under subsection (a) or (b) above, then each indemnifying party shall contribute to the amount paid or payable by such indemnified party as a result of the losses, claims, damages or liabilities referred to in subsection (a) or (b) above, (i) in such proportion as is appropriate to reflect the relative benefits received by the Company on the one hand and the Underwriters on the other from the offering of the Securities or (ii) if the allocation provided by clause (i) above is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) above but also the relative fault of the Company on the one hand and the Underwriters on the other in connection with the statements or omissions that resulted in such losses, claims,

damages or liabilities, as well as any other relevant equitable considerations. The relative benefits received by the Company on the one hand and the Underwriters on the other shall be deemed to be in the same proportion as the total net proceeds from the offering (before deducting expenses) received by the Company bear to the total underwriting discounts and commissions received by the Underwriters, in each case as set forth in the table on the cover page of the Prospectus. The relative fault shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission or alleged omission to state a material fact relates to information supplied by the Company or the Underwriters and the parties' relevant intent, knowledge, access to information and opportunity to correct or prevent such untrue statement or omission. The Company and the Underwriters agree that it would not be just and equitable if contributions pursuant to this subsection (d) were to be determined by pro rata allocation (even if the Underwriters were treated as one entity for such purpose) or by any other method of allocation which does not take account of the equitable considerations referred to in the first sentence of this subsection (d). The amount paid by an indemnified party as a result of the losses, claims, damages or liabilities referred to in the first sentence of this subsection (d) shall be deemed to include any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending against any action or claim which is the subject of this subsection (d). Notwithstanding the provisions of this subsection (d), no Underwriter shall be required to contribute any amount in excess of the amount by which the total underwriting discounts and commissions received by such Underwriter with respect to the Securities exceeds the amount of any damages that such Underwriter has otherwise been required to pay by reason of such untrue or alleged untrue statement or omission or alleged omission. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. The Underwriters' obligations in this subsection (d) to contribute are several in proportion to their respective underwriting obligations and not joint. The remedies provided for in this Section 6 are not exclusive and shall not limit any rights or remedies that might otherwise be available to any indemnified party at law or in equity.

(e) *Information Provided by the Underwriters*. The Underwriters severally confirm and the Company acknowledges that the statements with respect to the public offering of the Securities by the Underwriters set forth in the [ ] paragraphs under the caption "Underwriting" in the Time of Sale Disclosure Package and in the Prospectus are correct and constitute the only information concerning such Underwriters furnished in writing to the Company by or on behalf of the Underwriters specifically for inclusion in the Registration Statement, any Preliminary Prospectus, the Time of Sale Disclosure Package, the Prospectus or any issuer free writing prospectus.

7. ***Representations and Agreements to Survive Delivery***. All representations, warranties, and agreements of the Company herein or in certificates delivered pursuant hereto, and the agreements of the several Underwriters and the Company contained in Section 6 hereof, shall remain operative and in full force and effect regardless of any investigation made by or on behalf of any Underwriter or any controlling person thereof, or the Company or any of its officers, directors or controlling persons, and shall survive delivery of, and payment for, the Securities to and by the Underwriters hereunder and any termination of this Agreement.

8. ***Substitution of Underwriters***.

(a) *Obligation to Purchase Under Certain Circumstances*. If any Underwriter or Underwriters shall fail to take up and pay for the amount of Firm Shares agreed by such Underwriter or Underwriters to be purchased hereunder, upon tender of such Firm Shares in accordance with the terms hereof, and the amount of Firm Shares not purchased does not aggregate more than 10% of the total amount of Firm Shares set forth in Schedule I hereto, the remaining Underwriters shall be obligated to take up and pay for (in proportion to their respective underwriting obligations hereunder as set forth in Schedule I hereto except as may otherwise be determined by you) the Firm Shares that the withdrawing or defaulting Underwriters agreed but failed to purchase.

(b) *Termination Under Certain Circumstances*. If any Underwriter or Underwriters shall fail to take up and pay for the amount of Firm Shares agreed by such Underwriter or Underwriters to be purchased hereunder, upon tender of such Firm Shares in accordance with the terms hereof, and the amount of Firm Shares not purchased aggregates more than 10% of the total amount of Firm Shares set forth in Schedule I hereto, and arrangements satisfactory to you for the purchase of such Firm Shares by other persons are not made within 36 hours thereafter, this Agreement shall terminate. In the event of any such termination, neither the Company shall be under any liability to any Underwriter (except to the extent provided in Section 4(a)(vii) and Section 6 hereof) nor shall any Underwriter (other than an Underwriter who shall have failed, otherwise than for some reason permitted under this Agreement, to purchase the amount of Firm Shares agreed by such Underwriter to be purchased hereunder) be under any liability to the Company (except to the extent provided in Section 6 hereof).

(c) *Postponement of Closing*. If Firm Shares to which a default relates are to be purchased by the non-defaulting Underwriters or by any other party or parties, the Representatives or the Company shall have the right to postpone the First Closing Date for not more than seven business days in order that the necessary changes in the Registration Statement, in the Time of Sale Disclosure Package, in the Prospectus or in any other documents, as well as any other arrangements, may be effected. As used herein, the term "Underwriter" includes any person substituted for an Underwriter under this Section 8.

(d) *No Relief from Liability*. No action taken pursuant to this Section shall relieve any defaulting Underwriter from liability, if any, in respect of such default.

9. ***Termination***.

(a) *Right to Terminate*. You, as Representatives of the several Underwriters, shall have the right to terminate this Agreement by giving notice as hereinafter specified at any time at or prior to the First Closing Date, and the option referred to in Section 3(b), if exercised, may be cancelled at any time prior to the Second Closing Date, if (i) the Company shall have failed, refused or been unable, at or prior to such Closing Date, to perform any agreement on its part to be performed hereunder, (ii) any other condition of the Underwriters' obligations hereunder is not fulfilled, (iii) trading on the Nasdaq Stock Market or New York Stock Exchange shall have been wholly suspended, (iv) minimum or maximum prices for trading shall have been fixed, or maximum ranges for prices for securities shall have been required, on the Nasdaq Stock Market or New York

Stock Exchange, by such Exchange or by order of the Commission or any other Governmental Authority, (v) a banking moratorium shall have been declared by federal or state authorities, or (vi) there shall have occurred any outbreak or escalation of hostilities or any change in financial markets or any calamity or crisis that, in your judgment, is material and adverse and makes it impractical or inadvisable to proceed with the completion of the sale of and payment for the Securities. Any such termination shall be without liability of any party to any other party except that the provisions of Section 4(a)(vii) and Section 6 hereof shall at all times be effective.

(b) *Notice of Termination*. If you elect to terminate this Agreement as provided in this Section, the Company shall be notified promptly by you by telephone, confirmed by letter.

10. ***Default by the Company***.

(a) *Default by the Company*. If the Company shall fail at the First Closing Date to sell and deliver the number of Securities which it is obligated to sell hereunder, then this Agreement shall terminate without any liability on the part of any Underwriter or, except as provided in Section 4(a)(vii) and Section 6 hereof, any non-defaulting party.

(b) *No Relief from Liability*. No action taken pursuant to this Section shall relieve the Company from liability, if any, in respect of such default.

11. ***Notices***. Except as otherwise provided herein, all communications hereunder shall be in writing and (a) if to the Underwriters, shall be mailed via overnight delivery service or hand delivered via courier, to the Representatives c/o Piper Sandler & Co., 800 Nicollet Mall, Minneapolis, Minnesota 55402 and Wells Fargo Securities, LLC, 375 Park Avenue, New York, New York 10152, to the attention of Equity Capital Markets and separately, General Counsel; and (b) if to the Company, shall be mailed or delivered to it at 4330 La Jolla Village Drive, San Diego, California 92122, to the attention of Clarke Neumann, General Counsel, or in each case to such other address as the person to be notified may have requested in writing. Any party to this Agreement may change such address for notices by sending to the parties to this Agreement written notice of a new address for such purpose.

12. ***Persons Entitled to Benefit of Agreement***. This Agreement shall inure to the benefit of and be binding upon the parties hereto and their respective successors and assigns and the controlling persons, officers and directors referred to in Section 6. Nothing in this Agreement is intended or shall be construed to give to any other person, firm or corporation any legal or equitable remedy or claim under or in respect of this Agreement or any provision herein contained. The term “successors and assigns” as herein used shall not include any purchaser, as such purchaser, of any of the Securities from any of the several Underwriters.

13. ***Absence of Fiduciary Relationship***. The Company acknowledges and agrees that: (a) the Representatives have been retained solely to act as underwriters in connection with the sale of the Securities and that no fiduciary, advisory or agency relationship between the Company and the Representatives have been created in respect of any of the transactions contemplated by this Agreement, irrespective of whether the Representatives have advised or are

advising the Company on other matters; (b) the price and other terms of the Securities set forth in this Agreement were established by the Company following discussions and arms-length negotiations with the Representatives and the Company is capable of evaluating and understanding and understands and accepts the terms, risks and conditions of the transactions contemplated by this Agreement; (c) it has been advised that the Representatives and their affiliates are engaged in a broad range of transactions which may involve interests that differ from those of the Company and that the Representatives have no obligation to disclose such interest and transactions to the Company by virtue of any fiduciary, advisory or agency relationship; (d) it has been advised that the Representatives are acting, in respect of the transactions contemplated by this Agreement, solely for the benefit of the Representatives and the other Underwriters, and not on behalf of the Company; (e) it waives to the fullest extent permitted by law, any claims it may have against the Representatives for breach of fiduciary duty or alleged breach of fiduciary duty in respect of any of the transactions contemplated by this Agreement and agrees that the Representatives shall have no liability (whether direct or indirect) to the Company in respect of such a fiduciary duty claim on behalf of or in right of the Company, including stockholders, employees or creditors of the Company.

14. ***Governing Law; Waiver of Jury Trial***. This Agreement shall be governed by and construed in accordance with the laws of the State of New York. The Company (on its behalf and, to the extent permitted by applicable law, on behalf of its stockholders and affiliates) and each of the Underwriters hereby irrevocably waives, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Agreement or the transactions contemplated hereby.

15. ***Recognition of the U.S. Special Resolution Regimes***.

(a) In the event that any Underwriter that is a Covered Entity becomes subject to a proceeding under a U.S. Special Resolution Regime, the transfer from such Underwriter of this Agreement, and any interest and obligation in or under this Agreement, will be effective to the same extent as the transfer would be effective under the U.S. Special Resolution Regime if this Agreement, and any such interest and obligation, were governed by the laws of the United States or a state of the United States.

(b) In the event that any Underwriter that is a Covered Entity or a BHC Act Affiliate of such Underwriter becomes subject to a proceeding under a U.S. Special Resolution Regime, Default Rights under this Agreement that may be exercised against such Underwriter are permitted to be exercised to no greater extent than such Default Rights could be exercised under the U.S. Special Resolution Regime if this Agreement were governed by the laws of the United States or a state of the United States.

As used in this Section 15:

"***BHC Act Affiliate***" has the meaning assigned to the term "affiliate" in, and shall be interpreted in accordance with, 12 U.S.C. § 1841(k).

"***Covered Entity***" means any of the following:

(i) a “covered entity” as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 252.82(b);

(ii) a “covered bank” as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 47.3(b); or

(iii) a “covered FSI” as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 382.2(b).

“***Default Right***” has the meaning assigned to that term in, and shall be interpreted in accordance with, 12 C.F.R. §§ 252.81, 47.2 or 382.1, as applicable.

“***U.S. Special Resolution Regime***” means each of (i) the Federal Deposit Insurance Act and the regulations promulgated thereunder and (ii) Title II of the Dodd-Frank Wall Street Reform and Consumer Protection Act and the regulations promulgated thereunder.

16. ***Counterparts***. This Agreement may be executed in one or more counterparts and, if executed in more than one counterpart, the executed counterparts shall each be deemed to be an original and all such counterparts shall together constitute one and the same instrument.

17. ***General Provisions.*** This Agreement constitutes the entire agreement of the parties to this Agreement and supersedes all prior written or oral and all contemporaneous oral agreements, understandings and negotiations with respect to the subject matter hereof. This Agreement may not be amended or modified unless in writing by all of the parties hereto, and no condition herein (express or implied) may be waived unless waived in writing by each party whom the condition is meant to benefit. The Section headings herein are for the convenience of the parties only and shall not affect the construction or interpretation of this Agreement.

[Signature Page Follows]

Please sign and return to the Company the enclosed duplicates of this Agreement whereupon this Agreement will become a binding agreement between the Company and the several Underwriters in accordance with its terms.

Very truly yours,

Progenity, Inc.

By _____
Title:

Confirmed as of the date first above mentioned, on behalf of themselves and the other several Underwriters named in Schedule I hereto.

PIPER SANDLER & CO.

By _____
Managing Director

WELLS FARGO SECURITIES, LLC

By _____
Managing Director

SCHEDULE I

Underwriter	Number of Firm Shares (1)
Piper Sandler & Co.	
Wells Fargo Securities, LLC	
Robert W. Baird & Co.	
Raymond James & Associates, Inc.	
BTIG, LLC	
Total	

(1) The Underwriters may purchase up to an additional [●] Option Shares, to the extent the option described in Section 3(b) of the Agreement is exercised, in the proportions and in the manner described in the Agreement.

SCHEDULE II

Subsidiaries of the Company

1. Avero Laboratory Holdings LLC
2. SPX3, Inc.
3. Progenity Holding Company, Inc.
4. Molecular Diagnostic Health Sciences, LLC
5. Progenity UK Limited
6. Progenity Pty Ltd

SCHEDULE III

List of Individuals and Entities Executing Lock-Up Agreements

Officers

Non-Employee Directors

Significant Stockholders

SCHEDULE IV

Certain Permitted Free Writing Prospectuses

[None]

SCHEDULE V

Pricing Information

Number of Firm Shares Being Offered: [●]
Number of Option Shares Being Offered: [●]
Offering Price Per Share: $[●]
Underwriting Discounts and Commissions: 7.0%

SCHEDULE VI

Written Testing-the-Waters Communications

[Testing the Waters Communication dated [●].]

EXHIBIT A

Form of Lock-Up Agreement

[●], 2020

Piper Sandler & Co.
Wells Fargo Securities, LLC
As representatives of the underwriters named
in Schedule II to the Purchase Agreement
referred to below

c/o Piper Sandler & Co.
800 Nicollet Mall, Suite 800
Minneapolis, MN 55402

c/o Wells Fargo Securities, LLC
500 West 33rd Street, 14th Floor
New York, New York 10001

Dear Sirs and Madams:

As an inducement to the underwriters (the ***"Underwriters"***) to execute a purchase agreement (the ***"Purchase Agreement"***) providing for a public offering (the ***"Offering"***) of common stock, par value $0.001 (the ***"Common Stock"***), of Progenity, Inc. and any successor (by merger or otherwise) thereto (the ***"Company"***), the undersigned hereby agrees that without, in each case, the prior written consent of each of Piper Sandler & Co. and Wells Fargo Securities, LLC (the ***"Representatives"***) during the period specified in the second succeeding paragraph (the ***"Lock-Up Period"***), the undersigned will not: (1) offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, make any short sale or otherwise transfer or dispose of, directly or indirectly, any shares of Common Stock or any securities convertible into, exercisable or exchangeable for or that represent the right to receive Common Stock (including without limitation, Common Stock which may be deemed to be beneficially owned by the undersigned in accordance with the rules and regulations of the Securities and Exchange Commission and securities which may be issued upon exercise of a stock option or warrant) whether now owned or hereafter acquired (the ***"Undersigned's Securities"***); (2) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the Undersigned's Securities, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of Common Stock or such other securities, in cash or otherwise; (3) make any demand for or exercise any right with respect to, the registration of any Common Stock or any security convertible into or exercisable or exchangeable for Common Stock; or (4) publicly disclose the intention to do any of the foregoing.

The undersigned agrees that the foregoing restrictions preclude the undersigned from engaging in any hedging or other transaction which is designed to or which reasonably could be expected to lead to or result in a sale or disposition of the Undersigned's Securities even if such of the Undersigned's Securities would be disposed of by someone other than the undersigned. Such prohibited hedging or other transactions would include without limitation any short sale or any purchase, sale or grant of any right (including without limitation any put or call option) with respect to any of the Undersigned's Securities or with respect to any security that includes, relates to, or derives any significant part of its value from the Undersigned's Securities.

The Lock-Up Period will commence on the date of this Agreement and continue and include the date 180 days after the date of the final prospectus used to sell Common Stock in the Offering pursuant to the Purchase Agreement, to which you are or expect to become parties.

If the undersigned is an officer or director of the Company, (i) each of the Representatives agrees that, at least three business days before the effective date of any release or waiver of the foregoing restrictions in connection with a transfer of shares of Common Stock, the Representatives will notify the Company of the impending release or waiver, and (ii) the Company has agreed in the Purchase Agreement to announce the impending release or waiver by issuing a press release through a major news service at least two business days before the effective date of the release or waiver. Any release or waiver granted by the Representatives hereunder to any such officer or director shall only be effective two business days after the publication date of such press release. The provisions of this paragraph will not apply if both (a) the release or waiver is effected solely to permit a transfer not for consideration, and (b) the transferee has agreed in writing to be bound by the same terms described in this Agreement that are applicable to the transferor, to the extent and for the duration that such terms remain in effect at the time of the transfer.

Notwithstanding the foregoing, the undersigned may transfer the Undersigned's Securities (i) as a *bona fide* gift or gifts, (ii) to any immediate family member or other dependent of the undersigned, (iii) to any trust for the direct or indirect benefit of the undersigned or the immediate family of the undersigned, (iv) if the undersigned is a corporation, partnership, limited liability company, trust or other business entity (1) transfers to another corporation, partnership, limited liability company, trust or other business entity that is a direct or indirect affiliate (as defined in Rule 405 promulgated under the Securities Act of 1933, as amended) of the undersigned or (2) distributions of shares of Common Stock or any security convertible into or exercisable for Common Stock to limited partners, limited liability company members or equityholders of the undersigned, (v) if the undersigned is a trust, transfers to the beneficiary of such trust, (vi) transfers by testate succession or intestate succession, (vii) by operation of law, including pursuant to an order of a court (including a domestic order or a negotiated divorce settlement) or regulatory agency, or to comply with any regulations related to the undersigned's ownership of the Undersigned's Securities, (viii) to a nominee or custodian of a person or entity to whom a disposition or transfer would be permissible under clauses (i) through (vii) above, (ix) pursuant to a bona fide third party tender offer, merger, consolidation or other similar transaction made to all holders of Common Stock involving a Change of Control of the Company (including voting in favor of any such transaction or taking any other action in connection with such transaction); *provided*, that in the event that the tender offer, merger, consolidation or other such transaction is not completed, the Undersigned's Securities shall remain subject to the restrictions contained in this Agreement; and *provided further*, that "Change of Control" shall mean the transfer, in one transaction or in a series of related transactions, to a person or group of affiliated persons (other than an Underwriter pursuant to the Offering) of the Company's voting securities if, after such transfer, such person or group of affiliated persons would hold more than 50% of the outstanding voting securities of the Company (or the surviving entity), or (x) pursuant to the Purchase Agreement; *provided*, that in the case of clauses (i) through (viii), (A) such transfer shall not involve a disposition for value, (B) the transferee agrees in writing with the Underwriters to be bound by the terms of this Agreement, and (C) no filing by any party under Section 16(a) of the Securities Exchange Act of 1934, as amended (the ***"Exchange Act"***), shall be required or shall be made voluntarily in connection with such transfer during the Lock-Up Period. For purposes of this Agreement, "immediate family" shall mean any relationship by blood, marriage, domestic partnership or adoption, not more remote than first cousin.

In addition, the foregoing restrictions shall not apply to (i) the exercise of stock options granted pursuant to the Company's equity incentive plans; *provided*, that such restrictions shall apply to any of the Undersigned's Securities issued upon such exercise, or (ii) the establishment of any contract, instruction or plan (a ***"Plan"***) that satisfies all of the requirements of Rule 10b5-1(c)(1)(i)(B) under the Exchange Act; *provided* that no sales of the Undersigned's Securities shall be made pursuant to such a Plan prior to the expiration of the Lock-Up Period, and such a Plan may only be established if no public announcement of the establishment or existence thereof and no filing with the Securities and Exchange Commission or other regulatory authority in respect thereof or transactions thereunder or contemplated thereby, by the undersigned, the Company or any other person, shall be required, and no such announcement or filing is made voluntarily, by the undersigned, the Company or any other person, prior to the expiration of the Lock-Up Period.

In furtherance of the foregoing, the Company and its transfer agent and registrar are hereby authorized to decline to make any transfer of shares of Common Stock if such transfer would constitute a violation or breach of this Agreement.

The undersigned hereby represents and warrants that the undersigned has full power and authority to enter into this Agreement and that upon request, the undersigned will execute any additional documents necessary to ensure the validity or enforcement of this Agreement. All authority herein conferred or agreed to be conferred and any obligations of the undersigned shall be binding upon the successors, assigns, heirs or personal representatives of the undersigned.

The undersigned understands that this Agreement shall be automatically terminated and be of no further force and effect, and the undersigned shall be released from all obligations under this Agreement if (i) the Company notifies the Underwriters that it does not intend to proceed with the Offering, (ii) the Purchase Agreement does not become effective, or if the Purchase Agreement (other than the provisions thereof which survive termination) shall terminate or be terminated prior to payment for and delivery of the Common Stock to be sold thereunder, (iii) the registration statement filed with the Securities and Exchange Commission with respect to the Offering is withdrawn, or (iv) the Offering is not completed by September 30, 2020. The undersigned understands that the Underwriters are entering into the Purchase Agreement and proceeding with the Offering in reliance upon this Agreement.

This Agreement shall be governed by, and construed in accordance with, the laws of the State of New York.

Very truly yours,

_____

Printed Name of Holder

By: _____

Signature

_____

Printed Name of Person Signing
(and indicate capacity of person signing if signing as custodian, trustee, or on behalf of an entity)

EXHIBIT B

Form of Company Press Release for Waivers or Releases of Officer/Director Lock-Up Agreements

Progenity, Inc.

[Date]

Progenity, Inc. (the "Company") announced today that Piper Sandler and Wells Fargo Securities, as the representatives of the underwriters, are [waiving] [releasing] [a] lock-up restriction[s] with respect to an aggregate of [#] common shares held by certain [officers] [directors] of the Company. These [officers] [directors] entered into lock-up agreements with the representatives in connection with the Company's initial public offering.

This [waiver] [release] will take effect on [date that is at least 2 business days following date of this press release].

This press release is not an offer for sale of the securities in the United States or in any other jurisdiction where such offer is prohibited, and such securities may not be offered or sold in the United States absent registration or an exemption from registration under the United States Securities Act of 1933, as amended.

Exhibit 3.1

SEVENTH AMENDED AND RESTATED CERTIFICATE OF INCORPORATION

OF

PROGENITY, INC.

(Pursuant to Sections 242 and 245 of the General Corporation Law of the State of Delaware)

PROGENITY, INC., a corporation organized and existing under and by virtue of the provisions of the General Corporation Law of the State of Delaware (the "General Corporation Law"),

DOES HEREBY CERTIFY:

FIRST: That the name of the corporation is Progenity, Inc., and that the corporation was originally incorporated pursuant to the General Corporation Law on January 9, 2012 under the name Ascendant MDx, Inc.

SECOND: The corporation's Sixth Amended and Restated Certificate of Incorporation (the "Sixth Amended and Restated Certificate of Incorporation") was filed with the Secretary of State of the State of Delaware on November 12, 2019.

THIRD: That the Board of Directors of the corporation duly adopted resolutions proposing to amend and restate the Sixth Amended and Restated Certificate of Incorporation of the corporation, declaring such amendment and restatement to be advisable and in the best interests of the corporation and its stockholders, and authorizing appropriate officers of the corporation to solicit the consent of the stockholders therefor, which resolution setting forth the proposed amendment and restatement is as follows:

RESOLVED, that the Sixth Amended and Restated Certificate of Incorporation of the corporation be amended and restated in its entirety to read as follows:

* * * * * *

ARTICLE I

The name of this corporation is Progenity, Inc. (the "Corporation").

ARTICLE II

The address of the registered office of the Corporation in the State of Delaware and the County of Kent is 850 New Burton Road, Suite 201, Dover, DE 19904 and the name of the registered agent at that address is COGENCY GLOBAL INC.

ARTICLE III

The purpose of the Corporation is to engage in any lawful act or activity for which a corporation may be organized under the General Corporation Law.

ARTICLE IV

(A) **Classes of Stock**. The Corporation is authorized to issue two classes of stock designated as "Common Stock" and "Preferred Stock," respectively. The total number of shares which the Corporation is authorized to issue is 480,155,000 shares, each with a par value of $0.001 per share. 325,000,000 shares shall be Common Stock and 155,155,000 shares shall be Preferred Stock.

(B) **Rights, Preferences and Restrictions of Preferred Stock**. The Preferred Stock authorized by this Seventh Amended and Restated Certificate of Incorporation may be issued from time to time in one or more series. The first series of Preferred Stock shall be designated "Series A Preferred Stock" and shall consist of 4,120,000 shares. The second series of Preferred Stock shall be designated "Series B Preferred Stock" and shall consist of 151,035,000 shares. The rights, preferences, privileges, and restrictions granted to and imposed on the Preferred Stock are as set forth below in this Article IV(B).

1. **Dividends**.

(a) **Dividends with Common Stock**. The Corporation shall not declare, pay or set aside any dividends on shares of Common Stock (other than dividends on shares of Common Stock payable in shares of Common Stock) unless (in addition to the obtaining of any consents required elsewhere in this Seventh Amended and Restated Certificate of Incorporation) the holders of the Preferred Stock then outstanding shall simultaneously receive a dividend on each outstanding share of Preferred Stock in an amount equal to that dividend per share of Preferred Stock as would equal the product of (i) the dividend payable on each share of Common Stock and (ii) the number of shares of Common Stock then issuable upon

conversion of such share of Preferred Stock, in each case calculated on the record date for determination of holders entitled to receive such dividend.

(b) **No Other Dividends**. The Corporation shall not declare, pay or set aside any dividends on shares of Preferred Stock other than in connection with dividends on the Common Stock as set forth in Article IV(B)(1)(a).

2. **Liquidation**.

(a) **Series A Preference**. In the event of any liquidation, dissolution or winding up of the Corporation, either voluntary or involuntary, the holders of Series A Preferred Stock shall be entitled to receive, after the completion of the distribution required by Section 2(b) below, and prior and in preference to any distribution of any of the assets of the Corporation to the holders of Common Stock by reason of their ownership thereof, an amount per share equal to the sum of the Series A Original Issue Price (as defined below), plus declared but unpaid dividends on such share (the amount payable pursuant to this sentence is hereinafter referred to as the "Series A Preference Amount"). For purposes of this Seventh Amended and Restated Certificate of Incorporation, "Series A Original Issue Price" shall mean $0.48543 per share for each share of the Series A Preferred Stock (as adjusted for stock splits, stock dividends, reclassification or the like with respect to such series of Preferred Stock at any time after the Filing Date (as defined below)). If, upon the occurrence of any such liquidation, dissolution or winding up and the completion of the distribution required by Section 2(b) below, the remaining assets of the Corporation legally available for distribution among the holders of the Series A Preferred Stock shall be insufficient to permit the payment to such holders of the full Series A Preference Amount, the entire remaining assets of the Corporation legally available for distribution shall be distributed ratably among the holders of the Series A Preferred Stock, with each such holder receiving the same proportion of the preferential amount such holder would otherwise be entitled to receive upon such distribution if the full preference amount with respect to such holder's shares were paid.

(b) **Series B Preference**. In the event of any liquidation, dissolution or winding up of the Corporation, either voluntary or involuntary, the holders of Series B Preferred Stock shall be entitled to receive, prior and in preference to any distribution of any of the assets of the Corporation to the holders of Common Stock or Series A Preferred Stock, by reason of their ownership thereof, an amount per share equal to the sum of 1.5 times the Series B Original Issue Price (as defined below), plus declared but unpaid dividends on such share (the amount payable pursuant to this sentence is hereinafter referred to as the "Series B Preference Amount"). For purposes of this Seventh Amended and Restated Certificate of Incorporation, "Series B Original Issue Price" shall mean $2.25 per share for each share of the Series B Preferred Stock (as adjusted for stock splits, stock dividends, reclassification or the like with respect to such series of Preferred Stock at any time after the Filing Date), and each of the Series A Original Issue Price and Series B Original Issue Price, an "Original Issue Price." If, upon the occurrence of any such liquidation, dissolution or winding up, the assets of the Corporation legally available for distribution among the holders of the Series B Preferred Stock shall be insufficient to permit the payment to such holders of the full Series B Preference Amount, the entire assets of the Corporation legally available for distribution shall be distributed ratably among the holders of the Series B Preferred Stock, with each such holder receiving the same

proportion of the preferential amount such holder would otherwise be entitled to receive upon such distribution if the full Series B Preference Amount with respect to such holder's shares were paid.

(c) **Remaining Assets**. Upon the completion of the distributions required by Sections 2(a) and 2(b) above, the remaining assets of the Corporation legally available for distribution to stockholders shall be distributed among the holders of the Series A Preferred Stock and the Common Stock pro rata based on the number of shares of Common Stock held by each (assuming conversion of all such Series A Preferred Stock) until the holders of the Series A Preferred Stock shall have received an aggregate of $1.4563 per share for each share of Series A Preferred Stock (as adjusted for stock splits, stock dividends, reclassification and the like with respect to such series of Preferred Stock at any time after the Filing Date) then held by them, plus declared but unpaid dividends (including amounts paid pursuant to Section 2(a) above); thereafter, if assets of the Corporation legally available for distribution remain in the Corporation, the holders of the Common Stock shall receive all of such remaining assets of the Corporation pro rata based on the number of shares of Common Stock held by each.

(d) **Certain Acquisitions**.

(i) **Deemed Liquidation**. For purposes of this Section 2, a liquidation, dissolution, or winding up of the Corporation shall be deemed to occur if the Corporation shall (1) sell, convey, or otherwise dispose of, in a single transaction or series of related transactions, all or substantially all of its assets or business, provided that this Section 2(d)(i)(1) shall not apply to a sale, conveyance or other disposition to a wholly-owned subsidiary of the Corporation, or (2) merge with or into or consolidate with any other corporation, limited liability company or other entity (other than a wholly-owned subsidiary of the Corporation), provided that this Section 2(d)(i)(2) shall not apply to a merger effected exclusively for the purpose of changing the domicile of the Corporation, to an equity financing in which the Corporation is the surviving entity, or to a transaction in which the stockholders of the Corporation immediately prior to the transaction own more than 50% of the voting power of the surviving entity following the transaction; provided, further, that any such sale, conveyance or other disposal as described in Section 2(d)(i)(1) above and any such merger or consolidation as described in Section 2(d)(i)(2) above shall require the consent of a majority of the shares of Series B Preferred Stock then outstanding, voting together as a separate class, unless such deemed liquidation as described in Section 2(d)(i)(1) or (2) above results in consideration of not less than $2.70 per share (as adjusted for stock splits, stock dividends, reclassification or the like with respect to the Series B Preferred Stock at any time after the Filing Date) with respect to each share of Series B Preferred Stock or the Common Stock into which it is then convertible.

(ii) **Valuation of Consideration**. In the event of any liquidation, dissolution or winding up of the Corporation, either voluntary or involuntary, if the consideration received is other than cash, its value will be deemed its fair market value as determined in good faith by the Board of Directors of the Corporation (the "Board of Directors"), provided that any securities shall be valued as follows:

(A) Securities not subject to investment letter or other similar restrictions on free marketability covered by (B) below:

(1) If traded on a securities exchange, the value shall be based on a formula approved by the Board of Directors and derived from the closing prices of the securities on such exchange over a specified time period;

(2) If actively traded over-the-counter, the value shall be based on a formula approved by the Board of Directors and derived from the closing prices of the securities on an applicable market or quotation system over a specified time period; and

(3) If there is no active public market, the value shall be the fair market value thereof, as determined in good faith by the Board of Directors.

(B) The method of valuation of securities subject to investment letter or other restrictions on free marketability (other than restrictions arising solely by virtue of a stockholder's status as an affiliate or former affiliate) shall be to make an appropriate discount from the market value determined as above in Section 2(d)(ii)(A) to reflect the approximate fair market value thereof, as determined in good faith by the Board of Directors.

(iii) **Notice of Transaction**. The Corporation shall give each holder of record of Preferred Stock written notice of any impending liquidation, dissolution, or winding up of the Corporation (including any deemed liquidation) not later than ten (10) days prior to the stockholders' meeting called to approve such transaction, or ten (10) days prior to the closing of such transaction, whichever is earlier, and shall also notify such holders in writing of the final approval of such transaction. The first of such notices shall describe the material terms and conditions of the impending transaction and the provisions of this Section 2, and the Corporation shall thereafter give such holders prompt notice of any material changes in such terms and conditions. The transaction shall in no event take place sooner than ten (10) days after the Corporation has given the first notice provided for herein or sooner than ten (10) days after the Corporation has given notice of any material changes provided for herein; provided, however, that such periods may be shortened upon the written consent of the holders of Preferred Stock that are entitled to such notice rights or similar notice rights and that represent a majority of the voting power of all then outstanding shares of Preferred Stock, voting together as a single class on an as-converted to Common Stock basis.

