UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2022

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM TO**

Commission File Number 001-39334

BIORA THERAPEUTICS, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**27-3950390**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
4330 La Jolla Village Drive, Suite 300, San Diego, CA	**92122**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (833) 727-2841

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	BIOR	The Nasdaq Global Market

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). YES ☒ NO ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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.

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 13(a) of the Exchange Act. ☐

Indicate by check mark whether the Registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on The Nasdaq Stock Market on June 30, 2022, was approximately $114,439,824.

The number of shares of Registrant's Common Stock outstanding as of March 20, 2023 was 11,828,453.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its 2023 Annual Meeting of Stockholders, to be held on or about June 14, 2023, are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. Such proxy statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

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EXPLANATORY NOTE

All share and per share information included in this Annual Report on Form 10-K has been retroactively adjusted to reflect a 1-for-25 reverse stock split completed on January 3, 2023.

TRADEMARKS

Biora Therapeutics™, BIOJET™, NAVICAP™, and GITRAC™ are trademarks of Biora Therapeutics, Inc. Any other brand names or trademarks appearing in this Annual Report on Form 10-K are the property of their respective holders.

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, ("Annual Report") contains “forward-looking statements” within the meaning of the federal securities laws, which statements involve substantial risks and uncertainties and are based on estimates and assumptions. All statements, other than statements of historical facts included in this Annual Report, 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 “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,” “anticipate,” “target,” “forecast” 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 Annual Report. Such risks, uncertainties, and other factors include, among others, the following risks, uncertainties, and factors:

- our plans and ability to successfully research, develop and commercialize new products and product candidates;
- the size and growth potential of the markets for our products under development, and our ability to serve those markets;
- the rate and degree of market acceptance and clinical utility of our products under development, if approved;
- coverage and reimbursement for our products under development;
- the performance of third parties in connection with the development of our products under development, including third-party contract research organizations and suppliers;
- regulatory developments in the United States and foreign countries;
- our ability to obtain and maintain regulatory approval or clearance of our products under development on expected timelines;
- 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 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 Annual Report, 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 Annual Report apply only as of the date made and are expressly qualified in their entirety by the cautionary statements included in this Annual Report. Except as required by law, we disclaim any intent to publicly update or revise any forward-looking statements to reflect subsequent events or circumstances.

PART I

In this Annual Report, "Biora," "Biora Therapeutics," "we," "us" and "our" refer to Biora Therapeutics, Inc., and our wholly-owned subsidiaries on a consolidated basis, unless the context otherwise provides.

Item 1. Business.

Overview

Biora Therapeutics, Inc. is a biotechnology company developing oral biotherapeutics that could enable new treatment approaches in the delivery of therapeutics. Our therapeutics pipeline includes two therapeutic delivery platforms:

- **NAVICAP™ Targeted Oral Delivery Platform**: Targeted oral delivery of therapeutics to the site of disease in the gastrointestinal ("GI") tract designed to improve outcomes for patients with Inflammatory Bowel Disease ("IBD"); and
- **BIOJET™ Systemic Oral Delivery Platform**: Systemic oral delivery of biotherapeutics designed to replace injection with needle-free, oral delivery of large molecules for better management of chronic diseases.

Our therapeutic pipeline is shown below.

Targeted Therapeutics for GI-Related Disorders

Our NAVICAP targeted drug delivery platform, previously known as the Drug Delivery System, or DDS, is a drug-device combination product utilizing an ingestible smart capsule for targeted delivery of therapeutics in the GI tract to improve treatment of IBD. Once swallowed, the capsule is designed to autonomously identify specific locations in the GI tract and release a therapeutic dose at the site of disease. The NAVICAP device is about the size of a "000" capsule, or approximately the size of a fish oil capsule, and has a drug capacity of up to 500µL. To date, the NAVICAP device has demonstrated a favorable safety profile and high accuracy rate in identifying entry into the colon in both normal healthy volunteers and active ulcerative colitis ("UC") patients. Biora was a recipient of a Crohn's and Colitis Foundation ("CCF") IBD Ventures development grant to support development and further clinical evaluation of the targeted therapeutics program in 2022.

Of the 1.6 million patients in the United States who suffer from IBD, only 15-30% of patients achieve remission of symptoms after induction with any drug therapy, likely due to challenges in safely achieving therapeutic drug levels in the affected tissues. Our NAVICAP platform utilizes a novel therapeutic approach that has the potential to improve IBD patient outcomes by maximizing the

available dose at the site of disease while reducing systemic toxicity. By reducing systemic drug levels, this approach may also enable combination therapy.

Targeted Therapeutics Market

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 UC. According to the 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 invaders 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 in perpetuating the inflammation. We estimate the IBD therapeutics market to be in excess of $15 billion.

Ulcerative Colitis

The CCF estimates that UC may affect as many as 907,000 Americans. 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 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 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. Despite multiple therapeutics being approved for UC that work through a range of mechanisms, outcomes for these patients remains poor with few patients achieving long-term remission. Data suggests that only 15-30% of patients achieve remission of symptoms after induction with any drug therapy. Many of these therapies have side effects that limit dosing, which leads to insufficient drug levels in diseased tissue. There is growing data that suggests the amount of drug in tissue is a key driver of patient outcomes. For anti-TNF-alphas such as infliximab and adalimumab, clinical studies have shown that the tissue TNF-alpha level far exceeds the amount of drug reaching the actively-inflamed tissue in patients with active IBD. We believe that current approaches to drug delivery are inadequate to suppress the inflammatory response. In addition, we presented, in conjunction with our academic collaborators, compelling evidence to support the importance of drug levels in tissue at the 17th Congress of the European Crohn's and Colitis Organization and at the 34th edition of the Belgian Week of Gastroenterology. Material presented included data from patients with moderate to severe UC taking commercial formulations of tofacitinib. GI tissue biopsies were obtained from these patients, which identified a clear correlation between higher concentrations of drug in the tissue and improved outcomes.

Our Solution:* NAVICAP *Targeted Drug Delivery Platform

Our NAVICAP platform is designed to deliver drugs to the site of disease in the GI tract to improve treatment of IBD. Using this platform, we are developing a pipeline of investigational drug-device combinations that are designed to overcome the limitation of current treatments. Our products are designed to treat disease at the 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. Through preclinical studies we have shown that a range of molecules, including monoclonal antibodies targeting key pathways including TNF-alpha, integrins and interleukins, were found in inflamed colonic tissue when given directly into the lumen of the colon. We have conducted preclinical studies which indicate that these molecules, given locally in animal models, can be efficacious. We believe delivering 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.

NAVICAP *drug delivery device*

NAVICAP *Targeted Drug Delivery Device*

The NAVICAP drug delivery device is an investigational, clinical-stage, single-use ingestible device approximately the size of a fish oil capsule and rounded for ease of swallowing. It has a drug capacity of up to 500µL with an outer casing made of inert material. It is designed to passively deliver a precise dose of drug that can act locally in the GI tract, thereby potentially limiting systemic absorption and the associated toxicity side effects.

GITRAC™ *Autonomous Location Technology*

The NAVICAP device incorporates our GITRAC autonomous location technology, which is designed to autonomously identify the ileal/ileocecal region of the GI tract and deliver medication to that region. GITRAC 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, such as the pyloric and ileocecal transition. GITRAC differs from other GI tract localization technologies that rely on pH levels and other physiological factors, which are not specific and are highly variable, especially in patients with IBD. The GITRAC technology was evaluated in 47 subjects across three clinical studies with 85% accurate detection of colon entry.

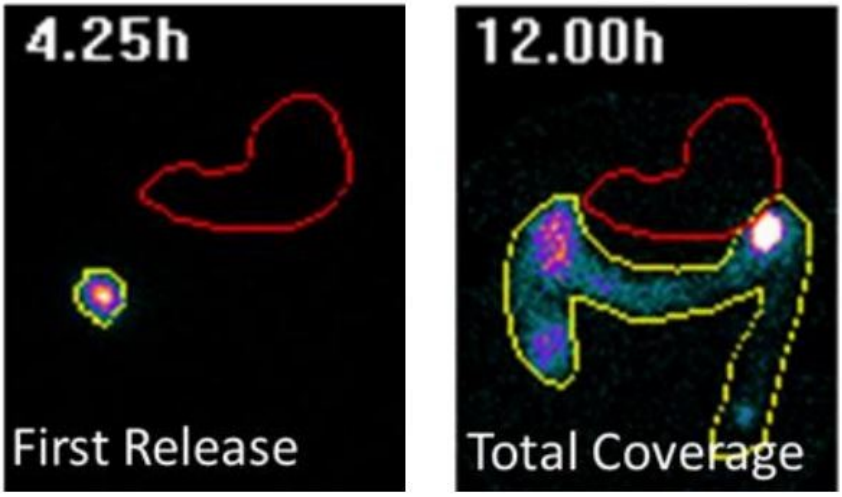
Clinical Studies

We have conducted three separate clinical studies to evaluate the NAVICAP device function in humans.

PM-601 Device function study in healthy volunteers in a fasted state

We conducted a clinical study to evaluate the safety and tolerability of the device as well as the ability to identify entry into the colon and release payload. In the study, 12 normal healthy volunteers were enrolled and administered a single NAVICAP device loaded with a radioisotope that can be imaged with sequential gamma scintigraphy. Imaging was correlated with data recovered from the device to confirm time of detection of entry into the colon and release of the radioisotope. The results of the study demonstrated that the device was well tolerated and 10/12 (83%) of devices accurately identified entry into the colon. The scintigraphic images below are taken

from a subject in the study and demonstrate release in the first part of the colon and eventual total coverage of the colon by the radioisotope.



PM-602 Device function study in patients with active UC

In this clinical device performance study, we evaluated whether the NAVICAP device can accurately identify entry to the colon, activate, and release a payload in patients with active UC, which presents a challenging environment of inflammation, bleeding, and highly variable motility. The NAVICAP device was ingested orally, and after localization, released a payload that included radioisotopes. Scintigraphic imaging was used to evaluate device localization and payload delivery to the large intestine. Study results demonstrated that the device was well tolerated and performed as intended in active UC patients. All devices (7/7) accurately identified entry into the colon, triggered release of a liquid payload, and achieved distribution across the colon. This study was funded in part by the CCF.

PM-611 Device function study in healthy volunteers – fasted and fed

In this clinical study, we evaluated whether the NAVICAP device is impacted by food, potentially enabling non-fasted administration. Results of the study demonstrated that the NAVICAP device was well tolerated and functioned as intended in healthy volunteers using four different fasted/fed dosing schedules.100% of analyzed devices successfully identified entry to the colon in all fasted/fed schedules (39/39), and 97.4% of analyzed devices activated the payload release function (38/39). This study confirmed that the potential effect of food on the function of the NAVICAP device is minimal.

Lead Programs

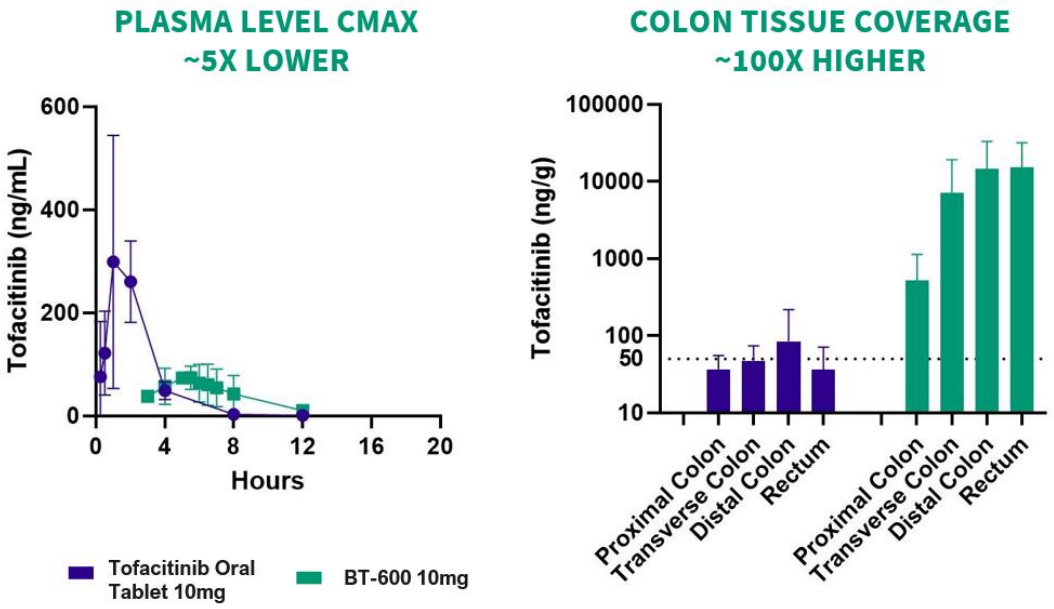
We have two lead programs, BT-600 (NAVICAP + tofacitinib) and BT-001 (NAVICAP + variant of adalimumab). Both tofacitinib and adalimumab have been approved for treatment of UC, but are dose limited by safety concerns at higher doses. Existing research, including research we have generated, suggest that efficacy may be limited by insufficient drug reaching diseased tissue in the colon. We believe our technology can deliver sufficient amounts of these drugs to the site of disease to improve outcomes for patients suffering from UC.

BT-600 Liquid formulation of tofacitinib delivered via NAVICAP *for the treatment of ulcerative colitis*

We are developing BT-600 (formerly known as PGN-600) as an orally-delivered liquid formulation of tofacitinib for the treatment of UC. BT-600 is our most advanced targeted therapeutics candidate. Tofacitinib is approved for UC and dose-limited based on safety concerns, making it an ideal therapy for targeted delivery. We have generated data in animal models of colitis that tofacitinib delivered directly to the colon can lead to significantly higher colon tissue concentrations than equivalent standard oral doses.

We conducted a preclinical study of BT-600 in a canine model comparing seven-day daily administration of 10 mg standard oral tablet formulation of tofacitinib to 10 mg of liquid formulation of tofacitinib delivered via NAVICAP (BT-600). We evaluated mean concentration of tofacitinib in tissues at day seven and systemic tofacitinib levels by area under the curve at days one and six.

The pharmacokinetic ("PK") data obtained with BT-600 and tofacitinib oral tablet is illustrated in the graphs presented below.



Results of the study demonstrated BT-600 was well tolerated with a favorable safety profile and that when tofacitinib was delivered to the colon drug levels in blood were reduced as compared to oral tofacitinib tablets. In addition, tissue drug levels were at least 25 times higher along the length of the colon as compared to oral tofacitinib tablets. We believe these results indicate that BT-600 has the potential to increase local tissue concentrations while lowering systemic levels that could lead to a safer and more efficacious treatment.

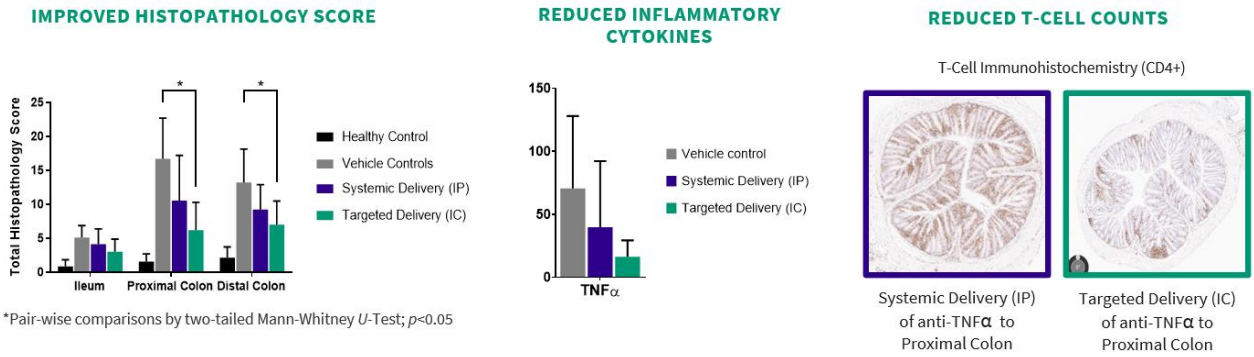
We recently completed a preclinical study of BT-600 in a canine model comparing 14-day daily administration of 10 mg standard oral tablet formulation of tofacitinib to 10 mg of liquid formulation of tofacitinib delivered via NAVICAP (BT-600). Over 600 planned devices were administered and we observed no adverse events or safety signals. We are continuing development of BT-600 and, subject to regulatory approval, we plan to initiate a Phase 1a clinical trial of BT-600 in healthy volunteers during the second half of 2023 evaluating both blood and colon tissue concentrations of tofacitinib, and a potential Phase 1b trial in active UC patients in the first half of 2024. We believe that if we demonstrate similar results clinically to what has been observed preclinically, and given the known efficacy of the currently-approved doses of tofacitinib, BT-600 has the potential to improve the management of UC patients.

BT-001 Liquid formulation of Anti-TNF-alpha monoclonal antibody delivered via NAVICAP *for the treatment of ulcerative colitis*

We are developing BT-001 (formerly known as PGN-001) as an orally-delivered variant of adalimumab for the treatment of UC. Multiple anti-TNF-alpha targeting therapies have been approved for UC, but data suggests patients may not have enough drug in the tissue to engage the target, TNF-alpha, and reduce inflammation. We have conducted a series of preclinical studies demonstrating the potential of locally-delivered anti-TNF-alpha antibodies to reduce disease burden in UC models.

We conducted a study in an adoptive T cell transfer model of colitis in mice and compared an anti-TNF-alpha delivered by intraperitoneal ("IP") injection every three days to daily delivery directly to the colon by intracecal ("IC") catheter. We also compared treatment naïve animals and vehicle controls. Treatment duration was 42 days and at day 42, blood and tissues were collected for

bioanalysis of inflammatory cytokines and tissues were fixed for histopathologic analysis. The results are presented in the graphs below.



Results of the study demonstrate significant reduction in mean concentration of inflammatory cytokines in groups treated with anti-TNF-alpha by IC or IP route when compared with vehicle control (IP and IC) in colon tissue. Targeted IC anti-TNFα treatment showed a significant improvement in mean histopathologic score when compared with the vehicle controls (IP and IC) groups in proximal and distal colon tissues, indicating that anti-TNF-alpha treatment was generally more effective in this group. Targeted IC anti-TNF-alpha treatment showed the greatest magnitude of lymphocyte reductions when compared with vehicle control groups. We believe this study supports the potential efficacy of locally-delivered anti-TNF-alpha antibodies and BT-001.

BT-001 is currently in preclinical-stage development with an anti-TNF-alpha antibody formulation that we have developed and scaled to Good Manufacturing Practice ("GMP")-grade material.

Systemic Therapeutics

Our systemic therapeutics program uses the BIOJET ingestible capsule, previously known as the Oral Biotherapeutic Delivery System, or OBDS, which is designed for needle-free, oral delivery of large molecules to achieve high systemic exposure. The BIOJET device is approximately the size of a multivitamin. Our technology has the potential to deliver a range of molecules, including monoclonal antibodies, peptides, and nucleic acids. These substances cannot survive stomach acids and are too large to be absorbed in the intestine and, therefore, are currently delivered by injection. However, there is significant aversion to injections among patients, with approximately 20% of adults affected by fear of needles and overall strong patient and physician preference for oral delivery of therapies as compared to injections. This aversion to painful injections affects compliance with therapy, which in turn impacts patient outcomes. For example, diabetes patients initiating treatment with an injectable GLP-1 agonist reported 71% higher discontinuation rate as compared to those starting oral therapy and 42% of patients failed to maintain treatment due to injection concerns.

The BIOJET systemic drug delivery platform is a novel platform for the delivery of therapeutics that would otherwise require injection. Once swallowed, the capsule is designed to move through the intestinal tract and trigger in the small intestine, where it uses needle-free, liquid-jet release to inject drug directly into the small intestine for optimized bioavailability.

The BIOJET platform is designed to enable delivery of liquid drug, reducing or eliminating the need for reformulation, and allowing for dosing of up to 400 µL. This makes the technology potentially broadly applicable for large molecule candidates. With more frequent administration, oral delivery has the potential to improve drug efficacy and safety as compared to current injection regimens.

Systemic Therapeutics Market

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, UC, and a range of cancers. We estimate the total biologics market to be in excess of $250 billion (or over $100 billion for monoclonal antibodies alone).

To reduce injections, many biologics have been developed for less frequent dosing, such as weekly or monthly injections; however, this means larger amounts of drug are in circulation, which can lead to safety concerns. This also means that before the next dose, drug levels can drop lower than desired, potentially impacting efficacy. An ideal dosing regimen may be a more frequent dosing schedule, such as daily, to maintain drug levels within a smaller window that is optimal for safety and efficacy.

To date, efforts to deliver biologics orally have seen limited success. The primary mechanism has been chemical agents formulated with drugs that facilitate passage from the gut lumen into the GI tissue. These approaches are limited to small peptides and, even then, bioavailability of less than 1% is achieved. We believe that an average bioavailability of around 10 to 15% with repeat dosing will prove satisfactory for a large number of biologics.

Our Solution: Systemic Therapeutics

We are developing drug-device combinations designed to deliver biologics systemically, via a more desirable oral route of administration. Our unique approach to oral delivery of biologic drugs is through use of an ingestible capsule designed for needle-free jet injection of a liquid drug formulation into the tissue of the small intestine where it can be absorbed systemically. We believe systemic therapeutics can (1) help improve patient compliance and lower IV infusion costs, (2) help expand the market for drugs across a range of chronic use indications, and (3) help biotherapeutics become more competitive with small molecules.

BIOJET *Systemic Drug Delivery Platform*

Our BIOJET systemic drug delivery platform is designed to orally deliver large molecules through a needle-free injection in the small intestine for systemic uptake. The BIOJET capsule protects the drug from acids and proteolytic enzymes and upon reaching the small intestine, an enteric trigger degrades, activating the needle-free liquid-jet formation and delivery. We initially developed an endoscopically- or surgically-placed, liquid-jet device for optimization and early preclinical work. 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 average bioavailability of approximately 19% (n=18), 29% (n=11), and 27% (n=11), respectively. We have since progressed to an autonomous, fully integrated preclinical device for further evaluation.

BIOJET *Drug Delivery Device*

The BIOJET device is approximately the size of a multivitamin, is shaped like a standard capsule for ease of swallowing and can deliver a drug payload of up to 400 µL. The large payload and liquid delivery make the platform broadly applicable to a range of molecules, including monoclonal antibodies, peptides, and nucleic acids.

We conducted a preclinical study with an autonomous BIOJET device delivered orally to canines. The study was a single-dose study evaluating safety and tolerability of the device in addition to the ability of the device to activate and deliver payload when it reached the small intestine. We evaluated device function by loading the device with a contrast agent (iohexal) and sequentially imaged

post-administration as the device transited through the body. The images below are taken from the study and show the contrast agent inside the capsule in the stomach and after deployment in the small intestine.

Immediately after dosing in the stomach

After deployment in the small intestine

This study demonstrated that the device can reliably deploy in the small intestine, which supports oral administration of the BIOJET device. We are continuing to advance development of the BIOJET platform through preclinical testing.

Lead Programs

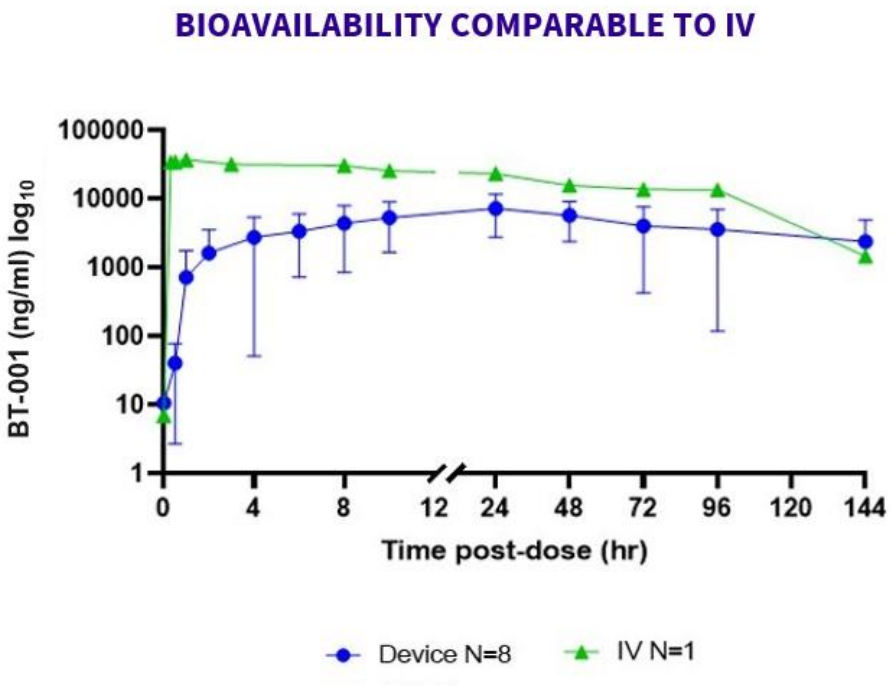
We have two lead programs, BT-002 (variant of adalimumab) and BT-200 (GLP-1RA). Adalimumab is approved for a range of inflammatory disorders and generated over $18 billion in 2022 in annual sales, making it the best-selling drug globally. An oral variant of adalimumab presents a significant opportunity for the many patients that would like to avoid painful injections. GLP-1RAs are a leading class of therapeutics for type 2 diabetes and have a projected market of over $19 billion by 2028. As a result of our use of known molecules, we believe that rapid proof of concept with preclinical and phase 1 PK results is possible.