(iv) **Allocation of Escrow and Contingent Consideration**. In the event of any deemed liquidation as described in Section 2(d)(i) above, if any portion of the consideration payable to the stockholders of the Corporation is placed into escrow and/or is payable to the stockholders of the Corporation subject to contingencies, the acquisition agreement shall provide that (1) the portion of such consideration that is not placed in escrow and not subject to any contingencies (the "Initial Consideration") shall be allocated among the holders of capital stock of the Corporation in accordance with this Section 2 as if the Initial Consideration were the only consideration payable in connection with such deemed liquidation and (2) any additional consideration which becomes payable to the stockholders of the Corporation from time to time upon release from escrow or satisfaction of contingencies shall be allocated among the holders of capital stock of the Corporation in accordance with Section 2 after taking into account the previous payment of the Initial Consideration (and any additional

consideration paid to stockholders of the Corporation prior to such determination time) as part of the same transaction.

(v) **Waiver**. Notwithstanding the foregoing, the distributions by the Corporation upon a deemed liquidation as described in Section 2(d)(i)(1) above may be waived by the vote or written consent of the holders of a majority of the shares of each of the then outstanding series of Preferred Stock, each voting as a separate class.

(vi) **Effect of Noncompliance**. The Corporation shall not have the power to effect any deemed liquidation as described in Section 2(d)(i)(2) above unless the agreement or plan of merger or consolidation for such transaction provides that the consideration payable to the stockholders of the Corporation shall be allocated among the holders of capital stock of the Corporation in accordance with Sections 2(a), (b) and (c). In the event the requirements of this Section 2(d) are not complied with or waived, the Corporation shall forthwith either cause the closing of the transaction to be postponed until such requirements have been complied with or waived, or terminate or cancel such transaction.

3. **Redemption**. The Preferred Stock is not mandatorily redeemable.

4. **Conversion**. The holders of the Preferred Stock shall have conversion rights as follows (the "Conversion Rights"):

(a) **Right to Convert**.

(i) Subject to Section 4(c), each share of Preferred Stock shall be convertible, at the option of the holder thereof, at any time after the date of issuance of such share, at the office of the Corporation or any transfer agent for such stock, into such number of fully paid and nonassessable shares of Common Stock as is determined by dividing the applicable Original Issue Price for such series by the applicable Conversion Price for such series, determined as hereafter provided, in effect on the date the certificate for such share of Preferred Stock is surrendered for conversion (such quotient, as of such time, the "Conversion Rate" for such series). The initial Conversion Price per share of Series A Preferred Stock shall be $0.0245, and the initial Conversion Price per share of Series B Preferred Stock shall be $2.25. Each such initial Conversion Price shall be subject to adjustment as set forth in Sections 4(d) and 4(f).

(ii) In addition, in the event of the consummation of a Qualified IPO (as defined below), the Conversion Price per share of Series B Preferred Stock shall be adjusted, as of immediately prior to the automatic conversion of such shares in accordance with Section 4(b)(i), to equal the lesser of (1) the then current Conversion Price per share of Series B Preferred Stock and (2) the "Price to Public" per share of Common Stock specified in the final prospectus with respect to the Qualified IPO (the "Public Price").

(iii) Notwithstanding anything contained in clause (ii) above, in the event of the consummation of an IPO (as defined below) where the Public Price is less than $2.70 per share of Common Stock (adjusted for any stock splits, stock dividends, reclassification and the like with respect to the Common Stock at any time after the Filing Date), in lieu of the adjustment set forth in clause (ii), the Conversion Rate per share of Series B Preferred Stock shall be adjusted, as of immediately prior to the consummation of the IPO, such that each share

of Series B Preferred Stock shall be convertible into a number of shares of Common Stock equal to the quotient of (1) the Series B Original Issue Price divided by (2) the Public Price multiplied by 0.833 (for the avoidance of doubt, the adjustment right described in this clause (iii) shall not obligate any holder of Series B Preferred Stock to convert such shares of Series B Preferred Stock into shares of Common Stock unless such IPO is a Qualified IPO).

(b) **Automatic Conversion**. Each share of a series of Preferred Stock shall automatically be converted into shares of Common Stock at the Conversion Rate at the time in effect for the applicable series of Preferred Stock immediately upon the earlier of (i) the closing of the Corporation's sale of its Common Stock in a firm commitment underwritten public offering (an "IPO") pursuant to a registration statement under the Securities Act of 1933, as amended (the "Securities Act"), where the Public Price is not less than $2.25 per share (appropriately adjusted for any stock split, dividend, combination or other recapitalization after the Filing Date) and which results in aggregate cash proceeds to the Corporation of at least $50,000,000 (net of underwriting discounts and commissions) (such IPO, a "Qualified IPO"), or (ii) the date specified by written consent or affirmative vote or agreement of the holders of at least 75% of the then outstanding shares of such series of Preferred Stock. Such conversion shall be deemed to have been made, as applicable, on the date of closing of the IPO or the conversion date described in the stockholder consent, vote or agreement approving such conversion of the applicable series of Preferred Stock, and the persons entitled to receive shares of Common Stock issuable upon such conversion shall be treated for all purposes as the record holders of such shares of Common Stock as of such date.

(c) **Mechanics of Conversion**. Before any holder of Preferred Stock shall be entitled to voluntarily convert the same into shares of Common Stock, such holder shall surrender the certificate or certificates therefor, duly endorsed, at the office of the Corporation or of any transfer agent for such series of Preferred Stock, and shall give written notice to the Corporation at its principal corporate office, of the election to convert the same and shall state therein the name or names in which the certificate or certificates for shares of Common Stock are to be issued. The Corporation shall, as soon as practicable thereafter, issue and deliver at such office to such holder of Preferred Stock, or to the nominee or nominees of such holder, a certificate or certificates for the number of shares of Common Stock to which such holder shall be entitled as aforesaid. Such conversion shall be deemed to have been made immediately prior to the close of business on the date of such surrender of the shares of such series of Preferred Stock to be converted, duly endorsed, and the person or persons entitled to receive the shares of Common Stock issuable upon such conversion shall be treated for all purposes as the record holder or holders of such shares of Common Stock as of such date. If the conversion is in connection with an underwritten offering of securities registered pursuant to the Securities Act the conversion may, at the option of any holder tendering such Preferred Stock for conversion, be conditioned upon the closing with the underwriters of the sale of securities pursuant to such offering, in which event the person(s) entitled to receive Common Stock upon conversion of such Preferred Stock shall not be deemed to have converted such Preferred Stock until immediately prior to the closing of such sale of securities.

(d) **Conversion Price Adjustments of Preferred Stock for Certain Dilutive Issuances, Splits and Combinations**. The Conversion Price of each series of the Preferred Stock shall be subject to adjustment from time to time as follows:

(i) **Issuance of Additional Stock below Purchase Price**. If the Corporation shall issue, on or after April 3, 2020 (the "Filing Date"), any Additional Stock (as defined below) without consideration or for a consideration per share less than the Conversion Price applicable to a series of Preferred Stock in effect immediately prior to the issuance of such Additional Stock, the Conversion Price for such series of Preferred Stock in effect immediately prior to each such issuance shall automatically be adjusted as set forth in this Section 4(d)(i), unless otherwise provided in this Section 4(d)(i).

(A) **Adjustment Formula**. Whenever the Conversion Price for a series of Preferred Stock is adjusted pursuant to this Section (4)(d)(i), the new Conversion Price for such series of Preferred Stock shall be determined in accordance with the following formula:

$$CP_2 = CP_1 * (A + B) \div (A + C).$$

For purposes of the foregoing formula, the following definitions shall apply:

(1) "CP_2" shall mean the Conversion Price for such series of Preferred Stock in effect immediately after such issue of Additional Stock;

(2) "CP_1" shall mean the Conversion Price for such series of Preferred Stock in effect immediately prior to such issue of Additional Stock;

(3) "A" shall mean the number of shares of Common Stock outstanding immediately prior to such issue of Additional Stock (treating for this purpose as outstanding all shares of Common Stock issuable (1) upon exercise of all options and warrants outstanding immediately prior to such issue and (2) upon conversion or exchange of all Preferred Stock outstanding immediately prior to such issue);

(4) "B" shall mean the number of shares of Common Stock that would have been issued if such Additional Stock had been issued at a price per share equal to CP_1 (determined by dividing the aggregate consideration received by the Corporation in respect of such issue by CP_1); and

(5) "C" shall mean the number of shares of such Additional Stock issued in such transaction.

(B) **Definition of "Additional Stock"**. For purposes of this Section 4(d)(i), "Additional Stock" shall mean any shares of Common Stock issued (or deemed to have been issued pursuant to Section 4(d)(i)(E)) by the Corporation after the Filing Date other than:

(1) Common Stock issued pursuant to stock dividends, stock splits or similar transactions, as described in Section 4(d)(ii) hereof;

(2) Shares of Common Stock issued or issuable to employees, consultants or directors of the Corporation or its affiliates pursuant to a stock option plan or restricted stock or restricted stock unit plan approved by the Board of Directors;

(3) Capital stock, or options or warrants to purchase capital stock, issued to financial institutions or lessors in connection with commercial credit arrangements, equipment financings, commercial property lease transactions or similar transactions;

(4) Shares of Common Stock or Preferred Stock issuable upon exercise of warrants outstanding as of the Filing Date, including that certain warrant to purchase shares of Series B Preferred Stock issued by the Corporation to Athyrium Opportunities III Co-Invest 1 LP ("Athyrium") as of October 27, 2017 and amended on August 27, 2019;

(5) Capital stock, or warrants or options to purchase capital stock, issued in connection with bona fide acquisitions, mergers or similar transactions, the terms of which are approved by the Board of Directors;

(6) Shares of Common Stock issued or issuable upon conversion of the Preferred Stock, including the Series B Preferred Stock;

(7) Shares of Common Stock issued or issuable in a public offering prior to or in connection with which all outstanding shares of Preferred Stock will be converted to Common Stock;

(8) Capital stock, or options or warrants to purchase capital stock, issued or issuable to an entity as a component of any business relationship with such entity also involving a material marketing, distribution, product development, supply and/or technology licensing arrangement; and

(9) Shares of Common Stock issued or issuable in connection with any transaction where such securities so issued are excepted from the definition of "Additional Stock" by the affirmative vote of a majority of the then outstanding shares of each series of Preferred Stock as to which the Conversion Price would otherwise be adjusted as a result of such transaction, each voting as a separate class.

(C) **No Fractional Adjustments**. No adjustment of the Conversion Price for the Preferred Stock shall be made in an amount less than one cent per share, provided that any adjustments which are not required to be made by reason of this sentence shall be carried forward and shall be either taken into account in any subsequent adjustment made prior to three years from the date of the event giving rise to the adjustment being carried forward, or shall be made at the end of three years from the date of the event giving rise to the adjustment being carried forward.

(D) **Determination of Consideration**. In the case of the issuance of Additional Stock for cash, the consideration shall be deemed to be the amount of cash paid therefor before deducting any reasonable discounts, commissions or other expenses allowed, paid or incurred by the Corporation for any underwriting or otherwise in connection with the issuance and sale thereof. In the case of the issuance of Additional Stock for a consideration in whole or in part other than cash, the consideration other than cash shall be

deemed to be the fair market value thereof as determined by the Board of Directors irrespective of any accounting treatment.

(E) **Deemed Issuances of Common Stock**. In the case of the issuance (whether before, on or after the Filing Date) of options to purchase or rights to subscribe for Common Stock, securities by their terms convertible into or exchangeable for Common Stock or options to purchase or rights to subscribe for such convertible or exchangeable securities, in each case for Common Stock that is Additional Stock, the following provisions shall apply for all purposes of this Section 4(d)(i):

(1) The aggregate maximum number of shares of Common Stock deliverable upon exercise (assuming the satisfaction of any conditions to exercisability, including without limitation, the passage of time, but without taking into account potential antidilution adjustments) of such options to purchase or rights to subscribe for Common Stock shall be deemed to have been issued at the time such options or rights were issued and for a consideration equal to the consideration (determined in the manner provided in Section 4(d)(i)(D)), if any, received by the Corporation upon the issuance of such options or rights plus the minimum exercise price provided in such options or rights (without taking into account potential antidilution adjustments) for the Common Stock covered thereby.

(2) The aggregate maximum number of shares of Common Stock deliverable upon conversion of, or in exchange for (assuming the satisfaction of any conditions to convertibility or exchangeability, including, without limitation, the passage of time, but without taking into account potential antidilution adjustments), any such convertible or exchangeable securities or upon the exercise of options to purchase or rights to subscribe for such convertible or exchangeable securities and subsequent conversion or exchange thereof shall be deemed to have been issued at the time such securities were issued or such options or rights were issued and for a consideration equal to the consideration, if any, received by the Corporation for any such securities and related options or rights (excluding any cash received on account of accrued interest or accrued dividends), plus the minimum additional consideration, if any, to be received by the Corporation (without taking into account potential antidilution adjustments) upon the conversion or exchange of such securities or the exercise of any such related options or rights (the consideration in each case to be determined in the manner provided in Section 4(d)(i)(D)).

(3) In the event of any increase in the number of shares of Common Stock deliverable or decrease in the consideration payable to the Corporation upon exercise of such options or rights or upon conversion of or in exchange for such convertible or exchangeable securities, other than a change resulting from the antidilution provisions thereof, then such options or rights or such convertible or exchangeable securities shall be deemed to have been issued effective upon such increase in the number of shares of Common Stock or decrease in the consideration, and the applicable Conversion Price of each series of the Preferred Stock shall be recomputed to reflect such change, but no further adjustment shall be made for the actual issuance of Common Stock or any payment of such consideration upon the exercise of any such options or rights or the conversion or exchange of such securities, and provided further that to the extent that the applicable Conversion Price of any series of the Preferred Stock had in any way been affected by or computed upon issuance or prior adjustment of such options, rights or

securities, such adjustments shall be recomputed as set forth in subclause (4) below to reflect only that number of shares of Common Stock, if any, actually issued upon the exercise of such options or rights or upon the conversion or exchange of such securities.

(4) Upon the expiration of any such options or rights, the termination of any such rights to convert or exchange or the expiration of any options or rights related to such convertible or exchangeable securities, the Conversion Price of each series of the Preferred Stock, to the extent in any way affected by or computed using such options, rights or securities or options or rights related to such securities, shall be recomputed to reflect the issuance of only the number of shares of Common Stock (and convertible or exchangeable securities which remain in effect) actually issued upon the exercise of such options or rights, upon the conversion or exchange of such securities or upon the exercise of the options or rights related to such securities.

(5) The number of shares of Common Stock deemed issued and the consideration deemed paid therefor pursuant to Sections 4(d)(i)(E)(1) and 4(d)(i)(E)(2) shall be appropriately adjusted to reflect any change, termination or expiration of the type described in either Section 4(d)(i)(E)(3) or 4(d)(i)(E)(4).

(F) **No Increased Conversion Price**. Notwithstanding any other provisions of this Section (4)(d)(i), except to the limited extent provided for in Sections 4(d)(i)(E)(3) and 4(d)(i)(E)(4), no adjustment of the Conversion Price pursuant to this Section 4(d)(i) shall have the effect of increasing the Conversion Price above the Conversion Price in effect immediately prior to such adjustment.

(ii) **Stock Splits and Dividends**. In the event that the Corporation should at any time or from time to time after the Filing Date fix a record date for the effectuation of a split or subdivision of the outstanding shares of Common Stock or the determination of holders of Common Stock entitled to receive a dividend or other distribution payable in additional shares of Common Stock or other securities or rights convertible into, or entitling the holder thereof to receive directly or indirectly, additional shares of Common Stock (hereinafter referred to as "Common Stock Equivalents") without payment of any consideration by such holder for the additional shares of Common Stock or the Common Stock Equivalents (including the additional shares of Common Stock issuable upon conversion or exercise thereof), then, as of such record date (or the date of such dividend distribution, split or subdivision if no record date is fixed), the applicable Conversion Price of each series of Preferred Stock shall be appropriately decreased so that the number of shares of Common Stock issuable on conversion of each share of such series shall be increased in proportion to such increase in the aggregate number of shares of Common Stock outstanding and those issuable with respect to such Common Stock Equivalents, with the number of shares issuable with respect to Common Stock Equivalents determined from time to time in the manner provided for deemed issuances in Section 4(d)(i)(E).

(iii) **Reverse Stock Splits**. If the number of shares of Common Stock outstanding at any time after the Filing Date is decreased by a combination of the outstanding shares of Common Stock, then, following the record date of such combination, the Conversion Price for the Preferred Stock shall be appropriately increased so that the number of

shares of Common Stock issuable on conversion of each share of such series of Preferred Stock shall be decreased in proportion to such decrease in the aggregate number of shares of Common Stock outstanding.

(e) **Other Distributions**. In the event the Corporation shall declare a distribution payable in securities of other persons, evidences of indebtedness issued by the Corporation or other persons, assets (excluding cash dividends) or options or rights not referred to in Section 4(d)(i)(E), then, in each such case for the purpose of this Section 4(e), the holders of Preferred Stock shall be entitled to a proportionate share of any such distribution as though they were the holders of the number of shares of Common Stock into which their shares of Preferred Stock are convertible as of the record date fixed for the determination of the holders of Common Stock entitled to receive such distribution.

(f) **Recapitalizations**. If at any time or from time to time after the Filing Date there shall be a recapitalization of the Common Stock (other than a subdivision, combination or merger or sale of assets transaction provided for elsewhere in this Section 4 or Section 2) provision shall be made so that the holders of the Preferred Stock shall thereafter be entitled to receive upon conversion of such Preferred Stock the number of shares of stock or other securities or property of the Corporation or otherwise, to which a holder of the shares of Common Stock deliverable upon conversion of such Preferred Stock would have been entitled on and at the time of such recapitalization. In any such case, appropriate adjustment shall be made in the application of the provisions of this Section 4 with respect to the rights of the holders of such Preferred Stock after the recapitalization to the end that the provisions of this Section 4 (including adjustment of the Conversion Price then in effect and the number of shares issuable upon conversion of such Preferred Stock) shall be applicable after that event and be as nearly equivalent as practicable.

(g) **No Impairment**. The Corporation will not, by amendment of this Seventh Amended and Restated Certificate of Incorporation (except in accordance with Section 6 hereof and applicable law) or through any reorganization, recapitalization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms to be observed or performed under this Section 4 by the Corporation, but will at all times in good faith assist in the carrying out of all the provisions of this Section 4 and in the taking of all such action as may be necessary or appropriate in order to protect the Conversion Rights of the holders of Preferred Stock against impairment.

(h) **No Fractional Shares and Certificate as to Adjustments**.

(i) No fractional shares shall be issued upon the conversion of any share or shares of the Preferred Stock, and the number of shares of Common Stock to be issued shall be rounded down to the nearest whole share. The number of shares issuable upon such conversion shall be determined on the basis of the total number of shares of Preferred Stock the holder is at the time converting into Common Stock and the number of shares of Common Stock issuable upon such aggregate conversion.

(ii) Upon the occurrence of each adjustment or readjustment of the Conversion Price of any series of Preferred Stock pursuant to this Section 4, the Corporation, at its expense, shall promptly compute such adjustment or readjustment in accordance with the terms hereof and prepare and furnish to each holder of such series of Preferred Stock a certificate setting forth such adjustment or readjustment and showing in detail the facts upon which such adjustment or readjustment is based. The Corporation shall, upon the written request at any time of any holder of a series of Preferred Stock, furnish or cause to be furnished to such holder a like certificate setting forth (A) such adjustment and readjustment, (B) the Conversion Price for such series of Preferred Stock at the time in effect, and (C) the number of shares of Common Stock and the amount, if any, of other property which at the time would be received upon the conversion of a share of such series of Preferred Stock.

(i) **Notices of Record Date**. In the event of any taking by the Corporation of a record of the holders of any class of securities for the purpose of determining the holders thereof who are entitled to receive any dividend (other than a cash dividend) or other distribution, any right to subscribe for, purchase or otherwise acquire any shares of stock of any class or any other securities or property, or to receive any other right, the Corporation shall mail to each holder of Preferred Stock, at least ten (10) business days prior to the date specified therein, a notice specifying the date on which any such record is to be taken for the purpose of such dividend, distribution or right, and the amount and character of such dividend, distribution or right. Nothing herein shall be deemed to limit the obligations of the Corporation to pay the holders of Preferred Stock dividends pursuant to Article IV(B)(1).

(j) **Reservation of Stock Issuable Upon Conversion**. The Corporation shall at all times reserve and keep available out of its authorized but unissued shares of Common Stock, solely for the purpose of effecting the conversion of the shares of the Preferred Stock, such number of its shares of Common Stock as shall from time to time be sufficient to effect the conversion of all outstanding shares of Preferred Stock; and if at any time the number of authorized but unissued shares of Common Stock shall not be sufficient to effect the conversion of all then outstanding shares of Preferred Stock, in addition to such other remedies as shall be available to the holder of Preferred Stock, the Corporation will take such corporate action as may, in the opinion of its counsel, be necessary to increase its authorized but unissued shares of Common Stock to such number of shares as shall be sufficient for such purposes, including, without limitation, engaging in best efforts to obtain the requisite stockholder approval of any necessary amendment to this Seventh Amended and Restated Certificate of Incorporation.

(k) **Notices**. Any notice required by the provisions of this Section 4 to be given to the holders of shares of Preferred Stock shall be deemed given if deposited in the United States mail, postage prepaid, and addressed to each holder of record at its address appearing on the books of the Corporation.

5. **Voting Rights; Directors**.

(a) Except as otherwise expressly provided herein or by law, the holder of each share of Preferred Stock shall have the right to one vote for each share of Common Stock into which such Preferred Stock could then be converted, and with respect to

such vote, such holder shall have full voting rights and powers equal to the voting rights and powers of the holders of Common Stock, and shall be entitled, notwithstanding any provision hereof, to notice of any stockholders' meeting in accordance with the Bylaws of the Corporation, and shall be entitled to vote, together with holders of Common Stock, with respect to any question upon which holders of Common Stock have the right to vote. Fractional votes shall not, however, be permitted and any fractional voting rights available on an as-converted basis (after aggregating all shares into which shares of Preferred Stock held by each holder could be converted) shall be rounded to the nearest whole number (with one-half being rounded upward).

(b) At each meeting of stockholders at which members of the Board of Directors are to be elected, or whenever members of the Board of Directors are to be elected by written consent of the stockholders:

(i) the holders of a majority of the shares of Series A Preferred Stock then outstanding, voting together as a separate class, shall be entitled to elect such number of directors to serve on the Board of Directors as would be proportionate to the shares of Common Stock issuable upon conversion of the Series A Preferred Stock then outstanding relative to all Voting Shares (rounded to the nearest whole person, with one-half being rounded upward, unless such rounding upwards would not enable the Series B Preferred Stock then outstanding, voting together as a class, to elect at least one director), but never less than a majority; provided, that at least 2,500,000 shares of the Series A Preferred Stock are outstanding (as adjusted for stock splits, stock dividends, reclassification or the like with respect to such series of Preferred Stock at any time after the Filing Date);

(ii) the holders of a majority of the shares of Series B Preferred Stock then outstanding shall be entitled to elect such number of directors to serve on the Board of Directors as would be proportionate to the shares of Common Stock issuable upon conversion of the Series B Preferred Stock then outstanding relative to all Voting Shares (rounded to the nearest whole person, with one-half being rounded upward), unless such proportionate share would not enable the Series A Preferred Stock, voting together as a separate class, to elect a majority of the Board, in which case, the holders of a majority of the shares of Series B Preferred Stock then outstanding shall be entitled to elect such number of directors to serve on the Board of Directors equal to one less than a majority, but never less than one; provided, that (A) at least 40,000,000 shares of the Series B Preferred Stock are outstanding (in each case, as adjusted for stock splits, stock dividends, reclassification or the like with respect to such series of Preferred Stock at any time after the Filing Date), and (B) the outstanding shares of Series B Preferred Stock constitute at least ten percent (10%) of all Voting Shares (provided that this clause (B) shall not apply so long as Athyrium or an affiliate thereof holds a majority of the outstanding Series B Preferred Stock); and

(iii) the holders of a majority of the shares of Common Stock and Preferred Stock then outstanding, voting together as a single class on an as-converted to Common Stock basis, shall be entitled to elect the remaining members of the Board of Directors, if any.

For purposes of this Seventh Amended and Restated Certificate of Incorporation, "Voting Shares" shall mean as of any date, the shares of Common Stock outstanding as of such date and

the shares of Common Stock issuable upon conversion of all outstanding shares of Preferred Stock on such date.

(c) In the case of any vacancy in the office of a director occurring among the directors elected by the holders of Series A Preferred Stock, voting together as a separate class, in accordance with the provisions of Section 5(b)(i) above, the remaining director or directors so elected by the holders of Series A Preferred Stock (or, if there is no remaining director, the holders of a majority of the Series A Preferred Stock voting together as a separate class), shall elect a successor or successors to serve for the unexpired term of the director whose office is vacant.

(d) In the case of any vacancy in the office of a director occurring among the director or directors elected by the holders Series B Preferred Stock, voting together as a class, in accordance with the provisions of Section 5(b)(ii) above, the remaining director or directors so elected by the holders of Series B Preferred Stock (or, if there is no remaining director, the holders of a majority of Series B Preferred Stock voting together as a separate class), shall elect a successor or successors to serve for the unexpired term of the director whose office is vacant.

(e) In the case of any vacancy in the office of a director occurring among the director or directors elected by the Common Stock and Preferred Stock, voting together as a single class, in accordance with the provisions of Section 5(b)(iii) above, the remaining director or directors (or, if there is no remaining director, the holders of a majority of the Common Stock and Preferred Stock, voting together as a single class on an as-converted to Common Stock basis), shall elect a successor or successors to serve for the unexpired term of the director whose office is vacant.

6. **Protective Provisions**.

(a) So long as shares of Preferred Stock convertible into at least 30,000,000 shares of Common Stock are outstanding (as appropriately adjusted for stock splits, stock dividends, reclassification or the like at any time after the Filing Date), the Corporation shall not, either directly or indirectly by amendment, merger, consolidation or otherwise, do any of the following without first obtaining the approval (by vote or written consent, as provided by law) of the holders of a majority of the then outstanding shares of Preferred Stock, voting together as a class on an as converted to Common Stock basis:

(i) effect a transaction described in Section 2(d)(i) above;

(ii) authorize or issue, or obligate itself to issue, any other equity security, including any security (other than Series A Preferred Stock and/or Series B Preferred Stock) convertible into or exercisable for any equity security, being on a parity with the Series A Preferred Stock and/or Series B Preferred Stock with respect to voting, dividends, redemption, conversion or upon liquidation; or

(iii) redeem, purchase or otherwise acquire (or pay into or set funds aside for a sinking fund for such purpose) any share or shares of Preferred Stock or Common Stock; provided, however, that this restriction shall not apply to the repurchase of

shares of Common Stock from employees, officers, directors, consultants or other persons (other than Harry Stylli) performing services for the Corporation or any subsidiary pursuant to agreements under which the Corporation has the option to repurchase such shares at cost upon the occurrence of certain events, such as the termination of employment, or through the exercise of any right of first refusal.

(b) So long as at least 2,500,000 shares of Series A Preferred Stock are outstanding (as adjusted for stock splits, stock dividends, reclassification or the like with respect to such series of Preferred Stock at any time after the Filing Date), the Corporation shall not, either directly or indirectly by amendment, merger, consolidation or otherwise, do any of the following without first obtaining the approval (by vote or written consent, as provided by law) of the holders of a majority of the then outstanding shares of Series A Preferred Stock, voting together as a separate class:

(i) alter or change the rights, preferences or privileges of the shares of Series A Preferred Stock by amendment of this Seventh Amended and Restated Certificate of Incorporation or the Bylaws of the Corporation, so as to affect adversely the shares of such series;

(ii) increase or decrease (other than by redemption or conversion) the total number of authorized shares of Series A Preferred Stock or Series B Preferred Stock; or

(iii) authorize or issue, or obligate itself to issue, any other equity security, including any security convertible into or exercisable for any equity security, having a preference over the Series A Preferred Stock with respect to voting, dividends, redemption or upon liquidation (for the avoidance of doubt, the designation of a new series of Preferred Stock that is *pari passu* or junior to the Series A Preferred Stock shall not require approval pursuant to this Section 6(b)).

(c) So long as at least 40,000,000 shares of Series B Preferred Stock are outstanding (as adjusted for stock splits, stock dividends, reclassification or the like with respect to such series of Preferred Stock at any time after the Filing Date), the Corporation shall not, either directly or indirectly by amendment, merger, consolidation or otherwise, do any of the following without first obtaining the approval (by vote or written consent, as provided by law) of the holders of a majority of the then outstanding shares of Series B Preferred Stock, voting together as a separate class:

(i) alter or change the rights, preferences or privileges of the shares of Series B Preferred Stock by amendment of this Seventh Amended and Restated Certificate of Incorporation or the Bylaws of the Corporation, so as to affect adversely the shares of such series;

(ii) increase or decrease (other than by redemption or conversion) the total number of authorized shares of Series A Preferred Stock or Series B Preferred Stock;

(iii) authorize or issue, or obligate itself to issue, any other equity security, including any security convertible into or exercisable for any equity security, having a preference over the Series B Preferred Stock with respect to voting, dividends, redemption or upon liquidation (for the avoidance of doubt, the designation of a new series of Preferred Stock that is *pari passu* or junior to the Series B Preferred Stock shall not require approval pursuant to this Section 6(c));

(iv) enter into any transaction with (A) Harry Stylli, (B) any Affiliate or Immediate Family Member (as such terms are defined in the Fourth Amended and Restated Investors' Rights Agreement, dated as of August 27, 2019, among the Corporation and the stockholders of the Corporation named therein) of Harry Stylli or (C) any other individual, corporation, partnership, trust, limited liability company, association or other entity with respect to which Harry Stylli, beneficially owns directly or indirectly, (1) in the aggregate more than 35% of the economic interests, or (2) the power to elect or appoint more than 35% of the members of the board of directors thereof (or equivalent governing body) (each person or entity described in this clause (iv), a "Stylli Party");

(v) (1) sell, convey, or otherwise dispose of, in a single transaction or series of related transactions, the Corporation's assets, including the equity of any of the Corporation's subsidiaries, or (2) acquire, merge or amalgamate with or into or consolidate with any other corporation, limited liability company or other entity (other than a wholly-owned subsidiary of the Corporation), in each case, where such transaction or series of related transactions has an aggregate value (including the value of any shares exchanged by the Corporation) of at least $10 million and is not in the ordinary course of business (each, as determined in good faith by the Board of Directors); provided, that this Section 6(c)(v) shall not apply to a merger effected exclusively for the purpose of changing the domicile of the Corporation; or

(vi) enter into any financing transaction that results in the Corporation's securities trading on a public stock exchange, other than a Qualified IPO.

7. **Status of Converted and Reacquired Stock**. In the event any shares of Preferred Stock shall be converted pursuant to Section 4 hereof or shall be reacquired by the Corporation (via exchange, repurchase, redemption or otherwise), the shares so converted or reacquired shall be automatically retired and cancelled and may not be reissued by the Corporation. Following any such conversion or reacquisition of shares of Preferred Stock, the Corporation shall, without further action of its stockholders, file with the Delaware Secretary of State a certificate identifying the shares of Preferred Stock so converted or reacquired and stating that their reissuance is prohibited under this Seventh Amended and Restated Certificate of Incorporation, which upon filing shall have the effect of amending this Seventh Amended and Restated Certificate of Incorporation to reduce the number of authorized shares of the series to which such shares belong, and, if such retired shares constitute all the shares of such series, eliminating from this Seventh Amended and Restated Certificate of Incorporation all reference to such series of Preferred Stock.

(C) **Common Stock**. The rights, preferences, privileges and restrictions granted to and imposed on the Common Stock are as set forth below in this Article IV(C).

1. **Dividend Rights**. Subject to the prior rights of holders of all classes of stock at the time outstanding having prior rights as to dividends, the holders of the Common Stock shall be entitled to receive, if, when and as declared by the Board of Directors, out of any assets of the Corporation legally available therefor, such dividends as may be declared from time to time by the Board of Directors.

2. **Liquidation Rights**. Upon the liquidation, dissolution or winding up of the Corporation, the assets of the Corporation shall be distributed as provided in Article IV(B)(2).

3. **Redemption**. The Common Stock is not mandatorily redeemable.

4. **Voting Rights**. Each holder of Common Stock shall have the right to one vote per share of Common Stock, and shall be entitled to notice of any stockholders' meeting in accordance with the Bylaws of the Corporation, and shall be entitled to vote upon such matters and in such manner as may be provided by law. Notwithstanding the foregoing, the number of authorized shares of Common Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by (in addition to any vote of the holders of Preferred Stock that may be required by the terms of this Seventh Amended and Restated Certificate of Incorporation) the affirmative vote of the holders of Voting Shares representing a majority of all outstanding Voting Shares, irrespective of the provisions of Section 242(b)(2) of the General Corporation Law.

ARTICLE V

The number of directors which shall constitute the Board of Directors shall consist of not less than three (3) nor more than nine (9) persons. The number of directors shall initially be seven (7) and, thereafter, shall be fixed, within the limits set forth in the preceding sentence, exclusively by one or more resolutions adopted from time to time by the affirmative vote of a majority of the Board of Directors.

ARTICLE VI

Except as otherwise provided in this Seventh Amended and Restated Certificate of Incorporation, in furtherance and not in limitation of the powers conferred by statute, the Board of Directors is expressly authorized to make, alter or repeal the Bylaws of the Corporation.

ARTICLE VII

Elections of directors need not be by written ballot unless otherwise provided in the Bylaws of the Corporation.

ARTICLE VIII

To the fullest extent permitted by law, a director of the Corporation shall not be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director. If the General Corporation Law is amended after approval by the stockholders of this Article VIII to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the General Corporation Law as so amended.

The right to exculpation conferred in this Article VIII shall be a contract between the Corporation and each director who is covered by this Article VIII while this Seventh Amended and Restated Certificate of Incorporation is in effect. Any repeal or modification of the foregoing provisions of this Article VIII by the stockholders of the Corporation shall not adversely affect any right or protection of a director of the Corporation existing at the time of, or increase the liability of any director of the Corporation with respect to any acts or omissions occurring prior to, such repeal or modification. Notwithstanding the foregoing provisions of this Article VIII, any right or protection provided hereunder shall be deemed to vest at the time that the act or omission occurred.

ARTICLE IX

The following indemnification provisions shall apply to the persons enumerated below.

1. Right to Indemnification of Directors and Officers. The Corporation shall indemnify and hold harmless, to the fullest extent permitted by applicable law as it presently exists or may hereafter be amended, any person (an "Indemnified Person") who was or is made or is threatened to be made a party or is otherwise involved in any action, suit or proceeding, whether civil, criminal, administrative or investigative (a "Proceeding"), by reason of the fact that such person is or was a director or officer of the Corporation or, while a director or officer of the Corporation, is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation or of a partnership, joint venture, limited liability company, trust, enterprise or other entity, including service with respect to employee benefit plans, against all liability and loss suffered and expenses (including attorneys' fees) reasonably incurred by such Indemnified Person in such Proceeding. Notwithstanding the preceding sentence, except as otherwise provided in Section 3 of this Article IX, the Corporation shall be required to indemnify an Indemnified Person in connection with a Proceeding (or part thereof) commenced by such Indemnified Person only if the commencement of such Proceeding (or part thereof) by the Indemnified Person was authorized in advance by the Board of Directors.

2. Prepayment of Expenses of Directors and Officers. The Corporation shall pay the expenses (including attorneys' fees) incurred by an Indemnified Person in defending any Proceeding in advance of its final disposition, provided, however, that such payment of expenses in advance of the final disposition of the Proceeding shall be made only upon receipt of an undertaking by or on behalf of the Indemnified Person to repay all amounts advanced if it should be ultimately determined that the Indemnified Person is not entitled to be indemnified under this Article IX or otherwise.

3. Claims by Directors and Officers. If a claim for indemnification or advancement of expenses under this Article IX is not paid in full within 30 days after a written claim therefor by the Indemnified Person has been received by the Corporation, the Indemnified Person may file suit to recover the unpaid amount of such claim and, if successful in such suit, in whole or in part, shall be entitled to be paid the expense of prosecuting such claim. In any such action the Corporation shall have the burden of proving that the Indemnified Person is not entitled to the requested indemnification or advancement of expenses under applicable law.

4. Indemnification of Employees and Agents. The Corporation may indemnify and advance expenses to any person who was or is made or is threatened to be made or is otherwise involved in any Proceeding by reason of the fact that such person is or was an employee or agent of the Corporation or, while an employee or agent of the Corporation, is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation or of a partnership, joint venture, limited liability company, trust, enterprise or nonprofit entity, including service with respect to employee benefit plans, against all liability and loss suffered and expenses (including attorneys' fees) reasonably incurred by such person in connection with such Proceeding. The ultimate determination of entitlement to indemnification of persons who are non-director or officer employees or agents of the Corporation shall be made in such manner as is determined by the Board of Directors in its sole discretion. Without limiting the foregoing, the Corporation shall not be required to indemnify any such person in connection with a Proceeding initiated by such person if the Proceeding was not authorized in advance by the Board of Directors.

5. Advancement of Expenses of Employees and Agents. The Corporation may pay the expenses (including attorneys' fees) incurred by an employee or agent in defending any Proceeding in advance of its final disposition on such terms and conditions as may be determined by the Board of Directors.

6. Non-Exclusivity of Rights. The rights conferred on any person by this Article IX shall not be exclusive of any other rights which such person may have or hereafter acquire under any statute, any other provision of this Seventh Amended and Restated Certificate of Incorporation, the Bylaws of the Corporation, agreement, vote of stockholders or disinterested directors or otherwise.

7. Other Indemnification. Subject to Section 9 of this Article IX, the Corporation's obligation, if any, to indemnify any person who was or is serving at its request as a director, officer or employee of another corporation, partnership, limited liability company, joint venture, trust, organization or other enterprise shall be reduced by any amount such person may collect as indemnification from such other corporation, partnership, limited liability company, joint venture, trust, organization or other enterprise.

8. Insurance. The Board of Directors may, to the full extent permitted by applicable law as it presently exists, or may hereafter be amended from time to time, authorize an appropriate officer or officers to purchase and maintain at the Corporation's expense insurance: (a) to indemnify the Corporation for any obligation that it incurs as a result of the indemnification of directors, officers, employees, and agents under the provisions of this

Article IX; and (b) to indemnify or insure directors, officers, employees, and agents against liability asserted against such person and incurred by such person in any such capacity, or arising out of such person's status as such, whether or not the Corporation would have the power to indemnify such person against such liability under the provisions of this Article IX.

9. Primacy of Corporation's Indemnification Obligation. The Corporation shall be the indemnitor of first resort for any director who is entitled to indemnification and advancement pursuant to this Article IX (i.e., the Corporation's obligations to indemnify a director shall be primary and any obligation of any third party employer or affiliate of such director to advance expenses or to provide indemnification for the same expenses or liabilities incurred by such director are secondary) and it shall be required to advance the full amount of expenses incurred by such director and shall be liable for the full amount of all expenses, judgments, penalties, fines and amounts paid in settlement to the extent legally permitted and as required by this Seventh Amended and Restated Certificate of Incorporation (or any other agreement between the Corporation and such director), without regard to any rights such director may have against any third party employer or affiliate of such director.

10. Amendment or Repeal. The right to indemnification and advancement conferred in this Article IX shall be a contract between the Corporation and each person who is covered by this Article IX while this Seventh Amended and Restated Certificate of Incorporation is in effect. Any repeal or modification of the provisions of this Article IX shall not adversely affect any right or protection hereunder of any person who is covered by this Article IX in respect of any Proceeding (regardless of when such Proceeding is first threatened, commenced or completed) arising out of, or related to, any act or omission occurring prior to the time of such repeal or modification. Notwithstanding the foregoing provisions of this Article IX, any right or protection provided hereunder shall be deemed to vest at the time that the act or omission occurred, irrespective of when and whether a Proceeding challenging such act or omission is first threatened or commenced. The rights provided hereunder shall inure to the benefit of any Indemnified Person and such person's heirs, executors, administrators and other legal representatives.

ARTICLE X

The Corporation renounces, to the fullest extent permitted by law, any interest or expectancy of the Corporation in, or in being offered an opportunity to participate in, any Excluded Opportunity. An "Excluded Opportunity" is any matter, transaction or interest that is presented to, or acquired, created or developed by, or which otherwise comes into the possession of a Covered Person (as defined below), unless such matter, transaction or interest is presented to, or acquired, created or developed by, or otherwise comes into the possession of, a Covered Person expressly and solely in such Covered Person's capacity as an officer or director of the Corporation. For purposes of this Article X, a "Covered Person" shall mean (i) any director of the Corporation, or (ii) any holder of Preferred Stock or any partner, member, director, stockholder, employee or agent of any such holder.

ARTICLE XI

(A) Forum. Unless the Corporation, in writing, selects or consents to the selection of an alternative forum, the sole and exclusive forum for any current or former stockholder (including any current or former beneficial owner) to bring internal corporate claims (as defined below), to the fullest extent permitted by law, and subject to applicable jurisdictional requirements, shall be the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another state or federal court located within the State of Delaware). For purposes of this Article XI, "internal corporate claims" means claims, including claims in the right of the Corporation: (a) that are based upon a violation of a duty by a current or former director, officer, employee or stockholder in such capacity, or (b) as to which the General Corporation Law confers jurisdiction upon the Court of Chancery. If any action the subject matter of which is within the scope of this Article XI is filed in a court other than the Court of Chancery (or, if the Court of Chancery does not have jurisdiction, another state or federal court located within the State of Delaware) (a "Foreign Action") by any current or former stockholder (including any current or former beneficial owner), such stockholder shall be deemed to have consented to: (i) the personal jurisdiction of the Court of Chancery (or such other state or federal court located within the State of Delaware, as applicable) in connection with any action brought in any such court to enforce this Article XI, and (ii) having service of process made upon such stockholder in any such action by service upon such stockholder's counsel in the Foreign Action as agent for such stockholder.

(B) Enforceability. If any provision of this Article XI shall be held to be invalid, illegal or unenforceable as applied to any person or entity or circumstance for any reason whatsoever, then, to the fullest extent permitted by law, the validity, legality and enforceability of such provision in any other circumstance and of the remaining provisions of this Article XI (including, without limitation, each portion of any sentence of this Article XI containing any such provision held to be invalid, illegal or unenforceable that is not itself held to be invalid, illegal or unenforceable) and the application of such provision to other persons or entities or circumstances shall not in any way be affected or impaired thereby.

* * * * * *

FOURTH: That the foregoing amendment and restatement was approved by the holders of the requisite number of shares of the corporation in accordance with Section 228 of the General Corporation Law.

FIFTH: That this Seventh Amended and Restated Certificate of Incorporation, which restates and integrates and further amends the provisions of the corporation's Certificate of Incorporation, as amended, has been duly adopted in accordance with Sections 242 and 245 of the General Corporation Law.

IN WITNESS WHEREOF, this Seventh Amended and Restated Certificate of Incorporation has been executed by a duly authorized officer of the corporation on this 3rd day of April, 2020.

By: /s/ Eric d'Esparbes
Eric d'Esparbes
Chief Financial Officer

[SIGNATURE PAGE TO SEVENTH AMENDED AND RESTATED CERTIFICATE OF INCORPORATION OF PROGENITY, INC.]

CERTIFICATE OF AMENDMENT TO THE

SEVENTH AMENDED AND RESTATED CERTIFICATE OF INCORPORATION

OF

PROGENITY, INC.

(Pursuant to Section 242 of the General Corporation Law of the State of Delaware)

Progenity, Inc. (the "Corporation"), a corporation organized and existing under and by virtue of the provisions of the General Corporation Law of the State of Delaware (the "General Corporation Law"):

DOES HEREBY CERTIFY:

FIRST: That the name of this corporation is Progenity, Inc., and that this corporation was originally incorporated pursuant to the General Corporation Law on January 9, 2012 under the name Ascendant MDx, Inc.

SECOND: This corporation's Seventh Amended and Restated Certificate of Incorporation (the "Seventh Amended and Restated Certificate of Incorporation") was filed with the Secretary of State of the State of Delaware on April 3, 2020.

THIRD: This Certificate of Amendment to the Seventh Amended and Restated Certificate of Incorporation (the "Certificate of Amendment") has been duly adopted in accordance with Section 242 of the General Corporation Law and amends the provisions of the Corporation's Seventh Amended and Restated Certificate of Incorporation (the "Restated Certificate").

FOURTH: This Certificate of Amendment has been approved and duly adopted by the Board of Directors of the Corporation pursuant to resolutions proposing to amend the Seventh Amended and Restated Certificate, declaring such amendment to be advisable and in the best interests of this corporation and its stockholders, and authorizing appropriate officers of this corporation to solicit the consent of the stockholders therefor.

FIFTH: The terms and provisions of this Certificate of Amendment have been duly approved by written consent of the required number of shares of outstanding stock of the Corporation in accordance with Sections 228 and 242 of the General Corporation Law.

SIXTH: The following is hereby inserted into paragraph (C) of Article IV of the Seventh Amended and Restated Certificate of Incorporation immediately before the first sentence therein:

"Effective upon the filing of this Certificate of Amendment to the Seventh Amended and Restated Certificate of Incorporation with the Secretary of State of

the State of Delaware (the "Effective Time"), every six and one hundred seventy-eight thousandths (6.178) shares of Common Stock then issued and outstanding or held in the treasury of the Corporation immediately prior to the Effective Time shall automatically be combined into one (1) share of Common Stock, without any further action by the holders of such shares (the "Stock Split"). The Stock Split shall occur automatically without any further action by the holders of the shares of Common Stock and Preferred Stock affected thereby. All rights, preferences and privileges of the Common Stock and the Preferred Stock shall be appropriately adjusted to reflect the Stock Split in accordance with this Seventh Amended and Restated Certificate of Incorporation."

[*Remainder of page intentionally left blank*]

IN WITNESS WHEREOF, this Certificate of Amendment has been executed by a duly authorized officer of this corporation on this 10th day of June, 2020.

By: */s/ Eric d'Esparbes*

Eric d'Esparbes
Chief Financial Officer

[SIGNATURE PAGE TO CERTIFICATE OF AMENDMENT OF PROGENITY, INC.]

EIGHTH AMENDED & RESTATED CERTIFICATE OF INCORPORATION

OF

PROGENITY, INC.
(a Delaware corporation)

(Pursuant to Sections 242 and 245 of the General Corporation Law of the State of Delaware (the "DGCL"))

PROGENITY, INC., a corporation organized and existing under and by virtue of the provisions of the DGCL,

DOES HEREBY CERTIFY:

FIRST: That the name of the corporation is Progenity, Inc. (the "Corporation"), and that the Corporation was originally incorporated pursuant to the DGCL on January 9, 2012 under the name Ascendant MDx, Inc.

SECOND: The Corporation's Seventh Amended and Restated Certificate of Incorporation (the "Seventh Amended and Restated Certificate of Incorporation") was filed with the Secretary of State of the State of Delaware on April 3, 2020.

THIRD: That the stockholders of the Corporation duly authorized and approved the amendment and restatement of the Seventh Amended and Restated Certificate of Incorporation of the Corporation, as approved by the Board of Directors of the Corporation, in accordance with Section 228 of the DGCL.

FOURTH: That the Board of Directors of the Corporation duly adopted resolutions proposing to amend and restate the Seventh Amended and Restated Certificate of Incorporation of the Corporation, declaring such amendment and restatement to be advisable and in the best interests of the Corporation and its stockholders, and authorizing appropriate officers of the Corporation to solicit the consent of the stockholders therefor, which resolution setting forth the proposed amendment and restatement is as follows:

RESOLVED, that the Seventh Amended and Restated Certificate of Incorporation of the Corporation be amended and restated in its entirety to read as follows:

ARTICLE I
NAME

The name of the Corporation is Progenity, Inc.

ARTICLE II
AGENT

The address of the Corporation's registered office in the State of Delaware is 850 New Burton Road, Suite 201, Dover, DE 19904. The name of its registered agent at such address is COGENCY GLOBAL INC.

ARTICLE III
PURPOSE

The purpose of the Corporation is to engage in any lawful act or activity for which corporations may be organized under the DGCL.

ARTICLE IV
STOCK

Section 4.1 Authorized Stock. The total number of shares which the Corporation shall have authority to issue is 360,000,000, of which 350,000,000 shall be designated as Common Stock, par value $.001 per share (the "Common Stock"), and 10,000,000 shall be designated as Preferred Stock, par value $.001 per share (the "Preferred Stock").

Section 4.2 Common Stock.

(a) Each holder of Common Stock, as such, shall be entitled to one vote for each share of Common Stock held of record by such holder on all matters on which stockholders generally are entitled to vote; provided, however, that, except as otherwise required by law, holders of Common Stock, as such, shall not be entitled to vote on any amendment to this Certificate of Incorporation, including any certificate of designations relating to any series of Preferred Stock (each hereinafter referred to as a "Preferred Stock Designation"), that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together with the holders of one or more other such series, to vote thereon pursuant to this Certificate of Incorporation (including any Preferred Stock Designation).

(b) Dividends. Subject to the rights of the holders of any outstanding series of Preferred Stock, the holders of shares of Common Stock shall be entitled to receive dividends to the extent permitted by law when, as and if declared by the Board of Directors of the Corporation (the "Board of Directors").

(c) Liquidation. Upon the dissolution, liquidation or winding up of the Corporation, subject to the rights of the holders of any outstanding series of Preferred Stock, the holders of shares of Common Stock shall be entitled to receive the assets of the Corporation available for distribution to its stockholders ratably in proportion to the number of shares held by them.

Section 4.3 Preferred Stock. The Preferred Stock may be issued from time to time in one or more series. Subject to limitations prescribed by law and the provisions of this Article IV (including any Preferred Stock Designation), the Board of Directors is hereby authorized to

provide by resolution and by causing the filing of a Preferred Stock Designation for the issuance of the shares of Preferred Stock in one or more series, and to establish from time to time the number of shares to be included in each such series, and to fix the designations, powers, preferences, and relative, participating, optional or other rights, if any, and the qualifications, limitations or restrictions, if any, of the shares of each such series.

Section 4.4 No Class Vote on Changes in Authorized Number of Shares of Stock. Subject to the rights of the holders of any outstanding series of Preferred Stock, the number of authorized shares of Common Stock or Preferred Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of at least a majority of the voting power of the stock outstanding and entitled to vote thereon irrespective of the provisions of Section 242(b)(2) of the DGCL.

ARTICLE V
BOARD OF DIRECTORS

Section 5.1 Number. Except as otherwise provided for or fixed pursuant to the provisions of Article IV hereof (including any Preferred Stock Designation), the Board of Directors shall consist of such number of directors as shall be determined from time to time solely by resolution adopted by the affirmative vote of a majority of the total number of directors then authorized.

Section 5.2 Vacancies and Newly Created Directorships; Removal.

(a) Subject to the rights of the holders of any outstanding series of Preferred Stock, and unless otherwise required by law, newly created directorships resulting from any increase in the authorized number of directors and any vacancies in the Board of Directors resulting from death, resignation, retirement, disqualification, removal from office or other cause shall be filled solely by the affirmative vote of a majority of the remaining directors then in office, even though less than a quorum of the Board of Directors, or by the sole remaining director. Any director so chosen shall hold office until the next election of directors and until his or her successor shall have been duly elected and qualified. No decrease in the authorized number of directors shall shorten the term of any incumbent director.

(b) Any director, or the entire Board of Directors, may be removed, with or without cause, by the affirmative vote of at least a majority of the voting power of the stock outstanding and entitled to vote thereon; provided, however, that whenever the holders of any class or series are entitled to elect one or more directors by this Certificate of Incorporation (including any Preferred Stock Designation), with respect to the removal without cause of a director or directors so elected, the vote of the holders of the outstanding shares of that class or series and not the vote of the outstanding shares as a whole shall apply.

(c) During any period when the holders of any series of Preferred Stock have the right to elect additional directors as provided for or fixed pursuant to the provisions of Article IV hereof (including any Preferred Stock Designation) (the “Preferred Stock Directors”), and upon commencement and for the duration of the period during which such right continues: (i) the then otherwise total authorized number of directors of the Corporation shall automatically

be increased by such number of directors that the holders of any series of Preferred Stock have a right to elect, and the holders of such Preferred Stock shall be entitled to elect the additional directors so provided for or fixed pursuant to such provisions; and (ii) each Preferred Stock Director shall serve until such Preferred Stock Director's successor shall have been duly elected and qualified, or until such Preferred Stock Director's right to hold such office terminates pursuant to such provisions, whichever occurs earlier, subject to his or her earlier death, disqualification, resignation or removal. Except as otherwise provided for or fixed pursuant to the provisions of Article IV hereof (including any Preferred Stock Designation), whenever the holders of any series of Preferred Stock having such right to elect additional directors are divested of such right pursuant to such provisions, the terms of office of all such Preferred Stock Directors elected by the holders of such Preferred Stock, or elected to fill any vacancies resulting from the death, resignation, disqualification or removal of such additional directors, shall forthwith terminate (in which case each such Preferred Stock Director shall cease to be qualified as a director and shall cease to be a director) and the total authorized number of directors of the Corporation shall be automatically reduced accordingly.

Section 5.3 Powers. Except as otherwise required by the DGCL or as provided in this Certificate of Incorporation (including any Preferred Stock Designation), the business and affairs of the Corporation shall be managed by or under the direction of the Board of Directors.

Section 5.4 Election; Annual Meeting of Stockholders.

(a) Ballot Not Required. The directors of the Corporation need not be elected by written ballot unless the Bylaws of the Corporation so provide.

(b) Notice. Advance notice of nominations for the election of directors, and of business other than nominations, to be proposed by stockholders for consideration at a meeting of stockholders of the Corporation shall be given in the manner and to the extent provided in or contemplated by the Bylaws of the Corporation.

(c) Annual Meeting. The annual meeting of stockholders, for the election of directors to succeed those whose terms expire and for the transaction of such other business as may properly come before the meeting, shall be held at such place, if any, either within or without the State of Delaware, on such date, and at such time as the Board of Directors shall fix.

ARTICLE VI
STOCKHOLDER ACTION

Except as otherwise provided for or fixed pursuant to the provisions of Article IV hereof (including any Preferred Stock Designation), no action that is required or permitted to be taken by the stockholders of the Corporation may be effected by consent of stockholders in lieu of a meeting of stockholders; provided, however, that at any time when (i) Harry Stylli, (ii) Athyrium Capital Management, LP, and (iii) Andrew Midler, including for each any entities affiliated therewith, collectively, beneficially own (as defined by Securities and Exchange Commission rules promulgated under Section 13 of the Securities Exchange Act of 1934, as amended) shares representing more than 50% of the voting power of the stock outstanding and entitled to vote, any action required or permitted to be taken at any annual or special meeting of the stockholders

of the Corporation may be taken without a meeting, without prior notice and without a vote by consent in accordance with Section 228 of the DGCL.

ARTICLE VII
SPECIAL MEETINGS OF STOCKHOLDERS

Except as otherwise required by law, and except as otherwise provided for or fixed pursuant to the provisions of Article IV hereof (including any Preferred Stock Designation), a special meeting of the stockholders of the Corporation may be called at any time only by the Board of Directors. Only such business shall be conducted at a special meeting of stockholders as shall have been brought before the meeting by or at the direction of the Board of Directors.

ARTICLE VIII
EXISTENCE

The Corporation shall have perpetual existence.

ARTICLE IX
AMENDMENT

Section 9.1 Amendment of Certificate of Incorporation. The Corporation reserves the right at any time, and from time to time, to amend, alter, change or repeal any provision contained in this Certificate of Incorporation (including any Preferred Stock Designation), and other provisions authorized by the laws of the State of Delaware at the time in force may be added or inserted, in the manner now or hereafter prescribed by the laws of the State of Delaware, and all powers, preferences and rights of any nature conferred upon stockholders, directors or any other persons by and pursuant to this Certificate of Incorporation (including any Preferred Stock Designation) in its present form or as hereafter amended are granted subject to this reservation.

Section 9.2 Amendment of Bylaws. In furtherance and not in limitation of the powers conferred by the laws of the State of Delaware, but subject to the terms of any series of Preferred Stock then outstanding, the Board of Directors is expressly authorized to adopt, amend or repeal the Bylaws of the Corporation. Except as otherwise provided in this Certificate of Incorporation (including the terms of any Preferred Stock Designation that require an additional vote) or the Bylaws of the Corporation, and in addition to any requirements of law, the affirmative vote of at least a majority of the voting power of the stock outstanding and entitled to vote thereon, voting together as a single class, shall be required for the stockholders to adopt, amend or repeal, or adopt any provision inconsistent with, any provision of the Bylaws of the Corporation.

ARTICLE X
LIABILITY OF DIRECTORS

Section 10.1 No Personal Liability. To the fullest extent permitted by the DGCL as the same exists or as may hereafter be amended, no director of the Corporation shall be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director.

Section 10.2 Amendment or Repeal. Any amendment, alteration or repeal of this Article X that adversely affects any right of a director shall be prospective only and shall not limit or eliminate any such right with respect to any proceeding involving any occurrence or alleged occurrence of any action or omission to act that took place prior to such amendment, alteration or repeal.

ARTICLE XI
FORUM FOR ADJUDICATION OF DISPUTES

Section 11.1 Forum. Unless the Corporation, in writing, selects or consents to the selection of an alternative forum, the sole and exclusive forum for any internal corporate claims (as defined below), to the fullest extent permitted by law, and subject to applicable jurisdictional requirements, shall be the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have, or declines to accept, jurisdiction, another state court or a federal court located within the State of Delaware). For purposes of this Article XI, "internal corporate claims" means claims, including claims in the right of the Corporation: (a) that are based upon a violation of a duty by a current or former director, officer, employee or stockholder in such capacity; or (b) as to which the DGCL confers jurisdiction upon the Court of Chancery. Notwithstanding anything herein to the contrary, and for the avoidance of doubt: (y) this Article XI shall not apply to suits brought to enforce a duty or liability created by the Securities Exchange Act of 1934, as amended; and (z) unless the Corporation consents in writing to the selection of an alternative forum, the federal district courts of the United States of America shall be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended.

Section 11.2 Consent to Jurisdiction. If any action the subject matter of which is within the scope of this Article XI is filed in a court other than the Court of Chancery (or, if the Court of Chancery does not have, or declines to accept, jurisdiction, another state court or a federal court located within the State of Delaware) (a "Foreign Action") by any current or former stockholder (including any current or former beneficial owner), such stockholder shall be deemed to have consented to: (a) the personal jurisdiction of the Court of Chancery (or such other state or federal court located within the State of Delaware, as applicable) in connection with any action brought in any such court to enforce this Article XI; and (b) having service of process made upon such stockholder in any such action by service upon such stockholder's counsel in the Foreign Action as agent for such stockholder.

Section 11.3 Enforceability. If any provision of this Article XI shall be held to be invalid, illegal or unenforceable as applied to any person or entity or circumstance for any reason whatsoever, then, to the fullest extent permitted by law, the validity, legality and enforceability of such provision in any other circumstance and of the remaining provisions of this Article XI (including, without limitation, each portion of any sentence of this Article XI containing any such provision held to be invalid, illegal or unenforceable that is not itself held to be invalid, illegal or unenforceable) and the application of such provision to other persons or entities or circumstances shall not in any way be affected or impaired thereby.

[The remainder of this page has been intentionally left blank.]

IN WITNESS WHEREOF, this Eighth Amended and Restated Certificate of Incorporation has been executed by a duly authorized officer of the corporation on this day of , 2020.

By: _____
Chief Financial Officer

[SIGNATURE PAGE TO EIGHTH AMENDED AND RESTATED CERTIFICATE OF INCORPORATION OF PROGENITY, INC.]

AMENDED & RESTATED BYLAWS

OF

PROGENITY, INC.
(a Delaware corporation)

ARTICLE I
CORPORATE OFFICES

Section 1.1 Registered Office. The registered office of the Corporation shall be fixed in the Certificate of Incorporation of the Corporation (the "Certificate of Incorporation").

Section 1.2 Other Offices. The Corporation may also have an office or offices, and keep the books and records of the Corporation, except as otherwise required by law, at such other place or places, either within or without the State of Delaware, as the Corporation may from time to time determine or the business of the Corporation may require.

ARTICLE II
MEETINGS OF STOCKHOLDERS

Section 2.1 Annual Meeting. The annual meeting of stockholders, for the election of directors to succeed those whose terms expire and for the transaction of such other business as may properly come before the meeting, shall be held at such place, if any, either within or without the State of Delaware, on such date, and at such time as the Board of Directors of the Corporation (the "Board of Directors") shall fix. The Board of Directors may postpone, reschedule or cancel any annual meeting of stockholders previously scheduled by the Board of Directors.

Section 2.2 Special Meeting. Except as otherwise required by law, and except as otherwise provided for or fixed pursuant to the Certificate of Incorporation, including any certificate of designations relating to any series of Preferred Stock of the Corporation (each hereinafter referred to as a "Preferred Stock Designation"), a special meeting of the stockholders of the Corporation may be called at any time only by the Board of Directors. The Board of Directors may postpone, reschedule or cancel any special meeting of stockholders previously scheduled by the Board of Directors. Only such business shall be conducted at a special meeting of stockholders as shall have been brought before the meeting by or at the direction of the Board of Directors.

Section 2.3 Notice of Stockholders' Meetings.

(a) Whenever stockholders are required or permitted to take any action at a meeting, notice of the place, if any, date, and time of the meeting of stockholders, the record date for determining the stockholders entitled to vote at the meeting (if such date is different from the record date for determining the stockholders entitled to notice of the meeting), the means of remote communications, if any, by which stockholders and proxyholders may be deemed to be present in person and vote at such meeting and, if the meeting is to be held solely by means of

remote communications, the means for accessing the list of stockholders contemplated by Section 2.5 of these Bylaws, shall be given. The notice shall be given not less than 10 nor more than 60 days before the date on which the meeting is to be held, to each stockholder entitled to vote at such meeting as of the record date for determining the stockholders entitled to notice of the meeting, except as otherwise provided by law, the Certificate of Incorporation (including any Preferred Stock Designation) or these Bylaws. In the case of a special meeting, the purpose or purposes for which the meeting is called also shall be set forth in the notice.

(b) Except as otherwise required by law, notice may be given in writing directed to a stockholder's mailing address as it appears on the records of the Corporation and shall be given: (i) if mailed, when notice is deposited in the U.S. mail, postage prepaid; and (ii) if delivered by courier service, the earlier of when the notice is received or left at such stockholder's address.

(c) So long as the Corporation is subject to the Securities and Exchange Commission's proxy rules set forth in Regulation 14A under the Securities Exchange Act of 1934 (the "Exchange Act"), notice shall be given in the manner required by such rules. To the extent permitted by such rules, or if the Corporation is not subject to Regulation 14A, notice may be given by electronic transmission directed to the stockholder's electronic mail address, and if so given, shall be given when directed to such stockholder's electronic mail address unless the stockholder has notified the Corporation in writing or by electronic transmission of an objection to receiving notice by electronic mail or such notice is prohibited by Section 232(e) of the General Corporation Law of the State of Delaware (the "DGCL"). If notice is given by electronic mail, such notice shall comply with the applicable provisions of Sections 232(a) and 232(d) of the DGCL.

(d) Notice may be given by other forms of electronic transmission with the consent of a stockholder in the manner permitted by Section 232(b) of the DGCL, and shall be deemed given as provided therein.

(e) An affidavit that notice has been given, executed by the Secretary of the Corporation, Assistant Secretary or any transfer agent or other agent of the Corporation, shall be *prima facie* evidence of the facts stated in the notice in the absence of fraud. Notice shall be deemed to have been given to all stockholders who share an address if notice is given in accordance with the "householding" rules set forth in Rule 14a-3(e) under the Exchange Act and Section 233 of the DGCL.

(f) When a meeting is adjourned to another time or place, notice need not be given of the adjourned meeting if the place, if any, date and time thereof, and the means of remote communications, if any, by which stockholders and proxyholders may be deemed to be present in person and vote at such adjourned meeting are announced at the meeting at which the adjournment is taken; provided, however, that if the adjournment is for more than 30 days, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting. If after the adjournment a new record date for stockholders entitled to vote is fixed for the adjourned meeting, the Board of Directors shall fix a new record date for notice of such adjourned meeting in accordance with Section 7.6(a), and shall give notice of the adjourned

meeting to each stockholder of record entitled to vote at such adjourned meeting as of the record date fixed for notice of such adjourned meeting.

Section 2.4 Organization.

(a) Unless otherwise determined by the Board of Directors, meetings of stockholders shall be presided over by the Chairman of the Board of Directors, or in his or her absence, by the Lead Independent Director or, in his or her absence, by another person designated by the Board of Directors. The Secretary of the Corporation, or in his or her absence, an Assistant Secretary, or in the absence of the Secretary and all Assistant Secretaries, a person whom the chairman of the meeting shall appoint, shall act as secretary of the meeting and keep a record of the proceedings thereof.