BT-002: Liquid formulation of anti-TNF-alpha monoclonal antibody delivered via BIOJET for the treatment of autoimmune conditions

We are developing BT-002 (formerly PGN-OB1) as a combination product of a variant of adalimumab and the BIOJET device for the treatment of inflammatory conditions. Several anti-TNF-alpha antibodies have been approved to treat a range of autoimmune conditions. However, all require either intravenous or subcutaneous injection. An oral anti-TNF-alpha antibody may represent a significant market opportunity. BT-002 is currently in preclinical stage development with an anti-TNF-alpha antibody formulation that we have developed and scaled to GMP-grade material.

We have conducted a series of porcine preclinical studies demonstrating the ability of the BIOJET device to consistently trigger and release payload and achieve high bioavailability. The porcine model is preferred for bioavailability, as the pig intestine anatomy more closely resembles human intestinal anatomy than canine and is therefore more appropriate, especially for our method of delivery. However, the porcine stomach anatomy requires endoscopic placement of the device. In porcine studies with endoscopic placement of

the device and autonomous delivery, we have achieved up to 67% bioavailability, with an average of 23% bioavailability in animals where drug was detected in blood. The PK data obtained with BT-002 is illustrated in the graph below.



In February 2023, we announced preliminary results from a preclinical study for the BT-002 program, which assessed the bioavailability of a variant of adalimumab when delivered via BIOJET liquid jet injection technology in a porcine model. A single dose of 56 mg of a variant of adalimumab (a dose similar to those of subcutaneously administered monoclonal antibodies) was administered to a total of nine animals, using the BIOJET device. The device was administered and activated endoscopically. Following administration, drug was detected in the blood in all animals with an average bioavailability of 51.3%, and variability similar to that observed by others with subcutaneous injection. These results demonstrate the potential of our liquid jet delivery technology to perform comparably to subcutaneous injection. We expect to release detailed results in conjunction with a planned presentation of the data during 2023.

BT-200: Liquid formulation of a GLP-1 receptor agonist delivered with via BIOJET *for the treatment of type 2 diabetes*

We are developing BT-200 (formerly PGN-OB2) as a combination product of a GLP-1 receptor agonist and the BIOJET device for the treatment of type 2 diabetes. We believe oral GLP-1RAs will be preferred by patients to injectables, resulting in a significant market opportunity.

In February 2023, we announced preliminary results from preclinical testing to assess the bioavailability of semaglutide, a GLP-1 receptor agonist, when delivered via BIOJET liquid jet technology in a porcine model. Seven animals received a single dose of 0.96 mg of a liquid formulation of semaglutide using the BIOJET device, which was administered and activated endoscopically, with comparison to a control animal with drug administered intravenously. Following administration of semaglutide, drug was detected in the blood in all seven animals with an average bioavailability of 37%, and with variability similar to that observed by others with subcutaneous injection. We expect to release detailed results in conjunction with a planned presentation of the data during 2023.

Collaborations and Partnerships

Our strategy is to advance our own pipeline while partnering with third parties to also leverage their drug candidates and resources to help make the BIOJET platform a leader in the oral delivery of biotherapeutics. We are currently engaged in three ongoing collaborations, two of which are with large pharmaceutical companies for the use of the BIOJET platform with their molecules and one of which is with Ionis Pharmaceuticals, Inc. for the delivery of antisense oligonucleotides via BIOJET. As we advance development of our BIOJET platform we intend to expand our existing collaborations and pursue additional partnership opportunities with large pharmaceutical companies.

GI Sampling and Diagnostics

We have previously developed two additional ingestible devices focused on GI sampling and diagnostics.

Our Recoverable Sampling System ("RSS") platform is an ingestible smart capsule designed to autonomously identify locations in the GI tract, and collect and preserve a sample for analysis. This platform, if successfully developed, has the potential to analyze and characterize the GI tract. We have previously demonstrated the ability of the RSS to collect and preserve microbiome samples from within the GI tract of normal healthy volunteers.

Our PIL Dx ("PIL Dx") platform is an ingestible smart capsule designed to sample, measure, and transmit results. This platform has the potential for on-board fluorescent assays measuring bacteria, proteins, and drugs, plus additional detection modalities. If successfully developed, the PIL Dx could address unmet healthcare needs by more precisely identifying and diagnosing chronic GI diseases like small intestinal bacterial overgrowth, IBD and non-alcoholic fatty liver disease.

We are not currently in active development with the RSS and PIL Dx platforms but may develop them in the future.

Competition

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 technologies, 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, developing similar or superior products, 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, reimbursement, patent protection and patents of our competitors.

Targeted Therapeutics Competition

The current IBD market is both established and mature, comprised of a range of therapeutic agents, including branded and generic small molecules, biologics and 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 via oral administration, we will face competition from several companies whose current research and development ("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, Eli Lilly, Galapagos, Gilead, J&J, Pfizer, Protagonist, Roche, Takeda, and UCB.

Systemic Therapeutics Competition

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, some of which are the subject of issued patents and pending patent applications, including issued patents and pending patent applications directed to ingestible devices for the oral administration of therapeutic agents.

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: Enteris Biopharma and Novo Nordisk;
- Enteric coating technologies designed to prevent gastric degradation of active pharmaceutical ingredients and facilitate GI delivery: Catalent, Cosmo Pharmaceuticals, Intract Pharma, Lonza, and Tillotts Pharma; and

- Ingestible devices designed for the delivery of a therapeutic payload: Novo Nordisk, Lyndra Therapeutics, Rani Therapeutics, Biograil, Eli Lilly and Amgen.

Our Strengths

Our business is built on a strong foundation designed to allow us to differentiate ourselves from potential competitors and drive the development of innovative platforms and product solutions.

Our strengths include:

- ***Breadth and depth of R&D capabilities driving breakthrough innovation***. We have built a first-class 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 patient needs. Our technical expertise along the product development spectrum includes medical device, therapeutics and diagnostic expertise, and enables us to leverage existing knowledge to solve new challenges. Our targeted therapeutics and systemic therapeutics team is comprised of over 25 full-time, experienced drug developers, engineers, researchers, manufacturers and innovators working to create solutions to improve patient outcomes. In addition to our full-time staff, our team is augmented by more than 50 contract researchers, manufacturers, and consultants.
- ***Drug-Device combination platforms targeting large, underserved markets***. We are developing multiple therapeutics with a platform approach based on innovative drug-device combinations, which could represent a paradigm shift from existing therapeutics approaches. We believe these platforms have the potential to address significant unmet medical needs.
- ***Comprehensive intellectual property portfolio***. We hold the rights to approximately 300 issued patents and pending patent applications that include claims that are directed to a range of therapeutic and device 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 to potential competitors.
- ***Proven leadership with industry expertise***. Our senior management team and board of directors consist of veteran biotechnology, drug development and commercialization, and healthcare professionals with deep industry experience. These individuals have extensive experience with numerous well-regarded biotechnology, pharmaceuticals, medical device and healthcare 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 to transform biotherapeutic use and delivery. To realize our vision, we intend to:

- ***Focus on developing products that address the most critical needs of patients***. One of our primary goals as a company is to develop products that have the greatest impact on patients. We focus our R&D efforts on technologies that have the potential to disrupt current treatment paradigms and transform how healthcare is provided, thereby improving patients' lives. 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.
- ***Develop and commercialize a disruptive pipeline of drug-device combination products***. Our platform is focused on addressing unmet medical needs of patients with GI disorders and beyond. Leveraging our capsule technologies and platforms, we are developing investigational devices and drug-device combinations designed for therapeutic purposes. We believe our product candidates, if successfully developed and approved or cleared, could transform patient management. Ultimately, we intend to pursue commercialization of such product candidates ourselves or via strategic partnership.
- ***Opportunistic approach to drug candidate selection***. Using our platforms, 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 drug development programs in a scalable and capital-efficient manner. 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.

- ***Leverage our robust R&D capabilities to drive breakthrough innovation***. We continually strive to innovate in ways that will allow us to disrupt current treatment paradigms. Through our robust R&D pipeline, we seek to unlock novel approaches in the oral delivery of biotherapeutics. Our drug-device combinations could enable new treatment approaches in the areas of (1) delivery of therapeutics to the site of disease in the GI tract, which are designed to improve outcomes for patients with IBD, and (2) systemic delivery of biotherapeutics, which are designed to replace injection with needle free, oral capsules.
- ***Focus on maximizing value generation through partnerships and licensing***. Our strategy is to continue to develop our product candidates while simultaneously seeking out ways to monetize the assets during and after development. We initially target existing and well-known drugs that enable more rapid proof of concept and potentially abbreviated regulatory pathways. We intend to enter into additional collaborations and partnerships with pharmaceutical companies as part of our strategy to continue the development of our targeted and systemic drug delivery products.

Intellectual Property

The proprietary nature of, and intellectual property protection for, our 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 trade secrets 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 technologies, processes, databases, information, and materials. We seek and maintain patent protection in the United States and internationally for our approximately 300 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.

Drug-Device and Diagnostics Device Patent Portfolio

Intellectual property rights relating to our targeted and systemic therapeutics technologies and other ingestible device-enabled technologies include a patent portfolio consisting of approximately 70 distinct patent families comprising around 165 issued patents and approximately 135 pending applications. Of these patents and applications, the latest to expire issued U.S. patents are projected to expire in 2039 and the latest to expire U.S. patent applications, if and when issued, would be projected to expire in 2042, in each case, subject to potential term extensions. Twenty-four 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 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 patents and pending applications in this portfolio include claims that are directed to a range of gastroenterology-related and drug delivery methods, systems, and compositions, including but not limited to, the following:

- ingestible drug delivery mechanisms and systems for both topical and systemic delivery of therapeutics;
- ingestible devices for diagnosing, treating, and aiding in the treatment of GI diseases and conditions;
- GI-specific drug formulations and dosing regimens;
- autonomous localization of an ingestible device in the GI tract using visible or infrared light;
- treatment of GI-related and non-GI diseases and conditions using ingestible devices;
- GI sampling mechanisms and compositions, including preservatives for GI analytes; and
- ingestible device assays, optics and analytics for detecting and quantifying GI analytes.

Government Regulation

Regulations Related to Clinical Laboratories

Prior to the Strategic Transformation and the shutdown of commercial operations in our laboratory in Ann Arbor, MI and the sale of our affiliated business Avero Diagnostics, both of which occurred in 2021, we operated clinical laboratories. During that time, we were required to comply with various regulations applicable to clinical laboratories and laboratory developed tests, as well as various

healthcare fraud and abuse statutes that applied to our commercial operations, each which are described in detail in our prior SEC filings.

Regulations Related to Our Drug-Device Combination Product Candidate

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 U.S. Food and Drug Administration (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). Certain of these applicable regulations are described below.

Medical Device Regulation

Pursuant to its authority under the Federal Food, Drug and Cosmetic Act (the "FD&C Act"), the FDA has jurisdiction over medical devices, including in-vitro diagnostics devices and other products we are currently developing. The FDA regulates, among other things, the research, design, development, preclinical 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 premarket approval application ("PMA"). We are developing 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 Quality System Regulation ("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 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 ("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 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, 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, 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 for many reasons, including:

- the device may not be shown safe or effective to the FDA's satisfaction;

- the data from preclinical 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 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 PMAs 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, except that the supplement is limited to information needed to support any changes from the device covered by the approved PMA 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, 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 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 investigational device exemption ("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 institutional review board ("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 Good Clinical Practices ("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.

Breakthrough Devices and Safer Technologies Programs

The Breakthrough Devices Program is a voluntary program intended to expedite the review, development, assessment and review of certain medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human diseases or conditions for which no approved or cleared treatment exists or that offer significant advantages over existing approved or

cleared alternatives. For Breakthrough Devices, the FDA intends to provide interactive and timely communication with the sponsor during device development and throughout the review process. FDA also intends to assign staff to be available within a reasonable time to address questions by institutional review committees concerning the conditions and clinical testing expectations applicable to the investigational use of a Breakthrough Device. In addition, all submissions for devices designated as Breakthrough Devices will receive priority review, meaning that the review of the submission is placed at the top of the appropriate review queue and receives additional review resources, as needed.

In January 2021, FDA released final guidance on the Safer Technologies Program ("STeP"), which is intended for medical devices that treat or diagnose diseases or conditions that are less serious than those eligible for the Breakthrough Devices Program, including non-life-threatening or reasonably reversible conditions. STeP is modeled after the Breakthrough Devices Program and is intended to provide similar benefits, including expedited development and FDA review of submissions, for medical devices and device-led combination products that are likely to offer a safer treatment or diagnosis as compared to currently available alternatives.

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 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 will need to 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. In addition, the EU has adopted the EU Medical Device Regulation (EU 2017/745) (the “EU MDR”) which imposes stricter requirements for the marketing and sale of medical devices than in the U.S., including in the area of clinical evaluation requirements, quality systems and post-market surveillance. The transition period provided for in the EU MDR for existing CE certifications issued under the previous Medical Devices Directive will end on May 26, 2024. Complying with these regulations may require us to incur significant expenditures. Failure to meet these regulatory requirements could adversely impact our business in the EU and other regions that tie their product registrations to the EU requirements.

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 New Drug Application ("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 the FDA has approved a Biologics License Application ("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 ("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 current good manufacturing practices ("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 risk evaluation and mitigation strategy ("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 ("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 10 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 (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 ("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 ("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 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 ("NCE")—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.

The Biologics Price Competition and Innovation Act

The Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act of 2010, (collectively, the "ACA") includes a subtitle called the Biologics Price Competition and Innovation Act ("BPCIA"), 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 12-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.

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 ("CTA"), much like an IND, prior to the commencement of clinical trials. In the EU, for example, the conduct of clinical trials is currently governed by the EU Clinical Trials Regulation (EU) No. 536/2014 ("CTR"). The CTR replaced the Clinical Trials Directive 2001/20/EC ("Clinical Trials Directive") effective January 31, 2022, and introduced a complete overhaul of the existing regulation of clinical trials for medicinal products in the EU.

Under the new CTR, a sponsor may submit a single application for approval of a clinical trial through a centralized EU clinical trials portal. One national regulatory authority (the reporting EU Member State proposed by the applicant) will take the lead in validating and evaluating the application consult and coordinate with the other concerned Member States. If an application is rejected, it may be amended and resubmitted through the EU clinical trials portal. If an approval is issued, the sponsor may start the clinical trial in all concerned Member States. However, a concerned EU Member State may in limited circumstances declare an "opt-out" from an approval and prevent the clinical trial from being conducted in such Member State. The CTR also aims to streamline and simplify the rules on safety reporting, and introduces enhanced transparency requirements such as mandatory submission of a summary of the clinical trial results to the EU Database.

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 of 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 will be 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. In December 2019, FDA issued draft guidance intended to clarify how sponsors of combination products can: establish the scientific relevance of information from another development program to support an application for FDA approval of a combination product. In December 2020, FDA issued final guidance on how sponsors of combination products can obtain feedback from FDA on scientific and regulatory questions pertaining to the combination product.

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 regulations by both the federal government and the states in which we conduct our business. For example, the regulations promulgated under the Health Insurance Portability and Accountability Act of 1996

("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), impose privacy, security and breach reporting obligations with respect to protected health information ("PHI") 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, that require the business associates to protect any PHI provided by the covered entity against improper use or disclosure, amongst other things. Additionally, HITECH mandates the reporting of certain breaches of PHI to the U.S. Department of Health and Human Services ("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 PHI, 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.

In addition to applicability of HIPAA or other data privacy laws or regulations, failing to take what the Federal Trade Commission ("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, ("FTCA"). 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. 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 acts or 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 California Consumer Privacy Act of 2018 ("CCPA"), as amended by the California Privacy Rights Act of 2020 ("CPRA"), and the EU General Data Protection Regulation (Regulation (EU) 2016/679) and related implementing laws in individual EU Member States (collectively, the "GDPR"), as well as the United Kingdom version of the GDPR (which combines the GDPR and the United Kingdom's Data Protection Act 2018) may govern the privacy and security of personal 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 (some information may be exempt from most of CCPA/CPRA if, for example, subject to HIPAA or may be jurisdictionally limited), can result in the imposition of significant civil and/or criminal penalties and private litigation.

Especially in the EU, there has been increased attention to privacy and data protection issues with the potential to directly affect our business. The GDPR, which went into effect on May 25, 2018, imposes penalties of up to EUR 20 million (approx. $24 million) or 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher. The GDPR increased responsibility and liability in relation to personal data that we process. It also imposes a number of strict obligations and restrictions on the ability to process (processing includes collection, analysis and transfer of) personal data of individuals, in particular with respect to health data from clinical trials and adverse event reporting. The GDPR includes requirements relating to the legal basis of the processing (such as consent of the individuals to whom the personal data relates), the information provided to the individuals prior to processing their personal data, the notification obligations to the national data protection authorities, and the security and confidentiality of the personal data. EU Member States may also impose additional requirements in relation to the health, genetic and biometric data

through their national legislation. In addition, the GDPR imposes specific restrictions on the transfer of personal data to countries outside of the EU that are not considered by the European Commission as providing an adequate level of data protection (including the United States). Appropriate safeguards are required to enable such transfers. Among the appropriate safeguards that can be used, the data exporter may use the standard contractual clauses ("SCCs"). When relying on SCCs, the data exporters are also required to conduct a transfer risk assessment to verify if anything in the law and/or practices of the third country may impinge on the effectiveness of the SCCs in the context of the transfer at stake and, if so, to identify and adopt supplementary measures that are necessary to bring the level of protection of the data transferred to the EU standard of essential equivalence. Where no supplementary measure is suitable, the data exporter should avoid, suspend or terminate the transfer.

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.

Employees

As of December 31, 2022, we had 54 employees, all of whom were full-time employees. None of our employees are 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.

Matters Related to Discontinued Laboratory Operations

Our historical operations included 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. Previously, the core business was focused on the prenatal carrier screening and noninvasive prenatal test market, targeting preconception planning and routine pregnancy management for genetic disease risk assessment. Through our prior affiliation with Mattison Pathology, LLP, a Texas limited liability partnership doing business as Avero Diagnostics ("Avero"), located in Lubbock and Dallas, Texas, our operations also included anatomic and molecular pathology testing products in the United States.

In June 2021, we announced a strategic transformation ("Strategic Transformation") that included the closure of our genetics lab in Ann Arbor, Michigan and the sale of our Avero laboratory business in December 2021, together referred to as the Laboratory Operations. We have excluded from continuing operations for all periods presented in this report revenues and expenses associated with its Laboratory Operations, which are reported as discontinued operations in the consolidated financial statements. See Note 4 to our audited consolidated financial statements for additional information on the Laboratory Operations.

Preeclampsia

We had historically been developing a rule-out test for preeclampsia, branded as the Preecludia™ test, as part of our discontinued Laboratory Operations. In connection with our Strategic Transformation, we deprioritized this project and discontinued further investment in its development. On November 29, 2022, we announced that we had signed an agreement to license the Preecludia™ test to Avero Diagnostics (formerly known as Northwest Pathology) for commercial development in exchange for commercial milestone payments and royalties on net sales.

Single-Molecule Detection

Historically, we also had been developing a novel, single-molecule counting assay, initially for use in noninvasive prenatal testing, but potentially applicable to other known genomic, epigenomic, and proteomic targets, as part of our discontinued Laboratory Operations. In connection with our Strategic Transformation, we deprioritized this project and discontinued further investment in its development. On May 4, 2022, we completed the divesture of the single-molecule detection platform and contributed all assets related to the platform to newly-formed Enumera Molecular, Inc. ("Enumera"), which intends to develop and commercialize the platform. We received a minority ownership stake in Enumera in exchange for the assets.

Reimbursement

Prior to the discontinuation of our Laboratory Operations, we operated clinical laboratories. Laboratory tests are classified for reimbursement purposes under a coding system known as Current Procedure Terminology ("CPT"), which labs and their physician customers must use to bill payors and to receive payment for molecular tests. These CPT codes are associated with the particular

molecular test that we have provided to the patient. Once the American Medical Association establishes a CPT code, the Centers for Medicare and Medicaid Services ("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.

Prior to the discontinuation of our Laboratory Operations, we submitted 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 received small amounts of revenue in connection with the reimbursement for tests that were run prior to the closure of our Ann Arbor lab through September 2022. Subsequently, we expect that our primary sources of revenue will shift to potential grants and partnership revenues, though these amounts, if and when received, may be relatively small in magnitude.

Commercial Third-Party Payors

In the past, we submitted claims for reimbursement and received associated payments from commercial third-party payors. Our contracts with commercial third-party payors provide for contracted rates of reimbursement. For instances where we were not contracted with a particular commercial third-party payor, we submitted claims seeking reimbursement on a non-contracted basis.

In cases where we were an in-network provider in a commercial third-party payor health plan, we are 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: United HealthCare Services, Inc. and UnitedHealthcare Insurance Company ("United"), and Aetna Health Management, Inc. ("Aetna"). 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. As of December 31, 2021 the settlement with these commercial payors has been fully paid. Each of these settlement agreements provides for a release of past claims by the parties.

Payor Dispute

On November 16, 2020, we received a letter from Anthem, Inc. ("Anthem"), informing us that Anthem is seeking recoupment for historical payments made by Anthem in an aggregate amount of approximately $27.4 million. The historical payments for which Anthem was seeking recoupment were claimed to relate primarily to discontinued legacy billing practices for our former non-invasive prenatal tests ("NIPT") and microdeletion tests and secondarily to the implementation of the new CPT code for reimbursement for our former Preparent expanded carrier screening tests.

We have historically negotiated and settled similar claims with third-party payors. Although our practice in resolving disputes with other similar large commercial payors has generally led to agreed settlement amounts substantially less than the originally claimed amount, there can be no assurance that we will be successful in a similar settlement amount in any ongoing or future dispute. Historical settlement amounts and payment time periods may not be indicative of the final settlement terms with Anthem, if any. We dispute this claim of recoupment with Anthem in full, with offsets for amounts owed by Anthem to us. We had previously established an accrual for the estimated probable loss for this matter. During the year ended December 31, 2022, we reversed this accrual for a portion of the matter in view of applicable statute of limitations and have reflected this change in revenues from discontinued operations.

Corporate Information

We were incorporated in Delaware in January 2012 under the name Ascendant MDx, Inc.. In August 2013, we changed our name to Progenity, Inc., and in April 2022, we changed our name to Biora Therapeutics, Inc. Through our predecessor, Ascendant MDx, a California corporation, we commenced our operations in 2010. Our principal executive offices are located at 4330 La Jolla Village Drive, Suite 300, San Diego, CA 92122, and our telephone number is (833) 727-2841. Our website is www.bioratherapeutics.com. Information contained on or accessible through our website is not a part of this Annual Report, and the inclusion of our website address in this Annual Report is an inactive textual reference only.

We file electronically with the Securities and Exchange Commission (the "SEC") our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). We make available on our website at

www.bioratherapeutics.com, under “Investors,” free of charge, copies of these reports as soon as reasonably practicable after filing or furnishing these reports with the SEC.

Implications of Being an Emerging Growth Company and a Smaller Reporting 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, 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. We may also elect to take advantage of other reduced reporting requirements in future filings. As a result, our stockholders may not have access to certain information that they may deem important and the information that we provide to our stockholders may be different than, and not comparable to, information presented by other public reporting companies. We could remain an emerging growth company until the earlier of (1) the last day of the year following the fifth anniversary of the completion of our initial public offering ("IPO"), (2) the last day of the year in which we have total annual gross revenue of at least $1.235 billion, (3) the last day of the year in which we are deemed to be a “large accelerated filer” as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year or (4) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

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.

We are also a smaller reporting company, as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as (i) our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Item 1A. 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 Annual Report on Form 10-K, including "Management's Discussion & Analysis" and the financial statements and related notes, before deciding to make an investment decision with respect to 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. We caution you that the risks, uncertainties and other factors referred to below and elsewhere in this Annual Report on Form 10-K 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 this "Risk Factors" section, unless the context requires otherwise, references to "we," "us," "our," "Biora," "Biora Therapeutics" or the "company" refer to Biora Therapeutics, Inc. and its subsidiaries.

Risk Factor Summary

- We have incurred losses in the past, and we may not be able to achieve or sustain profitability in the future.
- 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, and if we cannot raise additional capital when needed, we may have to curtail or cease operations.
- We rely on a limited number of suppliers or, in some cases, single suppliers, and may not be able to find replacements or immediately transition to alternative suppliers on a cost-effective basis, or at all.
- The manufacturing of our therapeutics product candidates, and other products under development, is highly exacting and complex, and we depend on third parties to supply materials and manufacture certain products and components.
- We operate in a highly competitive business environment.
- Our success depends on our ability to develop new product candidates, which is complex and costly and the results are uncertain.
- We are still developing our therapeutics pipeline and are in the early stages of its development, have conducted some early preclinical studies, and limited early clinical studies, and to date have generated no therapeutics products or product revenue. There can be no assurance that we will develop any therapeutics products that deliver 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 outstanding debt, and any new debt, may impair our financial and operating flexibility.
- We may not be able to obtain and maintain the third-party relationships that are necessary to develop, fund, commercialize, and manufacture some or all of our product candidates.
- If third-party payors do not adequately reimburse for our products under development, they might not be purchased or used, which may adversely affect our revenue and profitability.
- 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.

Risks Related to Our Business and Industry

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

We expect to incur significant costs in connection with the development, approval, and commercialization of our products under development. Even if we succeed in creating such product candidates from these investments, those innovations still may fail to result in commercially successful products.

Other than potential revenues from partnerships similar to those we have entered into in the recent past, we do not expect to generate significant revenues in the immediate future. We do not expect to generate sufficient revenue to cover our costs for the foreseeable future, including research and development and clinical study expenses related to furthering our product pipeline. We may

not generate significant revenue in the future until we are able to achieve commercialization of our product candidates or enter into licensing or collaboration agreements with respect to such product candidates.

Since we or any collaborators or licensees may not successfully develop additional product candidates, obtain required regulatory authorizations, manufacture products at an acceptable cost or with appropriate quality, or successfully market and sell such product candidates 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 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.

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, and if we cannot raise additional capital when needed, we may have to curtail or cease operations.

We expect to incur significant costs in connection with our operations, including, but not limited to, the research and development, marketing authorization, and/or commercialization of new medical devices, therapeutics, and other products. These development activities generally require a substantial investment before we can determine commercial viability, and the proceeds from our offerings to date will not be sufficient to fully fund these activities. In addition, as a result of the Strategic Transformation, our revenue has been significantly reduced. We will need to raise additional funds through public or private equity or debt financings, collaborations, licensing arrangements or sales of assets to continue to fund or expand our operations. Following the Strategic Transformation, we no longer generate revenue from our historical testing business, and we would be dependent on such additional sources of capital, including public or private equity or debt financings, collaborations, licensing arrangements or sales of assets for all of our future capital requirements if we do not achieve commercialization of our product candidates.

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 for our therapeutics pipeline;
- 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 any future expansion of our sales and marketing efforts;
- potential and pending litigation, potential payor recoupments of reimbursement amounts, and other contingencies;
- the commercial success of our future products;
- the termination costs associated with our Strategic Transformation; and
- any proceeds from strategic transactions.

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, a further decline in our share price or a 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, including through our ATM Facility (as defined below), 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.

To minimize dilution to our equity holders, we are also exploring non-dilutive financing options, which could include licenses or collaborations and/or sales of certain assets or business lines. 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. To the extent that we raise additional funds through strategic transactions, including a sale of one of our lines of business, we may not ultimately realize the value of or synergies from such transactions and our long-term prospects could be diminished as a result of the divestiture of these assets. We may also be required to use some or all of these sale proceeds to pay down indebtedness, which would then not serve to increase our working capital.

If we are not able to obtain adequate funding when needed, we may be required to delay development programs or other 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 product candidates, which could reduce the economic value of those products to us. If we engage in strategic transactions with respect to revenue-producing assets or business lines, our revenue may be adversely affected and such transactions could negatively affect the viability of our business. Each of the foregoing may harm our business, operating results, and financial condition, and may impact our ability to continue as a going concern.

We maintain our cash at financial institutions, often in balances that exceed federally-insured limits. The failure of financial institutions could adversely affect our ability to pay our operational expenses or make other payments.

Our cash held in non-interest-bearing and interest-bearing accounts exceeds the Federal Deposit Insurance Corporation ("FDIC") insurance limits. If such banking institutions were to fail, we could lose all or a portion of those amounts held in excess of such insurance limitations. For example, the FDIC took control of Silicon Valley Bank on March 10, 2023. The Federal Reserve subsequently announced that account holders would be made whole. However, the FDIC may not make all account holders whole in the event of future bank failures. In addition, even if account holders are ultimately made whole with respect to a future bank failure, account holders' access to their accounts and assets held in their accounts may be substantially delayed. Any material loss that we may experience in the future or inability for a material time period to access our cash and cash equivalents could have an adverse effect on our ability to pay our operational expenses or make other payments, which could adversely affect our business.

We rely on a limited number of suppliers or, in some cases, single suppliers, 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 under development, including those for which we are required to obtain marketing authorization from the FDA and would need to obtain a 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 or yield of the items manufactured would heighten the risks that we face. For example, our targeted therapeutics device under development includes complex components including circuit boards that have to be built to exacting standards, and the failure of a manufacturer to meet our requirements on time, as we have experienced in the past and continue to experience, could lead to delays in our plans for testing, pre-clinical and clinical studies and other development activities. 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 products under development 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.

The manufacturing of our therapeutics product candidates, and other products under development, is highly exacting and complex, and we depend on third parties to supply materials and manufacture certain products and components.

Manufacturing is highly exacting and complex due, in part, to strict regulatory requirements governing the manufacture of our future products and product candidates, including medical devices with complex components, including but not limited to, circuit boards 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, 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 cGMP regulations 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 therapeutics product candidates, including BT-600, BT-001, BT-200, and BT-002, are drug-device combination products that will be regulated under the drug and biological product regulations of the FD&C Act, and Public Health Service Act (the "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 QSR, or similar regulatory requirements outside the United States.

In addition, we or third parties may experience other problems with the manufacturing, quality control, yields, 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, delays to development and preclinical study timelines, lost collaboration opportunities, damage to collaborator relations, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches of products. For example, our therapeutics devices under development includes complex components including circuit boards that have to be built to exacting standards, and the failure of a manufacturer to meet our requirements on time, as we have experienced in the past and continue to experience, could lead to delays in our plans for testing, pre-clinical and clinical studies and other development activities. 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.

We may be unable to successfully divest certain assets or recover any of the costs of our investment in certain R&D programs.

In connection with our Strategic Transformation, we have divested certain assets that do not align with our current operational plans and strategies, including the sale of certain laboratory assets and the divesture of Avero. We have explored the potential divestiture and/or out-license of other assets and intellectual property as well. It is possible that we will be unable to successfully divest and/or license these assets, and we may never recover any of the costs of our historical R&D investments.

On May 4, 2022, we completed the divesture of our single-molecule detection platform and contributed all assets related to the single-molecule detection platform to newly-formed Enumera, which intends to develop and commercialize the platform. We received a minority ownership stake in Enumera in exchange for the assets. It is possible that the value of our equity stake in Enumera will decrease over time, and it is possible that we may never recover any of the costs of the historical R&D investments related to this platform.

Additionally, on November 29, 2022, we announced that we had signed an agreement to license our Preecludia™ rule-out test for preeclampsia to Avero Diagnostics (formerly known as Northwest Pathology) for commercial development in exchange for commercial milestone payments and royalties on net sales. There is no assurance that Avero will be able to successfully commercialize the test. As a result, there is no assurance that we will receive any payments from the transaction and we may never recover any of the costs of the historical R&D investments related to this program.

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.

We expect our future products, if approved, 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 therapeutics competitors, see Part I, Item 1. “Business—Competition.”

Additionally, we compete to acquire the intellectual property assets that we require to continue to develop and broaden our product pipeline. In addition to our in-house research and development efforts, we may 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 under development less competitive or obsolete. Our future growth depends, in part, on our ability to provide products that are more effective than those of our competitors and to keep pace with rapid medical and scientific change. Sales of 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 our 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 develop 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 new products and product candidates to the market are important elements of our business strategy. However, the development of 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.

In the development of 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 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 a commercial laboratory. This process is conducted in various stages, and each stage presents the risk that we will not achieve our goals and will 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 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, our future

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 therapeutics pipeline and are in the early stages of its development, have conducted some early preclinical studies, and limited early clinical studies, and to date have generated no therapeutics products or product revenue. There can be no assurance that we will develop any therapeutics products that deliver 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 therapeutics pipeline to date have been limited to developing our platform technology, undertaking preclinical studies and feasibility studies with human subjects, and conducting research to identify potential product candidates. To date, we have only conducted limited feasibility studies in humans to evaluate whether our platform localization technology enables identification of the location of our ingestible medical devices within the gastrointestinal tract as well as the function of our devices.

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 and we are in the early stages of our development programs. Our therapeutics pipeline 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 therapeutics pipeline is significantly more limited than if we had an operating history or approved commercial therapeutics products. Our success in developing commercial products that are based on our therapeutics pipeline 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;
- our ability to attract and retain key personnel with the appropriate expertise and experience to potentially develop our product candidates; and
- the ability of third-party manufacturers to manufacture our product candidates in accordance with 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 therapeutics 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:

- 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 therapeutics pipeline 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 for IND submissions and 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. Once filed, our IND submissions may not become effective if the FDA raises concerns with respect to those submissions. Further, 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 even if we achieve positive results in earlier trials, 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 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 initiation or completion of our clinical trials for a number of reasons, which could adversely affect the costs, timing, or success of our clinical trials, including related to the following:

- we may be required to submit an 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 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 ("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 or our investigators may have to suspend or terminate clinical trials for various reasons, including a finding that the subjects are being exposed to unacceptable health risks or based on a requirement or recommendation from regulators, IRBs or other parties due to safety signals or noncompliance with regulatory requirements;

- 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;
- 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 product candidates 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 product candidates. 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 product candidates. Results of earlier studies may not be predictive of future clinical trial results, or the safety or efficacy profile for such products or product candidates.

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 results of operations, liquidity and financial condition. 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 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 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 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 products under development, particularly in new areas such as in drug-device combination 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 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 under development or the underlying technology do not receive sufficient favorable exposure in peer-reviewed publications, or are not published, the rate of healthcare provider adoption of our products under development and positive reimbursement coverage decisions for our products under development could be negatively affected. The publication of clinical data in peer-reviewed journals can be a crucial step in commercializing and obtaining reimbursement for products under development, and our inability to control when, if ever, results are published may delay or limit our ability to derive sufficient revenues from any test or other product that is the subject of a study. The performance achieved in published studies might 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.

Our outstanding debt, and any new debt, may impair our financial and operating flexibility.

As of December 31, 2022, we had approximately $127.8 million of Convertible Notes outstanding (the "Convertible Notes"). Certain of our debt agreements contain various restrictive covenants.

The indenture, dated as of December 7, 2020, by and between the Company and The Bank of New York Mellon Trust Company, N.A., as trustee (the "Indenture"), for our Convertible Notes does not prohibit us or our subsidiaries from incurring additional indebtedness in the future, with certain exceptions. Under the Convertible Notes, we will not, and we will not permit any subsidiary of ours to, create, incur, assume or permit to exist any lien on any property or asset now owned or later acquired by us or any subsidiary that secures any indebtedness for borrowed money, other than (i) secured indebtedness for borrowed money in existence on the date of the Indenture; (ii) permitted refinancing indebtedness incurred in exchange for, or the net proceeds of which are used to renew, refund, refinance, replace, defease or discharge any secured indebtedness for borrowed money permitted by clause (i) of this sentence; and (iii) additional secured indebtedness for borrowed money that, in an aggregate principal amount (or accredited value, as applicable), does not exceed $15.0 million at any time outstanding.

Accordingly, we may incur a significant amount of additional indebtedness in the future. Our current indebtedness and the incurrence of additional indebtedness could have significant negative consequences for our stockholders and our business, results of operations and financial condition by, among other things:

- making it more difficult for us to satisfy our obligations under our existing debt instruments;
- increasing our vulnerability to general adverse economic and industry conditions;
- limiting 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;
- requiring 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;
- limiting our flexibility to plan for, or react to, changes in our business and the industries in which we operate;
- further diluting our current stockholders as a result of issuing shares of our common stock upon conversion of our Convertible Notes; and
- placing us at a competitive disadvantage with competitors that are less leveraged than us or have better access to capital.

Our ability to make principal and interest payments will depend on our ability to generate cash in the future. Our business may not generate sufficient funds, and we may otherwise be unable to maintain sufficient cash reserves, to pay amounts due under our indebtedness, and our cash needs may increase 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.

In addition, any future indebtedness that we may incur may contain financial and other restrictive covenants that limit our ability to operate our business, raise capital or make payments under our other indebtedness. If we fail to comply with these covenants or to make payments under our indebtedness when due, then we would be in default under that indebtedness, which could, in turn, result in that and our other indebtedness becoming immediately payable in full.

Actual or perceived failures to comply with applicable data protection, privacy, consumer protection 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 PHI, is subject to HIPAA, as amended by 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 unauthorized access, use or disclosure. If a breach affects 500 patients or more, covered entities must report it to 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, on June 28, 2018, California enacted the CCPA, which went into effect on January 1, 2020 and was amended by the CPRA, which went into effect on January 1, 2023. The CPRA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal data. The CPRA provides for civil penalties for violations, as well as a private right of action for data breaches that could increase data breach litigation. The CPRA 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.

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, including our historical testing 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 Standard. 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 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 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, there can be no assurance that such measures will successfully prevent service interruptions or data security incidents.

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 personnel in our industry and especially in the areas where our 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, fund, 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, including, 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 and products under development, 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 parties for matters related to the design of our product candidates and for 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 certain aspects of the design, preclinical testing, and clinical trials for our products under development. 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.

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;
- 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 therapeutics product candidates because they are combination products.

Some of our therapeutics 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 therapeutics 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 therapeutics product candidates under the early stages of 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 therapeutics product candidates are prescribed only by trained professionals, the potential for misuse of our therapeutics 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 therapeutics pipeline. 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 or to medical devices. 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 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 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. 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 product candidates 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 therapeutics pipeline that require FDA approval of an 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 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 therapeutics pipeline 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 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 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.

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.

Unfavorable global economic conditions, whether brought about by global crises, health epidemics, military conflicts and war, geopolitical and trade disputes or other factors, may have a material adverse effect on our business and financial results.

Our business is sensitive to global economic conditions, which can be adversely affected by public health crises (including the COVID-19 pandemic) and epidemics, political and military conflicts, trade and other international disputes, significant natural disasters (including as a result of climate change) or other events that disrupt macroeconomic conditions. Adverse macroeconomic conditions, including inflation, slower growth or recession, new or increased tariffs and other barriers to trade, changes to fiscal and monetary policy or government budget dynamics (particularly in the pharmaceutical and biotech areas), tighter credit, higher interest rates, volatility in financial markets, high unemployment, labor availability constraints, currency fluctuations and other challenges in the global economy have in the past adversely affected, and may in the future adversely affect, us and our business partners and suppliers.

For example, military conflicts or wars (such as the ongoing conflict between Russia and Ukraine) can cause exacerbated volatility and disruptions to various aspects of the global economy. The uncertain nature, magnitude, and duration of hostilities stemming from such conflicts, including the potential effects of sanctions and counter-sanctions, or retaliatory cyber-attacks on the world economy and markets, have contributed to increased market volatility and uncertainty, which could have an adverse impact on macroeconomic factors that affect our business and operations, such as worldwide supply chain issues. It is not possible to predict the short and long-term implications of military conflicts or wars or geopolitical tensions which could include further sanctions, uncertainty about economic and political stability, increases in inflation rate and energy prices, cyber-attacks, supply chain challenges and adverse effects on currency exchange rates and financial markets.

Additionally, our operations and facilities, as well as operations of our service providers and manufacturers, may be located in areas that are prone to earthquakes and other natural disasters. Such operations and facilities are also subject to the risk of interruption by fire, drought, power shortages, nuclear power plant accidents and other industrial accidents, terrorist attacks and other hostile acts, ransomware and other cybersecurity attacks, telecommunication failure, labor disputes, public health crises (including the COVID-19 pandemic) and other events beyond our control. Global climate change is resulting in certain types of natural disasters occurring more frequently or with more intense effects. If a natural disaster or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. Because we rely on a single or limited sources for the supply and manufacture of many critical components, a business interruption affecting such sources would exacerbate any negative consequences on our business. We may not carry sufficient business interruption insurance to compensate us for all losses that may occur.

Any public health crises, including the COVID-19 pandemic, may affect our operations and those of third parties on which we rely, including our business partners and suppliers. To date, we are aware of certain suppliers for our R&D activities who have experienced operational delays directly related to the COVID-19 pandemic. In the past three years, the COVID-19 pandemic has caused, and likely will continue to cause, significant volatility and uncertainty in U.S. and international markets, disruptions to our business and delays in our preclinical studies, clinical trials and timelines, including as a result of impacts associated with protective health measures that we, other businesses and governments are taking or might have to take again in the future to manage the pandemic. The extent to which the COVID-19 pandemic and measures taken in response thereto impact our business, results of operations and financial condition will depend on future developments which are highly uncertain and difficult to predict.

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, as we increase our research and development efforts, we expect to incur costs in advance of achieving the anticipated benefits of such efforts.

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.

The development and expansion of our business through joint ventures, licensing and other strategic transactions may result in similar risks that reduce the benefits we anticipate from these strategic alliances and cause us to suffer other adverse consequences.

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 ("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.

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

As of December 31, 2022, we had net operating loss ("NOL") carryforwards of approximately $504.8 million for federal income tax purposes, and $246.3 million for state income tax purposes. The federal NOLs will be carried forward indefinitely and the state NOLs begin expiring in 2028. 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 (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.

Reimbursement Risks Related to Our Historical Testing Business

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

Prior to the shutdown of our Laboratory Operations, which occurred in 2021, we operated clinical laboratories and billed for tests. 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 (see Note 10 to our consolidated financial statements included elsewhere in this Annual Report for additional information regarding current recoupment requests). We continue to receive recoupment requests and we expect these disputes and requests for recoupment may continue for a period of time in the future. 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 government and commercial payors in order to settle claims related to past billing practices that have since been discontinued. For more information on these disputes, see Part I, Item 1. “Business—Reimbursement—Commercial Third-Party Payors.” Additionally, 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 and the healthcare enforcement authorities of Office of Inspector General of the Department of Health and Human Services ("OIG"). 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 a third-party payor successfully challenges that payment to us 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. We may also decide to negotiate and settle with a third-party payor in order to resolve an allegation of overpayment. In the past, we have negotiated and settled these types of claims with third-party payors. We may be required to resolve further disputes in the future. For example, the Company is currently in the process of reviewing several managed Medicaid payor recoupment requests aggregating to $1.1 million. We can provide no assurance that we will not receive similar claims for recoupment from other third-party payors in the future. For more information on this claim, see Part I, Item 1. “Business—Reimbursement—Payor Dispute.” 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.

If the validity of an informed consent from a patient is challenged, we could be forced to refund amounts previously paid by third-party payors, or to exclude a 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 testing 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 area or could call into question the results of our clinical trials. In addition, we could be requested to refund amounts previously paid by third-party payors for tests where an informed consent is challenged. We could become involved in legal challenges, which could require significant management and financial resources and adversely affect our operating results.

We may be unable to obtain or maintain third-party payor coverage and reimbursement for our future tests or products.

Our future success will depend on our or our potential partners' ability to obtain or maintain adequate reimbursement coverage from third-party payors. Third-party reimbursement for our testing historically represented a significant portion of our revenues, and we expect third-party payors such as third-party commercial payors and government healthcare programs to be a source of revenue in the future. It is to be determined whether and to what extent certain of our products 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 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.

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 significant fines for each violation and administrative civil money penalties, 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 ("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 significant fines 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 significant civil monetary penalties, plus 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 significant civil monetary penalties for each wrongful act;
- the prohibition on reassignment by the program beneficiary of Medicare claims to any party;
- The federal Healthcare Fraud Statute, 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 PHI 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 PHI; 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, various other healthcare professionals, including physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse midwives, 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
- similar healthcare laws in the European Union and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

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 significant mandatory civil penalties 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.

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

Our product candidates 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 therapeutics pipeline 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, preclinical, 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 future 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 or other regulatory marketing authorizations for a new or enhanced product, the FDA or such other regulator may condition, withdraw, or materially modify its marketing authorization.

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

Our therapeutics 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 product candidates, if approved. As a part of the regulatory process of obtaining marketing authorization for new products and modifications to 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 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 therapeutics pipeline, 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 or a non-U.S. regulatory agency 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 or such other non-U.S. regulatory agency 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. regulatory 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 Part I, Item 3. "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 amendments to our corporate integrity agreement with the OIG. 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.

Current and future legislation may increase the difficulty and cost for us, and any collaborators, to obtain marketing approval of and commercialize our drug candidates and affect the prices we, or they, may obtain.

To date, there have been several recent U.S. congressional inquiries and proposed and enacted state and federal legislation and regulation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient support programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. Heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. We expect that additional state and federal healthcare reform measures will be adopted in the future, particularly in light of the new presidential administration, any of which could limit the amounts that federal and state governments will pay for healthcare therapies, which could result in reduced demand for our product candidates or additional pricing pressures. Most recently, on August 16, 2022, President Biden signed into law the Inflation Reduction Act of 2022 (“IRA”), which contains provisions intended to lower beneficiary drug spending. Beginning in 2023, the IRA authorizes the CMS to negotiate Medicare reimbursement rates for certain prescription drug products, which may put limits on prices paid for drugs by government health programs. We cannot be sure whether additional legislation or rulemaking related to the IRA will be issued or enacted, or what impact, if any, such changes will have on the profitability of any of our drug candidates, if approved for commercial use, in the future.

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 ("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 under development. 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.

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 BT-600, a GI-targeted tofacitinib, for which we may seek FDA approval through the Section 505(b)(2) regulatory pathway. We expect that BT-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 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 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 therapeutics 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 under development.

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. For example, we have identified a number of third-party patents that may be asserted against us with respect to certain of our future products, and have identified pending patent applications for which the ultimate claim scope and validity are uncertain. We believe that we do not infringe the relevant claims of these third-party patents and/or that the relevant claims of these patents are likely invalid or unenforceable. We may choose to challenge the validity of these patents, though the outcome of any challenge that we may initiate in the future is uncertain. We may also decide in the future to seek a license to those third-party patents, but we might not be able to do so on reasonable terms. Certain third parties, including our competitors or collaborators, have asserted and 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 have a material and adverse effect on our business, operating results, and financial condition. See Part I, Item 3. "Legal Proceedings—Ravgen Lawsuit" for more information regarding a patent infringement suit filed by Ravgen, Inc. related to our laboratory developed test business, which is no longer in operation. There can be no assurance that we will prevail in the Ravgen matter. For example, in a patent infringement suit filed by Ravgen against another laboratory asserting the same patents, a Texas jury found the laboratory liable for infringement and awarded significant damages.

As we move into new markets and develop enhancements to and new applications for our product candidates, competitors have asserted and may in the future 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 collaborators, 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 products under development 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 that may be open to different interpretations. 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 future products may infringe. In addition, our competitors or other parties may assert that our product candidates and the methods they employ may be covered by patents held by them. If any of our products 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. 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 life sciences 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 the future in a loss in market share of our products under development, 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, including our competitors in the targeted and systemic therapeutics fields, may independently develop similar or alternative technologies, ingestible devices, or design around our patented or patent pending 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 under development.