(b) The date and time of the opening and the closing of the polls for each matter upon which the stockholders shall vote at a meeting of stockholders shall be announced at the meeting. The Board of Directors may adopt such rules and regulations for the conduct of any meeting of stockholders as it shall deem appropriate. Except to the extent inconsistent with such rules and regulations as adopted by the Board of Directors, the chairman of the meeting shall have the authority to adopt and enforce such rules and regulations for the conduct of any meeting of stockholders and the safety of those in attendance as, in the judgment of the chairman, are necessary, appropriate or convenient for the conduct of the meeting. Rules and regulations for the conduct of meetings of stockholders, whether adopted by the Board of Directors or by the chairman of the meeting, may include, without limitation, establishing: (i) an agenda or order of business for the meeting; (ii) rules and procedures for maintaining order at the meeting and the safety of those present; (iii) limitations on attendance at or participation in the meeting to stockholders entitled to vote at the meeting, their duly authorized and constituted proxies and such other persons as the chairman of the meeting shall permit; (iv) restrictions on entry to the meeting after the time fixed for the commencement thereof; (v) limitations on the time allotted for consideration of each agenda item and for questions and comments by participants; (vi) regulations for the opening and closing of the polls for balloting and matters that are to be voted on by ballot (if any); and (vii) procedures (if any) requiring attendees to provide the Corporation advance notice of their intent to attend the meeting. Subject to any rules and regulations adopted by the Board of Directors, the chairman of the meeting may convene and, for any or no reason, from time to time, adjourn and/or recess any meeting of stockholders pursuant to Section 2.7. The chairman of the meeting, in addition to making any other determinations that may be appropriate to the conduct of the meeting, shall have the power to declare that a nomination or other business was not properly brought before the meeting if the facts warrant (including if a determination is made, pursuant to Section 2.10(c)(i) of these Bylaws, that a nomination or other business was not made or proposed, as the case may be, in accordance with Section 2.10 of these Bylaws), and if such chairman should so declare, such nomination shall be disregarded or such other business shall not be transacted.

Section 2.5 List of Stockholders. The Corporation shall prepare, at least 10 days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting; provided, however, that if the record date for determining the stockholders entitled to vote is less than 10 days before the date of the meeting, the list shall reflect the stockholders entitled to vote as of the 10th day before the meeting date. Such list shall be arranged in

alphabetical order and shall show the address of each stockholder and the number of shares registered in the name of each stockholder. Nothing in this Section 2.5 shall require the Corporation to include electronic mail addresses or other electronic contact information on such list. Such list shall be open to the examination of any stockholder, for any purpose germane to the meeting at least 10 days prior to the meeting: (a) on a reasonably accessible electronic network, provided that the information required to gain access to such list is provided with the notice of meeting; or (b) during ordinary business hours at the principal place of business of the Corporation. In the event that the Corporation determines to make the list available on an electronic network, the Corporation may take reasonable steps to ensure that such information is available only to stockholders of the Corporation. If the meeting is to be held at a place, then a list of stockholders entitled to vote at the meeting shall be produced and kept at the time and place of the meeting during the whole time thereof and may be examined by any stockholder who is present. If the meeting is to be held solely by means of remote communication, then the list shall also be open to the examination of any stockholder during the whole time of the meeting on a reasonably accessible electronic network, and the information required to access such list shall be provided with the notice of the meeting. Except as otherwise required by law, the stock ledger shall be the only evidence as to who are the stockholders entitled to examine the list of stockholders required by this Section 2.5 or to vote in person or by proxy at any meeting of stockholders.

Section 2.6 Quorum. Except as otherwise required by law, the Certificate of Incorporation (including any Preferred Stock Designation) or these Bylaws, at any meeting of stockholders, a majority of the voting power of the stock outstanding and entitled to vote at the meeting, present in person or represented by proxy, shall constitute a quorum for the transaction of business; provided, however, that where a separate vote by a class or series or classes or series is required, a majority of the voting power of the stock of such class or series or classes or series outstanding and entitled to vote on that matter, present in person or represented by proxy, shall constitute a quorum entitled to take action with respect to such matter. If a quorum is not present or represented at any meeting of stockholders, then the chairman of the meeting, or a majority of the voting power of the stock present in person or represented by proxy at the meeting and entitled to vote thereon, shall have power to adjourn or recess the meeting from time to time in accordance with Section 2.7, until a quorum is present or represented. Subject to applicable law, if a quorum initially is present at any meeting of stockholders, the stockholders may continue to transact business until adjournment or recess, notwithstanding the withdrawal of enough stockholders to leave less than a quorum, but if a quorum is not present at least initially, no business other than adjournment or recess may be transacted.

Section 2.7 Adjourned or Recessed Meeting. Any annual or special meeting of stockholders, whether or not a quorum is present, may be adjourned or recessed for any or no reason from time to time by the chairman of the meeting, subject to any rules and regulations adopted by the Board of Directors pursuant to Section 2.4(b). Any such meeting may be adjourned for any or no reason (and may be recessed if a quorum is not present or represented) from time to time by a majority of the voting power of the stock present in person or represented by proxy at the meeting and entitled to vote thereon. At any such adjourned or recessed meeting at which a quorum is present, any business may be transacted that might have been transacted at the meeting as originally called.

Section 2.8 Voting; Proxies

(a) Except as otherwise required by law or the Certificate of Incorporation (including any Preferred Stock Designation), each holder of stock of the Corporation entitled to vote at any meeting of stockholders shall be entitled to one vote for each share of such stock held of record by such holder that has voting power upon the subject matter in question.

(b) Except as otherwise required by law, the Certificate of Incorporation (including any Preferred Stock Designation), these Bylaws or any law, rule or regulation applicable to the Corporation or its securities, at each meeting of stockholders at which a quorum is present, all corporate actions to be taken by vote of the stockholders shall be authorized by the affirmative vote of at least a majority of the voting power of the stock present in person or represented by proxy and entitled to vote on the subject matter, and where a separate vote by a class or series or classes or series is required, if a quorum of such class or series or classes or series is present, such act shall be authorized by the affirmative vote of at least a majority of the voting power of the stock of such class or series or classes or series present in person or represented by proxy and entitled to vote on the subject matter. Voting at meetings of stockholders need not be by written ballot.

(c) Every stockholder entitled to vote for directors, or on any other matter, shall have the right to do so either in person or by one or more persons authorized to act for such stockholder by proxy, but no such proxy shall be voted or acted upon after three years from its date, unless the proxy provides for a longer period. A proxy shall be irrevocable if it states that it is irrevocable and if, and only as long as, it is coupled with an interest sufficient in law to support an irrevocable power. A proxy may be made irrevocable regardless of whether the interest with which it is coupled is an interest in the stock itself or an interest in the Corporation generally. A stockholder may revoke any proxy which is not irrevocable by attending the meeting and voting in person or by delivering to the Secretary of the Corporation a revocation of the proxy or an executed new proxy bearing a later date.

Section 2.9 Submission of Information by Director Nominees.

(a) To be eligible to be a nominee for election or re-election as a director of the Corporation, a person must deliver to the Secretary of the Corporation at the principal executive offices of the Corporation the following information:

(i) a written representation and agreement, which shall be signed by such person and pursuant to which such person shall represent and agree that such person: (A) consents to serving as a director if elected and (if applicable) to being named in the Corporation's proxy statement and form of proxy as a nominee, and currently intends to serve as a director for the full term for which such person is standing for election; (B) is not and will not become a party to any agreement, arrangement or understanding with, and has not given any commitment or assurance to, any person or entity: (1) as to how the person, if elected as a director, will act or vote on any issue or question that has not been disclosed to the Corporation; or (2) that could limit or interfere with the person's ability to comply, if elected as a director, with such person's fiduciary duties under applicable law; (C) is not and will not become a party to any agreement, arrangement or understanding with any person or entity other than the

Corporation with respect to any direct or indirect compensation, reimbursement or indemnification in connection with service or action as a director or nominee that has not been disclosed to the Corporation; and (D) if elected as a director, will comply with all of the Corporation's corporate governance, conflict of interest, confidentiality, and stock ownership and trading policies and guidelines, and any other Corporation policies and guidelines applicable to directors (which will be promptly provided following a request therefor); and

(ii) all completed and signed questionnaires prepared by the Corporation (including those questionnaires required of the Corporation's directors and any other questionnaire the Corporation determines is necessary or advisable to assess whether a nominee will satisfy any qualifications or requirements imposed by the Certificate of Incorporation or these Bylaws, any law, rule, regulation or listing standard that may be applicable to the Corporation, and the Corporation's corporate governance policies and guidelines) (all of the foregoing, "Questionnaires"). The Questionnaires will be promptly provided following a request therefor.

(b) A nominee for election or re-election as a director of the Corporation shall also provide to the Corporation such other information as it may reasonably request. The Corporation may request such additional information as necessary to permit the Corporation to determine the eligibility of such person to serve as a director of the Corporation, including information relevant to a determination whether such person can be considered an independent director.

(c) Notwithstanding any other provision of these Bylaws, if a stockholder has submitted notice of an intent to nominate a candidate for election or re-election as a director pursuant to Section 2.10, the Questionnaires described in Section 2.9(a)(ii) above and the additional information described in Section 2.9(b) above shall be considered timely if provided to the Corporation promptly upon request by the Corporation, but in any event within five business days after such request, and all information provided pursuant to this Section 2.9 shall be deemed part of the stockholder's notice submitted pursuant to Section 2.10.

Section 2.10 Notice of Stockholder Business and Nominations.

(a) Annual Meeting.

(i) Nominations of persons for election to the Board of Directors and the proposal of business other than nominations to be considered by the stockholders may be made at an annual meeting of stockholders only: (A) pursuant to the Corporation's notice of meeting (or any supplement thereto); (B) by or at the direction of the Board of Directors (or any authorized committee thereof); or (C) by any stockholder of the Corporation who is a stockholder of record at the time the notice provided for in this Section 2.10(a) is delivered to the Secretary of the Corporation, who is entitled to vote at the meeting and who complies with the notice procedures set forth in this Section 2.10(a). For the avoidance of doubt, the foregoing clause (C) shall be the exclusive means for a stockholder to make nominations or propose other business at an annual meeting of stockholders (other than a proposal included in the Corporation's proxy statement pursuant to and in compliance with Rule 14a-8 under the Exchange Act).

(ii) For nominations or other business to be properly brought before an annual meeting by a stockholder pursuant to clause (C) of the foregoing paragraph, the stockholder must have given timely notice thereof in writing to the Secretary of the Corporation and, in the case of business other than nominations, such business must be a proper subject for stockholder action. To be timely, a stockholder's notice must be delivered to the Secretary of the Corporation at the principal executive offices of the Corporation not later than the close of business (as defined in Section 2.10(c)(ii) below) on the 90th day nor earlier than the close of business on the 120th day prior to the first anniversary of the preceding year's annual meeting; provided, however, that in the event that the date of the annual meeting is more than 30 days before or more than 60 days after such anniversary date, or if no annual meeting was held in the preceding year, notice by the stockholder to be timely must be so delivered not earlier than the close of business on the 120th day prior to such annual meeting and not later than the close of business on the later of the 90th day prior to such annual meeting or the 10th day following the date on which public announcement (as defined in Section 2.10(c)(ii) below) of the date of such meeting is first made by the Corporation. In no event shall an adjournment or recess of an annual meeting, or a postponement of an annual meeting for which notice of the meeting has already been given to stockholders or a public announcement of the meeting date has already been made, commence a new time period (or extend any time period) for the giving of a stockholder's notice as described above. The number of nominees a stockholder may nominate for election at the annual meeting (or in the case of a stockholder giving the notice on behalf of a beneficial owner, the number of nominees a stockholder may nominate for election at the annual meeting on behalf of the beneficial owner) shall not exceed the number of directors to be elected at such annual meeting. For purposes of this Section 2.10, the 2020 annual meeting of stockholders shall be deemed to have been held on May 30, 2020. Such stockholder's notice shall set forth:

(A) as to each person whom the stockholder proposes to nominate for election or re-election as a director: (1) all information relating to such person that is required to be disclosed in solicitations of proxies for election of directors in an election contest, or is otherwise required, in each case pursuant to and in accordance with Regulation 14A under the Exchange Act; and (2) the information required to be submitted by nominees pursuant to Section 2.9(a)(i) above.

(B) as to any other business that the stockholder proposes to bring before the meeting, a brief description of the business desired to be brought before the meeting, the text of the proposal or business (including the text of any resolutions proposed for consideration and in the event that such business includes a proposal to amend the Bylaws of the Corporation, the language of the proposed amendment), the reasons for conducting such business at the meeting and any substantial interest (within the meaning of Item 5 of Schedule 14A under the Exchange Act) in such business of such stockholder and the beneficial owner (within the meaning of Section 13(d) of the Exchange Act), if any, on whose behalf the proposal is made;

(C) as to the stockholder giving the notice and the beneficial owner, if any, on whose behalf the nomination is made or the other business is proposed:

(1) the name and address of such stockholder, as they appear on the Corporation's books, and the name and address of such beneficial owner;

(2) the class or series and number of shares of stock of the Corporation which are owned of record by such stockholder and such beneficial owner as of the date of the notice, and a representation that the stockholder will notify the Corporation in writing within five business days after the record date for such meeting of the class or series and number of shares of stock of the Corporation owned of record by the stockholder and such beneficial owner as of the record date for the meeting; and

(3) a representation that the stockholder (or a qualified representative of the stockholder) intends to appear at the meeting to make such nomination or propose such business; and

(D) as to the stockholder giving the notice or, if the notice is given on behalf of a beneficial owner on whose behalf the nomination is made or the other business is proposed, as to such beneficial owner, and if such stockholder or beneficial owner is an entity, as to each director, executive, managing member or control person of such entity (any such individual or control person, a "control person"):

(1) the class or series and number of shares of stock of the Corporation which are beneficially owned (as defined in Section 2.10(c)(ii) below) by such stockholder or beneficial owner and by any control person as of the date of the notice, and a representation that the stockholder will notify the Corporation in writing within five business days after the record date for such meeting of the class or series and number of shares of stock of the Corporation beneficially owned by such stockholder or beneficial owner and by any control person as of the record date for the meeting;

(2) a description of any agreement, arrangement or understanding with respect to the nomination or other business between or among such stockholder, beneficial owner or control person and any other person, including, without limitation any agreements that would be required to be disclosed pursuant to Item 5 or Item 6 of Exchange Act Schedule 13D (regardless of whether the requirement to file a Schedule 13D is applicable) and a representation that the stockholder will notify the Corporation in writing within five business days after the record date for such meeting of any such agreement, arrangement or understanding in effect as of the record date for the meeting;

(3) a description of any agreement, arrangement or understanding (including, without limitation, any derivative or short positions, profit interests, options, hedging transactions, and borrowed or loaned shares) that has been entered into as of the date of the stockholder's notice by, or on behalf of, such stockholder, beneficial owner or control person, the effect or intent of which is to mitigate loss, manage risk or benefit from changes in the share price of any class or series of the Corporation's stock, or maintain, increase or decrease the voting power of the stockholder, beneficial owner or control person with respect to securities of the Corporation, and a representation that the stockholder will notify the Corporation in writing within five business days after the record date for such meeting of any such agreement, arrangement or understanding in effect as of the record date for the meeting; and

(4) a representation whether the stockholder or the beneficial owner, if any, will engage in a solicitation with respect to the nomination or other

business and, if so, the name of each participant in such solicitation (as defined in Item 4 of Schedule 14A under the Exchange Act) and whether such person intends or is part of a group which intends to deliver a proxy statement and/or form of proxy to holders of shares representing at least 50% of the voting power of the stock entitled to vote generally in the election of directors in the case of a nomination, or holders of at least the percentage of the Corporation's stock required to approve or adopt the business to be proposed in the case of other business.

(iii) Notwithstanding anything in Section 2.10(a)(ii) above or Section 2.10(b) below to the contrary, if the record date for determining the stockholders entitled to vote at any meeting of stockholders is different from the record date for determining the stockholders entitled to notice of the meeting, a stockholder's notice required by this Section 2.10 shall set forth a representation that the stockholder will notify the Corporation in writing within five business days after the record date for determining the stockholders entitled to vote at the meeting, or by the opening of business on the date of the meeting (whichever is earlier), of the information required under clauses (ii)(C)(2) and (ii)(D)(1)-(3) of this Section 2.10(a), and such information when provided to the Corporation shall be current as of the record date for determining the stockholders entitled to vote at the meeting.

(iv) This Section 2.10(a) shall not apply to a proposal proposed to be made by a stockholder if the stockholder has notified the Corporation of his or her intention to present the proposal at an annual or special meeting only pursuant to and in compliance with Rule 14a-8 under the Exchange Act and such proposal has been included in a proxy statement that has been prepared by the Corporation to solicit proxies for such meeting.

(v) Notwithstanding anything in this Section 2.10(a) to the contrary, in the event that the number of directors to be elected to the Board of Directors at an annual meeting is increased and there is no public announcement by the Corporation naming all of the nominees for directors or specifying the size of the increased Board of Directors made by the Corporation at least 10 days prior to the last day a stockholder may deliver a notice in accordance with Section 2.10(a)(ii) above, a stockholder's notice required by this Section 2.10(a) shall also be considered timely, but only with respect to nominees for any new positions created by such increase, if it shall be delivered to the Secretary of the Corporation at the principal executive offices of the Corporation not later than the close of business on the 10th day following the day on which such public announcement is first made by the Corporation.

(b) Special Meeting. Nominations of persons for election to the Board of Directors may be made at a special meeting of stockholders at which directors are to be elected pursuant to the Corporation's notice of meeting: (i) by or at the direction of the Board of Directors (or any authorized committee thereof); or (ii) provided that one or more directors are to be elected at such meeting, by any stockholder of the Corporation who is a stockholder of record at the time the notice provided for in this Section 2.10(b) is delivered to the Secretary of the Corporation, who is entitled to vote at the meeting and upon such election and who delivers notice thereof in writing setting forth the information required by Section 2.10(a) above and provides the additional information required by Section 2.9 above. In the event the Corporation calls a special meeting of stockholders for the purpose of electing one or more directors to the Board of Directors, any stockholder entitled to vote in such election of directors may nominate a person or persons (as the case may be) for election to such position(s) as specified in the

Corporation's notice of meeting, if the notice required by this Section 2.10(b) shall be delivered to the Secretary of the Corporation at the principal executive offices of the Corporation not earlier than the close of business on the 120th day prior to such special meeting and not later than the close of business on the later of the 90th day prior to such special meeting or the 10th day following the date on which public announcement of the date of the special meeting and of the nominees proposed by the Board of Directors to be elected at such meeting is first made by the Corporation. The number of nominees a stockholder may nominate for election at the special meeting (or in the case of a stockholder giving the notice on behalf of a beneficial owner, the number of nominees a stockholder may nominate for election at the annual meeting on behalf of such beneficial owner) shall not exceed the number of directors to be elected at such special meeting. In no event shall an adjournment, recess or postponement of a special meeting commence a new time period (or extend any time period) for the giving of a stockholder's notice as described above.

(c) General.

(i) Except as otherwise required by law, only such persons who are nominated in accordance with the procedures set forth in this Section 2.10 shall be eligible to be elected at any meeting of stockholders of the Corporation to serve as directors and only such other business shall be conducted at a meeting of stockholders as shall have been brought before the meeting in accordance with the procedures set forth in this Section 2.10. Except as otherwise required by law, each of the Board of Directors or the chairman of the meeting shall have the power to determine whether a nomination or any other business proposed to be brought before the meeting was made or proposed, as the case may be, in accordance with the procedures set forth in this Section 2.10 (including whether a stockholder or beneficial owner solicited (or is part of a group which solicited) or did not so solicit, as the case may be, proxies in compliance with such stockholder's representation as required by clause (a)(ii)(D)(4) of this Section 2.10). If any proposed nomination or other business is not in compliance with this Section 2.10, then except as otherwise required by law, the chairman of the meeting shall have the power to declare that such nomination shall be disregarded or that such other business shall not be transacted. Notwithstanding the foregoing provisions of this Section 2.10, unless otherwise required by law, or otherwise determined by the Board of Directors or the chairman of the meeting, if the stockholder does not provide the information required under Section 2.9 or clauses (a)(ii)(C)(2) and (a)(ii)(D)(1)-(3) of this Section 2.10 to the Corporation within the time frames specified herein, any such nomination shall be disregarded and any such other business shall not be transacted, notwithstanding that proxies in respect of such vote may have been received by the Corporation. Notwithstanding the foregoing provisions of this Section 2.10, unless otherwise required by law, or otherwise determined by the Board of Directors or the chairman of the meeting, if the stockholder (or a qualified representative of the stockholder) does not appear at the annual or special meeting of stockholders of the Corporation to present a nomination or other business (whether pursuant to the requirements of these Bylaws or in accordance with Rule 14a-8 under the Exchange Act), such nomination shall be disregarded and such other business shall not be transacted, notwithstanding that proxies in respect of such vote may have been received by the Corporation. To be considered a qualified representative of a stockholder pursuant to the preceding sentence, a person must be a duly authorized officer, manager or partner of such stockholder or authorized by a writing executed by such stockholder (or a reliable reproduction of the writing) delivered to the Corporation prior to the making of such nomination or proposal at

such meeting (and in any event not fewer than five days before the meeting) stating that such person is authorized to act for such stockholder as proxy at the meeting of stockholders.

(ii) For purposes of this Section 2.10, the "close of business" shall mean 6:00 p.m. local time at the principal executive offices of the Corporation on any calendar day, whether or not the day is a business day, and a "public announcement" shall mean disclosure in a press release reported by the Dow Jones News Service, Associated Press or a comparable national news service or in a document publicly filed by the Corporation with the Securities and Exchange Commission pursuant to Sections 13, 14 or 15(d) of the Exchange Act. For purposes of clause (a)(ii)(D)(1) of this Section 2.10, shares shall be treated as "beneficially owned" by a person if the person beneficially owns such shares, directly or indirectly, for purposes of Section 13(d) of the Exchange Act and Regulations 13D and 13G thereunder or has or shares pursuant to any agreement, arrangement or understanding (whether or not in writing): (A) the right to acquire such shares (whether such right is exercisable immediately or only after the passage of time or the fulfillment of a condition or both); (B) the right to vote such shares, alone or in concert with others; and/or (C) investment power with respect to such shares, including the power to dispose of, or to direct the disposition of, such shares.

(iii) Nothing in this Section 2.10 shall be deemed to affect any rights of the holders of any series of Preferred Stock to elect directors pursuant to any applicable provisions of the Certificate of Incorporation (including any Preferred Stock Designation).

Section 2.11 Action by Written Consent.

(a) Except as otherwise provided for or fixed pursuant to the Certificate of Incorporation (including any Preferred Stock Designation), no action that is required or permitted to be taken by the stockholders of the Corporation may be effected by consent of stockholders in lieu of a meeting of stockholder; provided, however, that at any time when (i) Harry Stylli, (ii) Athyrium Capital Management, LP, and (iii) Andrew Midler, including for each any entities affiliated therewith, collectively, beneficially own (as defined by Securities and Exchange Commission rules promulgated under Section 13 of the Securities Exchange Act of 1934) shares representing more than 50% of the voting power of the stock outstanding and entitled to vote, any action required or permitted to be taken at any annual or special meeting of stockholders of the Corporation may be taken without a meeting, without prior notice and without a vote, if a consent or consents in writing, setting forth the action so taken, are signed by the holders of the outstanding stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted. To be effective, a written consent must be delivered to the Corporation by delivery to its registered office in the State of Delaware, its principal place of business or an officer or agent of the Corporation having custody of the book in which proceedings of meetings of stockholders are recorded. Delivery made to the Corporation's registered office shall be by hand or by certified or registered mail, return receipt requested. No written consent shall be effective to take the corporate action referred to therein unless written consents signed by a sufficient number of holders to take action are delivered to the Corporation in accordance with this Section 2.11(a) within 60 days of the first date on which a written consent is so delivered to the Corporation. Any person executing a consent may provide, whether through instruction to an agent or otherwise, that such a consent shall be effective at a

future time (including a time determined upon the happening of an event), no later than 60 days after such instruction is given or such provision is made, if evidence of such instruction or provision is provided to the Corporation. Unless otherwise provided, any such consent shall be revocable prior to its becoming effective.

(b) Prompt notice of the taking of the corporate action without a meeting by less than unanimous written consent shall be given to those stockholders who have not consented in writing and who, if the action had been taken at a meeting, would have been entitled to notice of the meeting if the record date for notice of such meeting had been the date that written consents signed by a sufficient number of stockholders to take the action were delivered to the Corporation in the manner required by this Section 2.11.

Section 2.12 Inspectors of Election. Before any meeting of stockholders, the Corporation may, and shall if required by law, appoint one or more inspectors of election to act at the meeting and make a written report thereof. Inspectors may be employees of the Corporation. The Corporation may designate one or more persons as alternate inspectors to replace any inspector who fails to act. If no inspector or alternate is able to act at a meeting of stockholders, the chairman of the meeting may, and shall if required by law, appoint one or more inspectors to act at the meeting. Each inspector, before entering upon the discharge of his or her duties, shall take and sign an oath faithfully to execute the duties of inspector with strict impartiality and according to the best of his or her ability. Inspectors need not be stockholders. No director or nominee for the office of director at an election shall be appointed as an inspector at such election.

Such inspectors shall:

(a) determine the number of shares outstanding and the voting power of each, the number of shares represented at the meeting, the existence of a quorum, and the validity of proxies and ballots;

(b) determine and retain for a reasonable period a record of the disposition of any challenges made to any determination by the inspectors;

(c) count and tabulate all votes and ballots; and

(d) certify their determination of the number of shares represented at the meeting, and their count of all votes and ballots.

Section 2.13 Meetings by Remote Communications. The Board of Directors may, in its sole discretion, determine that a meeting of stockholders shall not be held at any place, but may instead be held solely by means of remote communication in accordance with Section 211(a)(2) of the DGCL. If authorized by the Board of Directors in its sole discretion, and subject to such guidelines and procedures as the Board of Directors may adopt, stockholders and proxyholders not physically present at a meeting of stockholders may, by means of remote communication: (a) participate in a meeting of stockholders; and (b) be deemed present in person and vote at a meeting of stockholders whether such meeting is to be held at a designated place or solely by means of remote communication, provided that: (i) the Corporation shall implement reasonable measures to verify that each person deemed present and permitted to vote at the meeting by

means of remote communication is a stockholder or proxyholder; (ii) the Corporation shall implement reasonable measures to provide such stockholders and proxyholders a reasonable opportunity to participate in the meeting and to vote on matters submitted to the stockholders, including an opportunity to read or hear the proceedings of the meeting substantially concurrently with such proceedings; and (iii) if any stockholder or proxyholder votes or takes other action at the meeting by means of remote communication, a record of such vote or other action shall be maintained by the Corporation.

Section 2.14 Delivery to the Corporation. Whenever this Article II requires one or more persons (including a record or beneficial owner of stock) to deliver a document or information to the Corporation or any officer, employee or agent thereof (including any notice, request, questionnaire, revocation, representation or other document or agreement), the Corporation shall not be required to accept delivery of such document or information unless the document or information is in writing exclusively (and not in an electronic transmission) and delivered exclusively by hand (including, without limitation, overnight courier service) or by certified or registered mail, return receipt requested.

ARTICLE III
DIRECTORS

Section 3.1 Powers. Except as otherwise required by the DGCL or as provided in the Certificate of Incorporation (including any Preferred Stock Designation), the business and affairs of the Corporation shall be managed by or under the direction of the Board of Directors. In addition to the powers and authorities these Bylaws expressly confer upon it, the Board of Directors may exercise all such powers of the Corporation and do all such lawful acts and things as are not by law, the Certificate of Incorporation (including any Preferred Stock Designation) or these Bylaws required to be exercised or done by the stockholders.

Section 3.2 Number, Term of Office and Election. Except as otherwise provided for or fixed pursuant to the Certificate of Incorporation (including any Preferred Stock Designation), the Board of Directors shall consist of such number of directors as shall be determined from time to time solely by resolution adopted by the affirmative vote of a majority of the total number of directors then authorized (hereinafter referred to as the "Whole Board"). At any meeting of stockholders at which directors are to be elected, directors shall be elected by a plurality of the votes cast. Each director shall hold office until the next election of directors and until his or her successor shall have been duly elected and qualified. Directors need not be stockholders unless so required by the Certificate of Incorporation (including any Preferred Stock Designation) or these Bylaws, wherein other qualifications for directors may be prescribed.

Section 3.3 Vacancies and Newly Created Directorships. Subject to the rights of the holders of any outstanding series of Preferred Stock, and unless otherwise required by law, newly created directorships resulting from any increase in the authorized number of directors and any vacancies in the Board of Directors resulting from death, resignation, retirement, disqualification, removal from office or other cause shall be filled solely by the affirmative vote of a majority of the remaining directors then in office, even though less than a quorum, or by the sole remaining director, and any director so chosen shall hold office until the next election of

directors. No decrease in the authorized number of directors shall shorten the term of any incumbent.

Section 3.4 Resignations and Removal.

(a) Any director may resign at any time upon notice given in writing or by electronic transmission to the Board of Directors, the Chairman of the Board of Directors or the Secretary of the Corporation. Such resignation shall take effect upon delivery, unless the resignation specifies a later effective date or time or an effective date or time determined upon the happening of an event or events. Unless otherwise specified therein, the acceptance of such resignation shall not be necessary to make it effective.

(b) Any director, or the entire Board of Directors, may be removed, with or without cause, by the affirmative vote of at least a majority of the voting power of the stock outstanding and entitled to vote thereon; provided, however, that whenever the holders of any class or series are entitled to elect one or more directors by the Certificate of Incorporation (including any Preferred Stock Designation), with respect to the removal without cause of a director or directors so elected, the vote of the holders of the outstanding shares of that class or series and not the vote of the outstanding shares as a whole shall apply.

Section 3.5 Regular Meetings. Regular meetings of the Board of Directors shall be held at such place or places, within or without the State of Delaware, on such date or dates and at such time or times, as shall have been established by the Board of Directors and publicized among all directors. A notice of each regular meeting shall not be required.

Section 3.6 Special Meetings. Special meetings of the Board of Directors for any purpose or purposes may be called at any time by the Chairman of the Board of Directors, the Chief Executive Officer, the Lead Independent Director (as defined below) or a majority of the directors then in office. The person or persons authorized to call special meetings of the Board of Directors may fix the place, within or without the State of Delaware, date and time of such meetings. Notice of each such meeting shall be given to each director, if by mail, addressed to such director at his or her residence or usual place of business, at least five days before the day on which such meeting is to be held, or shall be sent to such director by electronic transmission, or be delivered personally or by telephone, in each case at least 24 hours prior to the time set for such meeting. A notice of special meeting need not state the purpose of such meeting, and, unless indicated in the notice thereof, any and all business may be transacted at a special meeting.

Section 3.7 Participation in Meetings by Conference Telephone. Members of the Board of Directors, or of any committee thereof, may participate in a meeting of such Board of Directors or committee by means of conference telephone or other communications equipment by means of which all persons participating in the meeting can hear each other, and such participation shall constitute presence in person at such meeting.

Section 3.8 Quorum and Voting. Except as otherwise required by law, the Certificate of Incorporation or these Bylaws, a majority of the Whole Board shall constitute a quorum for the transaction of business at any meeting of the Board of Directors, and the vote of a majority of

the directors present at a duly held meeting at which a quorum is present shall be the act of the Board of Directors. The chairman of the meeting or a majority of the directors present may adjourn the meeting to another time and place whether or not a quorum is present. At any adjourned meeting at which a quorum is present, any business may be transacted which might have been transacted at the meeting as originally called.

Section 3.9 Board of Directors Action by Written Consent Without a Meeting. Unless otherwise restricted by the Certificate of Incorporation or these Bylaws, any action required or permitted to be taken at any meeting of the Board of Directors, or any committee thereof, may be taken without a meeting, provided that all members of the Board of Directors or committee, as the case may be, consent in writing or by electronic transmission to such action. After an action is taken, the consent or consents relating thereto shall be filed with the minutes or proceedings of the Board of Directors or committee in the same paper or electronic form as the minutes are maintained. Any person (whether or not then a director) may provide, whether through instruction to an agent or otherwise, that a consent to action shall be effective at a future time (including a time determined upon the happening of an event), no later than 60 days after such instruction is given or such provision is made and such consent shall be deemed to have been given at such effective time so long as such person is then a director and did not revoke the consent prior to such time. Any such consent shall be revocable prior to its becoming effective.

Section 3.10 Chairman of the Board. The Chairman of the Board shall preside at meetings of directors and shall perform such other duties as the Board of Directors may from time to time determine. If the Chairman of the Board is not present at a meeting of the Board of Directors, the Lead Independent Director shall preside, and if the Lead Independent Director is not present at a meeting of the Board of Directors, another director chosen by the Board of Directors shall preside.

Section 3.11 Lead Independent Director. The Independent Directors (as defined below) may elect a lead independent director from among the Independent Directors (the "Lead Independent Director"). The Lead Independent Director, if any, will chair meetings and executive sessions of the independent directors and will assume such other duties that the Board of Directors may designate from time to time or as prescribed by these Bylaws. "Independent Director" shall have the meaning ascribed to such term under the rules of the exchange upon which shares of the Corporation's Common Stock are primarily traded.

Section 3.12 Rules and Regulations. The Board of Directors shall adopt such rules and regulations not inconsistent with the provisions of law, the Certificate of Incorporation or these Bylaws for the conduct of its meetings and management of the affairs of the Corporation as the Board of Directors shall deem proper.

Section 3.13 Fees and Compensation of Directors. Unless otherwise restricted by the Certificate of Incorporation, directors may receive such compensation, if any, for their services on the Board of Directors and its committees, and as Lead Independent Director, and such reimbursement of expenses, as may be fixed or determined by resolution of the Board of Directors.