"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 product candidates and thereby cause significant market entry delay, defeat our ability to market our product candidates or cause us to abandon development and/or commercialization of a product candidate.

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 under development 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 Ownership of Our Common Stock

The market price of our common stock has fluctuated in the past, and is likely to continue to be volatile, which could subject us to litigation.

The market price of our common stock has fluctuated and is likely to be subject to further 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:

- our recent reverse stock split;
- 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 or divestitures, strategic and commercial partnerships and relationships, joint ventures, collaborations or capital commitments;
- issuance of new securities analysts' reports or changed recommendations for our stock;
- periodic fluctuations in our revenue;
- actual or anticipated changes in regulatory oversight of our products under development;
- developments or disputes concerning our intellectual property or other proprietary rights or alleged infringement of third party's rights by us or our products under development;
- 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, including slow or negative growth in the biotechnology industry generally.

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 may fail to qualify for continued listing on the Nasdaq Global Market, which could make it more difficult for our stockholders to sell their shares.

We are required to satisfy the continued listing requirements of the Nasdaq Global Market ("Nasdaq") to maintain such listing, including, among other things, the maintenance of a minimum closing bid price of $1.00 per share and a market value of our common stock of at least $50 million. On June 6, 2022, we received a notice from Nasdaq that we were not in compliance with the minimum bid price requirements set forth in Nasdaq Listing Rule 5450(a)(1) for continued listing on Nasdaq. Nasdaq Listing Rule 5450(a)(1) requires listed securities maintain a minimum closing bid price of $1.00 per share, and Nasdaq Listing Rule 5810(c)(3)(A) provides that a failure to meet the minimum closing bid price requirement exists if the deficiency continues for a period of 30 consecutive

business days. The notification of noncompliance had no immediate effect on the listing or trading of our common stock on Nasdaq. On January 19, 2023, we received notice from Nasdaq that the bid price deficiency had been cured and we are in compliance with all applicable continued listing standards.

There can be no assurance that we will be able to maintain compliance with Nasdaq's continued listing requirements. If our stock price does not increase or if we are unable to raise additional funds, and if our market capitalization does not meet the minimum standards, we may not be able to maintain the standards for continued listing on Nasdaq. In the event that we do not maintain compliance with the Nasdaq Listing Rules in the future, we expect to receive written notification that our common stock is subject to delisting. If our common stock is delisted by Nasdaq, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our common stock;
- reduced liquidity with respect to our common stock;
- a determination that our shares are "penny stock," which will require brokers trading in our shares to adhere to more stringent shares, and which may limit demand for our common stock among certain investors;
- a limited amount of news and analyst coverage for our company; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

Our common stock may become the target of "short squeezes."

In the recent past, the securities of several companies have increasingly experienced significant and extreme volatility in stock price due to short sellers of shares of their stock and buy-and-hold decisions of other investors, resulting in what is sometimes described as a "short squeeze." Short squeezes have caused extreme volatility in the stock prices of those companies and in the market and have led to the price per share of some of those companies to trade at a significantly inflated rate that is disconnected from the underlying value of the company. Sharp rises in a company's stock price may force traders in a short position to buy the stock to avoid even greater losses. Investors who purchase shares in those companies at an inflated rate face the risk of losing a significant portion of their original investment as the price per share has declined steadily as interest in those stocks have abated. Market activity suggests that we have been the target of a short squeeze, and this could occur again at any time, and stockholders may lose a significant portion or all of their investment if they purchase our shares at a rate that is significantly disconnected from our underlying value.

The issuance of shares of our common stock upon conversion of the Convertible Notes and exercise of warrants will dilute the ownership interests of our stockholders and could depress the trading price of our common stock.

We must settle conversions of our outstanding Convertible Notes and exercise of our outstanding warrants in shares of our common stock, together with cash in lieu of issuing any fractional share in the case of the Convertible Notes. The issuance of shares of our common stock upon conversion of the Convertible Notes or exercise of the warrants will dilute the ownership interests of our stockholders, which could depress the trading price of our common stock. In addition, the market's expectation that conversions or exercises may occur could depress the trading price of our common stock even in the absence of actual conversions or exercises. Moreover, the expectation of conversions or exercises could encourage the short selling of our common stock, which could place further downward pressure on the trading price of our common stock.

Hedging activity by investors in the Convertible Notes and warrants could depress the trading price of our common stock.

We expect that many investors in our outstanding Convertible Notes and warrants will seek to employ an arbitrage strategy. Under this strategy, investors typically short sell a certain number of shares of our common stock and adjust their short position over time while they continue to hold the Convertible Notes or warrants. Investors may also implement this type of strategy by entering into swaps on our common stock in lieu of, or in addition to, short selling shares of our common stock. This market activity, or the market's perception that it will occur, could depress the trading price of our common stock.

Provisions in the Indenture governing our outstanding Convertible Notes could delay or prevent an otherwise beneficial takeover of us.

Certain provisions in our Convertible Notes and the Indenture governing the Convertible Notes could make a third-party attempt to acquire us more difficult or expensive. For example, if a takeover constitutes a "fundamental change" (which is defined in the Indenture to include certain change-of-control events and the delisting of our common stock), then noteholders will have the right to require us to repurchase their Convertible Notes for cash. In addition, if a takeover constitutes a "make-whole fundamental change" (which is defined in the Indenture to include, among other events, fundamental changes and certain additional business combination transactions), then we may be required to temporarily increase the conversion rate for the Convertible Notes. In either case, and in

other cases, our obligations under the Convertible Notes and the Indenture could increase the cost of acquiring us or otherwise discourage a third party from acquiring us or removing incumbent management, including in a transaction that holders of our common stock may view as favorable.

We may be unable to raise the funds necessary to repurchase the Convertible Notes for cash following a fundamental change or to pay any cash amounts due upon conversion, and our other indebtedness may limit our ability to repurchase our outstanding Convertible Notes.

Noteholders may require us to repurchase their Convertible Notes following a "fundamental change" (which is defined in the Indenture governing the Convertible Notes to include certain change-of-control events and the delisting of our common stock) at a cash repurchase price generally equal to the principal amount of the Convertible Notes to be repurchased, plus accrued and unpaid interest, if any. Furthermore, additional cash amounts may be due upon conversion in certain circumstances if the number of shares that we deliver upon conversion of the Convertible Notes is limited by Nasdaq listing standards. We may not have enough available cash or be able to obtain financing at the time we are required to repurchase the Convertible Notes or pay these cash amounts upon their conversion. In addition, applicable law, regulatory authorities and the agreements governing our other indebtedness may restrict our ability to repurchase the Convertible Notes or pay these cash amounts upon their conversion. Our failure to repurchase Convertible Notes when required or pay these cash amounts upon their conversion will constitute a default under the Indenture governing the Convertible Notes. A default under the Indenture or the fundamental change itself could also lead to a default under agreements governing our other indebtedness, which may result in that other indebtedness becoming immediately payable in full. We may not have sufficient funds to satisfy all amounts due under the other indebtedness and the Convertible Notes.

The accounting method for the Convertible Notes could adversely affect our reported financial results.

The accounting method for reflecting the underlying shares of our common stock in our reported diluted earnings per share may adversely affect our reported earnings and financial condition. We expect that, under applicable accounting principles, the shares underlying our Convertible Notes will be reflected in our diluted earnings per share using the "if-converted" method. Under that method, diluted earnings per share would generally be calculated assuming that all the Convertible Notes were converted into shares of common stock at the beginning of the reporting period, unless the result would be anti-dilutive. The application of the if-converted method may reduce our reported diluted earnings per share.

Furthermore, the conversion features in our Convertible Notes are accounted for as a free-standing embedded derivative bifurcated from the principal balance of the Convertible Notes. The embedded derivative liability is remeasured at fair value each reporting period with positive or negative changes in fair value recorded in our consolidated statement of operations, which may adversely affect our reported earnings and financial condition and result in significant fluctuations in our future financial performance.

General Risk Factors

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

As of December 31, 2022, our current directors and executive officers, together with their affiliates, have significant ownership of our outstanding common stock. As a result, these stockholders, if they act, 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.

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.

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.

Sales of a substantial number of shares of our common stock in the public market, including through our ATM Facility or by our existing stockholders, 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.

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 our IPO, (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 $1.235 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 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 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.

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 depends in part on the research and reports that securities or industry analysts publish about us or our business. If few securities analysts provide 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 certificate of incorporation and 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, as amended and our second amended and restated bylaws 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 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 second 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.

Our certificate of incorporation provides 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, as amended to date, provides 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, as amended to date, and our second 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, as amended to date, provides 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, as amended to date, and our second 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.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

We currently lease approximately 25,800 square feet of office space in San Diego, California under several lease agreements that expire in June 2023. Additionally, we lease approximately 10,500 square feet of office and laboratory space in San Diego, California under a lease agreement that expires in January 2027. We also own approximately 21,500 square feet of laboratory space in Ann Arbor, Michigan. We also lease approximately 26,500 square feet of office space in Ann Arbor, Michigan under a lease agreement that expires in October 2023. We also lease approximately 4,000 square feet of property located in Irving, Texas, which is used for research and development, under a lease agreement that expires in November 2023. We believe our existing facilities will be sufficient for our needs for the foreseeable future.

Item 3. Legal Proceedings.

Refer to Note 10, “Commitments and Contingencies” to the audited financial statements included in this Annual Report on Form 10-K and our Annual Reports and Quarterly Reports on Form 10-Q for prior periods, for information on our historical and ongoing legal proceedings.

Colorado Recoupment

On July 21, 2021, we received a letter from the Colorado Department of Health Care Policy and Financing (the "Department"), informing us that, as a result of a post-payment review of Medicaid claims from October 2014 to June 2018, the Department is seeking recoupment for historical payments in an aggregate amount of approximately $5.7 million. In December 2021, we received additional correspondence informing us that the Department is seeking recoupment for an additional $3.3 million of historical payments from 2018.

The historical payments for which the Department is seeking recoupment primarily relate to our Preparent expanded carrier screening tests primarily on the basis that such tests were not medically necessary.

We previously entered into settlement agreements with 45 states, including the State of Colorado, as part of a settlement with respect to certain civil claims related to our discontinued legacy billing practices for our non-invasive prenatal tests and microdeletion tests and the provision of alleged kickbacks or inducements to physicians and patients.

We disputed these claims of recoupment with the Department and filed administrative complaints with the State of Colorado Office of Administrative Courts. During the year ended December 31, 2022, we concluded a settlement agreement resolution of the matter that included a dismissal of the complaints and a full release of all the claims, except for approximately $11,000 in claims, which we refunded.

California Subpoena

On July 19, 2021, we received a subpoena from the California Attorney General’s Office, Division of Public Rights (“OAG”), requesting documents and information related to our former genetic testing practices, including NIPT, particularly those with a nexus to California patients. The subpoena is captioned “In the Matter of the Investigation of: Prenatal Genetic Testing Companies.” The OAG has alleged that it has claims under California’s false advertising and unfair business practices laws based on representations about patient billing made in the historical marketing of our legacy genetic testing business. While we believe that our sales and marketing representations were appropriate, we are discussing a potential resolution with OAG, and producing additional materials in connection with those discussions, to determine if the matter can be concluded in our best interests. We are unable to predict the ultimate outcome of this action.

Texas OIG Inquiry

On October 16, 2019, we received an inquiry from the Texas Health & Human Services Commission Office of Inspector General (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. We submitted a written response to the inquiry on October 23, 2019. In October 2021, we received a letter from the TX OIG asking us to renew our engagement on the matter. During the year ended December 31, 2022, we fully resolved and settled the matter for an immaterial payment in exchange for a release of all claims.

Ravgen Lawsuit

On December 22, 2020, Ravgen, Inc. ("Ravgen"), filed suit in the District of Delaware (D. Del. Civil Action No. 1:20-cv-1734) asserting our infringement of two Ravgen patents based on our former NIPT testing business. The complaint seeks monetary damages and injunctive relief. We responded to the complaint on March 23, 2021.

We believe the claims in Ravgen's complaint are without merit, and we are vigorously defending against them. On March 1, 2022, the court ordered a stay of the litigation pending resolution of patent validity challenges made against the two patents in *inter partes* review proceedings currently pending before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. On February 13, 2023 the court ordered the stay lifted. Given the uncertainty of litigation, the early stages of the Ravgen litigation, and the legal standards that must be met for, among other things, success on the merits, we are unable to predict the ultimate outcome of these actions, and therefore cannot estimate the reasonably possible loss or range of loss, if any, that may result from this action.

IPO Litigation

On June 23, 2020, we closed our IPO. Lawsuits were filed on August 28, 2020 and September 11, 2020 against the Company, certain of its executive officers and directors, and the underwriters of the IPO. On December 3, 2020, the U.S. District Court for the SDCA consolidated the two actions, appointed Lin Shen, Lingjun Lin and Fusheng Lin to serve as Lead Plaintiffs, and approved Glancy Prongay & Murray LLP to be Lead Plaintiffs' Counsel. Lead Plaintiffs filed their first amended complaint on February 4, 2021. Together with the underwriters of the IPO, we moved to dismiss the first amended complaint. On September 1, 2021, the court granted our motion to dismiss, dismissing Lead Plaintiffs' claims without prejudice. On September 22, 2021, Lead Plaintiffs filed their second amended complaint. Together with the underwriters of the IPO, we moved to dismiss the second amended complaint on November 15, 2021. On January 13, 2023, the court again granted our motion to dismiss, dismissing Lead Plaintiffs' claims for failure to state a claim without prejudice. On February 3, 2023, Lead Plaintiffs filed their third amended complaint, adding information allegedly produced to Plaintiffs in response to freedom of information requests. The third amended complaint alleges that our registration statement and related prospectus for the IPO contained false and misleading statements and omissions in violation of the Securities Act by failing to disclose that (i) we had overbilled government payors for Preparent tests beginning in 2019 and ending in or before early 2020; (ii) there was a high probability that we had received, and would have to refund, a material amount of overpayments from government payors for Preparent tests; (iii) in February 2020 we ended a supposedly improper marketing practice on which the competitiveness of our business depended; and (iv) we were suffering from material negative trends with respect to testing volumes, average selling prices for our tests, and revenues. Lead Plaintiffs seek certification as a class, unspecified compensatory damages, interest, costs and expenses including attorneys' fees, and unspecified extraordinary, equitable, and/or injunctive relief. We intend to continue to vigorously defend against these claims. Subject to a reservation of rights, we are advancing expenses subject to indemnification to the underwriters of the IPO.

On June 4, 2021, a purported shareholder filed a lawsuit in the U.S. District Court for the SDCA, claiming to sue derivatively on behalf of the Company. The complaint names certain of the Company's officers and directors as defendants, and names the Company as a nominal defendant. Premised largely on the same allegations as the above-described securities lawsuit, it alleges that the individual defendants breached their fiduciary duties to the Company, wasted corporate assets, and caused the Company to issue a misleading proxy statement in violation of the Exchange Act. The complaint seeks the award of unspecified damages to the Company, equitable and injunctive remedies, and an order directing the Company to reform and improve its internal controls and board oversight. It also seeks the costs and disbursements associated with bringing suit, including attorneys', consultants', and experts' fees. The case is stayed pending the outcome of the motion to dismiss in the above-described securities lawsuit. We intend to vigorously defend against these claims.

On August 17, 2021, we received a letter purportedly on behalf of a stockholder of the Company demanding that our board of directors investigate and take action against certain of the Company's current and former officers and directors to recover damages for alleged breaches of fiduciary duties and related claims arising out of the IPO litigation discussed above. Our board of directors intends to evaluate the demand and any additional steps to be taken after the resolution of the IPO litigation discussed above.

Given the uncertainty of litigation, the preliminary stages of the IPO litigation, and the legal standards that must be met for, among other things, success on the merits, we are unable to predict the ultimate outcome of these actions, and therefore cannot estimate the reasonably possible loss or range of loss, if any, that may result from this action.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock, par value $0.001 per share, is traded on the Nasdaq Global Market under the symbol "BIOR".

Holders

As of March 20, 2023, there were approximately 50 stockholders of record of our common stock. Since many of our shares of common stock are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

Dividends

We anticipate that we will retain earnings, if any, to support operations research and development activities and finance the growth and development of our business and, therefore, do not expect to pay cash dividends in the foreseeable future. In addition, the terms of our convertible notes restrict our ability to pay dividends, subject to certain exceptions.

Recent Sales of Unregistered Securities

None.

Item 6. Reserved

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and notes thereto and other financial information included elsewhere in this Annual Report. Some of the information contained in this discussion and analysis includes forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those described in or implied by these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those discussed in the section titled "Risk Factors" included elsewhere in this Annual Report.

Overview

We are a biotechnology company developing oral biotherapeutics that could enable new treatment approaches in the delivery of therapeutics. Our therapeutics pipeline is divided into two therapeutic delivery mechanisms:

- Targeted delivery of therapeutics to the site of disease in the GI tract, designed to improve outcomes for patients with IBD; and
- Systemic delivery of biotherapeutics, designed to replace injection with needle-free, oral capsules.

Our mission is to improve human health through a more advanced approach to biotherapeutic delivery.

Our historical operations included a licensed Clinical License Improvement Amendment and College of American Pathologists certified laboratory specializing in the molecular testing markets serving women's health providers in the obstetric, gynecological, fertility, and maternal fetal medicine specialty areas. Previously, our core business was focused on the prenatal carrier screening and noninvasive prenatal test market, targeting preconception planning and routine pregnancy management for genetic disease risk assessment. Through our former affiliation with Mattison Pathology, LLP, a Texas limited liability partnership doing business as Avero Diagnostics ("Avero"), our historical operations also included anatomic and molecular pathology testing products in the United States.

Common Stock Reverse Split

On December 29, 2022, we filed a certificate of amendment to our eighth amended and restated certificate of incorporation (the "Certificate of Amendment") to effect, as of January 3, 2023, a 1-for-25 reverse split of our common stock. The Certificate of Amendment also decreased the number of authorized shares of our common stock from 350,000,000 to 164,000,000. All shares, options, restricted stock units, warrants and per share amounts included in this Annual Report on Form 10-K have been retroactively adjusted to reflect the stock split.

Strategic Transformation and Factors Affecting Our Performance

In June 2021, we announced a strategic transformation ("Strategic Transformation") pursuant to which we are refocusing our efforts on our robust research and development pipeline to better position the business for future growth. The Strategic Transformation includes the closure of our genetics laboratory in Ann Arbor, Michigan, the sale of our Avero laboratory business, a reduction in force and other cost-cutting measures and operational improvements.

Prior to the closure of our genetics laboratory in Ann Arbor, Michigan, we generated revenue by providing tests through our Ann Arbor laboratory, including throughout most of the second quarter of 2021. We received payments for such tests from payors, laboratory distribution partners, and self-paying individuals, and more than 95% of payments for our tests we received through reimbursement. We received reimbursement from several distinct channels: commercial third-party payors, laboratory distribution partners, and government health benefits programs such as Medicare and Medicaid. Due to the typical lag in payment following performance of a test, we expect to continue to receive reimbursement payments for a period of time following the closure of the laboratory.

In the second quarter of 2020, we added COVID-19 testing to our offering and began offering COVID-19 testing nationally in mid-November 2020. We are no longer performing COVID-19 testing following the shut-down of our Laboratory Operations.

We are engaged in research and development activities with respect to therapeutics product candidates. Following the Strategic Transformation, we are devoting substantially all of our resources to developing and perfecting our intellectual property rights, conducting research and development activities (including undertaking preclinical and clinical studies of our therapeutics product candidates), conducting clinical trials of our most advanced therapeutics product candidates, organizing and staffing our company,

business planning and raising capital. We do not have any therapeutics products approved for sale, and we have not generated any revenue from therapeutics product sales.

Our business involves significant investment in research and development activities for the development of new products. 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 targeted therapeutics and systemic therapeutics product candidates. The achievement of key development milestones is a key factor in evaluating our performance.

We expect to continue to incur significant expenses and increasing operating losses in the near term. While we materially reduced our spend profile as a result of the Strategic Transformation in 2021, we expect our expenses may increase in connection with our ongoing activities, as we:

- continue to advance the preclinical and clinical development of our lead targeted therapeutics and systemic therapeutics product candidates;
- initiate preclinical studies and clinical trials for additional targeted therapeutics and systemic therapeutics product candidates that we may identify in the future;
- increase personnel and infrastructure to support our clinical development, research and manufacturing efforts;
- build out and expand our in-house process development and engineering and manufacturing capabilities for R&D and clinical purposes;
- continue to develop, perfect and defend our intellectual property portfolio; and
- incur additional legal, accounting or other expenses in operating our business, including the additional costs associated with operating as a public company.

We do not expect to generate significant product revenue unless and until we successfully complete development and obtain regulatory and marketing approval of, and begin to sell, one or more of our targeted therapeutics and systemic therapeutics product candidates, which we expect will take several years. We expect to spend a significant amount in development costs prior to such time. We may never succeed in achieving regulatory and marketing approval for our therapeutics product candidates. We may obtain unexpected results from our preclinical and clinical trials. We may elect to discontinue, delay or modify preclinical and clinical trials of our therapeutics product candidates. A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. Accordingly, until such time as we can generate significant product revenue, if ever, we expect to continue to seek private or public equity and debt financing to meet our capital requirements. There can be no assurance that such funding may be available to us on acceptable terms, or at all, or that we will be able to commercialize our therapeutics product candidates. In addition, we may not be profitable even if we commercialize any of our therapeutics product candidates.

Key Components of Our Results of Operations

We are providing the following summary of our revenues, research and development expenses and selling, general and administrative expenses to supplement the more detailed discussion below. This summary excludes our revenues, research and development expenses, selling and marketing, general and administrative and other expenses associated with our Laboratory Operations, which are reported within loss from discontinued operations.

Revenue

Historically, all of our revenue has been derived from molecular laboratory tests, principally from the sale of NIPT, genetic carrier screening, and pathology molecular testing. If our development efforts for our therapeutics product candidates are successful and result in regulatory approval, we may generate revenue from future product sales. If we enter into license or collaboration agreements for any of our therapeutics product candidates, other pipeline products or intellectual property, we may generate revenue in the future from payments as a result of such license or collaboration agreements. We cannot predict if, when, or to what extent we will generate revenue from the commercialization and sale of our therapeutics product candidates or from license or collaboration agreements. We may never succeed in obtaining regulatory approval for any of our therapeutics product candidates.

Research and Development

Research and development expenses consist primarily of costs associated with developing new products, including our therapeutics product candidates. Research and development expenses also 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 our targeted therapeutics and systemic therapeutics programs through preclinical studies and clinical trials. We expect our investment in research and development to remain relatively flat as we pursue regulatory approval of our product candidates and as we seek to expand our pipeline of product candidates.

Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. While we plan to partner with large pharmaceutical companies, especially for the later stage clinical work, we still expect our research and development expenses to increase over the next several years as we conduct additional preclinical studies and clinical trials, including later-stage clinical trials, for our current and future product candidates and pursue regulatory approval of our product candidates. The process of conducting the necessary preclinical and clinical research to obtain regulatory approval is costly and time consuming. The actual probability of success for our product candidates may be affected by a variety of factors including:

- the safety and efficacy of our product candidates;
- early clinical data for our product candidates;
- investment in our clinical programs;
- the ability of collaborators to successfully develop our licensed product candidates;
- competition;
- manufacturing capability; and
- commercial viability.

We may never succeed in achieving regulatory approval for any of our product candidates due to the uncertainties discussed above. We are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of our product candidates, if ever.

Due to the impact of the COVID-19 pandemic, certain of our research and development activities have been delayed and may be further delayed. For more information on risks related to COVID-19, see "Risk Factors—Unfavorable global economic conditions, whether brought about by global crises, health epidemics, military conflicts and war, geopolitical and trade disputes or other factors, may have a material adverse effect on our business and financial results."

Selling, General and Administrative

Selling, 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 costs for communication, advertising, conferences, and professional fees of audit, legal, and recruiting services. Additionally, expenses related to maintaining compliance with the stipulations of the government settlement and the legal costs associated with the legal matters described in Part I, Item 3. “Legal Proceedings” in this Annual Report are included. We expect our selling, general and administrative expenses to decrease as a result of our discontinued Laboratory Operations and decreased headcount.

Interest Expense, Net

Interest expense, net is primarily attributable to borrowings under our Credit Agreement (as defined below), our mortgages payable, lease agreements and interest income earned from our cash and cash equivalents.

Gain (Loss) on Warrant Liabilities

Gain (loss) on warrant liabilities consists of changes in the fair value of our liability-classified warrants to purchase common stock.

Other Income, Net

Other income, net primarily consists of changes in the fair value of our embedded derivative liability related to the Convertible Notes and inducement loss on our Convertible Notes.

Income Tax Provision

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 more 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. Due to losses generated in the past and projected future taxable losses anticipated in the future, we established a 100% valuation allowance on net deferred tax assets.

Results of Operations.

Comparison of Years Ended December 31, 2022 and 2021

	Year Ended December 31,	
	2022	2021
	(in thousands)	
Statement of Operations Data:		
Revenues	$ 305	$ 1,247
Operating expenses:		
Research and development	24,049	45,785
Selling, general and administrative	38,037	73,299
Total operating expenses	62,086	119,084
Loss from operations	(61,781)	(117,837)
Interest expense, net	(10,990)	(12,636)
Gain (loss) on warrant liabilities	20,904	(54,157)
Other income, net	2,617	5,990
Loss before income taxes	(49,250)	(178,640)
Income tax benefit	(420)	(119)
Loss from continuing operations	(48,830)	(178,521)
Gain (loss) from discontinued operations	10,673	(68,891)
Net loss	$ (38,157)	$ (247,412)

Revenue

As a result of the classification of the Company's Laboratory Operations to discontinued operations, all revenue from Laboratory Operations has been classified as discontinued operations. The remaining revenue is related to license and collaboration agreements.

Research and Development Expenses

	Year Ended December 31,		Increase/	
	2022	2021	(Decrease)	% Change
	(in thousands)			
Research and development	$ 24,049	$ 45,785	$ (21,736)	(47.5)%

The decrease in research and development expenses was primarily attributable to a decrease in salary and benefits, consulting and professional fees, and a decrease in the cost of supplies and facilities.

Selling, General and Administrative Expenses

	Year Ended December 31,		Increase/ (Decrease)	% Change
	2022	2021		
	(in thousands)			
Selling, general and administrative	$ 38,037	$ 73,299	$ (35,262)	(48.1)%

The decrease in selling, general and administrative expenses was primarily attributable to a decrease in salary and benefits, consulting and professional fees, software costs, business insurance and facilities costs.

Interest Expense, Net

	Year Ended December 31,		Increase/ (Decrease)	% Change
	2022	2021		
	(in thousands)			
Interest expense, net	$ 10,990	$ 12,636	$ (1,646)	(13.0)%

The decrease in interest expense, net was due to a decrease in the balance of Convertible Notes due to conversions during 2021.

Gain (Loss) on Warrant Liabilities

	Year Ended December 31,		Increase/ (Decrease)	% Change
	2022	2021		
	(in thousands)			
Gain (loss) on warrant liabilities	$ 20,904	$ (54,157)	$ 75,061	*

* The change is more than 100%

The change in gain (loss) on warrant liabilities was due to the change in fair value of the warrant liabilities for warrants issued during 2021 and in November 2022.

Other Income, Net

	Year Ended December 31,		Increase/ (Decrease)	% Change
	2022	2021		
	(in thousands)			
Other income, net	$ 2,617	$ 5,990	$ (3,373)	(56.3)%

The decrease in other income, net was primarily due to a gain recognized on our embedded derivative liability related to the Convertible Notes and an inducement loss related to conversions of Convertible Notes for the year ended December 31, 2021 that did not reoccur in 2022 and a loss on asset disposals during 2022, offset by a gain of $5.7 million on our investment in Enumera.

Income Tax Benefit

	Year Ended December 31,		Increase/ (Decrease)	% Change
	2022	2021		
	(in thousands)			
Income tax benefit	$ 420	$ 119	$ 301	*

* The change is more than 100%

The increase in income tax benefit was primarily due to federal and state income tax refunds, offset by recognition of a deferred tax liability related to Enumera.

Discontinued Operations

	Year Ended December 31,		Increase/ (Decrease)	% Change
	2022	2021		
	(in thousands)			
Gain (loss) from discontinued operations	$ 10,673	$ (68,891)	$ 79,564	*

* The change is more than 100%

The change in gain (loss) from discontinued operations was due to the closure of our Laboratory Operations during 2021 and a partial reversal of a third-party payor accrual. See Notes 4 and 10 to our consolidated financial statements included elsewhere in this Annual Report for additional information regarding discontinued operations and commitments and contingencies.

Liquidity and Capital Resources.

Since our inception, our primary sources of liquidity have been generated by our operations, sales of common stock, preferred stock, warrants to purchase common stock and preferred stock and cash from debt financings, including Convertible Notes.

As of December 31, 2022, we had $30.5 million of cash and cash equivalents and $127.8 million of Convertible Notes, net outstanding. Our accumulated deficit as of December 31, 2022, was $826.8 million. For the year ended December 31, 2022, we had a net loss of $38.2 million and cash used in operations of $64.4 million. Our primary requirements for liquidity have been to fund our working capital needs, capital expenditures, dividends, research and development, and general corporate needs.

While we have greatly reduced our cash burn following the Strategic Transformation, we do not expect that our current cash and cash equivalents will be sufficient to fund our operations for at least 12 months from the issuance date of the consolidated financial statements for the year ended December 31, 2022, and will require additional capital to fund our operations. As a result, substantial doubt exists about our ability to continue as a going concern for 12 months following the issuance date of the consolidated financial statements for the year ended December 31, 2022. We therefore intend to raise additional capital through equity offerings, including our ATM Facility, and/or debt financings or from other potential sources of liquidity, which may include new collaborations, licensing or other commercial agreements for one or more of our research programs or patent portfolios. 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. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from global political tensions and economic uncertainty.

Convertible Notes

In December 2020, in connection with a private offering of the convertible notes pursuant to Rule 144A under the Securities Act, we issued a total of $168.5 million principal amount of our Convertible Notes. The Convertible Notes were issued pursuant to, and are governed by, the Indenture. The Convertible Notes are due on December 1, 2025, unless earlier repurchased, redeemed or converted, and accrue interest at a rate per annum equal to 7.25% payable semi-annually in arrears on June 1 and December 1 of each year, with the initial payment on June 1, 2021.

The Convertible Notes are our senior, unsecured obligations and are (i) equal in right of payment with our existing and future senior, unsecured indebtedness; (ii) senior in right of payment to our existing and future indebtedness that is expressly subordinated to the Convertible Notes; (iii) effectively subordinated to our existing and future secured indebtedness, to the extent of the value of the collateral securing that indebtedness; and (iv) structurally subordinated to all existing and future indebtedness and other liabilities, including trade payables, and (to the extent we are not a holder thereof) preferred equity, if any, of our subsidiaries.

At any time, noteholders may convert their Convertible Notes at their option into shares of our common stock, together, if applicable, with cash in lieu of any fractional share, at the then-applicable conversion rate. The initial conversion rate is 11.1204 shares of common stock per $1,000 principal amount of Convertible Notes, which represents an initial conversion price of approximately $89.92 per share of common stock. Noteholders that converted their Convertible Notes before December 1, 2022 were, in certain circumstances, entitled to an additional cash payment representing the present value of any remaining interest payments on the Convertible Notes through December 1, 2022. The conversion rate and conversion price are subject to customary adjustments

upon the occurrence of certain events. In addition, if certain corporate events that constitute a Make-Whole Fundamental Change (as defined in the Indenture) occur, then the conversion rate will, in certain circumstances, be increased for a specified period of time.

The Convertible Notes are redeemable, in whole and not in part, at our option at any time on or after December 1, 2023, at a cash redemption price equal to the principal amount of the Convertible Notes to be redeemed, plus accrued and unpaid interest, if any, to, but excluding, the redemption date, but only if the last reported sale price per share of the our common stock exceeds 130% of the conversion price on (i) each of at least 20 trading days, whether or not consecutive, during the 30 consecutive trading days ending on, and including, the trading day immediately before the date we send the related redemption notice; and (ii) the trading day immediately before the date we send such notice. In addition, calling the Convertible Notes will constitute a Make-Whole Fundamental Change, which will result in an increase to the conversion rate in certain circumstances for a specified period of time.

The Convertible Notes have customary provision relating to the occurrence of Events of Default (as defined in the Indenture), which include the following: (i) certain payment defaults on the Convertible Notes (which, in the case of a default in the payment of interest on the Convertible Notes, will be subject to a 30-day cure period); (ii) our failure to send certain notices under the Indenture within specified periods of time; (iii) our failure to comply with certain covenants in the Indenture relating to the Company's ability to consolidate with or merge with or into, or sell, lease or otherwise transfer, in one transaction or a series of transactions, all or substantially all of our assets and assets of our subsidiaries, taken as a whole, to another person; (iv) a default by us in our other obligations or agreements under the Indenture or the Convertible Notes if such default is not cured or waived within 60 days after notice is given in accordance with the Indenture; (v) certain defaults by us or any of our subsidiaries with respect to indebtedness for borrowed money of at least $7.5 million; (vi) the rendering of certain judgments against us or any of our subsidiaries for the payment of at least $7.5 million, where such judgments are not discharged or stayed within 60 days after the date on which the right to appeal has expired or on which all rights to appeal have been extinguished; and (vii) certain events of bankruptcy, insolvency and reorganization involving us or any of our significant subsidiaries. As of December 31, 2022, we were in compliance with all such covenants.

In October 2021, we entered into privately-negotiated agreements with certain holders of Convertible Notes to exchange an aggregate of $20.2 million principal amount for 340,554 shares of our common stock. In addition, we issued an aggregate of 17,112 shares of common stock to certain investors in consideration for a waiver of certain contractual lock-up provisions to which we agreed in connection with prior offerings of securities.

In addition to the transaction discussed above, holders of Convertible Notes exchanged an aggregate of $15.6 million principal amount for 173,477 shares of our common stock during the year ended December 31, 2021.

PIPE Financings

In February 2021, we entered into a Securities Purchase Agreement for a private placement with certain institutional and accredited investors, pursuant to which the purchasers purchased an aggregate of 174,825 units representing (i) 174,825 shares of the Company's common stock, par value $0.001 per share, and (ii) warrants to purchase up to 174,825 shares of common stock. The purchase price for each unit was $143.00, for an aggregate purchase price of approximately $25.0 million. The transaction closed on February 25, 2021. The warrants are exercisable at an exercise price of $171.50 per share, subject to adjustments as provided under the terms of the warrants. The warrants were immediately exercisable and expire on the fifth anniversary of the initial date of issuance. If exercised for cash, the warrants would result in additional gross proceeds to us of approximately $30.0 million.

In June 2021, we entered into a Securities Purchase Agreement for a private placement with certain institutional and accredited investors, pursuant to which the purchasers agreed to purchase an aggregate of 647,773 units representing (i) 647,773 shares of the Company's common stock, par value $0.001 per share (or pre-funded warrants in lieu thereof), and (ii) warrants to purchase up to 647,773 shares of common stock. The purchase price for each unit was $61.75, for an aggregate purchase price of approximately $40.0 million. The transaction closed on June 14, 2021. The warrants are exercisable at an exercise price of $71.00 per share, subject to adjustments as provided under the terms of the warrants. The warrants were immediately exercisable and expire on the fifth anniversary of the date of issuance. The pre-funded warrants were exercisable at an initial exercise price of $0.001 per share and had no expiration date. If exercised for cash, the warrants would result in additional gross proceeds to us of approximately $46.0 million. In July 2021, we issued 20,000 shares of common stock as a result of the exercise of the outstanding pre-funded warrants at an exercise price of $0.025 per share.

Registered Offerings

In August 2021, we issued and sold an aggregate of (i) 1,600,000 shares of common stock and (ii) warrants to purchase 1,600,000 shares of common stock in an underwritten public offering (the "August 2021 Offering"). Each share was sold together with one warrant to purchase one share of common stock at a combined public offering price of $25.00 per share of the common stock and

the accompanying warrant. We received approximately $37.4 million in net proceeds, after deducting underwriting discounts and commissions and other offering expenses payable by the Company. The warrants have an exercise price of $25.00 per share, are exercisable at any time, and will expire five years following the date of issuance. The agreement also allowed for the purchase of up to an additional 240,000 shares at the option of the underwriters, which was partially exercised for warrants to purchase an aggregate of 77,280 shares of common stock.

In October 2021, we entered into a securities purchase agreement with certain institutional and accredited investors relating to the offering and sale of 533,333 shares of common stock at a purchase price of $37.50 per share in a registered direct offering. We received approximately $18.7 million in net proceeds, after deducting placement agent fees and other offering expenses payable by the Company.

In November 2022, the Company entered into a securities purchase agreement with certain institutional and accredited investors relating to the offering and sale of an aggregate of (i) 1,300,250 shares of common stock and (ii) warrants to purchase 1,300,250 shares of common stock in a registered direct offering (the "November 2022 Offering"). Each share was sold together with one warrant to purchase one share of common stock at a combined public offering price of $7.50 per share of the common stock and the accompanying warrant. We received approximately $9.0 million in net proceeds, after deducting placement agent fees and offering expenses. Approximately $3.8 million of the gross proceeds were received in the form of a waiver of the Company's December 1, 2022 interest payment on the Convertible Notes. The warrants have an exercise price of $8.22 per share, are exercisable six months following the date of issuance, and will expire five years following the initial exercise date.

Additionally, the Company agreed with certain institutional investors to amend outstanding warrants previously issued in 2021 to purchase (i) up to 104,895 shares of common stock with an exercise price of $171.50 per share and (ii) up to 403,887 shares of common stock with an exercise price of $71.00 per share. Accordingly, the Company agreed to (i) lower the exercise price of such existing warrants to $8.22 per share, (ii) provide that such existing warrants, as amended, will not be exercisable until May 9, 2023 and (iii) extend the original expiration date of such existing warrants to May 9, 2028. 323,887 of the amended warrants are held by affiliates of Athyrium.

At-The-Market Sales Agreement and Offering

In November 2021, we entered into an At Market Issuance Sales Agreement ("ATM Sale Agreement") with B. Riley Securities, Inc., BTIG, LLC, and H.C. Wainwright & Co. LLC ("Agents"), pursuant to which we may offer and sell shares of common stock having an aggregate offering price of up to $90.0 million, from time to time, in “at the market” offerings through the Agents (the "ATM Facility"). In connection with the November 2022 Offering we reduced the aggregate offering price to $70.0 million. Sales of the shares of common stock, if any, will be made at prevailing market prices at the time of sale, or as otherwise agreed with the Agents. The Agents will receive a commission from the Company of up to 3.0% of the gross proceeds of any shares of common stock sold under the ATM Sale Agreement. During the three months ended December 31, 2021, we received net proceeds of $4.6 million, after deducting commissions and other offering expenses, from the sale of 70,550 shares under the ATM Sale Agreement. We sold such shares at a weighted average purchase price of $71.00 per share. During the three months ended December 31, 2022, the Company received net proceeds of $0.6 million, after deducting commissions and other offering expenses, from the sale of 52,620 shares under the ATM Sale Agreement. The Company sold such shares at a weighted average purchase price of $10.93 per share. During the year ended December 31, 2022, the Company received net proceeds of $7.1 million, after deducting commissions and other offering expenses, from the sale of 317,155 shares under the ATM Sale Agreement. The Company sold such shares at a weighted average purchase price of $30.27 per share.

Mortgages

In January 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 mortgage was paid off in November 2021. We previously had a mortgage with American Bank of Commerce (originally executed in February 2008) outstanding on Avero’s property located in Lubbock, Texas, which was used primarily for laboratory testing. The mortgage was paid off in December 2021 prior to the sale of Avero.

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 expenses will continue to increase as we focus on developing our therapeutics 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. 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 (in thousands):

	Year Ended December 31,	
	2022	2021
Cash used in operating activities	$ (64,417)	$ (167,486)
Cash used in investing activities	(792)	(1,242)
Cash provided by financing activities	7,298	165,049

Operating Activities

Net cash used in operating activities in the year ended December 31, 2022 was primarily attributable to a $38.2 million net loss, adjusted for non-cash charges, primarily driven by a $20.9 million change in the warrant liabilities fair value, a $10.7 million gain from discontinued operations and $5.7 million gain on investment in Enumera, offset by $7.8 million of stock-based compensation expense, $2.7 million loss on extinguishment of convertible notes and $1.4 million of debt discount amortization. The net cash outflow from changes in operating assets and liabilities was attributable to a $5.0 million decrease in accounts payable and a $1.7 million decrease in other long-term liabilities, offset by a $3.4 million decrease in prepaid expenses and other current assets. Additionally, net cash provided by operating activities from discontinued operations contributed $1.8 million of inflows.

Net cash used in operating activities in the year ended December 31, 2021 was primarily attributable to a $247.4 million net loss, adjusted for a $68.9 million loss from discontinued operations and non-cash charges, primarily driven by an $18.4 million change in the derivative liability fair value, offset by a $54.2 million change in the warrant liabilities fair value, $12.0 million of stock-based compensation expense and an $11.3 million inducement loss. The net cash outflow from changes in operating assets and liabilities was attributable to a $22.9 million decrease in accrued expenses and other liabilities and an $8.7 million decrease in accounts payable, offset by a $4.4 million increase in other long-term liabilities. Additionally, net cash used in operating activities from discontinued operations contributed $27.2 million of outflows.

Investing Activities

Net cash used in investing activities during the year ended December 31, 2022 was attributable to $0.8 million in purchases of property and equipment. Net cash used in investing for the year ended December 31, 2021 was attributable to $0.9 million in purchases of property and equipment and $0.4 million from discontinued operations.

Financing Activities

Net cash provided by financing activities during the year ended December 31, 2022 was primarily attributable to $9.0 million in net proceeds from the issuance of common stock and $3.3 million in proceeds from the issuance of common stock warrants, partially offset by $5.1 million in payments for insurance financing. Net cash provided by financing activities during the year ended December 31, 2021 was primarily attributable to $79.4 million in net proceeds from the issuance of common stock warrants, $46.8 million in net proceeds from the issuance of common stock, and $46.0 million in net proceeds from the exercise of common stock warrants, partially offset by $3.8 million in payments for insurance financing and $1.3 million in principal payments on mortgages payable.

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 consolidated financial statements elsewhere in this annual report, we believe that the accounting policies discussed below are most critical to understanding and evaluating our historical and future performance.

Assets Held for Sale and Discontinued Operations

Assets classified as held for sale are reported at the lower of their carrying value or fair value less costs to sell. Depreciation and amortization of assets ceases upon designation as held for sale. Discontinued operations comprise activities that were disposed of, discontinued or held for sale at the end of the period, represent a separate major line of business that can be clearly distinguished for operational and financial reporting purposes and represent a strategic business shift having a major effect on the Company's operations and financial results according to Accounting Standard Codification ("ASC") Topic 205, *Presentation of Financial Statements.* We have included all of our revenues and expenses for the Progenity genetics laboratory and Avero, together referred to as the Laboratory Operations, as discontinued operations and all assets and liabilities as held for sale.

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.

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.

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.

Common Stock Warrant Liabilities

We account for the common stock warrants issued as part of the November 2022 Offering and August 2021 Offering as freestanding liability instruments in accordance with applicable accounting guidance based on the specific terms of the warrant agreement. As these warrants are classified as liabilities, they are remeasured each period until settled or until classified as equity. Any resulting gain or loss related to the changes in the fair value of the warrant liabilities are recorded to gain (loss) on warrant liabilities on the consolidated statements of operations. Changes in our inputs and assumptions, such as our stock price and the estimated volatility of common stock, could result in material changes in the valuation in future periods.

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.

Expected Volatility—Given the limited period of time our stock has been traded in an active market, the expected volatility is estimated by taking the average historical volatility for industry peers, consisting of several public companies in the Company's industry that are similar in size, stage, or financial leverage, over a period of time commensurate with the expected term of the awards.

Fair Value of Common Stock—The fair value of our common stock is the closing price of our common stock on the date of valuation.

Expected Term—The expected term represents the remaining contractual term of the warrant.

At December 31, 2022, the fair value of our warrant liabilities of $3.5 million, was estimated using the Black-Scholes Model with the following inputs and assumptions:

	December 31, 2022	December 31, 2021
Risk-free interest rate	4.0%	1.3%
Expected volatility	106.2% - 107.1%	91.9%
Stock price	$ 3.30	$ 52.25
Expected life (years)	3.6 - 5.4	4.6

Embedded Derivative Related to Convertible Notes

In December of 2020, we issued Convertible Notes due in December 2025 that had a conversion option which required bifurcation upon issuance and was periodically remeasured to fair value separately as an embedded derivative. The conversion option included additional interest payments payable to the noteholders if converted prior to December 1, 2022. We utilized a Monte Carlo simulation model to determine the fair value of the embedded features, which incorporates inputs including the common stock price, volatility of common stock, and time to maturity. The embedded feature was remeasured to fair value at each balance sheet date through September 30, 2022, with a resulting gain or loss related to the change in the fair value recorded to other income (expense), net in the consolidated statements of operations. The fair value of the embedded derivative was zero as of December 31, 2021, as presented in our consolidated balance sheet. As of December 31, 2022, the conversion option has expired and we no longer have an embedded derivative.

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 volatility, expected term, 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 typically 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 Company's key inputs and assumptions are as follows:

Fair Value of Common Stock—Prior to the IPO, our common stock was not publicly traded, therefore we estimated the fair value of common stock. Following the IPO, the fair value of our common stock for awards with service-based vesting is the closing price of our common stock on the date of grant or other relevant determination date.

Expected Term—The expected term represents the period that the stock-based awards are expected to be outstanding. We 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. For stock options granted to non-employees, the expected term equals the remaining contractual term of the option from the vesting date. For the 2020 Employee Stock Purchase Plan, the expected term is the period of time from the offering date to the purchase date.

Expected Volatility—Given the limited period of time our stock has been traded in an active market, the expected volatility is estimated by taking the average historical volatility for industry peers, consisting of several public companies in the Company's industry that are similar in size, stage, or financial leverage, over a period of time commensurate with 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 pay dividends.

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

	Year ended December 31,	
	2022	2021
Risk-free interest rate	2.0% - 4.2%	0.6% - 1.4%
Expected volatility	90.7% - 101.3%	52.9% - 77.0%
Expected dividend yield	—	—
Expected life (years)	5.5 - 6.3	3.0 - 6.3

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. 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 a quantitative assessment.

If a quantitative assessment is deemed necessary, we compare the fair value of the reporting unit with its carrying amount, including goodwill. An impairment loss will be recognized if the reporting unit's carrying amount exceeds its fair value, to the extent that it does not exceed the total carrying amount of goodwill. No impairment existed as of December 31, 2022 or December 31, 2021.

Recent Accounting Pronouncements

Refer to Note 2, "Summary of Significant Accounting Policies" to the consolidated financial statements included in this Annual Report for information on recently issued accounting pronouncements.

JOBS Act Accounting Election

We are an emerging growth company, as defined in the JOBS Act. Under the JOBS 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.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company, as defined by Rule 12b-2 under the Securities and Exchange Act of 1934 and in Item 10(f)(1) of Regulation S-K, and are not required to provide the information under this item.

Item 8. Financial Statements and Supplementary Data

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Biora Therapeutics, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Biora Therapeutics, Inc. and subsidiaries (the Company) as of December 31, 2022 and 2021, the related consolidated statements of operations, stockholders' deficit, and cash flows for the years then ended, 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, 2022 and 2021, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

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 raises 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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 30, 2023

BIORA THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	December 31,	
	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	$ 30,486	$ 88,397
Accounts receivable, net	—	653
Income tax receivable	828	—
Prepaid expenses and other current assets	4,199	7,232
Current assets of disposal group held for sale	2,603	2,493
Total current assets	38,116	98,775
Property and equipment, net	1,654	3,666
Right-of-use assets	1,482	—
Other assets	6,201	326
Goodwill	6,072	6,072
Total assets	$ 53,525	$ 108,839
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 3,606	$ 8,709
Accrued expenses and other current liabilities	16,161	34,157
Warrant liabilities	3,538	18,731
Current portion of capital lease obligations	—	12
Total current liabilities	23,305	61,609
Convertible notes, net of unamortized discount of $4,914 and $6,333 as of December 31, 2022 and December 31, 2021, respectively	127,811	126,392
Other long-term liabilities	4,696	5,814
Total liabilities	$ 155,812	$ 193,815
Commitments and contingencies (Note 10)		
Stockholders' deficit:		
Common stock – $0.001 par value. 164,000,000 shares authorized as of December 31, 2022 and December 31, 2021; 9,098,844 and 7,429,458 shares issued as of December 31, 2022 and December 31, 2021, respectively; 8,928,498 and 7,274,889 shares outstanding as of December 31, 2022 and December 31, 2021, respectively	8	6
Additional paid-in capital	743,626	722,782
Accumulated deficit	(826,843)	(788,686)
Treasury stock – at cost; 170,346 and 154,569 shares of common stock as of December 31, 2022 and December 31, 2021, respectively	(19,078)	(19,078)
Total stockholders' deficit	(102,287)	(84,976)
Total liabilities and stockholders' deficit	$ 53,525	$ 108,839

See notes to consolidated financial statements.