Section 3.14 Emergency Bylaws. In the event of any emergency, disaster or catastrophe, as referred to in Section 110 of the DGCL, or other similar emergency condition, as a result of which a quorum of the Board of Directors or a standing committee of the Board of Directors cannot readily be convened for action, then the director or directors in attendance at the meeting shall constitute a quorum. Such director or directors in attendance may further take action to appoint one or more of themselves or other directors to membership on any standing or temporary committees of the Board of Directors as they shall deem necessary and appropriate.

ARTICLE IV
COMMITTEES

Section 4.1 Committees of the Board of Directors. The Board of Directors may designate one or more committees, each such committee to consist of one or more of the directors of the Corporation. The Board of Directors may designate one or more directors as alternate members of any committee to replace any absent or disqualified member at any meeting of the committee. In the absence or disqualification of a member of a committee, the member or members present at any meeting and not disqualified from voting, whether or not he, she or they constitute a quorum, may unanimously appoint another member of the Board of Directors to act at the meeting in the place of any such absent or disqualified member. Any such committee, to the extent permitted by law and provided in the resolution of the Board of Directors establishing such committee, shall have and may exercise all the powers and authority of the Board of Directors in the management of the business and affairs of the Corporation, and may authorize the seal of the Corporation to be affixed to all papers which may require it; but no such committee shall have the power or authority in reference to the following matters: (a) approving or adopting, or recommending to the stockholders, any action or matter (other than the election or removal of directors) expressly required by the DGCL to be submitted to stockholders for approval; or (b) adopting, amending or repealing any bylaw of the Corporation. All committees of the Board of Directors shall keep minutes of their meetings and shall report their proceedings to the Board of Directors when requested or required by the Board of Directors.

Section 4.2 Meetings and Action of Committees. Unless the Board of Directors provides otherwise by resolution, any committee of the Board of Directors may adopt, alter and repeal such rules and regulations not inconsistent with the provisions of law, the Certificate of Incorporation or these Bylaws for the conduct of its meetings as such committee may deem proper. A majority of the directors then serving on a committee shall constitute a quorum for the transaction of business by the committee except as otherwise required by law, the Certificate of Incorporation or these Bylaws, and except as otherwise provided in a resolution of the Board of Directors; provided, however, that in no case shall a quorum be less than one-third of the directors then serving on the committee. Unless the Certificate of Incorporation, these Bylaws or a resolution of the Board of Directors requires a greater number, the vote of a majority of the members of a committee present at a meeting at which a quorum is present shall be the act of the committee.

ARTICLE V
OFFICERS

Section 5.1 Officers. The officers of the Corporation shall consist of a Chief Executive Officer, a President, a Chief Financial Officer, a Secretary, a Controller and such other officers as the Board of Directors may from time to time determine, including a Treasurer and one or more Senior Vice Presidents or Vice Presidents, each of whom shall be elected by the Board of Directors, each to have such authority, functions or duties as set forth in these Bylaws or as determined by the Board of Directors. Each officer shall be elected by the Board of Directors and shall hold office for such term as may be prescribed by the Board of Directors and until such person's successor shall have been duly elected and qualified, or until such person's earlier death, disqualification, resignation or removal. Any number of offices may be held by the same person; provided, however, that no officer shall execute, acknowledge or verify any instrument in more than one capacity if such instrument is required by law, the Certificate of Incorporation or these Bylaws to be executed, acknowledged or verified by two or more officers. The Board of Directors may require any officer, agent or employee to give security for the faithful performance of his or her duties.

Section 5.2 Compensation. The salaries of the officers of the Corporation and the manner and time of the payment of such salaries shall be fixed and determined by the Board of Directors or by a duly authorized officer and may be altered by the Board of Directors from time to time as it deems appropriate, subject to the rights, if any, of such officers under any contract of employment.

Section 5.3 Removal, Resignation and Vacancies. Any officer of the Corporation may be removed, with or without cause, by the Board of Directors or by a duly authorized officer, without prejudice to the rights, if any, of such officer under any contract to which the Corporation is a party. Any officer may resign at any time upon notice given in writing or by electronic transmission to the Corporation, without prejudice to the rights, if any, of the Corporation under any contract to which such officer is a party. If any vacancy occurs in any office of the Corporation, the Board of Directors may elect a successor to fill such vacancy for the remainder of the unexpired term and until a successor shall have been duly elected and qualified.

Section 5.4 Chief Executive Officer. The Chief Executive Officer shall have general supervision and direction of the business and affairs of the Corporation, shall be responsible for corporate policy and strategy, and shall report directly to the Board of Directors. Unless otherwise provided in these Bylaws or determined by the Board of Directors, all other officers of the Corporation shall report directly to the Chief Executive Officer or as otherwise determined by the Chief Executive Officer. The Chief Executive Officer shall, if present and in the absence of the Chairman of the Board of Directors, preside at meetings of the stockholders.

Section 5.5 President. The person holding the office of Chief Executive Officer shall be the President of the Corporation unless the Board of Directors shall have designated another individual as the President. Subject to the supervisory powers of the Chief Executive Officer (if the President is an officer other than the Chief Executive Officer), the President shall have general responsibility for the management and control of the operations of the Corporation. The

President shall, when requested, counsel with and advise the other officers of the Corporation and shall perform such other duties as the Board of Directors or the Chief Executive Officer may from time to time determine.

Section 5.6 Chief Financial Officer. The Chief Financial Officer shall exercise all the powers and perform the duties of the office of the chief financial officer and in general have overall supervision of the financial operations of the Corporation. The Chief Financial Officer shall, when requested, counsel with and advise the other officers of the Corporation and shall perform such other duties as the Board of Directors, the Chief Executive Officer or the President may from time to time determine.

Section 5.7 Vice Presidents. Each Vice President shall have such powers and duties as shall be prescribed by his or her superior officer, the Chief Executive Officer or the President. A Vice President shall, when requested, counsel with and advise the other officers of the Corporation and shall perform such other duties as the Board of Directors, the Chief Executive Officer, the President or another duly authorized officer may from time to time determine.

Section 5.8 Treasurer. The Treasurer shall supervise and be responsible for all the funds and securities of the Corporation, the deposit of all moneys and other valuables to the credit of the Corporation in depositories of the Corporation, borrowings and compliance with the provisions of all indentures, agreements and instruments governing such borrowings to which the Corporation is a party, the disbursement of funds of the Corporation and the investment of its funds, and in general shall perform all of the duties incident to the office of the Treasurer. The Treasurer shall, when requested, counsel with and advise the other officers of the Corporation and shall perform such other duties as the Board of Directors, the Chief Executive Officer, the President or the Chief Financial Officer may from time to time determine.

Section 5.9 Controller. The Controller shall be the chief accounting officer of the Corporation. The Controller shall, when requested, counsel with and advise the other officers of the Corporation and shall perform such other duties as the Board of Directors, the Chief Executive Officer, the President, the Chief Financial Officer or the Treasurer may from time to time determine.

Section 5.10 Secretary. The powers and duties of the Secretary are: (i) to act as Secretary at all meetings of the Board of Directors, of the committees of the Board of Directors and of the stockholders and to record the proceedings of such meetings in a book or books to be kept for that purpose; (ii) to see that all notices required to be given by the Corporation are duly given and served; (iii) to act as custodian of the seal of the Corporation, if any, and affix the seal or cause it to be affixed to all certificates of stock of the Corporation and to all documents, the execution of which on behalf of the Corporation under its seal is duly authorized in accordance with the provisions of these Bylaws; (iv) to have charge of the books, records and papers of the Corporation and see that the reports, statements and other documents required by law to be kept and filed are properly kept and filed; and (v) to perform all of the duties incident to the office of Secretary. The Secretary shall, when requested, counsel with and advise the other officers of the Corporation and shall perform such other duties as the Board of Directors, the Chief Executive Officer or the President may from time to time determine.

Section 5.11 Additional Matters. The Chief Executive Officer and the Chief Financial Officer of the Corporation shall have the authority to designate employees of the Corporation to have the title of Vice President, Assistant Vice President, Assistant Treasurer or Assistant Secretary. Any employee so designated shall have the powers and duties determined by the officer making such designation. The persons upon whom such titles are conferred shall not be deemed officers of the Corporation unless elected by the Board of Directors.

Section 5.12 Checks; Drafts; Evidences of Indebtedness. From time to time, the Board of Directors shall determine the method, and designate (or authorize officers of the Corporation to designate) the person or persons who shall have authority, to sign or endorse all checks, drafts, other orders for payment of money and notes, bonds, debentures or other evidences of indebtedness that are issued in the name of or payable by the Corporation, and only the persons so authorized shall sign or endorse such instruments.

Section 5.13 Corporate Contracts and Instruments; How Executed. Except as otherwise provided in these Bylaws, the Board of Directors may determine the method, and designate (or authorize officers of the Corporation to designate) the person or persons who shall have authority to enter into any contract or execute any instrument in the name of and on behalf of the Corporation. Such authority may be general or confined to specific instances. Unless so authorized, or within the power incident to a person's office or other position with the Corporation, no person shall have any power or authority to bind the Corporation by any contract or engagement or to pledge its credit or to render it liable for any purpose or for any amount.

Section 5.14 Signature Authority. Unless otherwise determined by the Board of Directors or otherwise provided by law or these Bylaws, contracts, evidences of indebtedness and other instruments or documents of the Corporation may be executed, signed or endorsed: (i) by the Chief Executive Officer or the President; or (ii) by the Chief Financial Officer. The authority of any Vice President, Treasurer, Secretary or Controller to execute, sign or endorse contracts, evidences of indebtedness and other instruments or documents of the Corporation shall be determined by the Board of Directors.

Section 5.15 Action with Respect to Securities of Other Corporations or Entities. The Chief Executive Officer or any other officer of the Corporation authorized by the Board of Directors or the Chief Executive Officer is authorized to vote, represent, and exercise on behalf of the Corporation all rights incident to any and all shares or other equity interests of any other corporation or entity or corporations or entities, standing in the name of the Corporation. The authority herein granted may be exercised either by such person directly or by any other person authorized to do so by proxy or power of attorney duly executed by the person having such authority.

Section 5.16 Delegation. The Board of Directors may from time to time delegate the powers or duties of any officer to any other officers or agents, notwithstanding the foregoing provisions of this Article V.

ARTICLE VI
INDEMNIFICATION AND ADVANCEMENT OF EXPENSES

Section 6.1 Right to Indemnification. Each person who was or is a party or is threatened to be made a party to, or was or is otherwise involved in, any action, suit, arbitration, alternative dispute resolution mechanism, investigation, inquiry, judicial, administrative or legislative hearing, or any other threatened, pending or completed proceeding, whether brought by or in the right of the Corporation or otherwise, including any and all appeals, whether of a civil, criminal, administrative, legislative, investigative or other nature (hereinafter a "proceeding"), by reason of the fact that he or she is or was a director or an officer (which means, for purposes of this Article VI, any individual designated by the Board of Directors as an officer for purposes of Section 16 of the Exchange Act) the Corporation or while a director or officer of the Corporation is or was serving at the request of the Corporation as a director, officer, employee, agent or trustee of another corporation or of a partnership, joint venture, trust or other enterprise, including service with respect to an employee benefit plan (hereinafter an "indemnitee"), or by reason of anything done or not done by him or her in any such capacity, shall be indemnified and held harmless by the Corporation to the fullest extent authorized by the DGCL, as the same exists or may hereafter be amended, against all expense, liability and loss (including attorneys' fees, judgments, fines, ERISA excise taxes, penalties and amounts paid in settlement by or on behalf of the indemnitee) actually and reasonably incurred by such indemnitee in connection therewith, all on the terms and conditions set forth in these Bylaws; provided, however, that, except as otherwise required by law or provided in Section 6.3 with respect to suits to enforce rights under this Article VI, the Corporation shall indemnify any such indemnitee in connection with a proceeding, or part thereof, voluntarily initiated by such indemnitee (including claims and counterclaims, whether such counterclaims are asserted by: (i) such indemnitee; or (ii) the Corporation in a proceeding initiated by such indemnitee) only if such proceeding, or part thereof, was authorized or ratified by the Board of Directors or the Board of Directors otherwise determines that indemnification or advancement of expenses is appropriate.

Section 6.2 Right to Advancement of Expenses.

(a) In addition to the right to indemnification conferred in Section 6.1, an indemnitee shall, to the fullest extent permitted by law, also have the right to be paid by the Corporation the expenses (including attorneys' fees) incurred in defending any proceeding in advance of its final disposition (hereinafter an "advancement of expenses"); provided, however, that an advancement of expenses shall be made only upon delivery to the Corporation of an undertaking (hereinafter an "undertaking"), by or on behalf of such indemnitee, to repay all amounts so advanced if it shall ultimately be determined by final judicial decision of a court of competent jurisdiction from which there is no further right to appeal (hereinafter a "final adjudication") that such indemnitee is not entitled to be indemnified for such expenses under this Article VI or otherwise.

(b) Notwithstanding the foregoing Section 6.2(a), the Corporation shall not make or continue to make advancements of expenses to an indemnitee (except by reason of the fact that the indemnitee is or was a director of the Corporation, in which event this Section 6.2(b) shall not apply) if a determination is reasonably made that the facts known at the time such

determination is made demonstrate clearly and convincingly that the indemnitee acted in bad faith or in a manner that the indemnitee did not reasonably believe to be in or not opposed to the best interests of the Corporation, or, with respect to any criminal proceeding, that the indemnitee had reasonable cause to believe his or her conduct was unlawful. Such determination shall be made: (i) by the Board of Directors by a majority vote of directors who are not parties to such proceeding, whether or not such majority constitutes a quorum; (ii) by a committee of such directors designated by a majority vote of such directors, whether or not such majority constitutes a quorum; or (iii) if there are no such directors, or if such directors so direct, by independent legal counsel in a written opinion to the Board of Directors, a copy of which shall be delivered to the indemnitee.

Section 6.3 Right of Indemnitee to Bring Suit. Subject to Section 6.2(b), if a request for indemnification under Section 6.1 is not paid in full by the Corporation within 60 days, or if a request for an advancement of expenses under Section 6.2 is not paid in full by the Corporation within 20 days, after a written request has been received by the Secretary of the Corporation (and other required documentation), the indemnitee may at any time thereafter bring suit against the Corporation in a court of competent jurisdiction in the State of Delaware seeking an adjudication of entitlement to such indemnification or advancement of expenses. If successful in whole or in part in any such suit, or in a suit brought by the Corporation to recover an advancement of expenses pursuant to the terms of an undertaking, the indemnitee shall be entitled to be paid also the expense of prosecuting or defending such suit to the fullest extent permitted by law. In any suit brought by the indemnitee to enforce a right to indemnification hereunder (but not in a suit brought by the indemnitee to enforce a right to an advancement of expenses) it shall be a defense that the indemnitee has not met any applicable standard of conduct for indemnification set forth in the DGCL. Further, in any suit brought by the Corporation to recover an advancement of expenses pursuant to the terms of an undertaking, the Corporation shall be entitled to recover such expenses upon a final adjudication that the indemnitee has not met any applicable standard of conduct for indemnification set forth in the DGCL. Neither the failure of the Corporation (including its directors who are not parties to such action, a committee of such directors, independent legal counsel or its stockholders) to have made a determination prior to the commencement of such suit that indemnification of the indemnitee is proper in the circumstances because the indemnitee has met the applicable standard of conduct set forth in the DGCL, nor an actual determination by the Corporation (including its directors who are not parties to such action, a committee of such directors, independent legal counsel or its stockholders) that the indemnitee has not met such applicable standard of conduct, shall create a presumption that the indemnitee has not met the applicable standard of conduct or, in the case of such a suit brought by the indemnitee, be a defense to such suit. In any suit brought by the indemnitee to enforce a right to indemnification or to an advancement of expenses hereunder, or brought by the Corporation to recover an advancement of expenses pursuant to the terms of an undertaking, the burden of proving that the indemnitee is not entitled to be indemnified, or to such advancement of expenses, under applicable law, this Article VI or otherwise shall be on the Corporation.

Section 6.4 Non-Exclusivity of Rights. The rights to indemnification and to the advancement of expenses conferred in this Article VI shall not be exclusive of any other right which any person may have or hereafter acquire under any law, agreement, vote of stockholders or disinterested directors, provisions of a certificate of incorporation or bylaws, or otherwise.

Section 6.5 Insurance. The Corporation may maintain insurance, at its expense, to protect itself and any director, officer, employee or agent of the Corporation or another corporation, partnership, joint venture, trust or other enterprise against any expense, liability or loss, whether or not the Corporation would have the power to indemnify such person against such expense, liability or loss under the DGCL.

Section 6.6 Indemnification of Employees and Agents of the Corporation. The Corporation may, to the extent and in the manner permitted by law, and to the extent authorized from time to time, grant rights to indemnification and to the advancement of expenses to any employee or agent of the Corporation.

Section 6.7 Nature of Rights. The rights conferred upon indemnitees in this Article VI shall be contract rights and such rights shall continue as to an indemnitee who has ceased to be a director or officer and shall inure to the benefit of the indemnitee's heirs, executors and administrators. Any amendment, alteration or repeal of this Article VI that adversely affects any right of an indemnitee or its successors shall be prospective only and shall not limit or eliminate any such right with respect to any proceeding involving any occurrence or alleged occurrence of any action or omission to act that took place prior to such amendment, alteration or repeal.

Section 6.8 Settlement of Claims. Notwithstanding anything in this Article VI to the contrary, the Corporation shall not be liable to indemnify any indemnitee under this Article VI for any amounts paid in settlement of any proceeding effected without the Corporation's written consent, which consent shall not be unreasonably withheld.

Section 6.9 Subrogation. In the event of payment under this Article VI, the Corporation shall be subrogated to the extent of such payment to all of the rights of recovery of the indemnitee (excluding insurance obtained on the indemnitee's own behalf), and the indemnitee shall execute all papers required and shall do everything that may be necessary to secure such rights, including the execution of such documents necessary to enable the Corporation effectively to bring suit to enforce such rights.

Section 6.10 Severability. If any provision or provisions of this Article VI shall be held to be invalid, illegal or unenforceable as applied to any person or entity or circumstance for any reason whatsoever, then, to the fullest extent permitted by law: (a) the validity, legality and enforceability of such provision in any other circumstance and of the remaining provisions of this Article VI (including, without limitation, all portions of any paragraph of this Article VI containing any such provision held to be invalid, illegal or unenforceable, that are not by themselves invalid, illegal or unenforceable) and the application of such provision to other persons or entities or circumstances shall not in any way be affected or impaired thereby; and (b) to the fullest extent possible, the provisions of this Article VI (including, without limitation, all portions of any paragraph of this Article VI containing any such provision held to be invalid, illegal or unenforceable, that are not themselves invalid, illegal or unenforceable) shall be construed so as to give effect to the intent of the parties that the Corporation provide protection to the indemnitee to the fullest extent set forth in this Article VI.

ARTICLE VII
CAPITAL STOCK

Section 7.1 Certificates of Stock. The shares of the Corporation shall be represented by certificates; provided, however, that the Board of Directors may provide by resolution or resolutions that some or all of any or all classes or series of stock shall be uncertificated shares. Any such resolution shall not apply to shares represented by a certificate until such certificate is surrendered to the Corporation. Every holder of stock represented by certificates shall be entitled to have a certificate signed by or in the name of the Corporation by any two authorized officers of the Corporation, including, without limitation, the Chief Executive Officer, the President, the Chief Financial Officer, the Treasurer, the Controller, the Secretary, or an Assistant Treasurer or Assistant Secretary, of the Corporation certifying the number of shares owned by such holder in the Corporation. Any or all such signatures may be facsimiles. In case any officer, transfer agent or registrar who has signed or whose facsimile signature has been placed upon a certificate has ceased to be such officer, transfer agent or registrar before such certificate is issued, it may be issued by the Corporation with the same effect as if such person were such officer, transfer agent or registrar at the date of issue.

Section 7.2 Special Designation on Certificates. If the Corporation is authorized to issue more than one class of stock or more than one series of any class, then the powers, the designations, the preferences, and the relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights shall be set forth in full or summarized on the face or back of the certificate that the Corporation shall issue to represent such class or series of stock; provided, however, that, except as otherwise provided in Section 202 of the DGCL, in lieu of the foregoing requirements there may be set forth on the face or back of the certificate that the Corporation shall issue to represent such class or series of stock a statement that the Corporation will furnish without charge to each stockholder who so requests the powers, the designations, the preferences, and the relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights. Within a reasonable time after the issuance or transfer of uncertificated stock, the registered owner thereof shall be given a notice, in writing or by electronic transmission, containing the information required to be set forth or stated on certificates pursuant to this Section 7.2 or Sections 151, 156, 202(a) or 218(a) of the DGCL or with respect to this Section 7.2 and Section 151 of the DGCL a statement that the Corporation will furnish without charge to each stockholder who so requests the powers, the designations, the preferences, and the relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights. Except as otherwise expressly provided by law, the rights and obligations of the holders of uncertificated stock and the rights and obligations of the holders of certificates representing stock of the same class and series shall be identical.

Section 7.3 Transfers of Stock. Transfers of shares of stock of the Corporation shall be made only on the books of the Corporation upon authorization by the registered holder thereof or by such holder’s attorney thereunto authorized by a power of attorney duly executed and filed with the Secretary of the Corporation or a transfer agent for such stock, and if such shares are represented by a certificate, upon surrender of the certificate or certificates for such shares

properly endorsed or accompanied by a duly executed stock transfer power and the payment of any taxes thereon; provided, however, that the Corporation shall be entitled to recognize and enforce any lawful restriction on transfer. Transfers may also be made in any manner authorized by the Corporation (or its authorized transfer agent) and permitted by Section 224 of the DGCL.

Section 7.4 Lost Certificates. The Corporation may issue a new share certificate or uncertificated shares in the place of any certificate theretofore issued by it, alleged to have been lost, stolen or destroyed, and the Corporation may require the owner of the lost, stolen or destroyed certificate or the owner's legal representative to give the Corporation a bond (or other adequate security) sufficient to indemnify it against any claim that may be made against it (including any expense or liability) on account of the alleged loss, theft or destruction of any such certificate or the issuance of such new certificate or uncertificated shares. The Board of Directors may adopt such other provisions and restrictions with reference to lost certificates, not inconsistent with applicable law, as it shall in its discretion deem appropriate.

Section 7.5 Registered Stockholders. The Corporation shall be entitled to recognize the exclusive right of a person registered on its books as the owner of shares to receive dividends, and to vote as such owner, and shall not be bound to recognize any equitable or other claim to or interest in such share or shares on the part of any other person, whether or not it shall have express or other notice thereof, except as otherwise required by law.

Section 7.6 Record Date for Determining Stockholders.

(a) In order that the Corporation may determine the stockholders entitled to notice of any meeting of stockholders or any adjourned meeting, the Board of Directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the Board of Directors, and which record date shall, unless otherwise required by law, not be more than 60 nor less than 10 days before the date of such meeting. If the Board of Directors so fixes a date, such date shall also be the record date for determining the stockholders entitled to vote at such meeting unless the Board of Directors determines, at the time it fixes such record date, that a later date on or before the date of the meeting shall be the date for making such determination. If no record date is fixed by the Board of Directors, the record date for determining stockholders entitled to notice of and to vote at a meeting of stockholders shall be at the close of business on the day next preceding the day on which notice is given, or, if notice is waived, at the close of business on the day next preceding the day on which the meeting is held. A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjourned meeting; provided, however, that the Board of Directors may fix a new record date for the determination of stockholders entitled to vote at the adjourned meeting, and in such case shall also fix as the record date for stockholders entitled to notice of such adjourned meeting the same or an earlier date as that fixed for determination of stockholders entitled to vote in accordance herewith at the adjourned meeting.

(b) In order that the Corporation may determine the stockholders entitled to receive payment of any dividend or other distribution or allotment of any rights, or entitled to exercise any rights in respect of any change, conversion or exchange of stock or for the purpose of any other lawful action, the Board of Directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the Board of

Directors, and which record date shall not be more than 60 days prior to such action. If no such record date is fixed, the record date for determining stockholders for any such purpose shall be at the close of business on the day on which the Board of Directors adopts the resolution relating thereto.

(c) Unless otherwise restricted by the Certificate of Incorporation (including any Preferred Stock Designation), in order that the Corporation may determine the stockholders entitled to express consent to corporate action in writing without a meeting, the Board of Directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the Board of Directors, and which record date shall not be more than 10 days after the date upon which the resolution fixing the record date is adopted by the Board of Directors. If no record date has been fixed by the Board of Directors, the record date for determining stockholders entitled to express consent to corporate action in writing without a meeting, when no prior action of the Board of Directors is required by law, shall be the first date on which a signed written consent setting forth the action taken or proposed to be taken was delivered to the Corporation in accordance with Section 2.11. If no record date has been fixed by the Board of Directors, the record date for determining stockholders entitled to express consent to corporate action in writing without a meeting, if prior action by the Board of Directors is required by law, shall be at the close of business on the day on which the Board of Directors adopts the resolution taking such prior action.

Section 7.7 Regulations. To the extent permitted by applicable law, the Board of Directors may make such additional rules and regulations as it may deem expedient concerning the issue, transfer and registration of shares of stock of the Corporation.

Section 7.8 Waiver of Notice. Whenever notice is required to be given under any provision of the DGCL or the Certificate of Incorporation or these Bylaws, a written waiver, signed by the person entitled to notice, or a waiver by electronic transmission by the person entitled to notice, whether before or after the time stated therein, shall be deemed equivalent to notice. Attendance of a person at a meeting shall constitute a waiver of notice of such meeting, except when the person attends a meeting for the express purpose of objecting at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Neither the business to be transacted at, nor the purpose of, any regular or special meeting of the stockholders, the Board of Directors or a committee of the Board of Directors need be specified in any written waiver of notice or any waiver by electronic transmission unless so required by the Certificate of Incorporation or these Bylaws.

ARTICLE VIII
GENERAL MATTERS

Section 8.1 Fiscal Year. The fiscal year of the Corporation shall begin on the first day of January of each year and end on the last day of December of the same year, or shall extend for such other 12 consecutive months as the Board of Directors may designate.

Section 8.2 Corporate Seal. The Board of Directors may provide a suitable seal, containing the name of the Corporation, which seal shall be in the charge of the Secretary of the Corporation. If and when so directed by the Board of Directors or a committee thereof,

duplicates of the seal may be kept and used by the Treasurer or by an Assistant Secretary or Assistant Treasurer.

Section 8.3 Reliance Upon Books, Reports and Records. Each director and each member of any committee designated by the Board of Directors shall, in the performance of his or her duties, be fully protected in relying in good faith upon the books of account or other records of the Corporation and upon such information, opinions, reports or statements presented to the Corporation by any of its officers or employees, or committees of the Board of Directors so designated, or by any other person as to matters which such director or committee member reasonably believes are within such other person's professional or expert competence and who has been selected with reasonable care by or on behalf of the Corporation.

Section 8.4 Subject to Law and Certificate of Incorporation. All powers, duties and responsibilities provided for in these Bylaws, whether or not explicitly so qualified, are qualified by the Certificate of Incorporation (including any Preferred Stock Designation) and applicable law.

Section 8.5 Electronic Signatures, etc. Except as otherwise required by the Certificate of Incorporation (including as otherwise required by any Preferred Stock Designation) or these Bylaws (including, without limitation, as otherwise required by Section 2.14), any document, including, without limitation, any consent, agreement, certificate or instrument, required by the DGCL, the Certificate of Incorporation (including any Preferred Stock Designation) or these Bylaws to be executed by any officer, director, stockholder, employee or agent of the Corporation may be executed using a facsimile or other form of electronic signature to the fullest extent permitted by applicable law. All other contracts, agreements, certificates or instruments to be executed on behalf of the Corporation may be executed using a facsimile or other form of electronic signature to the fullest extent permitted by applicable law. The terms "electronic mail," "electronic mail address," "electronic signature" and "electronic transmission" as used herein shall have the meanings ascribed thereto in the DGCL.

ARTICLE IX
AMENDMENTS

Section 9.1 Amendments. In furtherance and not in limitation of the powers conferred by the laws of the State of Delaware, the Board of Directors is expressly authorized to adopt, amend or repeal these Bylaws. Except as otherwise provided in the Certificate of Incorporation (including the terms of any Preferred Stock Designation that provides for a greater or lesser vote) or these Bylaws, and in addition to any other vote required by law, the affirmative vote of at least a majority of the voting power of the stock outstanding and entitled to vote thereon, voting together as a single class, shall be required for the stockholders to adopt, amend or repeal, or adopt any provision inconsistent with, any provision of these Bylaws.

The foregoing Bylaws were adopted by the Board of Directors on , 2020.

Exhibit 5.1

GIBSON DUNN

Gibson, Dunn & Crutcher LLP

555 Mission Street
San Francisco, CA 94105-0921
Tel 415.393.8200
www.gibsondunn.com

Client: 05557-00023

June 15, 2020

Progenity, Inc.
4330 La Jolla Village Drive, Suite 200
San Diego, CA 92122

Re: *Progenity, Inc.*
Registration Statement on Form S-1 (File No. 333-238738)

Ladies and Gentlemen:

We have examined the Registration Statement on Form S-1, File No. 333-238738, as amended (the "Registration Statement"), of Progenity, Inc., a Delaware corporation (the "Company"), filed with the Securities and Exchange Commission (the "Commission") pursuant to the Securities Act of 1933, as amended (the "Securities Act"), in connection with the offering by the Company of up to 7,666,667 shares of the Company's common stock, par value $0.001 per share (the "Shares").

In arriving at the opinion expressed below, we have examined originals, or copies certified or otherwise identified to our satisfaction as being true and complete copies of the originals, of specimen Common Stock certificates and such other documents, corporate records, certificates of officers of the Company and of public officials and other instruments as we have deemed necessary or advisable to enable us to render the opinions set forth below. In our examination, we have assumed without independent investigation the genuineness of all signatures, the legal capacity and competency of all natural persons, the authenticity of all documents submitted to us as originals and the conformity to original documents of all documents submitted to us as copies.

Based upon the foregoing, and subject to the assumptions, exceptions, qualifications and limitations set forth herein, we are of the opinion that the Shares, when issued against payment therefor as set forth in the Registration Statement, will be validly issued, fully paid and non-assessable.

We consent to the filing of this opinion as an exhibit to the Registration Statement, and we further consent to the use of our name under the caption "Legal Matters" in the Registration Statement and the prospectus that forms a part thereof. In giving these consents, we do not thereby admit that we are within the category of persons whose consent is required under Section 7 of the Securities Act or the Rules and Regulations of the Commission.

Very truly yours,

/s/ Gibson, Dunn & Crutcher LLP

PROGENITY, INC.

2018 EQUITY INCENTIVE PLAN (THIRD AMENDED & RESTATED)

ADOPTED BY THE BOARD: FEBRUARY 22, 2018 (FIRST AMENDMENT MARCH 6, 2019, SECOND AMENDMENT DECEMBER 5, 2019, THIRD AMENDMENT MARCH 4, 2020)

APPROVED BY THE STOCKHOLDERS: FEBRUARY 22, 2018 (FIRST AMENDMENT MARCH 6, 2019, SECOND AMENDMENT DECEMBER 5, 2019, THIRD AMENDMENT MARCH 4, 2020)

1. GENERAL.

(a) **Successor to and Continuation of Prior Plans**. The Plan is the successor to and continuation of the Company's Amended and Restated 2012 Stock Plan, as amended, and the Company's 2015 Consultant Stock Plan (each a "**Prior Plan**"). From and after 11:59 p.m. Pacific time on the Effective Date, no additional stock awards will be granted under a Prior Plan. All stock awards granted under a Prior Plan remain subject to the terms of that Prior Plan. All Awards granted on or after 11:59 p.m. Pacific Time on the Effective Date shall be subject to the terms of the Plan.

(b) **Eligible Award Recipients**. Employees, Directors and Consultants are eligible to receive Awards.

(c) **Available Awards**. The Plan provides for the grant of the following Awards: (i) Incentive Stock Options; (ii) Nonstatutory Stock Options; (iii) Stock Appreciation Rights; (iv) Restricted Stock Awards; (v) Restricted Stock Unit Awards; (vi) Performance Stock Awards; (vii) Performance Cash Awards; and (viii) Other Stock Awards.

(d) **Purpose**. The Plan, through the granting of Awards, is intended to help the Company secure and retain the services of eligible award recipients, provide incentives for such persons to exert maximum efforts for the success of the Company and any Affiliate and provide a means by which the eligible recipients may benefit from increases in the value of the Common Stock.

2. ADMINISTRATION.

(a) **Administration by Board**. The Board will administer the Plan. The Board may delegate administration of the Plan to a Committee or Committees, as provided in Section 2(c).

(b) **Powers of Board**. The Board will have the power, subject to, and within the limitations of, the express provisions of the Plan:

(i) To determine: (A) who will be granted Awards; (B) when and how each Award will be granted; (C) what type of Award will be granted; (D) the provisions of each

Award (which need not be identical), including when a person will be permitted to exercise or otherwise receive cash or Common Stock under the Award; (E) the number of shares of Common Stock subject to, or the cash value of, an Award; and (F) the Fair Market Value applicable to a Stock Award.

(ii) To construe and interpret the Plan and Awards granted under it, and to establish, amend and revoke rules and regulations for administration of the Plan and Awards. The Board, in the exercise of these powers, may correct any defect, omission or inconsistency in the Plan or in any Award Document or in the written terms of a Performance Cash Award, in a manner and to the extent it will deem necessary or expedient to make the Plan or Award fully effective.

(iii) To settle all controversies regarding the Plan and Awards granted under it.

(iv) To accelerate, in whole or in part, or to extend, in whole or in part, the time during which an Award may be exercised or vest, or at which cash or shares of Common Stock may be issued.

(v) To suspend or terminate the Plan at any time. Except as otherwise provided in the Plan or an Award Document, suspension or termination of the Plan will not materially impair a Participant's rights under his or her then-outstanding Award without his or her written consent, except as provided in subsection (viii) below.

(vi) To amend the Plan in any respect the Board deems necessary or advisable, including, without limitation, adopting amendments relating to Incentive Stock Options and nonqualified deferred compensation under Section 409A of the Code and/or making the Plan or Awards granted under the Plan exempt from or compliant with the requirements for Incentive Stock Options or exempt from or compliant with the requirements for nonqualified deferred compensation under Section 409A of the Code, subject to the limitations, if any, of applicable law. If required by applicable law or listing requirements, and except as provided in Section 9(a) relating to Capitalization Adjustments, the Company will seek stockholder approval of any amendment of the Plan that (A) increases the number of shares of Common Stock available for issuance under the Plan, (B) materially expands the class of individuals eligible to receive Awards under the Plan, (C) materially increases the benefits accruing to Participants under the Plan, (D) materially reduces the price at which shares of Common Stock may be issued or purchased under the Plan, (E) materially extends the term of the Plan, or (F) materially expands the types of Awards available for issuance under the Plan. Except as otherwise provided in the Plan (including subsection (viii) below) or an Award Document, no amendment of the Plan will materially impair a Participant's rights under a then-outstanding Award without the Participant's written consent.

(vii) To submit any amendment to the Plan for stockholder approval, including, but not limited to, amendments to the Plan intended to satisfy the requirements of (A) Section 422 of the Code regarding "incentive stock options" or (B) Rule 16b-3 of Exchange Act or any successor rule, if applicable.

(viii) To approve forms of Award Documents for use under the Plan and to amend the terms of any one or more outstanding Awards, including, but not limited to, amendments to provide terms more favorable to the Participant than previously provided in the Award Documents for such Awards, subject to any specified limits in the Plan that are not subject to Board discretion. A Participant's rights under any Award will not be impaired by any such amendment unless the Company requests the consent of the affected Participant, and the Participant consents in writing. However, a Participant's rights will not be deemed to have been impaired by any such amendment if the Board, in its sole discretion, determines that the amendment, taken as a whole, does not materially impair the Participant's rights. In addition, subject to the limitations of applicable law, if any, the Board may amend the terms of any one or more Awards without the affected Participant's consent (A) to maintain the qualified status of the Award as an Incentive Stock Option under Section 422 of the Code, (B) to change the terms of an Incentive Stock Option, if such change results in impairment of the Award solely because it impairs the qualified status of the Award as an Incentive Stock Option under Section 422 of the Code, (C) to clarify the manner of exemption from, or to bring the Award into compliance with, Section 409A of the Code, or (D) to comply with other applicable laws or listing requirements.

(ix) Generally, to exercise such powers and to perform such acts as the Board deems necessary or expedient to promote the best interests of the Company and that are not in conflict with the provisions of the Plan and/or Award Documents.

(x) To adopt such procedures and sub-plans as are necessary or appropriate (A) to permit or facilitate participation in the Plan by persons eligible to receive Awards under the Plan who are foreign nationals or employed outside the United States or (B) allow Awards to qualify for special tax treatment in a foreign jurisdiction; provided that Board approval will not be necessary for immaterial modifications to the Plan or any Award Document that are required for compliance with the laws of a foreign jurisdiction.

(c) **Delegation to Committee**. The Board may delegate some or all of the administration of the Plan to a Committee or Committees. If administration of the Plan is delegated to a Committee, the Committee will have, in connection with the administration of the Plan, the powers theretofore possessed by the Board that have been delegated to the Committee, including the power to delegate to a subcommittee of the Committee any of the administrative powers the Committee is authorized to exercise (and references in the Plan to the Board will thereafter be to the Committee or subcommittee). Any delegation of administrative powers will be reflected in the charter of the Committee to which the delegation is made, or resolutions, not inconsistent with the provisions of the Plan, adopted from time to time by the Board or Committee (as applicable). The Committee may, at any time, abolish the subcommittee and/or revest in the Committee any powers delegated to any subcommittee. Unless otherwise provided by the Board, delegation of authority by the Board to a Committee, or to an Officer pursuant to Section 2(d), does not limit the authority of the Board, which may continue to exercise any authority so delegated and may concurrently administer the Plan with the Committee and may, at any time, revest in the Board some or all of the powers previously delegated.

(d) **Delegation to an Officer**. The Board may delegate to one (1) or more Officers the authority to do one or both of the following: (i) designate Employees who are not Officers to be recipients of Options and SARs (and, to the extent permitted by applicable law, other Stock

Awards) and, to the extent permitted by applicable law, the terms of such Awards; and (ii) determine the number of shares of Common Stock to be subject to such Stock Awards granted to such Employees; provided, however, that the Board resolutions regarding such delegation will specify the total number of shares of Common Stock that may be subject to the Stock Awards granted by such Officer and that such Officer may not grant a Stock Award to himself or herself. Any such Stock Awards will be granted on the form of Stock Award Document approved by the Committee or the Board for use in connection with such Stock Awards, unless otherwise provided for in the resolutions approving the delegation authority.

(e) **Effect of Board's Decision**. All determinations, interpretations and constructions made by the Board (or a duly authorized Committee, subcommittee or Officer exercising powers delegated by the Board under this Section 2) in good faith will not be subject to review by any Person and will be final, binding and conclusive on all Persons, unless found by a court of competent jurisdiction to have been either (i) arbitrary and capricious or (ii) made in bad faith.

3. SHARES SUBJECT TO THE PLAN.

(a) **Share Reserve**.

(i) Subject to Section 9(a) relating to Capitalization Adjustments, the aggregate maximum number of shares of Common Stock that may be issued pursuant to Stock Awards from and after the date of adoption of the Plan by the Board will be forty-seven million fifty thousand (47,050,000) shares of Common Stock (the "**Share Reserve**").[1]

(ii) The Share Reserve will automatically increase on January 1st of each year, during the term of the Plan, commencing on January 1, 2021 and ending with a final increase on January 1, 2030, in an amount equal to four percent (4%) of the total number of shares of Capital Stock outstanding on December 31st of the preceding calendar year, calculated on a fully diluted, fully converted basis. The Board may provide that there will be no January 1st increase in the Share Reserve for such year or that the increase in the Share Reserve for such year will be a smaller number of shares of Common Stock than would otherwise occur pursuant to the preceding sentence.

(iii) For clarity, the Share Reserve is a limitation on the number of shares of Common Stock that may be issued under to the Plan. As a single share may be subject to grant more than once (e.g., if a share subject to a Stock Award is forfeited, it may be made subject to grant again as provided in Section 3(b) below), the Share Reserve is not a limit on the number of Stock Awards that can be granted.

(iv) Shares may be issued under the terms of the Plan in connection with a merger or acquisition as permitted by NASDAQ Listing Rule 5635(c), NYSE Listed Company Manual Section 303A.08, AMEX Company Guide Section 711 or other applicable rule, and such issuance will not reduce the number of shares available for issuance under the Plan.

(b) **Reversion of Shares to the Share Reserve**. If a Stock Award or any portion of a Stock Award (i) expires, is canceled, forfeited or otherwise terminates without all of the shares covered by the Stock Award having been issued or (ii) is settled in cash (i.e., the Participant

[1] Note: This share reserve does not reflect the approval of a reverse split by the Company on June 9, 2020, which reduced the Share Reserve to 7,615,733 shares of Common Stock.

receives cash rather than stock), such expiration, cancelation, forfeiture, termination or settlement will not reduce (or otherwise offset) the number of shares of Common Stock that are available for issuance under the Plan. If any shares of Common Stock issued under a Stock Award are forfeited back to or repurchased or otherwise reacquired by the Company because of the failure to meet a contingency or condition required to vest such shares in the Participant, then the shares that are forfeited, repurchased or reacquired will revert to and again become available for issuance under the Plan. Any shares retained or reacquired by the Company in satisfaction of tax withholding obligations on a Stock Award, as consideration for the exercise or purchase price of a Stock Award, or with the proceeds paid by the Participant under the terms of a Stock Award, will again become available for issuance under the Plan. If the Company repurchases shares of Common Stock with stock option exercise or stock purchase proceeds, such shares shall be added to the Share Reserve. For any Stock Award with respect to which a net number of shares of Common Stock are issued, whether in satisfaction of tax withholding obligations, exercise or purchase prices or otherwise, only the net number of shares shall reduce the Share Reserve.

(c) **Incentive Stock Option Limit**. Subject to Section 9(a) relating to Capitalization Adjustments, the aggregate maximum number of shares of Common Stock that may be issued on the exercise of Incentive Stock Options will be forty-seven million fifty thousand (47,050,000) shares of Common Stock.

(d) **Non-Employee Director Limit**. The aggregate dollar value of Stock Awards (based on the grant date fair value of the Stock Awards) granted under this Plan during any calendar year to any one non-employee Director shall not exceed $750,000.

(e) **Source of Shares**. The stock issuable under the Plan will be shares of authorized but unissued or reacquired Common Stock and may include shares repurchased by the Company on the open market or otherwise or shares classified as treasury shares.

4. ELIGIBILITY.

(a) **Eligibility for Specific Stock Awards**. Incentive Stock Options may be granted only to employees of the Company or a "parent corporation" or "subsidiary corporation" thereof (as such terms are defined in Sections 424(e) and 424(f) of the Code). Stock Awards other than Incentive Stock Options may be granted to Employees, Directors and Consultants; provided, however, that Stock Awards may not be granted to Employees, Directors and Consultants who are providing Continuous Service only to any "parent" of the Company, as such term is defined in Rule 405 of the Securities Act, unless (i) the stock underlying such Stock Awards is treated as "service recipient stock" under Section 409A of the Code (for example, because the Stock Awards are granted pursuant to a corporate transaction such as a spin off transaction), or (ii) the Company, in consultation with its legal counsel, has determined that such Stock Awards are otherwise exempt from or comply with the requirements of Section 409A of the Code.

(b) **Ten Percent Stockholders**. A Ten Percent Stockholder will not be granted an Incentive Stock Option unless the exercise price of such Option is at least 110% of the Fair Market Value on the date of grant and the Option is not exercisable after the expiration of five (5) years from the date of grant.

5. PROVISIONS RELATING TO OPTIONS AND STOCK APPRECIATION RIGHTS.

Each Option or SAR will be in such form and will contain such terms and conditions as the Board deems appropriate. All Options will be separately designated Incentive Stock Options or Nonstatutory Stock Options at the time of grant, and, if certificates are issued, a separate certificate or certificates will be issued for shares of Common Stock purchased on exercise of each type of Option. If an Option is not specifically designated as an Incentive Stock Option, or if an Option is designated as an Incentive Stock Option but some portion or all of the Option fails to qualify as an Incentive Stock Option under the applicable rules, then the Option (or portion thereof) will be a Nonstatutory Stock Option. The provisions of separate Options or SARs need not be identical; provided, however, that each Award Document will conform to (through incorporation of provisions hereof by reference in the applicable Award Document or otherwise) the substance of each of the following provisions:

(a) **Term**. Subject to Section 4(b) regarding Ten Percent Stockholders, no Option or SAR will be exercisable after the expiration of 10 years from the date of its grant or such shorter period specified in the Award Document.

(b) **Exercise Price**. Subject to Section 4(b) regarding Ten Percent Stockholders, the exercise price of each Option or SAR will be not less than 100% of the Fair Market Value of the Common Stock subject to the Option or SAR on the date the Award is granted. Notwithstanding the foregoing, an Option or SAR may be granted with an exercise price lower than 100% of the Fair Market Value of the Common Stock subject to the Award if such Award is granted pursuant to an assumption of or substitution for another option or stock appreciation right pursuant to a corporate transaction and in a manner consistent with the provisions of Section 409A of the Code and, if applicable, Section 424(a) of the Code. Each SAR will be denominated in shares of Common Stock equivalents.

(c) **Purchase Price for Options**. The purchase price of shares of Common Stock acquired pursuant to the exercise of an Option may be paid, to the extent permitted by applicable law and as determined by the Board in its sole discretion, by any combination of the methods of payment set forth below. The Board will have the authority to grant Options that do not permit all of the following methods of payment (or otherwise restrict the ability to use certain methods) and to grant Options that require the consent of the Company to use a particular method of payment. The permitted methods of payment are as follows:

(i) by cash, check, bank draft or money order payable to the Company;

(ii) pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board or a successor regulation, or a similar rule in a foreign jurisdiction of domicile of a Participant, that, prior to or contemporaneously with the issuance of shares of Common Stock subject to the Option, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the aggregate exercise price to the Company from the proceeds of sale of such stock;

(iii) by delivery to the Company (either by actual delivery or attestation) of shares of Common Stock;

(iv) if an Option is a Nonstatutory Stock Option, by a "net exercise" arrangement pursuant to which the Company will reduce the number of shares of Common Stock issuable upon exercise by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price; provided, however, that the Company will accept cash or other payment from the Participant to the extent of any remaining balance of the aggregate exercise price not satisfied by such reduction in the number of whole shares to be issued. Shares of Common Stock will no longer be subject to an Option and will not be exercisable thereafter to the extent that (A) shares issuable upon exercise are used to pay the exercise price pursuant to the "net exercise," (B) shares are delivered to the Participant as a result of such exercise, and (C) shares are withheld to satisfy tax withholding obligations; or

(v) in any other form of legal consideration that the Board determines is a benefit to the Company and specified in the applicable Award Document.

(d) **Exercise and Payment of a SAR**. To exercise any outstanding SAR, the Participant must provide written notice of exercise to the Company in compliance with the provisions of the Stock Appreciation Right Award Document evidencing such SAR. The appreciation distribution payable on the exercise of a SAR will be not greater than an amount equal to the excess of (A) the aggregate Fair Market Value (on the date of the exercise of the SAR) of a number of shares of Common Stock equal to the number of Common Stock equivalents in which the Participant is vested under such SAR (with respect to which the Participant is exercising the SAR on such date), over (B) the aggregate exercise price of the number of Common Stock equivalents with respect to which the Participant is exercising the SAR on such date. The appreciation distribution may be paid in Common Stock, in cash, in any combination of the two or in any other form of consideration, as determined by the Board and contained in the Award Document evidencing such SAR.

(e) **Transferability of Options and SARs**. The Board may, in its sole discretion, impose such limitations on the transferability of Options and SARs as the Board determines. In the absence of such a determination by the Board to the contrary, the following restrictions on the transferability of Options and SARs will apply:

(i) Restrictions on Transfer. An Option or SAR will not be transferable except by will or by the laws of descent and distribution (or pursuant to subsections (ii) and (iii) below), and will be exercisable during the lifetime of the Participant only by the Participant. The Board may permit transfer of the Option or SAR in a manner that is not prohibited by applicable tax and securities laws. Except as explicitly provided herein, neither an Option nor a SAR may be transferred for consideration.

(ii) Domestic Relations Orders. Subject to the approval of the Board or a duly authorized Officer, an Option or SAR may be transferred pursuant to the terms of a domestic relations order, official marital settlement agreement or other divorce or separation instrument as permitted by U.S. Treasury Regulation 1.421-1(b)(2). If an Option is an Incentive Stock Option, such Option may be deemed to be a Nonstatutory Stock Option as a result of such transfer.

(iii) Beneficiary Designation. Subject to the approval of the Board or a duly authorized Officer, a Participant may, by delivering written notice to the Company, in a form approved by the Company (or the designated broker), designate a third party who, on the death of the Participant, will thereafter be entitled to exercise the Option or SAR and receive shares of Common Stock or other consideration resulting from such exercise. In the absence of such a designation, the executor or administrator of the Participant's estate will be entitled to exercise the Option or SAR and receive the Common Stock or other consideration resulting from such exercise. However, the Company may prohibit designation of a beneficiary at any time, including due to any conclusion by the Company that such designation would be inconsistent with the provisions of applicable laws.

(f) **Vesting Generally**. The total number of shares of Common Stock subject to an Option or SAR may vest and therefore become exercisable in periodic installments based on completion of specified periods of Continuous Service that may or may not be equal. The Option or SAR may be subject to such other terms and conditions with respect to the time or times when it may or may not be exercised (which may be based on the satisfaction of performance goals or other criteria) as the Board may deem appropriate. The vesting provisions of individual Options or SARs may vary. The provisions of this Section 5(f) are subject to any Option or SAR provisions governing the minimum number of shares of Common Stock as to which an Option or SAR may be exercised.

(g) **Termination of Continuous Service**. Except as otherwise provided in the applicable Award Document, or other agreement between the Participant and the Company or any Affiliate, if a Participant's Continuous Service terminates (other than for Cause and other than upon the Participant's death or Disability), the Participant may exercise his or her Option or SAR (to the extent that the Participant was entitled to exercise such Award as of the date of termination of Continuous Service) within the period of time ending on the earlier of (i) the date three (3) months following the termination of the Participant's Continuous Service and (ii) the expiration of the term of the Option or SAR as set forth in the applicable Award Document. If, after termination of Continuous Service, the Participant does not exercise his or her Option or SAR within the applicable time frame, the Option or SAR will terminate.

(h) **Extension of Termination Date**. Except as otherwise provided in the applicable Award Document, or other agreement between the Participant and the Company or any Affiliate, if the exercise of an Option or SAR following the termination of the Participant's Continuous Service (other than for Cause and other than upon the Participant's death or Disability) would be prohibited at any time solely because the issuance of shares of Common Stock would violate any provisions of the Securities Act, then the Option or SAR will terminate on the earlier of (i) the expiration of a total period of three (3) months (that need not be consecutive) after the termination of the Participant's Continuous Service during which the exercise of the Option or SAR would not be in violation of such provisions, and (ii) the expiration of the term of the Option or SAR as set forth in the applicable Award Document. In addition, unless otherwise provided in a Participant's applicable Award Document, or other agreement between the Participant and the Company or any Affiliate, if the sale of any Common Stock received upon exercise of an Option or SAR following the termination of the Participant's Continuous Service (other than for Cause) would violate the Company's Insider Trading Policy (the "**Insider Trading Policy**"), and the Company does not waive the potential violation of the policy or

otherwise permit the sale, or allow the Participant to surrender shares of Common Stock to the Company in satisfaction of any exercise price and/or any withholding obligations under Section 8(h), then the Option or SAR will terminate on the earlier of (i) the expiration of a period of months (that need not be consecutive) equal to the applicable post-termination exercise period after the termination of the Participant's Continuous Service during which the sale of the Common Stock received upon exercise of the Option or SAR would not be in violation of the Insider Trading Policy, or (ii) the expiration of the term of the Option or SAR as set forth in the applicable Award Document.

(i) **Disability of Participant**. Except as otherwise provided in the applicable Award Document, or other agreement between the Participant and the Company or any Affiliate, if a Participant's Continuous Service terminates as a result of the Participant's Disability, the Participant may exercise his or her Option or SAR (to the extent that the Participant was entitled to exercise such Option or SAR as of the date of termination of Continuous Service), but only within such period of time ending on the earlier of (i) the date 12 months following such termination of Continuous Service, and (ii) the expiration of the term of the Option or SAR as set forth in the applicable Award Document. If, after termination of Continuous Service, the Participant does not exercise his or her Option or SAR within the applicable time frame, the Option or SAR (as applicable) will terminate.

(j) **Death of Participant**. Except as otherwise provided in the applicable Award Document, or other agreement between the Participant and the Company or any Affiliate, if (i) a Participant's Continuous Service terminates as a result of the Participant's death, or (ii) the Participant dies within the period (if any) specified in the Plan or the applicable Award Document, or other agreement between the Participant and the Company or any Affiliate, for exercisability after the termination of the Participant's Continuous Service (for a reason other than death), then the Option or SAR may be exercised (to the extent the Participant was entitled to exercise such Option or SAR as of the date of death) by the Participant's estate, by a person who acquired the right to exercise the Option or SAR by bequest or inheritance or by a person designated to exercise the Option or SAR upon the Participant's death, but only within the period ending on the earlier of (i) the date 18 months following the date of death, and (ii) the expiration of the term of such Option or SAR as set forth in the applicable Award Document. If, after the Participant's death, the Option or SAR is not exercised within the applicable time frame, the Option or SAR will terminate.

(k) **Termination for Cause**. Except as explicitly provided otherwise in a Participant's Award Document or other individual written agreement between the Company or any Affiliate and the Participant, if a Participant's Continuous Service is terminated for Cause, the Option or SAR will terminate upon the date on which the event giving rise to the termination for Cause first occurred, and the Participant will be prohibited from exercising his or her Option or SAR from and after the date on which the event giving rise to the termination for Cause first occurred (or, if required by law, the date of termination of Continuous Service). If a Participant's Continuous Service is suspended pending an investigation of the existence of Cause, all of the Participant's rights under the Option or SAR will also be suspended during the investigation period.

(l) **Non-Exempt Employees**. If an Option or SAR is granted to an Employee who is a non-exempt employee for purposes of the U.S. Fair Labor Standards Act of 1938, as amended, the Option or SAR will not be first exercisable for any shares of Common Stock until at least 6 months following the date of grant of the Option or SAR (although the Award may vest prior to such date). Consistent with the provisions of the U.S. Worker Economic Opportunity Act, (i) if such non-exempt Employee dies or suffers a Disability, (ii) upon a Corporate Transaction in which such Option or SAR is not assumed, continued, or substituted, (iii) upon a Change in Control, or (iv) upon the non-exempt Employee's retirement (as such term may be defined in the non-exempt Employee's applicable Award Document, in another agreement between the non-exempt Employee and the Company or any Affiliate, or, if no such definition, in accordance with the Company's then current employment policies and guidelines), the vested portion of any Options and SARs may be exercised earlier than 6 months following the date of grant. The foregoing provision is intended to operate so that any income derived by a non-exempt Employee in connection with the exercise or vesting of an Option or SAR will be exempt from his or her regular rate of pay. To the extent permitted and/or required for compliance with the U.S. Worker Economic Opportunity Act to ensure that any income derived by a non-exempt Employee in connection with the exercise, vesting or issuance of any shares of Common Stock under any other Stock Award will be exempt from such employee's regular rate of pay, the provisions of this paragraph will apply to all Stock Awards and are hereby incorporated by reference into such Stock Award Documents.

6. PROVISIONS OF STOCK AWARDS OTHER THAN OPTIONS AND SARS.

(a) **Restricted Stock Awards**. Each Restricted Stock Award Document will be in such form and will contain such terms and conditions as the Board deems appropriate. To the extent consistent with the Company's bylaws, at the Board's election, shares of Common Stock may be (x) held in book entry form subject to the Company's instructions until any restrictions relating to the Restricted Stock Award lapse, or (y) evidenced by a certificate, which certificate will be held in such form and manner as determined by the Board. The terms and conditions of Restricted Stock Award Documents may change from time to time, and the terms and conditions of separate Restricted Stock Award Documents need not be identical. Each Restricted Stock Award Document will conform to (through incorporation of the provisions hereof by reference in the agreement or otherwise) the substance of each of the following provisions:

(i) Consideration. A Restricted Stock Award may be awarded in consideration for (A) cash, check, bank draft or money order payable to the Company, (B) past services to the Company or an Affiliate, or (C) any other form of legal consideration (including future services) that the Board determines is a benefit to the Company, in its sole discretion, and permissible under applicable law.

(ii) Vesting. Shares of Common Stock awarded under the Restricted Stock Award Document may be subject to forfeiture to the Company in accordance with a vesting schedule and subject to such conditions as may be determined by the Board.

(iii) Termination of Participant's Continuous Service. If a Participant's Continuous Service terminates, the Company may receive through a forfeiture condition or a repurchase right, any or all of the shares of Common Stock held by the Participant that have not

vested as of the date of termination of Continuous Service under the terms of the Restricted Stock Award Document.

(iv) Transferability. Shares of Common Stock issued pursuant to an Award, and rights to acquire shares of Common Stock under the Restricted Stock Award Document, will be transferable by the Participant only upon such terms and conditions as are set forth in the Restricted Stock Award Document, as the Board determines in its sole discretion, so long as such shares of Common Stock remains subject to the terms of the Restricted Stock Award Document.

(v) Dividends. A Restricted Stock Award Document may provide that any dividends paid on Restricted Stock will be subject to the same vesting and forfeiture restrictions as apply to the shares of Common Stock subject to the Restricted Stock Award to which they relate.

(b) **Restricted Stock Unit Awards**. Each Restricted Stock Unit Award Document will be in such form and will contain such terms and conditions as the Board deems appropriate. The terms and conditions of Restricted Stock Unit Award Documents may change from time to time, and the terms and conditions of separate Restricted Stock Unit Award Documents need not be identical. Each Restricted Stock Unit Award Document will conform to (through incorporation of the provisions hereof by reference in the Agreement or otherwise) the substance of each of the following provisions:

(i) Consideration. At the time of grant of a Restricted Stock Unit Award, the Board will determine the consideration, if any, to be paid by the Participant upon delivery of each share of Common Stock subject to the Restricted Stock Unit Award. The consideration to be paid (if any) by the Participant for each share of Common Stock subject to a Restricted Stock Unit Award may be paid in any form of legal consideration that the Board determines is a benefit to the Company, in its sole discretion, and permissible under applicable law.

(ii) Vesting. At the time of the grant of a Restricted Stock Unit Award, the Board may impose such restrictions on or conditions to the vesting of the Restricted Stock Unit Award as it, in its sole discretion, deems appropriate.

(iii) Payment. A Restricted Stock Unit Award may be settled by the delivery of shares of Common Stock, their cash equivalent, any combination thereof or in any other form of consideration, as determined by the Board and contained in the Restricted Stock Unit Award Document.

(iv) Additional Restrictions. At the time of the grant of a Restricted Stock Unit Award, the Board, as it deems appropriate, may impose such restrictions or conditions that delay the delivery of the shares of Common Stock (or their cash equivalent) subject to a Restricted Stock Unit Award to a time after the vesting of such Restricted Stock Unit Award.

(v) Dividend Equivalents. Dividend equivalents may be credited in respect of shares of Common Stock covered by a Restricted Stock Unit Award, as determined by the Board and contained in the Restricted Stock Unit Award Document. At the sole discretion of the Board, such dividend equivalents may be converted into additional shares of Common Stock covered by the Restricted Stock Unit Award in such manner as determined by the Board. The Restricted

Stock Unit Award Document may provide that any additional shares of Common Stock covered by the Restricted Stock Unit Award credited by reason of such dividend equivalents will be subject to all of the same terms and conditions of the underlying Restricted Stock Unit Award Document to which they relate.

(vi) Termination of Participant's Continuous Service. Except as otherwise provided in the applicable Restricted Stock Unit Award Document, or other agreement between the Participant and the Company or any Affiliate, such portion of the Restricted Stock Unit Award that has not vested will be forfeited upon the Participant's termination of Continuous Service.

(c) **Performance Awards.**

(i) Performance Stock Awards. A Performance Stock Award is a Stock Award that is payable (including that may be granted, vest or exercised) contingent upon the attainment during a Performance Period of the achievement of certain performance goals. A Performance Stock Award may, but need not, require the completion of a specified period of Continuous Service. The length of any Performance Period, the performance goals to be achieved during the Performance Period, and the measure of whether and to what degree such performance goals have been attained will be conclusively determined by the Committee or the Board, in its sole discretion. In addition, to the extent permitted by applicable law and the applicable Award Document, the Board may determine that a Performance Stock Award may be payable in cash.

(ii) Performance Cash Awards. A Performance Cash Award is a cash award that is granted and/or becomes payable contingent upon the attainment during a Performance Period of the achievement of certain performance goals. A Performance Cash Award may also require the completion of a specified period of Continuous Service. At the time of grant of a Performance Cash Award, the length of any Performance Period, the performance goals to be achieved during the Performance Period, and the measure of whether and to what degree such performance goals have been attained will be conclusively determined by the Committee or the Board, in its sole discretion. The Board may specify the form of payment of Performance Cash Awards, which may be cash or other property, or may provide for a Participant to have the option for his or her Performance Cash Award, or such portion thereof as the Board may specify, to be paid in whole or in part in cash or other property.

(iii) Board Discretion. The Committee or the Board, retains the discretion to reduce or eliminate the compensation or economic benefit due upon attainment of performance goals and to define the manner of calculating the performance criteria it selects to use for a Performance Period.

(d) **Other Stock Awards**. Other forms of Stock Awards valued in whole or in part by reference to, or otherwise based on, shares of Common Stock, including the appreciation in value thereof (e.g., options or stock rights with an exercise price or purchase price less than 100% of the Fair Market Value of shares of Common Stock at the time of grant) may be granted either alone or in addition to Stock Awards provided for under Section 5 and the preceding provisions of this Section 6. Subject to the provisions of the Plan, the Board will have sole and

complete authority to determine the persons to whom and the time or times at which such Other Stock Awards will be granted, the number of shares of Common Stock (or the cash equivalent thereof) to be granted pursuant to such Other Stock Awards and all other terms and conditions of such Other Stock Awards.

7. COVENANTS OF THE COMPANY.

(a) **Availability of Shares**. The Company will keep available at all times the number of shares of Common Stock reasonably required to satisfy then-outstanding Stock Awards.

(b) **Securities Law Compliance**. No Award may be exercised or shares of Common Stock issued pursuant to an Award unless (a) a registration statement under the Securities Act shall at the time of such exercise or issuance be in effect with respect to the shares issuable pursuant to the Award or (b) in the opinion of legal counsel to the Company , the shares of Common Stock issuable pursuant to the Award may be issued in accordance with the terms of an applicable exemption from the registration requirements of the Securities Act. The Company will seek to obtain from each regulatory commission or agency having jurisdiction over the Plan such authority as may be required to grant Stock Awards and to issue and sell shares of Common Stock upon exercise of the Stock Awards; provided, however, that this undertaking will not require the Company to register under the Securities Act the Plan, any Stock Award or any shares of Common Stock issued or issuable pursuant to any such Stock Award. If, after reasonable efforts and at a reasonable cost, the Company is unable to obtain from any such regulatory commission or agency the authority that counsel for the Company deems necessary for the lawful issuance and sale of shares of Common Stock under the Plan, the Company will be relieved from any liability for failure to issue and sell Common Stock upon exercise of such Stock Awards unless and until such authority is obtained. A Participant will not be eligible for the grant of an Award or the subsequent issuance of cash or shares of Common Stock pursuant to the Award if such grant or issuance would be in violation of any applicable securities law.

(c) **No Obligation to Notify or Minimize Taxes**. The Company will have no duty or obligation to any Participant to advise such holder as to the time or manner of exercising such Stock Award. Furthermore, the Company will have no duty or obligation to warn or otherwise advise such holder of a pending termination or expiration of an Award or a possible period in which the Award may not be exercised. The Company has no duty or obligation to, and does not undertake to, provide tax advice or to minimize the tax consequences of an Award to the holder of such Award.

8. MISCELLANEOUS.

(a) **Repurchase Rights**. Prior to the Initial Public Offering Date, shares of Common Stock issued under the Plan may be subject to a right of first refusal, one or more repurchase options or reacquisition rights, drag-along rights, or other conditions and restrictions as determined by the Board in its discretion at the time the Award is granted. The Company shall have the right to assign at any time any repurchase right or other right that it may have with respect to a share of Common Stock issued under the Plan, whether or not such right is then exercisable, to one or more Persons as may be selected by the Company. Upon request by the Company, each Participant shall execute any agreement evidencing such transfer restrictions

prior to the issuance of shares of Common Stock hereunder and shall promptly present to the Company any certificates representing shares of Common Stock acquired hereunder for the placement on such certificates of appropriate legends evidencing any such transfer restrictions. To the extent required by any agreement of stockholders or other agreement to which the Company is or may become subject, persons acquiring shares of Common Stock issued under the Plan will be required to enter into such agreement upon acquiring such shares of Common Stock as a condition of acquiring such shares of Common Stock.

(b) **Provision of Information**. To the extent required by applicable law, the Company will provide information to Participants regarding the Company.

(c) **Use of Proceeds from Sales of Common Stock**. Proceeds from the sale of shares of Common Stock pursuant to Stock Awards will constitute general funds of the Company.