BIORA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share data)

	Year Ended December 31,	
	2022	2021
Revenues	$ 305	$ 1,247
Operating expenses:		
Research and development	24,049	45,785
Selling, general and administrative	38,037	73,299
Total operating expenses	62,086	119,084
Loss from operations	(61,781)	(117,837)
Interest expense, net	(10,990)	(12,636)
Gain (loss) on warrant liabilities	20,904	(54,157)
Other income, net	2,617	5,990
Loss before income taxes	(49,250)	(178,640)
Income tax benefit	(420)	(119)
Loss from continuing operations	(48,830)	(178,521)
Gain (loss) from discontinued operations	10,673	(68,891)
Net loss	(38,157)	(247,412)
Net loss per share from continuing operations, basic and diluted	$ (6.40)	$ (46.42)
Net gain (loss) per share from discontinued operations, basic and diluted	$ 1.40	$ (17.91)
Net loss per share, basic and diluted	$ (5.00)	$ (64.33)
Weighted average shares outstanding, basic and diluted	7,635,107	3,846,187

See notes to consolidated financial statements.

BIORA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT
(In thousands, except share data)

	Common Stock		Additional Paid-In	Accumulated	Treasury Stock		Total Stockholders'
	Shares	Amount	Capital	Deficit	Shares	Amount	Deficit
Balance at December 31, 2020	**2,371,477**	**$ 2**	**$ 453,046**	**$ (541,274)**	**(140,601)**	**$ (18,768)**	**$ (106,994)**
Issuance of common stock, net	3,006,481	2	46,552	—	—	—	46,554
Exercise of common stock options	12,930	—	532	—	(4,109)	(310)	222
Issuance of common stock under employee stock purchase plan	12,670	—	712	—	—	—	712
Issuance of common stock upon vesting of restricted stock units	32,780	—	(722)	—	(9,859)	—	(722)
Exercise of common stock warrants	1,411,251	1	118,009	—	—	—	118,010
Issuance of common stock warrants	—	—	42,864	—	—	—	42,864
Issuance of common stock upon conversion of debt, net	531,144	1	44,606	—	—	—	44,607
Issuance of common stock upon conversion of interest, net	50,725	—	3,627	—	—	—	3,627
Stock-based compensation expense	—	—	13,556	—	—	—	13,556
Net loss	—	—	—	(247,412)	—	—	(247,412)
Balance at December 31, 2021	**7,429,458**	**$ 6**	**$ 722,782**	**$ (788,686)**	**(154,569)**	**$ (19,078)**	**$ (84,976)**
Issuance of common stock, net	1,117,155	1	9,281	—	—	—	9,282
Issuance of common stock under employee stock purchase plan	6,694	—	98	—	—	—	98
Issuance of common stock upon vesting of restricted stock units	45,287	—	(267)	—	(15,777)	—	(267)
Issuance of common stock upon conversion of interest, net	500,250	1	3,928	—	—	—	3,929
Stock-based compensation expense	—	—	7,804	—	—	—	7,804
Net loss	—	—	—	(38,157)	—	—	(38,157)
Balance at December 31, 2022	**9,098,844**	**$ 8**	**$ 743,626**	**$ (826,843)**	**(170,346)**	**$ (19,078)**	**$ (102,287)**

See notes to consolidated financial statements.

BIORA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,	
	2022	2021
Operating Activities:		
Net loss	$ (38,157)	$ (247,412)
Adjustments to reconcile net loss to net cash used in operating activities:		
(Gain) loss from discontinued operations	(10,673)	68,891
Non-cash revenue reserve	—	979
Depreciation and amortization	907	1,437
Stock-based compensation expense	7,804	11,962
Loss on extinguishment of convertible notes and accrued interest	2,722	946
Amortization of debt discount and non-cash interest	1,419	1,572
Inducement loss on convertible notes	—	11,265
Loss on disposal of property and equipment	543	99
Impairment of property and equipment	545	—
Change in fair value of derivative liability	—	(18,365)
Change in fair value of warrant liabilities	(20,904)	54,157
Gain on investment in Enumera Molecular, Inc.	(5,731)	—
Changes in operating assets and liabilities:		
Income tax receivable	(828)	—
Prepaid expenses and other current assets	3,387	1,399
Other assets	—	(158)
Accounts payable	(5,072)	(8,686)
Accrued expenses and other liabilities	(417)	(22,910)
Income tax payable	—	79
Other long-term liabilities	(1,720)	4,412
Net cash used in operating activities - continuing operations	(66,175)	(140,333)
Net cash provided by (used in) operating activities - discontinued operations	1,758	(27,153)
Net cash used in operating activities	(64,417)	(167,486)
Investing Activities:		
Purchases of property and equipment	(792)	(855)
Net cash used in investing activities - continuing operations	(792)	(855)
Net cash used in investing activities - discontinued operations	—	(387)
Net cash used in investing activities	(792)	(1,242)
Financing Activities:		
Proceeds from issuance of common stock, net	9,014	46,776
Proceeds from issuance of common stock warrants	3,318	79,448
Proceeds from issuance of common stock under employee stock purchase plan	98	—
Proceeds from exercise of common stock warrants	—	46,000
Payments for financing of insurance premiums	(5,120)	(3,750)
Principal payments on mortgages payable	—	(1,348)
Principal payments on capital lease obligations	(12)	(295)
Net cash provided by financing activities - continuing operations	7,298	166,831
Net cash used in financing activities - discontinued operations	—	(1,782)
Net cash provided by financing activities	7,298	165,049
Net decrease in cash and cash equivalents	(57,911)	(3,679)
Cash and cash equivalents at beginning of period	88,397	92,076
Cash and cash equivalents at end of period	$ 30,486	$ 88,397

See notes to consolidated financial statements.

BIORA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,	
	2022	2021
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 5,871	$ 7,536
Cash paid for income taxes	31	367
Supplemental schedule of non-cash investing and financing activities:		
Settlement of warrant liability	$ —	$ 72,010
Issuance of common stock in settlement of accrued expenses	98	712
Conversion of convertible note	—	44,606
Assets in exchange for Enumera Molecular investment	6,000	—
Issuance of common stock and re-priced warrants upon settlement of accrued interest	3,929	3,627
Issuance of warrants upon settlement of accrued interest	2,300	—
Leased assets exchanged for operating lease liabilities	2,922	—
Change in fair value of re-priced equity classified warrants	619	—
Equity financing issuance costs incurred but not paid	116	200
Purchases of property and equipment in accounts payable	86	16

Note 1. Organization and Description of Business

Biora Therapeutics, Inc. (the “Company” or “Biora” or "Biora Therapeutics") is a biotechnology company developing oral biotherapeutics that could enable new treatment approaches in the delivery of therapeutics. The Company's therapeutics pipeline includes two therapeutic delivery platforms:

- NAVICAP™ Targeted Oral Delivery Platform: Targeted oral delivery of therapeutics to the site of disease in the gastrointestinal tract designed to improve outcomes for patients with Inflammatory Bowel Disease; and
- BIOJET™ Systemic Oral Delivery Platform: Systemic oral delivery of biotherapeutics designed to replace injections with needle-free, oral delivery of large molecules for better management of chronic diseases.

Biora Therapeutics, a Delaware corporation, was formerly known as Progenity, Inc. (“Progenity”), and commenced operations in 2010 with its corporate office located in San Diego, California. The Company's historical operations included a licensed Clinical Laboratory Improvement Amendments and College of American Pathologists certified laboratory located in Michigan specializing in molecular testing markets serving women’s health providers in the obstetric, gynecological, fertility, and maternal fetal medicine specialty areas in the United States. Previously, the Company's core business was focused on the carrier screening and noninvasive prenatal test market, targeting preconception planning, and routine pregnancy management for genetic disease risk assessment. Through its former 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 also included anatomic and molecular pathology testing products in the United States.

In order to refocus efforts and resources on its research and development pipeline, in June 2021, the Company announced a strategic transformation ("Strategic Transformation") that included the closure of the Progenity genetics laboratory in Ann Arbor, Michigan, and in December 2021, the Company sold Avero, together referred to as the Laboratory Operations. The Company has excluded from continuing operations for all periods presented in this report revenues and expenses associated with its Laboratory Operations, which are reported as discontinued operations. See Note 4 for additional information on the Laboratory Operations.

On April 12, 2022, the Company announced that it would rebrand to better reflect the current focus on its therapeutics pipeline, and would begin to operate as Biora Therapeutics, Inc., a Delaware corporation. The Company subsequently changed its name to Biora Therapeutics, Inc. on April 26, 2022.

On December 29, 2022, the Company filed a certificate of amendment ("the Certificate of Amendment") to its eighth amended and restated certificate of incorporation to effect, as of January 3, 2023, a 1-for-25 reverse split of the Company's common stock (the "Reverse Stock Split"). On January 3, 2023, the Company effected the Reverse Stock Split. See Note 2 for additional information.

Liquidity

As of December 31, 2022, the Company had cash and cash equivalents of $30.5 million and an accumulated deficit of $826.8 million. For the year ended December 31, 2022, the Company reported a net loss of $38.2 million and cash used in operating activities of $64.4 million. The Company’s primary sources of capital have historically been the sale of common stock and warrants, private placements of preferred stock and the incurrence of debt. As of December 31, 2022, the Company had $127.8 million of convertible senior notes, net ("Convertible Notes") outstanding (see Note 8). While the Company has greatly reduced its cash burn following the Strategic Transformation, management does not expect that the Company's current cash and cash equivalents will be sufficient to fund its operations for at least 12 months from the issuance date of the consolidated financial statements for the year ended December 31, 2022, and will require additional capital to fund the Company's operations. As a result, substantial doubt exists about the Company’s ability to continue as a going concern for 12 months following the issuance date of the consolidated financial statements for the year ended December 31, 2022.

The Company’s ability to continue as a going concern is dependent upon its ability to raise additional funding. Management believes that the Company’s liquidity position as of the date of this filing provides sufficient runway to achieve important research and development pipeline milestones. Management intends to raise additional capital through equity offerings and/or debt financings, or from other potential sources of liquidity, which may include new collaborations, licensing or other commercial agreements for one or more of the Company’s research programs or patent portfolios or divestitures of the Company's assets. Adequate funding, if needed, may not be available to the Company on acceptable terms, or at all. The Company’s ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the disruptions to, and volatility in, the credit and financial markets in the United States and worldwide. 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.

Note 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 Biora Therapeutics and its wholly-owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

The consolidated financial statements include the accounts of Biora Therapeutics, Inc., its wholly-owned subsidiaries, and, for the year ended December 31, 2021, an affiliated professional partnership with Avero with respect to which the Company had a specific management arrangement (see Note 3). All significant intercompany balances and transactions have been eliminated in consolidation.

The consolidated financial statements and notes thereto give retrospective effect to the Reverse Stock Split for all periods presented. All common stock, options exercisable for common stock, restricted stock units, warrants and per share amounts contained in the consolidated financial statements have been retrospectively adjusted to reflect the Reverse Stock Split for all periods presented. Concurrent with the Reverse Stock Split the Company effected a reduction in the number of authorized shares of common stock from 350,000,000 shares to 164,000,000 shares.

Financial Statement Presentation Change

In order to more closely align with the Company's business, and to better serve financial statement users, the Company has combined selling and marketing expenses with general and administrative expenses into a single selling, general and administrative expense line item. The Company's previous marketing expenses were associated with our discontinued Laboratory Operations and the Company no longer incurs these costs. Prior period amounts have been reclassified to conform to the current presentation.

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 stock options, the valuation of goodwill, the valuation of the derivative liability associated with the Convertible Notes, accrual for reimbursement claims and settlements, the valuation of warrant liabilities, the valuation of assets held for sale, assessing future tax exposure and the realization of deferred tax assets, and 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.

Assets Held for Sale and Discontinued Operations

Assets and liabilities are classified as held for sale when all of the following criteria for a plan of sale have been met: (1) management, having the authority to approve the action, commits to a plan to sell the assets; (2) the assets are available for immediate sale, in their present condition, subject only to terms that are usual and customary for sales of such assets; (3) an active program to locate a buyer and other actions required to complete the plan to sell the assets have been initiated; (4) the sale of the assets is probable and is expected to be completed within one year; (5) the assets are being actively marketed for a price that is reasonable in relation to their current fair value; and (6) actions required to complete the plan indicate that it is unlikely that significant changes to the plan will be made or the plan will be withdrawn. When all of these criteria have been met, the assets and liabilities are classified as held for sale

in the consolidated balance sheet. Assets classified as held for sale are reported at the lower of their carrying value or fair value less costs to sell. Depreciation and amortization of assets ceases upon designation as held for sale.

Discontinued operations comprise activities that were disposed of, discontinued or held for sale at the end of the period, represent a separate major line of business that can be clearly distinguished for operational and financial reporting purposes and represent a strategic business shift having a major effect on the Company's operations and financial results according to Accounting Standard Codification ("ASC") Topic 205, *Presentation of Financial Statements*.

Additional details surrounding the Company's assets and liabilities held for sale and discontinued operations are included in Note 4.

Investments

The Company accounts for investments in equity securities without a readily determinable fair value at cost, minus impairment. If the Company identifies observable price changes in orderly transactions for an identical or a similar investment of the same issuer, the Company will measure the equity security at fair value as of the date that the observable transaction occurred in accordance with ASC Topic 321, *Investments-Equity Securities*.

Revenue Recognition

Revenue is recognized in accordance with the Financial Accounting Standards Board ("FASB") 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 was primarily derived from providing molecular testing products, which were 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 contained a single performance obligation, which was the delivery of the test results, and the Company satisfied its performance obligation at a point in time upon the delivery of the results, which then triggered the billing for the product. The amount of revenue recognized reflects the amount of consideration the Company expected to be entitled to ("transaction price") and considered the effects of variable consideration. Revenue was recognized when control of the promised product was transferred to customers, in an amount that reflected the consideration the Company expected 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 are expensed as incurred because the related amortization period would be one year or less. The costs are included in selling and marketing expenses.
- No adjustments to amounts of promised consideration are 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 historically relied upon reimbursements from third-party government payors and private-payor insurance companies to collect accounts receivable. As a result of the Strategic Transformation, all revenue from Laboratory Operations has been classified as discontinued operations and there were no significant concentrations as of December 31, 2022. The Company's significant third-party payors and their related accounts receivable balances and revenues as a percentage of total accounts receivable balances as of December 31, 2021 and of revenues for the year ended December 31, 2021 are as follows:

	Percentage of Accounts Receivable
	December 31, 2021
Blue Shield of Texas	4.0%
United Healthcare	7.2%
Government Health Benefits Programs	55.8%

	Percentage of Revenue (1)
	Year Ended December 31, 2021
Blue Shield of Texas	10.7%
Aetna	7.3%
Cigna	5.7%
United Healthcare	6.7%
Government Health Benefits Programs	23.2%

(1) Percentage of revenue table shows amounts as a percentage of total revenue, including revenue classified as discontinued operations. Refer to Note 5 for details of the breakdown of revenue.

Accounts Receivable

Amounts included in accounts receivable for the year ended December 31, 2021 consist of receivables generated from the Company's genetics laboratory in Ann Arbor, Michigan. The Company continued to collect these receivables and did not include these amounts as assets held for sale. The accounts receivable amounts were recorded at the transaction price and considered the effects of variable consideration. The total consideration the Company expected to collect was an estimate and was fixed or variable. Variable consideration included reimbursement from third-party payors, laboratory distribution partners, and amounts from individual patients, and was 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.

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.

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.

Leases

The Company determines if an arrangement is or contains a lease at inception. For leases with a term greater than one year, lease right-of-use assets and lease liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. In determining the net present value of lease payments, the Company uses its incremental borrowing rate which represents an estimated rate of interest that the Company would have to pay to borrow equivalent funds on a collateralized basis at the lease commencement date. Leases are classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the statement of operations.

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 a quantitative assessment.

If a quantitative assessment is deemed necessary, the Company compares the fair value of the reporting unit with its carrying amount, including goodwill. An impairment loss will be recognized if the reporting unit's carrying amount exceeds its fair value, to the extent that it does not exceed the total carrying amount of goodwill. No impairment existed as of December 31, 2022 or December 31, 2021.

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. The Company recorded impairment of $0.5 million during the year ended December 31, 2022. No impairment was recorded for the year ended December 31, 2021.

Fair Value of Financial Instruments

The Company's financial assets and liabilities are carried at fair value or at amounts that, because of their short-term nature, approximate current fair value, with the exception of its Convertible Notes, which are carried at amortized cost. The carrying value of the Company's accounts 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 (see Note 7).

Embedded Derivative Related to Convertible Notes

In December 2020, the Company issued Convertible Notes with an embedded derivative that was required to be bifurcated from the host contract and remeasured to fair value at each balance sheet date. Any resulting gain or loss related to the change in the fair value of the embedded derivative was recorded to other income, net in the consolidated statements of operations. As of December 31, 2022, the conversion option has expired and the Company no longer has an embedded derivative.

Common Stock Warrant Liabilities

The Company accounts for common stock warrants issued as freestanding instruments in accordance with applicable accounting guidance as either liabilities or as equity instruments depending on the specific terms of the warrant agreements. Warrants classified as liabilities are remeasured each period until settled or until classified as equity. Any resulting gain or loss related to the changes in the fair value of the warrant liabilities are recorded to gain (loss) on warrant liabilities in the consolidated statements of operations. Changes in the Company's inputs and assumptions, such as the Company's stock price and volatility of common stock, could result in material changes in the valuation in future periods.

Repairs 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 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, General and Administrative

Selling, 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 costs for communication, advertising, conferences, and professional fees of audit, legal,

and recruiting services. Selling, general and administrative expenses are expensed as incurred. Advertising expense for the year ended December 31, 2021 was $0.6 million, and there were no advertising expenses for the year ended December 31, 2022.

Stock-Based Compensation

Stock-based compensation related to stock options, restricted stock units (“RSUs”) and the 2020 Employee Stock Purchase Plan (“ESPP”) awards granted to the Company’s employees is measured at the grant date based on the fair value of the award. The fair value is recognized as expense over the requisite service period, which is generally the vesting period of the respective awards. Compensation related to service-based awards is recognized starting on the grant date on a straight-line basis over the vesting period, which is typically four years. For the ESPP, the requisite service period is generally the period of time from the offering date to the purchase date. In addition, the Company grants stock option awards that vest upon achievement of certain performance criteria ("Performance Awards"). The fair value is recognized as expense over the requisite service period when the Company has concluded that achieving the performance criteria is probable. The probability of achieving the performance criteria is assessed each reporting period. The Company accounts for the forfeitures in the period in which they occur. The fair value of RSUs is estimated based on the closing price of the Company's common stock on the date of the grant.

The fair value of stock options, ESPP awards and Performance Awards is estimated using the Black-Scholes option-pricing model and 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. The Company’s inputs and assumptions with respect to these variables are as follows:

Fair Value of Common Stock—Prior to the IPO, the Company’s common stock was not publicly traded, therefore the Company estimated the fair value of its common stock. Following the initial public offering of the Company's common stock (the "IPO"), the fair value of the Company’s common stock for awards with service-based vesting is the closing price of its common stock on the date of grant or other relevant determination date.

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. For the ESPP, the expected term is the period of time from the offering date to the purchase date.

Expected Volatility—Given the limited period of time the Company’s stock has been traded in an active market, the expected volatility is estimated by taking the average historical volatility for industry peers, consisting of several public companies in the Company’s industry that are similar in size, stage, or financial leverage, over a period of time commensurate with 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 pay dividends.

Net Loss Per Share

Basic net loss per share is computed by dividing the net loss by the weighted average number of shares of common stock outstanding during the period. Diluted net loss per share is computed by dividing the net loss by the weighted average number of shares of common stock and potentially dilutive securities outstanding for the period. 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.

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.

Emerging Growth Company Status

The Company is an emerging growth company ("EGC"), as defined in the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"). Under the JOBS Act, EGCs 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. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it (i) is no longer an emerging growth company or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, these consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

Recent Accounting Pronouncements Adopted

In February 2016, the FASB issued Accounting Standards Update ("ASU") No. 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 Company adopted the provisions of this guidance on January 1, 2022, using the effective date method. As a result of adopting ASC 842, the Company recognized right-of-use assets and lease liabilities of $2.2 million and $2.2 million, respectively, on January 1, 2022. The difference between the right-of-use assets and lease liabilities is attributed to the elimination of deferred rent and prepaid rent. There was no adjustment to the opening balance of accumulated deficit as a result of the adoption. The Company elected to use the package of practical expedients available in the new lease standard, allowing it not to reassess: (a) whether expired or existing contracts contain leases under the new definition of a lease; (b) lease classification for expired or existing leases; and (c) whether previously capitalized initial direct costs would qualify for capitalization under the new lease standard.

In May 2021, the FASB issued ASU No. 2021-04, *Issuer's Accounting for Certain Modification or Exchanges of Freestanding Equity-Classified Written Call Options*, which provides a principles-based framework to determine whether an issuer should recognize the modification or exchange as an adjustment to equity or an expense. The Company adopted this standard on January 1, 2022, which did not have a material impact on the consolidated financial statements.

Recent Accounting Pronouncements Not Yet Adopted

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 standard is effective for the Company for annual reporting periods beginning after December 15, 2022. The Company does not expect the adoption of this standard to have a significant impact on its consolidated financial statements.

In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40)-Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which simplifies the accounting for convertible instruments, amends the guidance on derivative scope exceptions for contracts in an entity's own equity, and modifies the guidance on diluted earnings per share calculations as a result of these changes. The standard is effective for the Company for annual reporting periods beginning after December 15, 2023. The Company is currently evaluating the impact the adoption of this standard may have on its consolidated financial statements.

Note 3. Variable Interest Entity

In June 2015, the Company, through a wholly-owned subsidiary, entered into a series of agreements with Avero. The subsidiary entity entered into a purchase agreement to acquire certain assets from Mattison used in the operations of Avero. The purchase agreement was accounted for under the acquisition method in accordance with the provisions of ASC Topic 805, *Business*

Combinations. The subsidiary entity also entered into a nominee agreement which provided 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.

In December 2021, the Company entered into an asset purchase agreement with Northwest Pathology to sell certain assets and liabilities of Avero for $10.9 million. The Company no longer has any ownership interest in Avero and therefore does not consolidate Avero beginning at December 31, 2021. Prior to the date of sale, Avero's income statement activity is included in discontinued operations in the consolidated statements of operations.

In June 2015, the Company's subsidiary entity entered into a management services arrangement that authorized the Company to perform the management services in the manner that it deemed reasonably appropriate to meet the day-to-day business needs of Avero. The management services included funding ongoing operational needs, directing activities related to contract negotiation, billing, human resources, and legal and administrative matters and processes, among others. In exchange for the management services provided, the Company's subsidiary entity was entitled to receive an annual management fee equal to the amount of the net operating income of Avero. The agreement had a 10-year term, but was terminated at the time of the sale of Avero.

Through the management services arrangement with Avero, the Company had (1) the power to direct the activities of Avero that most significantly impact its economic performance, and (2) the obligation to absorb losses of Avero or the right to receive benefits from Avero that could potentially be significant to Avero. Based on these determinations, the Company determined that Avero was a variable interest entity ("VIE") and that the Company was the primary beneficiary. The Company did not own any equity interest in Avero; however, as these agreements provide the Company the controlling financial interest in Avero, the Company consolidated Avero’s balances and activities within its consolidated financial statements.