(d) **Corporate Action Constituting Grant of Awards**. Corporate action constituting a grant by the Company of an Award to any Participant will be deemed completed as of the latest date that all necessary corporate action has occurred and all material terms of the Award (including, in the case of stock options, the exercise price thereof) are fixed, unless otherwise determined by the Board, regardless of when the documentation evidencing the Award is communicated to, or actually received or accepted by, the Participant. In the event that the corporate records (e.g., Board consents, resolutions or minutes) documenting the corporate action constituting the grant contain terms (e.g., exercise price, vesting schedule or number of shares) that are inconsistent with those in the Award Document as a result of a clerical error in the papering of the Award Document, the corporate records will control and the Participant will have no legally binding right to the incorrect term in the Award Document.

(e) **Stockholder Rights**. No Participant will be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Common Stock subject to a Stock Award unless and until (i) such Participant has satisfied all requirements for exercise of, or the issuance of shares of Common Stock under, the Stock Award pursuant to its terms, and (ii) the issuance of the shares of Common Stock subject to such Stock Award has been entered into the books and records of the Company.

(f) **No Employment or Other Service Rights**. Nothing in the Plan, any Award Document or any other instrument executed thereunder or in connection with any Award granted pursuant thereto will confer upon any Participant any right to continue to serve the Company or an Affiliate in the capacity in effect at the time the Award was granted or any other capacity or will affect the right of the Company or an Affiliate to terminate (i) the employment of an Employee for any reason or no reason, with or without notice and with or without cause, including, but not limited to, Cause, (ii) the service of a Consultant pursuant to the terms of such Consultant's agreement with the Company or an Affiliate, or (iii) the service of a Director pursuant to the organizational documents of the Company or an Affiliate (including the certificate of incorporation and bylaws), and any applicable provisions of the corporate law of the state in which the Company or the Affiliate is incorporated, as the case may be.

(g) **Change in Time Commitment**. If after the date of grant of any Award to the Participant, the Participant's regular level of time commitment in the performance of his or her services for the Company and any Affiliates is reduced (for example, and without limitation, if the Participant is an Employee of the Company and the Employee has a change in status from a full-time Employee to a part-time Employee or takes an extended leave of absence), or the Participant's role or primary responsibilities are changed to a level that, in the good faith determination by the Board does not justify the Participant's unvested Awards, the Board has the unilateral right, which right shall be exercised in its sole discretion, to (i) make a corresponding reduction in the number of shares or cash amount subject to any portion of such Award that is scheduled to vest or become payable after the date of such change in time commitment, and (ii) in lieu of or in combination with such a reduction, extend the vesting or payment schedule applicable to such Award. In the event of any such reduction, the Participant will have no right with respect to any portion of the Award that is so reduced or extended.

(h) **Incentive Stock Option Limitations**. To the extent that the aggregate Fair Market Value (determined at the time of grant) of Common Stock with respect to which Incentive Stock Options are exercisable for the first time by any Optionholder during any calendar year (under all plans of the Company and any Affiliates) exceeds $100,000 (or such other limit established in the Code) or otherwise does not comply with the rules governing Incentive Stock Options, the Options or portions thereof that exceed such limit (according to the order in which they were granted) or otherwise do not comply with such rules will be treated as Nonstatutory Stock Options, notwithstanding any contrary provision of the applicable Option Agreement(s).

(i) **Investment Assurances**. The Company may require a Participant, as a condition of exercising or acquiring shares of Common Stock under any Stock Award, (i) to give written assurances satisfactory to the Company (A) as to the Participant's knowledge and experience in financial and business matters and/or to employ a purchaser representative reasonably satisfactory to the Company who is knowledgeable and experienced in financial and business matters and (B) that he or she is capable of evaluating, alone or together with the purchaser representative, the merits and risks of exercising the Stock Award, and (ii) to give written assurances satisfactory to the Company stating that the Participant is acquiring the shares of Common Stock subject to the Stock Award for the Participant's own account and not with any present intention of selling or otherwise distributing the shares of Common Stock. The foregoing requirements, and any assurances given pursuant to such requirements, will be inoperative if (x) the issuance of the shares of Common Stock upon the exercise of a Stock Award or acquisition of shares of Common Stock under the Stock Award has been registered under a then currently effective registration statement under the Securities Act, or (y) as to any particular requirement, a determination is made by counsel for the Company that such requirement need not be met in the circumstances under the then applicable securities laws. The Company may, upon advice of counsel to the Company, place legends on stock certificates issued under the Plan as such counsel deems necessary or appropriate in order to comply with applicable securities laws, including, but not limited to, legends restricting the transfer of the shares of Common Stock.

(j) **Withholding Obligations**. Unless prohibited by the terms of an Award Document, the Company may, in its sole discretion, satisfy any U.S. federal, state, local, foreign or other tax withholding obligation relating to an Award by any of the following means or by a

combination of such means: (i) causing the Participant to tender a cash payment; (ii) withholding shares of Common Stock from the shares of Common Stock issued or otherwise issuable to the Participant in connection with the Award (only up to the amount permitted that will not cause an adverse accounting consequence or cost); (iii) withholding cash from an Award settled in cash; (iv) withholding payment from any amounts otherwise payable to the Participant, including proceeds from the sale of shares of Common Stock issued pursuant to a Stock Award; or (v) by such other method as may be set forth in the Award Document.

(k) **Electronic Delivery**. Any reference herein to a "written" agreement or document will include any agreement or document delivered electronically, filed publicly at www.sec.gov (or any successor website thereto), or posted on the Company's intranet (or other shared electronic medium controlled by the Company to which the Participant has access).

(l) **Deferrals**. To the extent permitted by applicable law, the Board, in its sole discretion, may determine that the delivery of shares of Common Stock or the payment of cash, upon the exercise, vesting or settlement of all or a portion of any Award may be deferred and may establish programs and procedures for deferral elections to be made by Participants. Deferrals by Participants will be made in accordance with Section 409A of the Code (to the extent applicable to a Participant). Consistent with Section 409A of the Code, the Board may provide for distributions while a Participant is still an employee or otherwise providing services to the Company. The Board is authorized to make deferrals of Awards and determine when, and in what annual percentages, Participants may receive payments, including lump sum payments, following the Participant's termination of Continuous Service, and implement such other terms and conditions consistent with the provisions of the Plan and in accordance with applicable law.

(m) **Compliance with Section 409A**. Unless otherwise expressly provided for in an Award Document, or other agreement between the Participant and the Company or any Affiliate, the Plan and Award Documents will be interpreted to the greatest extent possible in a manner that makes the Plan and the Awards granted hereunder exempt from Section 409A of the Code, and, to the extent not so exempt, in compliance with Section 409A of the Code. If the Board determines that any Award granted hereunder is not exempt from and is therefore subject to Section 409A of the Code, the Award Document evidencing such Award will incorporate the terms and conditions necessary to avoid the consequences specified in Section 409A(a)(1) of the Code, and to the extent an Award Document is silent on terms necessary for compliance, such terms are hereby incorporated by reference into the Award Document. Notwithstanding anything to the contrary in the Plan (and unless the Award Document specifically provides otherwise), if the shares of Common Stock are publicly traded, and if a Participant holding an Award that constitutes "deferred compensation" under Section 409A of the Code is a "specified employee" for purposes of Section 409A of the Code, no distribution or payment of any amount that is due because of a "separation from service" (as defined in Section 409A of the Code without regard to alternative definitions thereunder) will be issued or paid before the date that is six (6) months following the date of such Participant's "separation from service" or, if earlier, the date of the Participant's death, unless such distribution or payment can be made in a manner that complies with Section 409A of the Code, and any amounts so deferred will be paid in a lump sum on the day after such six (6) month period elapses, with the balance paid thereafter on the original schedule.

(n) **Clawback/Recovery**. All Awards granted under the Plan will be subject to recoupment in accordance with any clawback policy that the Company is required to adopt pursuant to the listing standards of any national securities exchange or association on which the Company's securities are listed or as is otherwise required by the Dodd-Frank Wall Street Reform and Consumer Protection Act or other applicable law. In addition, the Board may impose such other clawback, recovery or recoupment provisions in an Award Document as the Board determines necessary or appropriate, including, but not limited to, a reacquisition right in respect of previously acquired shares of Common Stock or other cash or property upon the occurrence of Cause. No recovery of compensation under such a clawback policy will be an event giving rise to a right to resign for "good reason" or "constructive termination" (or similar term) under any agreement with the Company or an Affiliate.

9. ADJUSTMENTS UPON CHANGES IN COMMON STOCK; OTHER CORPORATE EVENTS.

(a) **Capitalization Adjustments**. In the event of a Capitalization Adjustment, the Board will appropriately and proportionately adjust: (i) the class(es) and maximum number of securities subject to the Plan pursuant to Section 3(a); (ii) the class(es) and maximum number of securities that may be issued pursuant to the exercise of Incentive Stock Options pursuant to Section 3(c); and (iii) the class(es) and number of securities or other property and value (including price per share of stock) subject to outstanding Stock Awards. The Board will make such adjustments, and its determination will be final, binding and conclusive.

(b) **Dissolution or Liquidation**. Except as otherwise provided in the Stock Award Document, or other agreement between the Participant and the Company or any Affiliate, in the event of a dissolution or liquidation of the Company, all outstanding Stock Awards (other than Stock Awards consisting of vested and outstanding shares of Common Stock not subject to a forfeiture condition or the Company's right of repurchase) will terminate immediately prior to the completion of such dissolution or liquidation, and the shares of Common Stock subject to the Company's repurchase rights or subject to a forfeiture condition may be repurchased or reacquired by the Company notwithstanding the fact that the holder of such Stock Award is providing Continuous Service; provided, however, that the Board may, in its sole discretion, cause some or all Stock Awards to become fully vested, exercisable and/or no longer subject to repurchase or forfeiture (to the extent such Stock Awards have not previously expired or terminated) before the dissolution or liquidation is completed but contingent on its completion.

(c) **Corporate Transaction**. The following provisions will apply to Stock Awards in the event of a Corporate Transaction unless otherwise provided in the instrument evidencing the Stock Award or any other written agreement between the Company or any Affiliate and the Participant or unless otherwise expressly provided by the Board at the time of grant of a Stock Award. In the event of a Corporate Transaction, then, notwithstanding any other provision of the Plan, the Board will take one or more of the following actions with respect to each outstanding Stock Award, contingent upon the closing or completion of the Corporate Transaction:

(i) arrange for the surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company) to assume or continue the Stock Award or to substitute a similar stock award for the Stock Award (including, but not limited to, an award to

acquire the same consideration per share paid to the stockholders of the Company pursuant to the Corporate Transaction);

(ii) arrange for the assignment of any reacquisition or repurchase rights held by the Company in respect of shares of Common Stock issued pursuant to the Stock Award to the surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company);

(iii) accelerate the vesting, in whole or in part, of the Stock Award (and, if applicable, the time at which the Stock Award may be exercised) to a date prior to the effective time of such Corporate Transaction as the Board will determine, with such Stock Award terminating if not exercised (if applicable) at or prior to the effective time of the Corporate Transaction, and with such accelerated vesting (and if applicable, such exercise) reversed if the Corporate Transaction does not become effective;

(iv) arrange for the lapse, in whole or in part, of any reacquisition or repurchase rights held by the Company with respect to the Stock Award;

(v) cancel or arrange for the cancellation of the Stock Award, to the extent not vested or not exercised prior to the effective time of the Corporate Transaction, in exchange for such cash consideration, if any, as the Board, in its reasonable determination, may consider appropriate as an approximation of the value of the canceled Stock Award, taking into account the value of the shares of Common Stock subject to the canceled Stock Award, the possibility that the Stock Award might not otherwise vest in full, and such other factors as the Board deems relevant;

(vi) cancel or arrange for the cancellation of the Stock Award, to the extent not vested or not exercised prior to the effective time of the Corporate Transaction, in exchange for a payment, in such form as may be determined by the Board equal to the excess, if any, of (A) the value in the Corporate Transaction of the property the Participant would have received upon the exercise of the Stock Award immediately prior to the effective time of the Corporate Transaction, over (B) any exercise price payable by such holder in connection with such exercise; and

(vii) continuation of the Stock Award.

The Board need not take the same action or actions with respect to all Stock Awards or portions thereof or with respect to all Participants. The Board may take different actions with respect to the vested and unvested portions of a Stock Award.

In the absence of any affirmative determination by the Board at the time of a Corporate Transaction, each outstanding Stock Award will be assumed or an equivalent Stock Award will be substituted by such successor corporation or a parent or subsidiary of such successor corporation (the "**Successor Corporation**"), unless the Successor Corporation does not agree to assume the Stock Award or to substitute an equivalent Stock Award, in which case the vesting of such Stock Award will accelerate in its entirety (along with, if applicable, the time at which the Stock Award may be exercised) to a date prior to the effective time of such Corporate Transaction as the Board will determine (or, if the Board will not determine such a date, to the

date that is 5 days prior to the effective date of the Corporate Transaction), with such Stock Award terminating if not exercised (if applicable) at or prior to the effective time of the Corporate Transaction, and with such exercise reversed if the Corporate Transaction does not become effective.

(d) **Change in Control**. A Stock Award may be subject to additional acceleration of vesting and exercisability upon or after a Change in Control as may be provided in the Stock Award Document for such Stock Award or as may be provided in any other written agreement between the Company or any Affiliate and the Participant, but in the absence of such provision, no such acceleration will occur.

10. TERMINATION OR SUSPENSION OF THE PLAN.

The Board may suspend or terminate the Plan at any time. No Awards may be granted after the tenth (10th) anniversary of the earlier of (i) the date the Board adopts the Plan, or (ii) the date the stockholders approve the Plan. No Awards may be granted under the Plan while the Plan is suspended or after it is terminated.

11. EFFECTIVE DATE OF PLAN

The Plan came into existence on the Effective Date and no Award shall be granted hereunder prior to such date.

12. CHOICE OF LAW.

The laws of the State of Delaware will govern all questions concerning the construction, validity and interpretation of the Plan, without regard to that state's conflict of laws rules.

13. DEFINITIONS. As used in the Plan, the following definitions will apply to the capitalized terms indicated below:

(a) "**Affiliate**" means, at the time of determination, any direct or indirect "parent" or "subsidiary" of the Company, as such terms are defined in Rule 405 of the Securities Act. The Board will have the authority to determine the time or times at which "parent" or "subsidiary" status is determined within the foregoing definition.

(b) "**Award**" means a Stock Award or a Performance Cash Award.

(c) "**Award Document**" means a written agreement between the Company and a Participant, or a written notice issued by the Company to a Participant, evidencing the terms and conditions of an Award.

(d) "**Board**" means the Board of Directors of the Company.

(e) "**Capital Stock**" means each and every class and series of common stock and preferred stock of the Company, regardless of the number of votes per share.

(f) "**Capitalization Adjustment**" means any change that is made in, or other events that occur with respect to, shares of Common Stock subject to the Plan or subject to any Stock Award after the Effective Date without the receipt of consideration by the Company through merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, stock split, reverse stock split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or other similar equity restructuring transaction, as that term is used in Financial Accounting Standards Board Accounting Standards Codification Topic 718 (or any successor thereto). Notwithstanding the foregoing, the conversion of any convertible securities of the Company will not be treated as a Capitalization Adjustment.

(g) "**Cause**" will have the meaning ascribed to such term in any written agreement between the Participant and the Company or any Affiliate defining such term and, in the absence of such agreement, such term means, with respect to a Participant, the occurrence of any of the following events: (i) Participant's failure substantially to perform his or her duties and responsibilities to the Company or any Affiliate or violation of a policy of the Company or any Affiliate; (ii) Participant's commission of any act of fraud, embezzlement, dishonesty or any other misconduct that has caused or is reasonably expected to result in injury to the Company or any Affiliate; (iii) unauthorized use or disclosure by Participant of any proprietary information or trade secrets of the Company or any other Person to whom the Participant owes an obligation of nondisclosure as a result of his or her relationship with the Company or any Affiliate; or (iv) Participant's breach of any of his or her obligations under any written agreement or covenant with the Company or any Affiliate. The determination as to whether a Participant is being terminated for Cause will be made in good faith by the Company and will be final and binding on the Participant. Any determination by the Company that the Continuous Service of a Participant was terminated with or without Cause for the purposes of outstanding Awards held by such Participant will have no effect upon any determination of the rights or obligations of the Company, any Affiliate or such Participant for any other purpose.

(h) "**Change in Control**" means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) any Exchange Act Person becomes the Owner, directly or indirectly, of securities of the Company representing more than 50% of the combined voting power of the Company's then outstanding securities. Notwithstanding the foregoing, a Change in Control will not be deemed to occur (A) on account of the acquisition of securities of the Company directly from the Company, (B) on account of the acquisition of securities of the Company by an investor, any affiliate thereof or any other Exchange Act Person that acquires the Company's securities in a transaction or series of related transactions the primary purpose of which is to obtain financing for the Company through the issuance of equity securities, or (C) solely because the level of Ownership held by any Exchange Act Person (the "**Subject Person**") exceeds the designated percentage threshold of the outstanding voting securities as a result of a repurchase or other acquisition of voting securities by the Company reducing the number of shares outstanding, provided that if a Change in Control would occur (but for the operation of this sentence) as a result of the acquisition of voting securities by the Company, and after such share acquisition, the Subject Person becomes the Owner of any additional voting securities that, assuming the repurchase or other acquisition had not occurred, increases the percentage of the then outstanding

voting securities Owned by the Subject Person over the designated percentage threshold, then a Change in Control will be deemed to occur;

(ii) there is consummated a merger, consolidation or similar transaction involving (directly or indirectly) the Company and, immediately after the consummation of such merger, consolidation or similar transaction, the stockholders of the Company immediately prior thereto do not Own, directly or indirectly, either (A) outstanding voting securities representing more than 50% of the combined outstanding voting power of the surviving Entity in such merger, consolidation or similar transaction or (B) more than 50% of the combined outstanding voting power of the parent of the surviving Entity in such merger, consolidation or similar transaction, in each case in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such transaction;

(iii) there is consummated a sale, lease, exclusive license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries, other than a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries to an Entity, more than 50% of the combined voting power of the voting securities of which are Owned by stockholders of the Company in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such sale, lease, license or other disposition; or

(iv) individuals who, on the date on which the Board adopts the Plan, are members of the Board (the "**Incumbent Board**") cease for any reason to constitute at least a majority of the members of the Board; provided, however, that if the appointment or election (or nomination for election) of any new Board member was approved or recommended by a majority vote of the members of the Incumbent Board then still in office, such new member will, for purposes of the Plan, be considered as a member of the Incumbent Board.

Notwithstanding the foregoing definition or any other provision of the Plan, (A) the term Change in Control will not include a sale of assets, merger or other transaction effected exclusively for the purpose of changing the domicile of the Company, and (B) the definition of Change in Control (or any analogous term) in an individual written agreement between the Company or any Affiliate and the Participant will supersede the foregoing definition with respect to Awards subject to such agreement; provided, however, that if no definition of Change in Control or any analogous term is set forth in such an individual written agreement, the foregoing definition will apply.

If required for compliance with Section 409A of the Code, in no event will a Change in Control be deemed to have occurred if such transaction is not also a "change in the ownership or effective control of" the Company or "a change in the ownership of a substantial portion of the assets of" the Company as determined under U.S. Treasury Regulation Section 1.409A-3(i)(5) (without regard to any alternative definition thereunder). The Board may, in its sole discretion and without a Participant's consent, amend the definition of "Change in Control" to conform to the definition of "Change in Control" under Section 409A of the Code, and the regulations thereunder.

(i) "**Code**" means the U.S. Internal Revenue Code of 1986, as amended, including any applicable regulations and guidance thereunder.

(j) "**Committee**" means a committee of one (1) or more Directors to whom authority has been delegated by the Board in accordance with Section 2(c).

(k) "**Common Stock**" means the common stock of the Company.

(l) "**Company**" means Progenity, Inc., a Delaware corporation.

(m) "**Consultant**" means any person, including an advisor, who is (i) engaged by the Company or an Affiliate to render consulting or advisory services and is compensated for such services, or (ii) serving as a member of the board of directors of an Affiliate and is compensated for such services. However, service solely as a Director, or payment of a fee for such service, will not cause a Director to be considered a "Consultant" for purposes of the Plan. Notwithstanding the foregoing, from and after the Initial Public Offering Date, a person is treated as a Consultant under the Plan only if a Form Registration Statement on Form S-8 or a successor form under the Securities Act is available to register either the offer or the sale of the Company's securities to such person.

(n) "**Continuous Service**" means that the Participant's service with the Company or an Affiliate, whether as an Employee, Director or Consultant, is not interrupted or terminated. A change in the capacity in which the Participant renders service to the Company or an Affiliate as an Employee, Consultant or Director or a change in the Entity for which the Participant renders such service, provided that there is no interruption or termination of the Participant's service with the Company or an Affiliate, will not terminate a Participant's Continuous Service. For example, a change in status from an Employee of the Company to a Consultant of an Affiliate or to a Director will not constitute an interruption of Continuous Service. If the Entity for which a Participant is rendering services ceases to qualify as an Affiliate, as determined by the Board in its sole discretion, such Participant's Continuous Service will be considered to have terminated on the date such Entity ceases to qualify as an Affiliate. To the extent permitted by law, the Board or the chief executive officer of the Company, in that party's sole discretion, may determine whether Continuous Service will be considered interrupted in the case of (i) any leave of absence approved by the Board or chief executive officer, including sick leave, military leave or any other personal leave, or (ii) transfers between the Company, an Affiliate, or their successors. In addition, if required for exemption from or compliance with Section 409A of the Code, the determination of whether there has been a termination of Continuous Service will be made, and such term will be construed, in a manner that is consistent with the definition of "separation from service" as defined under U.S. Treasury Regulation Section 1.409A-1(h) (without regard to any alternative definition thereunder). A leave of absence will be treated as Continuous Service for purposes of vesting in a Stock Award only to such extent as may be provided in the applicable Award Document, the Company's leave of absence policy, in the written terms of any leave of absence agreement or policy applicable to the Participant, or as otherwise required by law.

(o) "**Corporate Transaction**" means the consummation, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) a sale or other disposition of all or substantially all, as determined by the Board in its sole discretion, of the consolidated assets of the Company and its Subsidiaries;

(ii) a sale or other disposition of at least 90% of the outstanding securities of the Company;

(iii) a merger, consolidation or similar transaction following which the Company is not the surviving corporation; or

(iv) a merger, consolidation or similar transaction following which the Company is the surviving corporation but the shares of Common Stock outstanding immediately preceding the merger, consolidation or similar transaction are converted or exchanged by virtue of the merger, consolidation or similar transaction into other property, whether in the form of securities, cash or otherwise.

To the extent required for compliance with Section 409A of the Code, in no event will an event be deemed a Corporate Transaction if such transaction is not also a "change in the ownership or effective control of" the Company or "a change in the ownership of a substantial portion of the assets of" the Company as determined under U.S. Treasury Regulation Section 1.409A-3(i)(5) (without regard to any alternative definition thereunder).

(p) "**Director**" means a member of the Board.

(q) "**Disability**" means, with respect to a Participant, the inability of such Participant to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment that can be expected to result in death or that has lasted or can be expected to last for a continuous period of not less than 12 months as provided in Sections 22(e)(3) and 409A(a)(2)(C)(i) of the Code, and will be determined by the Board on the basis of such medical evidence as the Board deems warranted under the circumstances.

(r) "**Effective Date**" means February 22, 2018.

(s) "**Employee**" means any person providing services as an employee of the Company or an Affiliate. However, service solely as a Director, or payment of a fee for such services, will not cause a Director to be considered an "Employee" for purposes of the Plan.

(t) "**Entity**" means a corporation, partnership, limited liability company or other entity.

(u) "**Exchange Act**" means the U.S. Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

(v) "**Exchange Act Person**" means any natural person, Entity or "group" (within the meaning of Section 13(d) or 14(d) of the Exchange Act), except that "Exchange Act Person" will not include (i) the Company or any Subsidiary of the Company, (ii) any employee benefit plan of the Company or any Subsidiary of the Company or any trustee or other fiduciary holding securities under an employee benefit plan of the Company or any Subsidiary of the Company, (iii) an underwriter temporarily holding securities pursuant to a registered public offering of such securities, (iv) an Entity Owned, directly or indirectly, by the stockholders of the Company in

substantially the same proportions as their Ownership of stock of the Company, (v) any natural person, Entity or "group" (within the meaning of Section 13(d) or 14(d) of the Exchange Act) that, as of the date of adoption by the Board of the Plan, is the Owner, directly or indirectly, of securities of the Company representing more than 50% of the combined voting power of the Company's then outstanding securities, (vi) Harry Stylli, or any trust or Entity wholly owned by him or as to which he is the trustee and beneficiary, or (vii) Athyrium Capital Management, LP, or any fund managed by Athyrium Capital Management, LP.

(w) "**Fair Market Value**" means, as of any date, the value of a share of Common Stock determined as follows:

(i) If the Common Stock is listed on any established stock exchange or traded on any established market, the Fair Market Value of a share of Common Stock as of any date of determination will be, unless otherwise determined by the Board, the closing sales price for such stock as quoted on such exchange or market (or the exchange or market with the greatest volume of trading in the Common Stock) on the date of determination, as reported in a source the Board deems reliable.

(ii) Unless otherwise provided by the Board, if there is no closing sales price for the Common Stock on the date of determination, then the Fair Market Value will be the closing selling price on the last preceding date for which such quotation exists.

(iii) In the absence of such markets for the Common Stock, the Fair Market Value will be determined by the Board in good faith and in a manner that complies with Sections 409A and 422 of the Code.

The Board shall make a good faith determination of the Fair Market Value of any securities or derivative securities (including options) of the Company. For any options granted after the Initial Public Offering Date, the Board shall base the Fair Market Value of any options on the "fair value" determined for financial accounting purposes under Accounting Standards Codification 718.

(x) "**Incentive Stock Option**" means an option granted pursuant to Section 5 of the Plan that is intended to be, and that qualifies as, an "incentive stock option" within the meaning of Section 422 of the Code.

(y) "**Initial Public Offering**" means the initial underwritten public offering of shares of Common Stock pursuant to a registration statement filed and declared effective pursuant to the Securities Act.

(z) "**Initial Public Offering Date**" means the date of the underwriting agreement between the Company and the underwriters(s) managing the Initial Public Offering, pursuant to which shares of Common Stock are priced for the Initial Public Offering; provided that the Initial Public Offering contemplated by such underwriting agreement occurs.

(aa) "**Nonstatutory Stock Option**" means any option granted pursuant to Section 5 of the Plan that does not qualify as an Incentive Stock Option.

(bb) "**Officer**" means a person who is an officer of the Company within the meaning of Section 16 of the Exchange Act (whether or not shares of Common Stock are publicly traded).

(cc) "**Option**" means an Incentive Stock Option or a Nonstatutory Stock Option to purchase shares of Common Stock granted pursuant to the Plan.

(dd) "**Option Agreement**" means an Award Document evidencing the terms and conditions of an Option grant. Each Option Agreement will be subject to the terms and conditions of the Plan.

(ee) "**Optionholder**" means a person to whom an Option is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Option.

(ff) "**Other Stock Award**" means an award based in whole or in part by reference to shares of Common Stock that is granted pursuant to the terms and conditions of Section 6(d).

(gg) "**Other Stock Award Document**" means an Award Document evidencing the terms and conditions of an Other Stock Award grant. Each Other Stock Award Document will be subject to the terms and conditions of the Plan.

(hh) "**Own**," "**Owned**," "**Owner**," "**Ownership**", a Person will be deemed to "Own," to have "Owned," to be the "Owner" of, or to have acquired "Ownership" of securities if such Person, directly or indirectly, through any contract, arrangement, understanding, relationship or otherwise, has or shares voting power, which includes the power to vote or to direct the voting, with respect to such securities.

(ii) "**Participant**" means a person to whom an Award is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Stock Award.

(jj) "**Performance Cash Award**" means an award of cash granted pursuant to the terms and conditions of Section 6(c)(ii).

(kk) "**Performance Period**" means the period of time selected by the Board over which the attainment of one or more performance goals will be measured for the purpose of determining a Participant's right to and the payment of a Stock Award or a Performance Cash Award. Performance Periods may be of varying and overlapping duration, at the sole discretion of the Board.

(ll) "**Performance Stock Award**" means a Stock Award granted under the terms and conditions of Section 6(c)(i).

(mm) "**Person**" means a "person" as defined in Section 3(a)(9) of the Exchange Act and used in Section 13(d) and 14(d) thereof, including a "group" as defined in Section 13(d) thereof.

(nn) "**Plan**" means this 2018 Equity Incentive Plan of Progenity, Inc. (Third Amended and Restated).

(oo) "**Restricted Stock Award**" means an award of shares of Common Stock that is granted pursuant to the terms and conditions of Section 6(a).

(pp) "**Restricted Stock Award Document**" means an Award Document evidencing the terms and conditions of a Restricted Stock Award grant. Each Restricted Stock Award Document will be subject to the terms and conditions of the Plan.

(qq) "**Restricted Stock Unit Award**" means a right to receive shares of Common Stock that is granted pursuant to the terms and conditions of Section 6(b).

(rr) "**Restricted Stock Unit Award Document**" means an Award Document evidencing the terms and conditions of a Restricted Stock Unit Award grant. Each Restricted Stock Unit Award Document will be subject to the terms and conditions of the Plan.

(ss) "**Securities Act**" means the U.S. Securities Act of 1933, as amended.

(tt) "**Stock Appreciation Right**" or "**SAR**" means a right to receive the appreciation on Common Stock that is granted pursuant to the terms and conditions of Section 5.

(uu) "**Stock Appreciation Right Award Document**" means an Award Document evidencing the terms and conditions of a Stock Appreciation Right grant. Each Stock Appreciation Right Award Document will be subject to the terms and conditions of the Plan.

(vv) "**Stock Award**" means any right to receive shares of Common Stock granted under the Plan, including an Incentive Stock Option, a Nonstatutory Stock Option, a Restricted Stock Award, a Restricted Stock Unit Award, a Stock Appreciation Right, a Performance Stock Award, or any Other Stock Award. The right to receive cash under the terms of a Stock Award that is actually settled in shares of Common Stock shall not disqualify such award from satisfying the definition of a "Stock Award".

(ww) "**Stock Award Document**" means an Award Document evidencing the terms and conditions of a Stock Award grant. Each Stock Award Document will be subject to the terms and conditions of the Plan.

(xx) "**Subsidiary**" means, with respect to the Company, (i) any corporation of which more than 50% of the outstanding capital stock having ordinary voting power to elect a majority of the board of directors of such corporation (irrespective of whether, at the time, stock of any other class or classes of such corporation will have or might have voting power by reason of the happening of any contingency) is at the time, directly or indirectly, Owned by the Company, and (ii) any partnership, limited liability company or other Entity in which the Company has a direct or indirect interest (whether in the form of voting or participation in profits or capital contribution) of more than 50%.

(yy) "**Ten Percent Stockholder**" means a Person who Owns (or is deemed to Own pursuant to Section 424(d) of the Code) stock possessing more than 10% of the total combined voting power of all classes of stock of the Company or any Affiliate. END OF DOCUMENT

Exhibit 10.6

PROGENITY, INC.

2020 EMPLOYEE STOCK PURCHASE PLAN

Section 1. PURPOSE

The purpose of this Employee Stock Purchase Plan (the "Plan") is to provide an opportunity for Employees of Progenity, Inc., a Delaware corporation ("Sponsor") and its Participating Subsidiaries (collectively Sponsor and its Participating Subsidiaries shall be referred to as the "Company"), to purchase Common Stock of Sponsor and thereby to have an additional incentive to contribute to the prosperity of the Company. It is the intention of the Company that the Plan (excluding any sub-plans thereof except as expressly provided in the terms of such sub-plan) qualify as an "Employee Stock Purchase Plan" under Section 423 of the U.S. Internal Revenue Code of 1986, as amended (the "Code"), and the Plan shall be administered in accordance with this intent. In addition, the Plan authorizes the grant of options pursuant to sub-plans or special rules adopted by the Committee designed to achieve desired tax or other objectives in particular locations outside of the United States or to achieve other business objectives in the determination of the Committee, which sub-plans shall not be required to comply with the requirements of Section 423 of the Code or all of the specific provisions of the Plan, including but not limited to terms relating to eligibility, Offering Periods or Purchase Price.

Section 2. DEFINITIONS

(a) "Applicable Law" shall mean the legal requirements relating to the administration of an employee stock purchase plan under applicable U.S. state corporate laws, U.S. federal and applicable state securities laws, the Code, any stock exchange rules or regulations and the applicable laws of any other country or jurisdiction, as such laws, rules, regulations and requirements shall be in place from time to time.

(b) "Board" shall mean the Board of Directors of Sponsor.

(c) "Code" shall mean the Internal Revenue Code of 1986, as such is amended from time to time, and any reference to a section of the Code shall include any successor provision of the Code.

(d) "Commencement Date" shall mean, with respect to a given Offering Period, the first Trading Day during such Offering Period.

(e) "Committee" shall mean the Compensation Committee of the Board or the officer, officers or committee appointed by the Compensation Committee in accordance with Section 15 of the Plan (to the extent of the duties and responsibilities delegated by the Compensation Committee of the Board).

(f) "Common Stock" shall mean the common stock of Sponsor, par value $0.001 per share, or any securities into which such Common Stock may be converted.