Note 4. Strategic Transformation

In June 2021, the Company announced its Strategic Transformation to reallocate resources to research and development to better position the business for future growth. The plan included the closure of the Company's genetics laboratory in Ann Arbor, Michigan and the divestiture of Avero. This plan represents a strategic business shift having a major effect on the Company's operations and financial results. The Company classified the results of its Laboratory Operations as discontinued operations in its consolidated statements of operations and consolidated statements of cash flows for all periods presented. Additionally, the remaining assets have been reported as assets held for sale in the Company’s consolidated balance sheets as of December 31, 2022 and December 31, 2021. The Company recognized a loss of $19.3 million for the year ended December 31, 2021 for contract terminations, severance, inventory and fixed asset write-downs in discontinued operations related to the genetics laboratory shutdown. The Company received revenue in connection with the reimbursement for tests that were run prior to the closure of its Laboratory Operations through September 2022. In December 2021, the Company entered into an asset purchase agreement to sell certain assets and liabilities of Avero for gross proceeds of $10.9 million. The Company recognized a loss of $6.0 million in discontinued operations, calculated as proceeds less net assets of $15.1 million and transaction costs of $1.8 million, for the year ended December 31, 2021.

The following table presents the combined results of discontinued operations of the Laboratory Operations (in thousands):

	Year Ended December 31,	
	2022	2021
Revenues (1)	$ 11,848	$ 59,362
Cost of sales	—	63,741
Gross profit (loss)	11,848	(4,379)
Operating expenses:		
Research and development	—	1,590
Selling and marketing	—	38,753
General and administrative	1,175	18,247
Total operating expenses	1,175	58,590
Other expense, net	—	(5,922)
Net income (loss) from discontinued operations	$ 10,673	$ (68,891)

(1) Refer to Note 10 for further discussion regarding the partial reversal of a previously-established accrual related to a third-party claim of recoupment during the year ended December 31, 2022.

The following table presents the carrying amounts of the remaining assets held for sale related to the Laboratory Operations as of December 31, 2022 and December 31, 2021 (in thousands):

	December 31, 2022	December 31, 2021
Current assets of disposal group held for sale		
Property and equipment, net	2,603	2,493
Total current assets of disposal group held for sale (2)	$ 2,603	$ 2,493

(2) The Company is actively looking to sell the remaining assets of the Laboratory Operations and has classified them as held for sale and current in the consolidated balance sheets at December 31, 2022 and December 31, 2021.

Investment in Enumera Molecular, Inc.

In May 2022, the Company completed the divesture of its single-molecule detection platform. Under the terms of the agreements, the Company contributed intellectual property and fixed assets related to the single-molecule detection platform to a newly-formed entity, Enumera Molecular, Inc. ("Enumera"), which intends to develop and commercialize the platform. As of the transaction date, the Company received 25% minority ownership, on a fully-diluted basis, of 6,000,000 Series A-1 preferred shares with an estimated value of $6.0 million in exchange for the assets. The Company performed a VIE analysis and concluded Enumera does not meet the definition of a VIE. The Company also evaluated the characteristics of the investment and determined that the preferred stock is not in-substance common stock that would require equity method accounting. The Company concluded the appropriate accounting treatment for the investment in Enumera to be that of an equity security with no readily-determinable fair value and has recorded the investment at cost, less impairment, adjusted for subsequent observable price changes. The investment is included in other assets in the Company's consolidated balance sheets as of December 31, 2022. The Company recognized a gain of $5.7 million on the investment during the year ended December 31, 2022 included in other income, net on the consolidated statements of operations and there was no impairment recorded.

Northwest License Agreement

In November 2022, the Company entered into a license agreement with Northwest Pathology, doing business as Avero Diagnostics ("Northwest"), pursuant to which the Company licenses its Preecludia rule-out test for preeclampsia to Northwest for commercial development (the "Northwest License Agreement"). Under the terms of the Northwest License Agreement, Northwest receives rights to assets and intellectual property related to the Preecludia test and the Company will receive commercial milestone payments and royalties on net sales.

Note 5. Revenues

The Company's revenues are generated primarily through collaboration agreements. Under ASC 606, revenue is recognized when a customer obtains control of promised goods or services. The amount of revenue recognized reflects the consideration that the Company expects to be entitled to receive in exchange for these services. The Company analyzes the nature of these performance obligations in the context of individual agreements in order to assess the distinct performance obligations.

The Company applies the following five steps to recognize revenue: (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.

The Company evaluates all promised goods and services within a customer contract and determines which of such goods and services are separate performance obligations. This evaluation includes an assessment of whether the good or service is capable of being distinct and whether the good or service is separable from other promises in the contract.

The transaction price is determined based on the consideration to which the Company will be entitled in exchange for transferring goods and services to the customer. A contract may contain variable consideration, including potential payments for both milestone and research and development services. For certain potential milestone payments, the Company estimates the amount of variable consideration by using the most likely amount method. Each reporting period the Company re-evaluates the probability of achievement of such variable consideration and any related constraints. The Company will include variable consideration, without constraint, in the transaction price to the extent it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

If the contract contains a single performance obligation, the entire transaction price is allocated to the single performance obligation. Contracts that contain multiple performance obligations require an allocation of the transaction price among the performance obligations on a relative standalone selling price basis unless the transaction price is variable and meets the criteria to be allocated entirely to a performance obligation or to a distinct good or service that forms part of a single performance obligation.

Revenues historically were 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 entered into contracts with healthcare insurers related to tests provided to patients who had 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 were billed to insurance carriers, patients, or a combination of insurance carriers and patients. The Company also sold tests to laboratory partners, which are considered customers.

The Company evaluated its contracts with healthcare insurers, government payors, laboratory partners and patients and identified a single performance obligation, the delivery of a test result. The Company satisfied 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. Once the Company satisfied its performance obligations upon delivery of a test result and billed for the product, the timing of the collection of payments may vary based on the payment practices of the third-party payor. The Company billed patients directly for co-pays and deductibles that they are responsible for and also billed patients directly in cases where the customer did not have insurance. All of the historical test revenue is part of the Company's Laboratory Operations and has been included in discontinued operations in the consolidated statements of operations.

The Company had established an accrual for refunds of payments previously made by healthcare insurers based on historical experience and executed settlement agreements with healthcare insurers. Any refunds are accounted for as reductions in revenues in the statement of operations as an element of variable consideration.

The transaction price was an estimate and could 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 nine 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 characteristics. 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. The Company monitors these estimates at each reporting period based on actual cash collections and the 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.

The Company periodically updated its estimate of the variable consideration recognized for previously-delivered performance obligations. These updates resulted in an additional $2.0 million and $6.6 million of revenue reported for the years ended December 31, 2022 and December 31, 2021, respectively. These amounts included (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 10.

Disaggregation of Revenues

As a result of the classification of Laboratory Operations to discontinued operations, the Company is only showing disaggregation for prior year. The Company's current revenue is related to license and collaboration agreements. The following tables show revenues disaggregated by payor type and revenue classification (in thousands):

	Year Ended December 31, 2021
Commercial third-party payors	$ 42,100
Government health benefit programs (1)	14,085
Patient/laboratory distribution partners	4,424
Total revenues	$ 60,609

(1) The revenue amounts include accruals for reimbursement claims and settlements included in the estimates of variable consideration recorded during the year ended December 31, 2021. Revenues recognized reflect the effects of variable consideration, and include adjustments for estimates of disallowed cases, discounts, and refunds. The variable consideration includes reductions in revenues for the accrual for reimbursement claims and settlements.

Classification	Year Ended December 31, 2022	Year Ended December 31, 2021
Revenue from continuing operations	$ 305	$ 1,247
Revenue from discontinued operations	11,848	59,362
Total revenues	$ 12,153	$ 60,609

Note 6. Balance Sheet Components

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following (in thousands):

	December 31, 2022	December 31, 2021
Prepaid expenses	$ 3,634	$ 6,123
Other current assets	565	1,109
Total	$ 4,199	$ 7,232

Property and Equipment, Net

Property and equipment, net consisted of the following (in thousands):

	December 31, 2022	December 31, 2021
Computers and software	$ 2,715	$ 5,004
Building and leasehold improvements	750	437
Laboratory equipment	958	2,688
Furniture, fixtures, and office equipment	1,138	1,142
Construction in progress	92	16
Total property and equipment	5,653	9,287
Less accumulated depreciation and amortization	(3,999)	(5,621)
Property and equipment, net	$ 1,654	$ 3,666

Depreciation expense included in continuing operations was $0.9 million and $1.4 million for the years ended December 31, 2022 and 2021, respectively.

Other Assets

Other assets consisted of the following (in thousands):

	December 31, 2022	December 31, 2021
Investment in Enumera	$ 6,000	$ —
Other	201	326
Total	$ 6,201	$ 326

Goodwill

As part of the sale of Avero during the year ended December 31, 2021, the Company allocated goodwill using the relative fair value method to both the Avero business that was sold and the remaining Biora business. The $0.1 million allocated to Avero was included in the carrying value to determine the loss on sale.

A summary of the activity in goodwill is presented below (in thousands):

Balance at December 31, 2020 (1)	$ 6,219
Reduction of goodwill related to disposition	(147)
Balance at December 31, 2021 and December 31, 2022	$ 6,072

(1) The beginning balance as of December 31, 2020 includes the amount of Goodwill classified in assets held for sale.

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	December 31, 2022	December 31, 2021
Accrual for reimbursement claims and settlements, current (1)	$ 8,372	$ 18,127
Commissions and bonuses	1,433	3,883
Vacation and payroll benefits	1,724	6,894
Accrued professional services	307	652
Accrued interest	890	802
Lease liabilities, current	893	—
Insurance financing	445	489
Contract liabilities	47	301
Other (2)	2,050	3,009
Total	$ 16,161	$ 34,157

(1) All of the Company's revenues related to Laboratory Operations have been discontinued; amounts related to the revenue reserve generated from the Laboratory Operations remain on the balance sheet.
(2) Included in this amount are contracts that the Company will be responsible for that cannot be terminated; as there is no future benefit to the Company, they were expensed in discontinued operations in 2021.

Other Long-term Liabilities

Other long-term liabilities consisted of the following (in thousands):

	December 31, 2022	December 31, 2021
Accrual for reimbursement claims and settlements, net of current portion (1)	$ —	$ 192
Lease liabilities, net of current portion	601	—
Other (2)	4,095	5,622
Total	$ 4,696	$ 5,814

(1) All of the Company's revenues related to Laboratory Operations have been discontinued; amounts related to the revenue reserve generated from the Laboratory Operations remain on the balance sheet.
(2) Included in this amount are contracts that the Company will be responsible for that cannot be terminated; as there is no future benefit to the Company, they were expensed in discontinued operations in 2021.

Note 7. Fair Value Measurements

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the measurement date. The authoritative guidance establishes a three-level valuation hierarchy that prioritizes the inputs to valuation techniques used to measure fair value based upon whether such inputs are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions made by the reporting entity. This hierarchy requires the Company to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value. The three-level hierarchy for the inputs to valuation techniques is summarized as follows:

Level 1 - Quoted prices in active markets for identical assets and liabilities that the Company has the ability to access.

Level 2 - Observable market-based inputs or unobservable inputs that are corroborated by market data, such as quoted prices, interest rates, and yield curves.

Level 3 - Inputs that are unobservable data points that are not corroborated by market data.

There were no significant transfers between these fair value measurement classifications during the years ended December 31, 2022 and 2021.

Fair Value of Financial Instruments

The Company's Level 3 liabilities consist of the embedded derivative liability associated with the Company's Convertible Notes (see Note 8) and the warrant liabilities resulting from the November 2022 and August 2021 issuance of warrants (see Note 11). The Convertible Notes conversion feature was bifurcated and recorded as an embedded derivative liability with a corresponding discount at the date of issuance that is netted against the principal amount of the Convertible Notes. The Company utilizes a Monte Carlo simulation method to determine the fair value of the conversion feature, which utilizes inputs including the common stock price, volatility of common stock, the risk-free interest rate and the probability of conversion to common shares at the conversion rate in the event of a major transaction (e.g. a change in control). Due to the use of significant unobservable inputs, the overall fair value measurement of the conversion feature is classified as Level 3. As of December 31, 2021, the fair value of the embedded derivative liability was zero. As of December 31, 2022, the conversion option has expired and there is no longer an embedded derivative.

The Company uses the Black-Scholes Model to value the Level 3 warrant liabilities at inception and on subsequent valuation dates. This model incorporates transaction details such as the Company's stock price, contractual terms, maturity, risk free rates, and volatility. The significant unobservable input for the Level 3 warrant liabilities include volatility. Given the limited period of time the Company's stock has been traded in an active market, the expected volatility is estimated by taking the average historical price volatility for industry peers, consisting of several public companies in the Company's industry that are similar in size, stage, or financial leverage, over a period of time commensurate to the expected term of the warrants. At December 31, 2022 and 2021, the fair value of the warrant liabilities were estimated using the Black-Scholes Model with the following inputs and assumptions:

	December 31, 2022	December 31, 2021
Risk-free interest rate	4.0%	1.3%
Expected volatility	106.2% - 107.1%	91.9%
Stock price	$ 3.30	$ 52.25
Expected life (years)	3.6 - 5.4	4.6

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):

	Level 1	Level 2	Level 3
December 31, 2022			
Money market funds (1)	$ 5	$ —	$ —
Warrant Liabilities	$ —	$ —	$ 3,538
December 31, 2021			
Money market funds (1)	$ 85,866	$ —	$ —
Warrant Liabilities	$ —	$ —	$ 18,731

(1) Included in cash and cash equivalents in the accompanying consolidated balance sheets.

The carrying value of the Company's Convertible Notes does not approximate its fair value because the carrying value of the Convertible Notes reflects the balance of unamortized discount related to the derivative liability associated with the value of the

conversion feature assessed at inception. The carrying value of the Company's Convertible Notes, net of discount, was $127.8 million and $126.4 million at December 31, 2022 and 2021, respectively. Based on unadjusted quoted prices in active market obtained from third-party pricing services, the Company determined the fair value of the Convertible Notes was $71.8 million and $86.6 million as of December 31, 2022 and 2021, respectively.

Note 8. Convertible Notes

In December 2020, the Company issued a total of $168.5 million principal amount of Convertible Notes in a private offering of the Convertible Notes pursuant to Rule 144A under the Securities Act of 1933, as amended (the "Securities Act"). The Convertible Notes were issued pursuant to, and are governed by, an indenture, dated as of December 7, 2020, by and between the Company and The Bank of New York Mellon Trust Company, N.A., as trustee ("Indenture"). The Convertible Notes are due on December 1, 2025, unless earlier repurchased, redeemed or converted, and accrue interest at a rate per annum equal to 7.25% payable semi-annually in arrears on June 1 and December 1 of each year, with the initial payment on June 1, 2021. The outstanding principal amount of Convertible Notes was $132.7 million at both December 31, 2022 and December 31, 2021. During the years ended December 31, 2022 and 2021, the Company recognized interest expense on the Convertible Notes of $9.6 million and $11.7 million, respectively.

The Convertible Notes are the Company's senior, unsecured obligations and are (i) equal in right of payment with the Company's existing and future senior, unsecured indebtedness; (ii) senior in right of payment to the Company's existing and future indebtedness that is expressly subordinated to the Convertible Notes; (iii) effectively subordinated to the Company's existing and future secured indebtedness, to the extent of the value of the collateral securing that indebtedness; and (iv) structurally subordinated to all existing and future indebtedness and other liabilities, including trade payables, and (to the extent the Company is not a holder thereof) preferred equity, if any, of the Company's subsidiaries.

At any time, noteholders may convert their Convertible Notes at their option into shares of the Company's common stock, together, if applicable, with cash in lieu of any fractional share, at the then-applicable conversion rate. The initial conversion rate is 11.1204 shares of common stock per $1,000 principal amount of Convertible Notes, which represents an initial conversion price of approximately $89.92 per share of common stock. Noteholders that converted their Convertible Notes before December 1, 2022 were, in certain circumstances, entitled to an additional cash payment representing the present value of any remaining interest payments on the Convertible Notes through December 1, 2022. The conversion rate and conversion price are subject to customary adjustments upon the occurrence of certain dilutive events. In addition, if certain corporate events that constitute a "Make-Whole Fundamental Change" (as defined in the Indenture) occur, then the conversion rate will, in certain circumstances, be increased for a specified period of time.

The Convertible Notes are redeemable, in whole and not in part, at the Company's option at any time on or after December 1, 2023, at a cash redemption price equal to the principal amount of the Convertible Notes to be redeemed, plus accrued and unpaid interest, if any, to, but excluding, the redemption date, but only if the last reported sale price per share of the Company's common stock exceeds 130% of the conversion price on (i) each of at least 20 trading days, whether or not consecutive, during the 30 consecutive trading days ending on, and including, the trading day immediately before the date the Company sends the related redemption notice; and (ii) the trading day immediately before the date the Company sends such notice. In addition, calling the Convertible Notes will constitute a Make-Whole Fundamental Change, which will result in an increase to the conversion rate in certain circumstances for a specified period of time.

The Convertible Notes have customary provisions relating to the occurrence of "Events of Default" (as defined in the Indenture), which include the following: (i) certain payment defaults on the Convertible Notes (which, in the case of a default in the payment of interest on the Convertible Notes, will be subject to a 30-day cure period); (ii) the Company's failure to send certain notices under the Indenture within specified periods of time; (iii) the Company's failure to comply with certain covenants in the Indenture relating to the Company's ability to consolidate with or merge with or into, or sell, lease or otherwise transfer, in one transaction or a series of transactions, all or substantially all of the assets of the Company and its subsidiaries, taken as a whole, to another person; (iv) a default by the Company in its other obligations or agreements under the Indenture or the Convertible Notes if such default is not cured or waived within 60 days after notice is given in accordance with the Indenture; (v) certain defaults by the Company or any of its subsidiaries with respect to indebtedness for borrowed money of at least $7.5 million; (vi) the rendering of certain judgments against the Company or any of its subsidiaries for the payment of at least $7.5 million, where such judgments are not discharged or stayed within 60 days after the date on which the right to appeal has expired or on which all rights to appeal have been extinguished; and (vii) certain events of bankruptcy, insolvency and reorganization involving the Company or any of the Company's significant subsidiaries. As of December 31, 2022 and December 31, 2021, the Company was in compliance with all such covenants.

The Convertible Notes had a conversion option which was required to be bifurcated upon issuance and periodically remeasured to fair value separately as an embedded derivative. The conversion option included additional interest payments payable to the noteholders if converted prior to December 1, 2022 (the "Early Voluntary Conversion Option"). The conversion feature was bifurcated

and recorded separately as an embedded derivative as (1) the conversion feature was not clearly and closely related to the debt instrument and was not considered to be indexed to the Company's equity, (2) the conversion feature standing alone meets the definition of a derivative, and (3) the Convertible Notes are not remeasured at fair value each reporting period with changes in fair value recorded in the consolidated statement of operations.

The fair value of the embedded derivative was zero as of December 31, 2021. As of December 31, 2022, the conversion option has expired and there is no longer an embedded derivative. The prior year change in fair value of the derivative liability of $18.4 million is included in other income (expense), net in the consolidated statement of operations for the year ended December 31, 2021. As of December 31, 2022 and 2021, the unamortized debt discount was $4.9 million and $6.3 million, respectively. The Company amortizes the debt discount using the effective interest method over the term of the Convertible Notes, resulting in an effective interest rate of approximately 8.7%. For the years ended December 31, 2022 and 2021 the amortization of the Convertible Notes debt discount was $1.4 million and $1.6 million, respectively, and is included in interest expense, net in the consolidated statements of operations.

In October 2021, holders of Convertible Notes exchanged an aggregate of $20.2 million principal amount for 340,554 shares of the Company's common stock. As the Convertible Notes were exchanged for an amount over the fair value of shares issuable under the original conversion terms, the Company recorded an inducement loss of $9.8 million, included in other income (expense) in the consolidated statements of operations. In addition, the Company issued an aggregate of 17,112 shares of common stock to certain investors in consideration for a waiver of certain contractual lock-up provisions to which the Company agreed to in connection with prior offerings of its securities. The Company recorded an inducement loss of $1.4 million in other income (expense), net, in the consolidated statements of operations, related to these shares.

In addition to the transaction discussed above, holders of Convertible Notes exchanged an aggregate of $15.6 million principal amount for 173,477 shares of the Company's common stock during the year ended December 31, 2021. The Convertible Notes were converted under the Early Voluntary Conversion Option and the Company recognized a $0.9 million extinguishment loss, which is included in other income, net in the consolidated statements of operations.

Note 9. Related Party Transactions

In June 2021, affiliates of Athyrium Capital Management, LP ("Athyrium") participated in a private placement and acquired 323,886 units, representing 323,886 shares of common stock and warrants to purchase up to 323,886 shares of common stock at a price of $61.75 per unit (see Note 11). As of December 31, 2021, affiliates of Athyrium held 1,157,405 shares, or 15.6%, respectively, of the Company's common stock outstanding and warrants to purchase up to 323,883 and 16,006 shares of common stock at an exercise price of $71.00 and $347.50, respectively.

Athyrium also holds $103.5 million aggregate principal amount of Convertible Notes as of both December 31, 2022 and 2021 (see Note 8). During the year ended December 31, 2021, Athyrium entered into an agreement with the Company to waive its interest due of $3.6 million through June 1, 2021 and received 50,724 shares of common stock. As of both December 31, 2022 and 2021, the accrued interest expense related to the Convertible Notes was $0.6 million.

In November 2022, the Company entered into a securities purchase agreement with affiliates of Athyrium relating to the offering and sale of an aggregate of 500,250 shares of common stock and accompanying warrants to purchase 500,250 shares of common stock, at a combined purchase price of $7.50 per share and accompanying warrant in a registered direct offering. The warrants have an exercise price of $8.22 per share and will become exercisable commencing six months following the date of issuance and will expire five years following the initial exercise date. The Company received approximately $3.8 million in gross proceeds from the offering as an in-kind payment. The in-kind payment was in the form of a waiver of the Company's cash interest payment obligation of approximately $3.8 million due on certain of the Company's 7.25% Convertible Senior Notes due 2025 held by affiliates of Athyrium for the payment date occurring on December 1, 2022. Additionally, the Company agreed with Athyrium to amend outstanding warrants previously issued in 2021 to purchase up to 323,886 shares of common stock with an exercise price of $71.00 per share. The warrants have an amended exercise price of $8.22 per share, will become exercisable on May 9, 2023 and will expire five years following the initial exercise date.

As of December 31, 2022, Athyrium held 1,694,484 shares, or 19.0% of the Company's common stock outstanding and warrants to purchase up to 824,136 shares of common stock at an exercise price of $8.22.

In November 2022, the Company entered into a securities purchase agreement with an institutional investor relating to the offering and sale of an aggregate of 800,000 shares of common stock and accompanying warrants to purchase 800,000 shares of common stock, at a combined purchase price of $7.50 per share and accompanying warrant in a registered direct offering (see Note 11). Following this transaction, the institutional investor became a related party due to greater than 5% ownership.

On January 12, 2023, the Company issued warrants to purchase 90,000 shares of common stock to the institutional investor in exchange for the investor's agreement to waive the lockup provisions contained in the securities purchase agreement from the

November 2022 Offering (as defined below). The warrant has an exercise price of $8.22, is exercisable beginning on May 9, 2023 and expires on May 9, 2028.

Note 10. Commitments and Contingencies

Operating Leases

The Company has entered into various non-cancelable operating lease agreements, primarily for office space, laboratory space, and equipment. On January 1, 2022, the Company adopted ASC Topic 842, Leases. Results for reporting periods beginning after January 1, 2022 are presented under ASC 842, while prior period amounts are not adjusted and continue to be reported in accordance with historic accounting guidance. The right-of-use assets were $1.5 million as of December 31, 2022 and current and long-term lease liabilities were $0.9 million and $0.6 million, respectively, as of December 31, 2022, and are recorded in accrued expenses and other current liabilities and other long-term liabilities on the consolidated balance sheet.

Operating lease costs were $1.5 million for the year ended December 31, 2022 and cash paid for operating leases was $1.6 million. The weighted-average discount rate used was 7.8% and the weighted-average remaining lease term for all operating leases was 2.3 years. Rent expense included in continuing operations for operating leases was $5.1 million for the year ended December 31, 2021.