(g) "Compensation" shall mean the total cash compensation paid by the Company to an Employee with respect to an Offering Period, including salary, commissions, overtime, shift differentials and all or any portion of any item of compensation considered by the Company to be part of the Employee's regular earnings, but excluding items not considered by the Company to be part of the Employee's regular earnings. Items excluded from the definition of "Compensation" include but are not limited to such items as relocation bonuses, MBO bonuses and similar incentive bonuses, expense reimbursements, certain bonuses paid in connection with mergers and acquisitions, author incentives, recruitment and referral bonuses, foreign service premiums, differentials and allowances, imputed income pursuant to Section 79 of the Code, income realized as a result of participation in any stock option, restricted stock, restricted stock unit, stock purchase or similar equity plan maintained by Sponsor or a Participating Subsidiary, tuition and other reimbursements, taxable fringe benefits and severance benefits. The Committee shall have the authority to determine and approve all forms of pay to be included in the definition of Compensation and may change the definition on a prospective basis.

(h) "Effective Date" shall mean the date of the underwriting agreement between the Company and the underwriters(s) managing the initial public offering of the Common Stock, pursuant to which the Common Stock is priced for the initial public offering of the Company's securities pursuant to a registration statement filed and declared effective pursuant to the Securities Act.

(i) "Employee" shall mean an individual classified as an employee (within the meaning of Code Section 3401(c) and the regulations thereunder) by Sponsor or a Participating Subsidiary on Sponsor's or such Participating Subsidiary's payroll records during the relevant participation period. Notwithstanding the foregoing, no employee of Sponsor or a Participating Subsidiary shall be included within the definition of "Employee" if such person's customary employment is for less than twenty (20) hours per week or for less than five (5) months per year. Individuals classified as independent contractors, consultants, advisers, or members of the Board are not considered "Employees."

(j) "Enrollment Period" shall mean, with respect to a given Offering Period, that period established by the Committee prior to the commencement of such Offering Period during which Employees may elect to participate in order to purchase Common Stock at the end of that Offering Period in accordance with the terms of this Plan.

(k) "Exchange Act" shall mean the U.S. Securities Exchange Act of 1934, as amended from time to time, and any reference to a section of the Exchange Act shall include any successor provision of the Exchange Act.

(l) "Market Value" on a given date of determination (e.g., a Commencement Date or Purchase Date, as appropriate) means, as of any date, the value of the Common Stock determined as follows:

(i) If the Common Stock is listed on any established stock exchange or traded on any established market, the Market Value of a share of Common Stock as of any date of determination will be, unless otherwise determined by the Board or Committee, the closing sales price for such stock as quoted on such exchange or market (or the exchange or market with the

greatest volume of trading in the Common Stock) on the date of determination, as reported in a source the Board or Committee deems reliable.

(ii) Unless otherwise provided by the Board or Committee, if there is no closing sales price for the Common Stock on the date of determination, then the Market Value will be the closing selling price on the last preceding date for which such quotation exists.

(iii) In the absence of such markets for the Common Stock, the Market Value will be determined by the Board or Committee in good faith.

(m) "Offering Period" shall mean a period of no more than twenty-seven (27) months. The Plan shall be implemented by a series of Offering Periods with terms established by the Committee in accordance with the Plan. Once established, the duration and timing of Offering Periods may be changed or modified by the Committee as permitted by the Plan. If the Committee does not establish different rules with respect to an Offering Period, then the duration of an Offering Period shall be twenty-four (24) months and each Offering Period shall consist of four (4) consecutive purchase periods each having a duration of six (6) months (individually, a "Purchase Period"), commencing on the first Trading Day following one Purchase Date and ending with the next Purchase Date, except that the first Purchase Period of any Offering Period will commence on the Commencement Date and end with the next Purchase Date. If the Committee does not establish different rules with respect to the frequency of Offering Periods, a new Offering Period shall commence every six (6) months following the Commencement Date of the previous Offering Period.

(n) "Offering Price" shall mean the Market Value of a share of Common Stock on the Commencement Date for a given Offering Period.

(o) "Participant" shall mean a participant in the Plan as described in Section 5 of the Plan.

(p) "Participating Subsidiary" shall mean a Subsidiary that has been designated by the Committee in its sole discretion as eligible to participate in the Plan with respect to its Employees.

(q) "Plan" shall mean this 2020 Employee Stock Purchase Plan, including any sub-plans or appendices hereto.

(r) "Purchase Date" shall mean, for any Purchase Period, the last Trading Day of such Purchase Period.

(s) "Purchase Period" shall have the meaning set out in Section 2(m).

(t) "Purchase Price" shall have the meaning set out in Section 8(b).

(u) "Securities Act" shall mean the U.S. Securities Act of 1933, as amended, as amended from time to time, and any reference to a section of the Securities Act shall include any successor provision of the Securities Act.

(v) "Stockholder" shall mean a record holder of shares entitled to vote such shares of Common Stock under Sponsor's by-laws.

(w) "Subsidiary" shall mean any entity treated as a corporation (other than Sponsor) in an unbroken chain of corporations beginning with Sponsor, within the meaning of Code Section 424(f), whether or not such corporation now exists or is hereafter organized or acquired by Sponsor or a Subsidiary.

(x) "Trading Day" shall mean a day on which U.S. national stock exchanges are open for trading and the Common Stock is being actively traded on one or more of such markets.

Section 3. ELIGIBILITY

(a) Any Employee employed by Sponsor or by any Participating Subsidiary at the beginning of an Enrollment Period for a given Offering Period shall be eligible to participate in the Plan with respect to such Offering Period and future Offering Periods, provided that the Committee may establish administrative rules requiring that employment commence some minimum period (not to exceed 90 days) prior to an Enrollment Period and/or that customary employment exceed a specified number of hours or period during a calendar year (not to exceed 20 hours per week or 5 months in a calendar year) to be eligible to participate with respect to the associated Offering Period and provided further that an Employee may only participate in one Offering Period at a time. The Committee may also determine that a designated group of highly compensated Employees is ineligible to participate in the Plan so long as the excluded category fits within the definition of "highly compensated employee" in Code Section 414(q). If the Committee does not establish different rules with respect to an Offering Period, the minimum period of employment that must be completed prior to the beginning of an Enrollment Period shall be five (5) working days. No Employee who becomes eligible to participate in the Plan may become a participant in an Offering Period following the Commencement Date of such Offering Period or after the commencement of any minimum period of employment established pursuant to the preceding sentence with respect to such Offering Period.

(b) No Employee may participate in the Plan if immediately after an option is granted the Employee owns or is considered to own (within the meaning of Code Section 424(d)) shares of Common Stock, including Common Stock which the Employee may purchase by conversion of convertible securities or under outstanding options granted by Sponsor or its Subsidiaries, possessing five percent (5%) or more of the total combined voting power or value of all classes of stock of Sponsor or of any of its Subsidiaries. All Employees who participate in the Plan shall have the same rights and privileges under the Plan, except for differences that may be mandated by local law and that are consistent with Code Section 423(b)(5); provided that individuals participating in a sub-plan adopted pursuant to Section 16 hereof which is not designed to qualify under Code Section 423 need not have the same rights and privileges as Employees participating in the Code Section 423 Plan. No Employee may participate in more than one Offering Period at a time.

Section 4. OFFERING PERIODS

The Plan shall be implemented by a series of Offering Periods, which shall possess terms specified by the Committee in accordance with the terms of the Plan. Offering Periods shall continue until the Plan is terminated pursuant to Section 14 hereof. Once established, the Committee shall have the authority to change the frequency and/or duration of Offering Periods (including the Commencement Dates thereof) with respect to future Offering Periods if such change is announced prior to the scheduled occurrence of the Enrollment Period for the first Offering Period to be affected thereafter. If the Committee does not establish different rules with respect to an Offering Period, then the duration of an Offering Period shall be twenty-four (24) months and each Offering Period shall consist of four (4) Purchase Periods commencing on the first Trading Day following one Purchase Date and ending with the next Purchase Date, except that the first Purchase Period of any Offering Period will commence on the Commencement Date and end with the next Purchase Date. If the Committee does not establish different rules with respect to the frequency of Offering Periods, a new Offering Period shall commence every six (6) months following the Commencement Date of the previous Offering Period.

Section 5. PARTICIPATION

(a) An Employee who is eligible to participate in the Plan in accordance with its terms at the beginning of an Enrollment Period for an Offering Period and elects to participate in such Offering Period shall automatically receive an option in accordance with Section 8(a). Such an Employee shall become a Participant by completing and submitting, on or before the date prescribed by the Committee with respect to a given Offering Period, a completed payroll deduction authorization and Plan enrollment form provided by Sponsor or its Participating Subsidiaries or by following an electronic or other enrollment process as prescribed by the Committee. An eligible Employee may authorize payroll deductions at the rate of any whole percentage of the Employee's Compensation, not to be less than one percent (1.0%) and not to exceed fifteen percent (15.0%) (or such other percentages as the Committee may establish from time to time before an Enrollment Period for a future Offering Period) of such Employee's Compensation on each payday during the Offering Period. All payroll deductions will be held in a general corporate account or a trust account. No interest shall be paid or credited to the Participant with respect to such payroll deductions. Sponsor shall maintain or cause to be maintained a separate bookkeeping account for each Participant under the Plan and the amount of each Participant's payroll deductions shall be credited to such account. A Participant may not make any additional payments into such account, unless payroll deductions are prohibited under Applicable Law, in which case the provisions of Section 5(b) of the Plan shall apply. A Participant will automatically participate in each Offering Period commencing immediately following the last day of the prior Offering Period unless he or she withdraws or is deemed to withdraw from this Plan or terminates further participation in the Offering Period. A Participant is not required to file any additional agreement in order to continue participation in this Plan following the end of an Offering Period in which the Participant is then participating.

(b) Notwithstanding any other provisions of the Plan to the contrary, in locations where local law prohibits payroll deductions, an eligible Employee may elect to participate through contributions to his or her account under the Plan in a form acceptable to the Committee. In such event, any such Employees shall be deemed to be participating in a sub-plan, unless the

Committee otherwise expressly provides that such Employees shall be treated as participating in the Plan.

(c) Under procedures and at times established by the Committee, a Participant may withdraw from the Plan during an Offering Period, by completing and filing a new payroll deduction authorization and Plan enrollment form with the Company or by following electronic or other procedures prescribed by the Committee. If a Participant withdraws from the Plan during an Offering Period, his or her accumulated payroll deductions will be refunded to the Participant without interest, his or her right to participate in the current Offering Period will be automatically terminated and no further payroll deductions for the purchase of Common Stock will be made during the Offering Period. Any Participant who wishes to withdraw from the Plan during an Offering Period, must complete the withdrawal procedures prescribed by the Committee, subject to any rules established by the Committee, or changes to such rules, pertaining to the timing of withdrawals, limiting the frequency with which Participants may withdraw and re-enroll in the Plan, or imposing a waiting period on Participants wishing to re-enroll following withdrawal.

(d) Notwithstanding the preceding provisions of this Section 5, if the Market Value on the day of commencement of a Purchase Period, other than the first Purchase Period of such Offering Period, is less than the amount specified in Section 8(b)(i) for such Offering Period, each Participant who purchased shares of Common Stock in the preceding Purchase Period of such Offering Period shall automatically be withdrawn from that original Offering Period and re-enrolled in the next twenty four-month Offering Period.

(e) A Participant may not increase his or her rate of contribution through payroll deductions or otherwise during a given Offering Period. A Participant may decrease his or her rate of contribution through payroll deductions during a given Offering Period during such times specified by the Committee by filing a new payroll deduction authorization and Plan enrollment form or by following electronic or other procedures prescribed by the Committee. If a Participant has not followed such procedures to change the rate of contribution, the rate of contribution shall continue at the originally elected rate throughout the Offering Period and future Offering Periods. Notwithstanding the foregoing, to the extent necessary to comply with Section 423(b)(8) of the Code for a given calendar year, the Committee may reduce a Participant's payroll deductions to zero percent (0%) at any time during an Offering Period scheduled to end during such calendar year. Payroll deductions shall re-commence at the rate provided in such Participant's enrollment form at the beginning of the first Offering Period which is scheduled to end in the following calendar year, unless terminated by the Participant as provided in Section 5(c).

Section 6. TERMINATION OF EMPLOYMENT

In the event any Participant terminates employment with Sponsor and its Participating Subsidiaries for any reason (including death) prior to the expiration of an Offering Period, the Participant's participation in the Plan shall terminate and all amounts credited to the Participant's account shall be paid to the Participant or, in the case of death, to the Participant's heirs or estate, without interest. Whether a termination of employment has occurred shall be determined by the Committee. The Committee may provide that if a Participant's termination of employment

occurs within a certain period of time as specified by the Committee (not to exceed 30 days) prior to a Purchase Date during an Offering Period then in progress, his or her option for the purchase of shares of Common Stock will be exercised on such Purchase Date in accordance with Section 9 as if such Participant were still employed by the Company. If the Committee does not establish different rules with respect to an Offering Period, then a Participant must be employed on a Purchase Date in order for his or her option to be exercised on such Purchase Date. The Committee may also establish rules regarding when leaves of absence or changes of employment status will be considered to be a termination of employment, including rules regarding transfer of employment among Participating Subsidiaries, Subsidiaries and Sponsor, and the Committee may establish termination-of-employment procedures for the Plan that are independent of similar rules established under other benefit plans of Sponsor and its Subsidiaries; provided that such procedures are not in conflict with the requirements of Section 423 of the Code.

Section 7. STOCK

(a) Subject to adjustment as set forth in Section 11 and the "evergreen" provision in this Section 7, the aggregate number of shares of Common Stock which may be issued pursuant to the Plan shall not exceed Five Hundred Ten Thousand (510,000) shares (the "Share Reserve"). The Share Reserve will automatically increase on January 1st of each calendar year, for ten years, commencing on January 1 of the calendar year following the Effective Date, in an amount equal to the lesser of (i) one percent (1%) of the total number of shares of Common Stock outstanding on December 31st of the preceding calendar year or (ii) Six Hundred Thousand (600,000) shares (subject to adjustment as set forth in Section 11). The Board may act prior to January 1st of a given year to provide that there will be no January 1st increase of the Share Reserve for such year or that the increase in the Share Reserve for such year will be a smaller number of shares of Common Stock than would otherwise occur pursuant to the preceding sentence.

(b) Notwithstanding the above, subject to adjustment as set forth in Section 11, the maximum number of shares of Common Stock that may be issued to any Employee in a given Offering Period shall be that number of shares of Common Stock that could be purchased on the Commencement Date of such Offering Period with Fifty-Thousand Dollars (USD$50,000), taking into consideration any discount from the Offering Period pursuant to Section 8(b). The Committee may change this limitation at any time on a prospective basis to apply to future Offering Periods. If, on a given Purchase Date, the number of shares with respect to which options are to be exercised exceeds either maximum, the Committee shall make, as applicable, such adjustment or pro rata allocation of the shares remaining available for purchase in as uniform a manner as shall be practicable and as it shall determine to be equitable.

Section 8. OFFERING

(a) On the Commencement Date relating to each Offering Period, each eligible Employee, whether or not such Employee has elected to participate as provided in Section 5(a), shall be granted an option to purchase that number of whole shares of Common Stock (as adjusted as set forth in Section 11) not to exceed that number of shares of Common Stock determined in accordance with the last paragraph of Section 7 above (or such lower number of shares as determined by the Committee), which may be purchased with the payroll deductions

accumulated on behalf of such Employee during each Offering Period at the purchase price specified in Section 8(b) below, subject to the additional limitation that no Employee participating in the Plan shall be granted an option to purchase Common Stock under the Plan if such option would permit his or her rights to purchase stock under all employee stock purchase plans (described in Section 423 of the Code) of Sponsor and its Subsidiaries to accrue at a rate which exceeds Twenty-Five Thousand Dollars (USD$25,000) of the Market Value of such Common Stock (determined at the time such option is granted) for each calendar year in which such option is outstanding at any time. For purposes of the Plan, an option is "granted" on a Participant's Commencement Date. An option will expire upon the earliest to occur of (i) the termination of a Participant's participation in the Plan or such Offering Period, (ii) the beginning of a subsequent Offering Period in which such Participant is participating, or (iii) the termination of the Offering Period. For avoidance of doubt, if an option is granted to an Employee who is not a Participant in such Offering Period, that option shall expire upon the Commencement Date with any right or ability of such Employee to exercise the option. This Section 8(a) shall be interpreted so as to comply with Code Section 423(b)(8).

(b) The Purchase Price under each option shall be with respect to each Purchase Period in an Offering Period the lower of (i) a percentage (not less than eighty-five percent (85%)) ("Designated Percentage") of the Offering Price, or (ii) the Designated Percentage of the Market Value of a share of Common Stock on the Purchase Date on which the Common Stock is purchased; provided that the Purchase Price may be adjusted by the Committee pursuant to Sections 11 or 12 in accordance with Section 424(a) of the Code. For a given Offering Period, the Designated Percentage shall be established no later than the beginning of the Enrollment Period for such Offering Period. The Committee may change the Designated Percentage with respect to any future Offering Period, but not to below eighty-five percent (85%), and the Committee may determine with respect to any prospective Offering Period that the Purchase Price shall be the Designated Percentage of the Market Value of a share of the Common Stock solely on each Purchase Date. If the Committee does not establish the Designated Percentage prior to the beginning of the Enrollment Period for a given Offering Period, the Designated Percentage for such Offering Period shall be eighty-five percent (85%).

Section 9. PURCHASE OF STOCK

Unless a Participant withdraws from the Plan as provided in Section 5(c), terminates employment prior to the end of an Offering Period as provided in Section 6, or except as provided in Sections 7, 12 or 14(b), upon each Purchase Date in the Offering Period, a Participant's option shall be exercised automatically for the purchase of that number of whole shares of Common Stock which the accumulated payroll deductions credited to the Participant's account at that time shall purchase at the applicable price specified in Section 8(b) in accordance with the terms of the Plan, including Section 7. If a Participant's contributions are collected in a currency other than U.S. Dollars, then unless otherwise provided by the Committee with respect to an Offering Period, such contributions shall be converted into U.S. Dollars using an exchange rate prevailing on the Purchase Date as selected in the reasonable determination of the Sponsor. Notwithstanding the foregoing, Sponsor or its Participating Subsidiary may make such provisions and take such action as it deems necessary or appropriate for the withholding of taxes and/or social insurance and/or other amounts which Sponsor or its Participating Subsidiary determines is required by Applicable Law. Each Participant, however, shall be responsible for

payment of all individual tax liabilities arising under the Plan. The shares of Common Stock purchased upon exercise of an option hereunder shall be considered for tax purposes to be sold to the Participant on the Purchase Date. A Participant's option to purchase shares of Common Stock hereunder is exercisable only by him or her.

Section 10. PAYMENT AND DELIVERY

Within an administratively reasonable period of time after the exercise of an option, Sponsor shall deliver or cause to have delivered to the Participant a record of the Common Stock purchased and the balance of any amount of payroll deductions credited to the Participant's account not used for the purchase of Common Stock, except as specified below. The Committee may permit or require that shares be deposited directly with a broker designated by the Committee or to a designated agent of the Company, and the Committee may utilize electronic or automated methods of share transfer. The Committee may require that shares be retained with such broker or agent for a designated period of time and/or may establish other procedures to permit tracking of disqualifying dispositions of such shares. Sponsor or its Participating Subsidiary shall retain the amount of payroll deductions used to purchase Common Stock as full payment for the Common Stock and the Common Stock shall then be fully paid and non-assessable. No Participant shall have any voting, dividend, or other Stockholder rights with respect to shares subject to any option granted under the Plan until the shares subject to the option have been purchased and delivered to the Participant as provided in this Section 10. Following the last Purchase Date in an Offering Period, the Committee may in its discretion direct Sponsor to retain in a Participant's account for a subsequent Offering Period any payroll deductions which are not sufficient to purchase a whole share of Common Stock or return such amount to the Participant. Any other amounts left over in a Participant's account after the final Purchase Date in each Offering Period shall be returned to the Participant. If the Committee does not establish different rules with respect to an Offering Period, then all amounts left over in a Participant's account after the final Purchase Date of such Offering Period shall be returned to the Participant.

Section 11. RECAPITALIZATION

Subject to any required action by the Stockholders of Sponsor, if there is any change in the outstanding shares of Common Stock or other securities of Sponsor because of a merger, consolidation, spin-off, reorganization, recapitalization, dividend in property other than cash, extraordinary dividend whether in cash and/or other property, stock split, reverse stock split, stock dividend, liquidating dividend, combination or reclassification of the Common Stock or other securities (including any such change in the number of shares of Common Stock or other securities effected in connection with a change in domicile of Sponsor), or any other increase or decrease in the number of shares of Common Stock or other securities effected without receipt of consideration by Sponsor, provided that conversion of any convertible securities of Sponsor shall not be deemed to have been "effected without receipt of consideration," the type and number of securities covered by each option under the Plan which has not yet been exercised, the type and number of securities which have been authorized and remain available for issuance under the Plan, the maximum number of shares that may be added to the Plan in accordance with Section 7(a)(ii), as well as the maximum number of securities which may be purchased by a Participant in an Offering Period, and the price per share covered by each option under the Plan which has

not yet been exercised, shall be appropriately and proportionally adjusted by the Board, and the Board shall take any further actions which, in the exercise of its discretion, may be necessary or appropriate under the circumstances. The Board's determinations under this Section 11 shall be conclusive and binding on all parties.

Section 12. MERGER, LIQUIDATION, OTHER CORPORATE TRANSACTIONS

(a) In the event of the proposed liquidation or dissolution of Sponsor, each Offering Period will terminate immediately prior to the consummation of such proposed transaction, unless otherwise provided by the Board in its sole discretion, and all outstanding options shall automatically terminate and the amounts of all payroll deductions will be refunded without interest to the Participants.

(b) In the event of a proposed sale of all or substantially all of the assets of Sponsor, or the merger or consolidation or similar combination of Sponsor with or into another entity, then in the sole discretion of the Board, (1) each option shall be assumed or an equivalent option shall be substituted by the successor corporation or parent or subsidiary of such successor entity, (2) on a date established by the Board on or before the date of consummation of such merger, consolidation, combination or sale, such date shall be treated as the final Purchase Date of each Offering Period, and all outstanding options shall be exercised on such date, (3) all outstanding options shall terminate and the accumulated payroll deductions will be refunded without interest to the Participants, or (4) outstanding options shall continue unchanged.

Section 13. TRANSFERABILITY

Neither payroll deductions credited to a Participant's bookkeeping account nor any rights to exercise an option or to receive shares of Common Stock under the Plan may be voluntarily or involuntarily assigned, transferred, pledged, or otherwise disposed of in any way, and any attempted assignment, transfer, pledge, or other disposition shall be null and void and without effect. If a Participant in any manner attempts to transfer, assign or otherwise encumber his or her rights or interests under the Plan, other than as permitted by the Code, such act shall be treated as an election by the Participant to discontinue participation in the Plan pursuant to Section 5(c).

Section 14. AMENDMENT OR TERMINATION OF THE PLAN

(a) The Plan shall continue from the Effective Date until the time that the Plan is terminated in accordance with Section 14(b).

(b) The Board or the Committee may, in its sole discretion, insofar as permitted by law, terminate or suspend the Plan, or revise or amend it in any respect whatsoever, except that, without approval of the Stockholders, no such revision or amendment shall increase the number of shares subject to the Plan, other than an adjustment under Section 11 of the Plan, or make other changes for which Stockholder approval is required under Applicable Law. Upon a termination or suspension of the Plan, the Board may in its discretion (i) return without interest, the payroll deductions credited to Participants' accounts to such Participants or (ii) set an earlier final Purchase Date with respect to each Offering Period then in progress.

Section 15. ADMINISTRATION

(a) The Board has appointed the Compensation Committee of the Board to administer the Plan (the "Committee"), who will serve for such period of time as the Board may specify and whom the Board may remove at any time. The Committee will have the authority and responsibility for the day-to-day administration of the Plan, the authority and responsibility specifically provided in this Plan and any additional duty, responsibility and authority delegated to the Committee by the Board, which may include any of the functions assigned to the Board in this Plan. The Committee may delegate to a sub-committee and/or to officers or employees of Sponsor the day-to-day administration of the Plan. The Committee shall have full power and authority to adopt, amend and rescind any rules and regulations which it deems desirable and appropriate for the proper administration of the Plan, to construe and interpret the provisions and supervise the administration of the Plan, to make factual determinations relevant to Plan entitlements and to take all action in connection with administration of the Plan as it deems necessary or advisable, consistent with the delegation from the Board. Decisions of the Committee shall be final and binding upon all Participants. Any decision reduced to writing and signed by a majority of the members of the Committee shall be fully effective as if it had been made at a meeting of the Committee duly held. The Company shall pay all expenses incurred in the administration of the Plan.

(b) In addition to such other rights of indemnification as they may have as members of the Board or officers or employees of the Company, members of the Board and of the Committee and their delegates shall be indemnified by the Company against all reasonable expenses, including attorneys' fees, actually and necessarily incurred in connection with the defense of any action, suit or proceeding, or in connection with any appeal therein, to which they or any of them may be a party by reason of any action taken or failure to act under or in connection with the Plan, or any right granted under the Plan, and against all amounts paid by them in settlement thereof (provided such settlement is approved by independent legal counsel selected by the Sponsor) or paid by them in satisfaction of a judgment in any such action, suit or proceeding, except in relation to matters as to which it shall be adjudged in such action, suit or proceeding that such person is liable for gross negligence, bad faith or intentional misconduct in duties; provided, however, that within sixty (60) days after the institution of such action, suit or proceeding, such person shall offer to the Company, in writing, the opportunity at its own expense to handle and defend the same.

Section 16. COMMITTEE RULES FOR JURISDICTIONS OTHER THAN THE UNITED STATES

The Committee may adopt rules or procedures relating to the operation and administration of the Plan to accommodate the specific requirements of the laws and procedures of jurisdictions outside of the United States. Without limiting the generality of the foregoing, the Committee is specifically authorized to adopt rules and procedures regarding handling of payroll deductions or other contributions by Participants, payment of interest, conversion of local currency, data privacy security, payroll tax, withholding procedures and handling of stock certificates which vary with local requirements; however, if such varying provisions are not in accordance with the provisions of Section 423(b) of the Code, including but not limited to the requirement of Section 423(b)(5) of the Code that all options granted under the Plan shall have

the same rights and privileges unless otherwise provided under the Code and the regulations promulgated thereunder, then the individuals affected by such varying provisions shall be deemed to be participating under a sub-plan and not in the Plan. The Committee may also adopt sub-plans applicable to particular Subsidiaries or locations, which sub-plans may be designed to be outside the scope of Code Section 423 and shall be deemed to be outside the scope of Code Section 423 unless the terms of the sub-plan provide to the contrary. The rules of such sub-plans may take precedence over other provisions of this Plan, with the exception of Section 7, but unless otherwise superseded by the terms of such sub-plan, the provisions of this Plan shall govern the operation of such sub-plan. The Committee shall not be required to obtain the approval of the Stockholders prior to the adoption, amendment or termination of any sub-plan unless required by the laws of the jurisdiction in which Employees participating in the sub-plan are located.

Section 17. SECURITIES LAWS REQUIREMENTS

(a) No option granted under the Plan may be exercised to any extent unless the shares to be issued upon such exercise under the Plan are covered by an effective registration statement pursuant to the Securities Act and the Plan is in material compliance with all applicable provisions of any applicable national, regional, state, local or other jurisdiction, including, without limitation, the Securities Act, the Exchange Act, the rules and regulations promulgated thereunder, applicable state and foreign securities laws and the requirements of any stock exchange upon which the Shares may then be listed, subject to the approval of counsel for the Company with respect to such compliance. If on a Purchase Date in any Offering Period hereunder, the Plan is not so registered or in such compliance, options granted under the Plan which are not in material compliance shall not be exercised on such Purchase Date, and the Purchase Date shall be delayed until the Plan is subject to such an effective registration statement and such compliance, except that each Purchase Date shall not be delayed more than twelve (12) months and the final Purchase Date shall in no event be more than twenty-seven (27) months from the Commencement Date relating to such Offering Period. If, on the Purchase Date of any offering hereunder, as delayed to the maximum extent permissible, the Plan is not registered and in such compliance, options granted under the Plan which are not in material compliance shall not be exercised and all payroll deductions accumulated during the Offering Period (reduced to the extent, if any, that such deductions have been used to acquire shares of Common Stock) shall be returned to the Participants, without interest. The provisions of this Section 17 shall comply with the requirements of Section 423(b)(5) of the Code to the extent applicable.

(b) As a condition to the exercise of an option, Sponsor may require the person exercising such option to represent and warrant at the time of any such exercise that the Shares are being purchased only for investment and without any present intention to sell or distribute such Shares if, in the opinion of counsel for Sponsor, such a representation is required by any of the aforementioned applicable provisions of law.

Section 18. GOVERNMENTAL REGULATIONS

This Plan and Sponsor’s obligation to sell and deliver shares of its stock under the Plan shall be subject to the approval of any governmental authority required in connection with the Plan or the authorization, issuance, sale, or delivery of stock hereunder.

Section 19. NO ENLARGEMENT OF EMPLOYEE RIGHTS

Nothing contained in this Plan shall be deemed to give any Employee or other individual the right to be retained in the employ or service of Sponsor or any Participating Subsidiary or to interfere with the right of Sponsor or Participating Subsidiary to discharge any Employee or other individual at any time, for any reason or no reason, with or without notice.

Section 20. GOVERNING LAW

This Plan shall be governed by applicable laws of the State of Delaware without regard for the conflicts of laws provisions thereof, and other applicable law.

Section 21. EFFECTIVE DATE

This Plan shall be effective on the Effective Date, subject to approval of the Stockholders of Sponsor within twelve (12) months before or after its date of adoption by the Board.

Section 22. REPORTS

Individual accounts shall be maintained for each Participant in the Plan. Statements of account shall be made available to Participants at least annually, which statements shall set forth the amounts of payroll deductions, the Purchase Price, the number of shares of Common Stock purchased and the remaining cash balance, if any.

Section 23. DESIGNATION OF BENEFICIARY FOR OWNED SHARES

With respect to shares of Common Stock purchased by the Participant pursuant to the Plan and held in an account maintained by Sponsor or its assignee on the Participant's behalf, the Participant may be permitted to file a written designation of beneficiary, who is to receive any shares and cash, if any, from the Participant's account under the Plan in the event of such Participant's death subsequent to the end of a Purchase Period but prior to delivery to him or her of such shares and cash. In addition, a Participant may file a written designation of a beneficiary who is to receive any cash from the Participant's account under the Plan in the event of such Participant's death prior to any Purchase Date(s) of an Offering Period. If a Participant is married and the designated beneficiary is not the spouse, spousal consent shall be required for such designation to be effective to the extent required by local law. The Participant (and if required under the preceding sentence, his or her spouse) may change such designation of beneficiary at any time by written notice. Subject to local legal requirements, in the event of a Participant's death, Sponsor or its assignee shall deliver any shares of Common Stock and/or cash to the designated beneficiary. Subject to local law, in the event of the death of a Participant and in the absence of a beneficiary validly designated who is living at the time of such Participant's death, Sponsor shall deliver such shares of Common Stock and/or cash to the executor or administrator of the estate of the Participant, or if no such executor or administrator has been appointed (to the knowledge of Sponsor), Sponsor in its sole discretion, may deliver (or cause its assignee to deliver) such shares of Common Stock and/or cash to the spouse, or to any one or more dependents or relatives of the Participant, or if no spouse, dependent or relative is known to Sponsor, then to such other person as Sponsor may determine. The provisions of this Section 23 shall in no event require Sponsor to violate local law, and Sponsor shall be entitled to take

whatever action it reasonably concludes is desirable or appropriate in order to transfer the assets allocated to a deceased Participant's account in compliance with local law.

Section 24. ADDITIONAL RESTRICTIONS OF RULE 16b-3.

The terms and conditions of options granted hereunder to, and the purchase of shares of Common Stock by, persons subject to Section 16 of the Exchange Act shall comply with the applicable provisions of Rule 16b-3. This Plan shall be deemed to contain, and such options shall contain, and the shares of Common Stock issued upon exercise thereof shall be subject to, such additional conditions and restrictions, if any, as may be required by Rule 16b-3 to qualify for the maximum exemption from Section 16 of the Exchange Act with respect to Plan transactions.

Section 25. NOTICES

All notices or other communications by a Participant to Sponsor or the Committee under or in connection with the Plan shall be deemed to have been duly given when received in the form specified by Sponsor or the Committee at the location, or by the person, designated by Sponsor for the receipt thereof.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

The Board of Directors
Progenity, Inc.:

We consent to the use of our report included herein and to the reference to our firm under the heading “Experts” in the prospectus. Our report dated March 18, 2020, except for the stock split described in Note 15, which is as of June 10, 2020, refers the Company’s adoption of Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers* (*Topic 606*), as amended. Our report also contains an explanatory paragraph that states that the Company has suffered recurring losses from operations and has an accumulated deficit that raise substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of that uncertainty.

/s/ KPMG LLP

San Diego, California
June 15, 2020