As of December 31, 2022, future lease payments under the non-cancelable operating leases were as follows (in thousands):

Year ending December 31,	Minimum Operating Lease Payments
2023	$ 965
2024	235
2025	209
2026	215
2027 and thereafter	18
Total minimum lease payments	1,642
Less: interest	(148)
Present value of lease liabilities	$ 1,494

As of December 31, 2021, net minimum payments under the non-cancelable operating leases were as follows (in thousands):

Year ending December 31,	Minimum Operating Lease Payments
2022	$ 2,141
2023	1,086
2024	237
2025	208
2026 and thereafter	251
Total future minimum lease payments	$ 3,923

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 of Biora 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 may be subject to interpretation. As a former 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 complied in all material respects with the statutes, regulations, and other requirements applicable to its former laboratory operations.

Federal Investigations

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 (“SDCA”) around legacy commercial practices. In May 2018, the Company received a subpoena from the State of New York Medicaid Fraud Control Unit.

On July 21, 2020, July 23, 2020 and October 1, 2020, the Company entered into agreements ("the Agreements") with certain governmental agencies and the 45 states participating in the settlement (“State AGs”) to resolve, with respect to such agencies and State AGs, all of such agencies’ and State AGs’ outstanding civil, and, where applicable, federal criminal investigations described above. The Company paid approximately $5.0 million as required by the Agreements during the year ended December 31, 2021. As of December 31, 2021, the Company’s accrual consisted of $6.9 million in accrued expenses and other current liabilities and $0.2 million in other long-term liabilities. In November 2022, the Company entered into an agreement to extend the deadline for the Company’s payment due on December 31, 2022 to July 15, 2023 and the Company did not make any payments during the year ended December 31, 2022. The remaining amounts payable to the government 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. As of December 31, 2022, the Company’s accrual consists of $7.1 million in accrued expenses and other current liabilities.

Furthermore, the Company has agreed that, if during calendar years 2020 through 2023, and so long as amounts payable to the government remain unpaid, the Company receives any civil settlement, damages awards, or tax refunds, to the extent that the amounts exceed $5.0 million in a calendar year, it will pay 26% of the amount received in such civil settlement, damages award, or tax refunds as an accelerated payment of the scheduled amounts set forth above, up to a maximum total acceleration of $4.1 million. The Company did not receive any tax refunds during the years ended December 31, 2022 and 2021.

Non-Prosecution Agreement

Effective July 21, 2020, the Company entered into the Non-Prosecution Agreement, pursuant to which the Company agreed with the DOJ to (i) pay the restitution provided for under the SDCA Civil Settlement Agreement, (ii) not commit any felonies, (iii) continue to implement a compliance and ethics program designed to prevent and detect violations of applicable fraud and kickback laws throughout its operations and (iv) fulfill certain other disclosure, reporting and cooperation obligations. The DOJ agreed that it will not prosecute the Company for any conduct described in the Non-Prosecution Agreement provided that the Company performs its obligations under the Non-Prosecution Agreement during the period from July 21, 2020 through July 21, 2021. The Non-Prosecution Agreement expired on July 21, 2021.

Corporate Integrity Agreement

In connection with the resolution of the investigated matters, and in exchange for the Office of Inspector General of the Department of Health and Human Services ("OIG") agreement not to exercise its authority to permissively exclude the Company from participating in federal healthcare programs, effective July 21, 2020, the Company entered into a five-year Corporate Integrity Agreement with the OIG. The Corporate Integrity Agreement requires, among other matters, that the Company maintain a Compliance Officer, a Compliance Committee, board review and oversight of certain federal healthcare compliance matters, compliance programs, and disclosure programs; provide management certifications and compliance training and education; engage an independent review organization to conduct claims and arrangements reviews; and implement a risk assessment and internal review process. In view of the Company’s Strategic Transformation, including cessation of its Laboratory Operations and related billing for services, effective March 7, 2023 the OIG agreed to suspend the Company’s obligations under the Corporate Integrity Agreement.

Colorado Recoupment

On July 21, 2021, the Company received a letter from the Colorado Department of Health Care Policy and Financing (the "Department"), informing the Company that, as a result of a post-payment review of Medicaid claims from October 2014 to June 2018, the Department is seeking recoupment for historical payments in an aggregate amount of approximately $5.7 million. In December 2021, the Company received additional correspondence informing them that the Department is seeking recoupment for an additional $3.3 million of historical payments from 2018. The historical payments for which the Department is seeking recoupment primarily relate to the Company's Preparent expanded carrier screening tests primarily on the basis that such tests were not medically necessary.

The Company disputed these claims of recoupment with the Department and filed administrative complaints with the State of Colorado Office of Administrative Courts. During the year ended December 31, 2022, the Company concluded a settlement agreement resolution of the matter that included a dismissal of the complaints and a full release of all the claims, except for approximately $11,000 in claims, which the Company refunded.

California Subpoena

On July 19, 2021, the Company received a subpoena from the California Attorney General's Office, Division of Public Rights (the "OAG"), requesting documents and information related to the Company's former genetic testing practices, the Company's former non-invasive prenatal tests ("NIPT"), particularly those with a nexus to California patients. The subpoena is captioned "In the Matter of the Investigation of: Prenatal Genetic Testing Companies." The OAG has alleged that it has claims under California's false advertising and unfair business practices laws based on representations about patient billing made in the historical marketing of the Company's legacy genetic testing business. While the Company believes that its sales and marketing representations were appropriate, the Company is discussing a potential resolution with OAG, and producing additional materials in connection with those discussions, to determine if the matter can be concluded in the best interests of the Company. The Company is unable to predict the ultimate outcome of this action.

Payor Settlement Agreements

On September 30, 2019, the Company entered into a settlement agreement with United HealthCare Services, Inc. and UnitedHealthcare Insurance Company in which the Company agreed to pay an aggregate amount of $30.0 million. In November 2019, the Company and Aetna entered into a settlement agreement for $15.0 million. As of December 31, 2021 both settlements were fully paid.

Payor Dispute

On November 16, 2020, the Company received a letter from Anthem, Inc. ("Anthem") informing the Company that Anthem is seeking recoupment for historical payments made by Anthem in an aggregate amount of approximately $27.4 million. The historical payments for which Anthem is seeking recoupment are claimed to relate primarily to discontinued legacy billing practices for the Company's former NIPT and microdeletion tests and secondarily to the implementation of the new Current Procedure Terminology code for reimbursement for the Company's former Preparent expanded carrier screening tests.

The Company has historically negotiated and settled similar claims with third-party payors. Although the Company's practice in resolving disputes with other similar large commercial payors has generally led to agreed settlement amounts substantially less than the originally claimed amount, there can be no assurance that the Company will be successful in a similar settlement amount in any ongoing or future dispute. Historical settlement amounts and payment time periods may not be indicative of the final settlement terms with Anthem, if any. Management disputes this claim of recoupment with Anthem in full, with offsets for amounts owed by Anthem to the Company. Management had previously established an accrual for the estimated probable loss for this matter. During the year ended December 31, 2022, the Company reversed this accrual for a portion of the matter in view of applicable statute of limitations and has reflected this change in revenue within discontinued operations.

Payor Recoveries

As noted above, the regulations governing government reimbursement programs (e.g., Medicaid, Tricare, and Medicare) and commercial payor reimbursement programs are complex and may be subject to interpretation. As a former provider of services to patients covered under government reimbursement and commercial payor programs, the Company is routinely subject to post-payment review audits and other forms of reviews and investigations. For example, the Company is currently in the process of reviewing several managed Medicaid payor recoupment requests aggregating to $1.1 million. If a third-party payor successfully challenges that a payment to the Company for prior testing was in breach of contract or otherwise contrary to policy or law, they may recoup such payment. The Company may also decide to negotiate and settle with a third-party payor in order to resolve an allegation of overpayment. In the ordinary course of business, the Company addresses and evaluates a number of such claims from payors. In the past, the Company has negotiated and settled these types of claims with third-party payors. The Company may be required to resolve further disputes in the future. While management is unable to predict the exact outcome of any such claims, 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.

Texas OIG Inquiry

On October 16, 2019, the Company received an inquiry from the Texas Health & Human Services Commission Office of Inspector General ("TX OIG") alleging that the Company 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. The Company submitted a written response to the inquiry on October 23, 2019. In October 2021, the Company received a letter from the TX OIG asking the Company to renew its engagement on the matter. During the year ended December 31, 2022, the Company fully resolved and settled the matter for an immaterial payment by the Company in exchange for a release of all claims.

Ravgen Lawsuit

On December 22, 2020, Ravgen, Inc. ("Ravgen") filed suit in the District of Delaware (D. Del. Civil Action No. 1:20-cv-1734) asserting the Company's infringement of two Ravgen patents based on the Company's former NIPT testing business. The complaint seeks monetary damages and injunctive relief. The Company responded to the complaint on March 23, 2021. Management believes the claims in Ravgen's complaint are without merit, and the Company is vigorously defending against them. On March 1, 2022 the court ordered a stay of the litigation pending resolution of patent validity challenges made against the two patents in *inter partes* review proceedings currently pending before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. On February 13, 2023 the court ordered the stay lifted. Given the uncertainty of litigation, the early stages of the Ravgen litigation, and the legal standards that must be met for, among other things, success on the merits, the Company is unable to predict the ultimate outcome of these actions, and therefore cannot estimate the reasonably possible loss or range of loss, if any, that may result from this action.

IPO Litigation

On June 23, 2020, the Company closed its IPO. Lawsuits were filed on August 28, 2020 and September 11, 2020 against the Company, certain of its executive officers and directors, and the underwriters of the IPO. On December 3, 2020, the U.S. District Court for the Southern District of California consolidated the two actions, appointed Lin Shen, Lingjun Lin and Fusheng Lin to serve as Lead Plaintiffs, and approved Glancy Prongay & Murray LLP to be Lead Plaintiffs' Counsel. Lead Plaintiffs filed their first amended complaint on February 4, 2021. Together with the underwriters of the IPO, the Company moved to dismiss the first amended complaint. On September 1, 2021, the court granted the Company's motion to dismiss, dismissing Lead Plaintiffs' claims without prejudice. On September 22, 2021, Lead Plaintiffs filed their second amended complaint. Together with the underwriters of the IPO, the Company moved to dismiss the second amended complaint on November 15, 2021. On January 13, 2023, the court again granted our motion to dismiss, dismissing Lead Plaintiffs' claims for failure to state a claim without prejudice. On February 3, 2023, Lead Plaintiffs filed their third amended complaint, adding information allegedly produced to Plaintiffs in response to freedom of information requests. The third amended complaint alleges that the Company's registration statement and related prospectus for the IPO contained false and misleading statements and omissions in violation of the Securities Act by failing to disclose that (i) the Company had overbilled government payors for Preparent tests beginning in 2019 and ending in or before early 2020; (ii) there was a high probability that the Company had received, and would have to refund, a material amount of overpayments from government payors for Preparent tests; (iii) in February 2020 the Company ended a supposedly improper marketing practice on which the competitiveness of the Company's business depended; and (iv) the Company was suffering from material negative trends with respect to testing volumes, average selling prices for its tests, and revenues. Lead Plaintiffs seek certification as a class, unspecified compensatory damages, interest, costs and expenses including attorneys' fees, and unspecified extraordinary, equitable, and/or injunctive relief. The Company intends to continue to vigorously defend against these claims. Subject to a reservation of rights, the Company is advancing expenses subject to indemnification to the underwriters of the IPO.

On June 4, 2021, a purported shareholder filed a lawsuit in the U.S. District Court for the SDCA, claiming to sue derivatively on behalf of the Company. The complaint names certain of the Company's officers and directors as defendants, and names the Company as a nominal defendant. Premised largely on the same allegations as the above-described securities lawsuit, it alleges that the individual defendants breached their fiduciary duties to the Company, wasted corporate assets, and caused the Company to issue a misleading proxy statement in violation of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The complaint seeks the award of unspecified damages to the Company, equitable and injunctive remedies, and an order directing the Company to reform and improve its internal controls and board oversight. It also seeks the costs and disbursements associated with bringing suit, including attorneys', consultants', and experts' fees. The case is stayed pending the outcome of the motion to dismiss in the above-described securities lawsuit. The Company intends to vigorously defend against these claims.

On August 17, 2021, the Company received a letter purportedly on behalf of a stockholder of the Company demanding that the Company's board of directors investigate and take action against certain of the Company's current and former officers and directors to recover damages for alleged breaches of fiduciary duties and related claims arising out of the IPO litigation discussed above. This matter is pending the outcome of the companion securities litigation.

Given the uncertainty of litigation, the preliminary stages of the litigation and other matters described above, and the legal standards that must be met for, among other things, success on the merits, the Company is unable to predict the ultimate outcome of these actions, and therefore cannot estimate the reasonably possible loss or range of loss, if any, that may result from these actions.

Note 11. Stockholders' Equity

Common Stock

On January 3, 2023, the Company effected a 1-for-25 reverse stock split of the Company's common stock. The Reverse Stock Split, which has been retroactively reflected throughout this report, reduced the authorized shares of the Company to 164,000,000 and did not change the par value of the Company's common stock.

PIPE Financings

In February 2021, the Company entered into a Securities Purchase Agreement for a private placement with certain institutional and accredited investors ("February Purchasers"). Pursuant to the Securities Purchase Agreement, the February Purchasers purchased an aggregate of 174,825 units ("February Units"), representing (i) 174,825 shares of the Company's common stock and (ii) warrants to purchase up to 174,825 shares of common stock. The purchase price for each February Unit was $143.00, for an aggregate purchase price of approximately $25.0 million. The warrants are exercisable for cash at an exercise price of $171.50 per share, subject to adjustments as provided under the terms of the warrants. The warrants were immediately exercisable and expire on the fifth anniversary of the date of issuance.

Pursuant to ASC 815-40, Derivatives and Hedging – Contracts in Entity's Own Equity ("ASC 815"), the Company deemed the warrants to be liability classified and allocated the proceeds from issuance between the warrants and common stock using the with-and-without method. $12.8 million of the proceeds, equal to the fair value of the warrants determined using the Black-Scholes Model, were allocated to the warrant liability, and the remaining proceeds of $12.2 million were allocated to the common stock. The Company incurred a total of $1.4 million in issuance costs, which were allocated between the warrants and common stock on a relative fair value basis, $0.5 million and $0.9 million, respectively. The warrant liability was remeasured at $10.2 million as of March 31, 2021 and the Company recognized a gain on warrant liability in the amount of $2.6 million associated with this transaction during the three months ended March 31, 2021. On April 1, 2021, the registration statement to register the shares of common stock underlying the warrants was declared effective by the SEC. As a result, the warrants met the conditions to be classified in equity and the related warrant liability was reclassified from liability to equity on April 1, 2021.

In June 2021, the Company entered into a Securities Purchase Agreement for a private placement with certain institutional and accredited investors ("June Purchasers"). Pursuant to the Securities Purchase Agreement, the June Purchasers purchased an aggregate of 647,773 units ("June Units"), representing (i) 627,773 shares of the Company's common stock (ii) warrants to purchase up to 647,773 shares of common stock and (iii) pre-funded warrants to purchase up to 20,000 shares of common stock. The purchase price for each June Unit was $61.75, for an aggregate purchase price of approximately $40.0 million. The warrants are exercisable for cash at an exercise price of $71.00 per share, subject to adjustments as provided under the terms of the warrants. The warrants were immediately exercisable and expire on the fifth anniversary of the date of issuance. The pre-funded warrants are exercisable at an exercise price of $0.025 per share and have no expiration date. In July 2021, the Company issued 20,000 shares of common stock as a result of the exercise of the outstanding pre-funded warrants at an exercise price of $0.025 per share. During the year ended December 31, 2021, the Company issued 243,886 shares of common stock as a result of the exercise of outstanding warrants at an exercise price of $71.00 per share for proceeds of $17.3 million.

Pursuant to ASC 815, the Company deemed the warrants to be liability classified and allocated the proceeds from issuance between the warrants and common stock using the with-and-without method. $26.6 million of the proceeds, equal to the fair value of the warrants determined using the Black-Scholes Model, were allocated to the warrant liability, and the remaining proceeds of $13.4 million were allocated to the common stock. The Company incurred a total of $2.1 million in issuance costs, which were allocated between the warrants and common stock on a relative fair value basis, $0.7 million and $1.4 million, respectively. The warrant liability was remeasured at $31.8 million as of June 30, 2021 and the Company recognized a loss on warrant liability in the amount of $5.1 million in the consolidated statements of operations during the three months ended June 30, 2021. On June 30, 2021, the registration statement to register the shares of common stock underlying the warrants was declared effective by the SEC. As a result, the warrants met the conditions to be classified in equity and the related warrant liability was reclassified from liability to equity on June 30, 2021.

Registered Offerings

In August 2021, the Company issued and sold an aggregate of (i) 1,600,000 shares of common stock and (ii) warrants to purchase 1,600,000 shares of common stock in an underwritten public offering. Each share was sold together with one warrant to purchase one share of common stock at a combined public offering price of $25.00 per share of the common stock and the accompanying warrant. The warrants have an exercise price of $25.00 per share, are exercisable at any time, and will expire five years following the date of issuance. In addition, the Company granted the underwriter a 30-day option to purchase up to 240,000 shares of common stock ("Overallotment Stock Option") and/or warrants to purchase 240,000 shares of common stock ("Overallotment Warrant Option") at a price of $24.75 per share of common stock and/or $0.25 per warrant. The warrants and Overallotment Warrant

Options were issued in the money based on the public offering terms. The Company received approximately $37.4 million in net proceeds, after deducting underwriting discounts and commissions and other offering expenses payable by the Company.

Pursuant to ASC 815, the Company deemed the Overallotment Stock Option to meet the scope exception for equity classification, and the warrants and Overallotment Warrant Option to be classified as a liability (collectively "the Warrant Liability") at fair value initially with subsequent changes in fair value recorded in earnings. The warrants were recorded at a fair value of $41.8 million and the Overallotment Warrant Option at a fair value of $6.2 million, both determined using the Black-Scholes Model. As the total fair value of the Warrant Liability exceeds the total proceeds of $37.4 million, the Company recorded a loss of the $8.1 million excess to gain (loss) on warrant liabilities in the consolidated statements of operations. Accordingly, there were no proceeds allocated to the common stock issued or the Overallotment Stock Option granted as part of this transaction. The Company incurred a total of $2.8 million in issuance costs, which were allocated between the warrants, Overallotment Warrant Option, common stock and Overallotment Stock Option on a relative fair value basis.

The Overallotment Warrant Option was partially exercised in August for warrants to purchase an aggregate of 77,280 shares of common stock and the Company recognized a gain on the warrant liability in the amount of $3.4 million in the consolidated statements of operations. The remaining Overallotment Warrant Option expired in September 2021 and the Company recognized a gain of $1.9 million in the consolidated statements of operations. The Warrant Liability was remeasured at $18.7 million as of December 31, 2021 and the Company recognized a loss on warrant liability in the amount of $6.7 million in the consolidated statements of operations during the year ended December 31, 2021. The Warrant Liability was remeasured at $0.5 million as of December 31, 2022 and the Company recognized a gain on warrant liability in the amount of $18.2 million in the consolidated statements of operations during the year ended December 31, 2022.

During the year ended December 31, 2021, the Company issued 1,147,365 shares of common stock as a result of the exercise of outstanding warrants at an exercise price of $25.00 per share for proceeds of $28.7 million. The Warrant Liability was remeasured upon exercise of the warrants throughout the period, resulting in a loss on warrant liability in the amount of $41.6 million in the consolidated statements of operations during the year ended December 31, 2021.

In October 2021, the Company entered into a securities purchase agreement with certain institutional and accredited investors for the purchase and sale of 533,333 shares of the Company's common stock, at a purchase price of $37.50 per share in a registered direct offering. The Company received approximately $18.7 million in net proceeds, after deducting placement agent fees and other offering expenses payable by the Company.

In November 2022, the Company entered into a securities purchase agreement with certain institutional and accredited investors relating to the offering and sale of an aggregate of (i) 1,300,250 shares of common stock and (ii) warrants to purchase 1,300,250 shares of common stock in registered direct offering (the “November 2022 Offering”). Each share was sold together with one warrant to purchase one share of common stock at a combined public offering price of $7.50 per share of the common stock and the accompanying warrant. The Company received approximately $9.0 million in net proceeds, after deducting placement agent fees and offering expenses. Approximately $3.8 million of the gross proceeds were received in the form of a waiver of the Company's December 1, 2022 interest payment on the Convertible Notes. The warrants have an exercise price of $8.22 per share, are exercisable six months following the date of issuance, and will expire five years following the initial exercise date.

Additionally, the Company agreed with certain institutional investors to amend outstanding warrants previously issued (i) in the February Units to purchase up to 104,895 shares of common stock with an exercise price of $171.50 per share and (ii) in the June Units to purchase up to 403,887 shares of common stock with an exercise price of $71.00 per share. Accordingly, the Company agreed to (i) lower the exercise price of such existing warrants to $8.22 per share, (ii) provide that such existing warrants, as amended, will not be exercisable until May 9, 2023 and (iii) extend the original expiration date of such existing warrants to May 9, 2028.

Pursuant to ASC 815, the Company deemed the new warrants to be classified as a liability at fair value initially with subsequent changes in fair value recorded in earnings. The warrants were recorded at a fair value of $6.0 million determined using the Black-Scholes Model. As the total fair value of the warrant liability and common stock exceeds the in-kind payment proceeds of $3.8 million, the Company recorded an extinguishment loss of the $1.6 million excess to other income, net in the consolidated statements of operations. The warrant liability was remeasured at $3.0 million as of December 31, 2022 and the Company recognized a gain on warrant liability in the amount of $3.0 million in the consolidated statements of operations during the year ended December 31, 2022. The Company incurred a total of $0.8 million in issuance costs, which were allocated between the warrants and common stock on a relative fair value basis. The modified warrants are equity classified both before and after the modification and were fair valued as of the date of the amendment, this resulted in an increase in the value of the warrants and an additional $0.9 million was recorded to additional paid in capital on the consolidated balance sheet.

At-The-Market Sales Agreement and Offering

In November 2021, the Company entered into an At Market Issuance Sales Agreement ("ATM Sale Agreement") with B. Riley Securities, Inc., BTIG, LLC, and H.C. Wainwright & Co. LLC ("Agents"), pursuant to which the Company may offer and sell shares of common stock having an aggregate offering price of up to $90.0 million from time to time, in “at the market” offerings through the Agents. In connection with the November 2022 Offering, the aggregate price was reduced to $70.0 million. Sales of the shares of common stock, if any, will be made at prevailing market prices at the time of sale, or as otherwise agreed with the Agents. The Agents will receive a commission from the Company of up to 3.0% of the gross proceeds of any shares of common stock sold under the ATM Sale Agreement. During the three months ended December 31, 2021, the Company received net proceeds of $4.6 million, after deducting commissions and other offering expenses, from the sale of 70,550 shares under the ATM Sale Agreement. The Company sold such shares at a weighted average purchase price of $71.00 per share. During the three months ended December 31, 2022, the Company received net proceeds of $0.6 million, after deducting commissions and other offering expenses, from the sale of 52,620 shares under the ATM Sale Agreement. The Company sold such shares at a weighted average purchase price of $10.93 per share. During the year ended December 31, 2022, the Company received net proceeds of $7.1 million, after deducting commissions and other offering expenses, from the sale of 317,155 shares under the ATM Sale Agreement. The Company sold such shares at a weighted average purchase price of $30.27 per share.

Preferred Stock

Pursuant to the Company’s eighth amended and restated certificate of incorporation, which went into effect immediately prior to the completion of the IPO, the Company was authorized to issue 10,000,000 shares of undesignated preferred stock. This amount and the par value of preferred stock remained unchanged after the reverse stock split.

On November 10, 2022, the Board declared a dividend of one one-thousandth of a share of Series X Preferred Stock, par value $0.001 per share (“Series X Preferred Stock”), for each outstanding share of common stock to stockholders of record as of November 21, 2022. This Series X Preferred Stock entitled its holders to 3,000 votes per share exclusively on the vote for the proposal to approve the Reverse Stock Split. All shares of Series X Preferred Stock that were not present to vote on the Reverse Stock Split were redeemed by the Company (the “Initial Redemption”). Any outstanding shares of Series X Preferred Stock that were not redeemed pursuant to an Initial Redemption would be redeemed in whole, but not in part, (i) if such redemption is ordered by the Board in its sole discretion, automatically and effective on such time and date specified by the Board in its sole discretion or (ii) automatically upon the effectiveness of the Certificate of Amendment implementing the Reverse Stock Split. At the December 19, 2022 special meeting of the Company's stockholders, the holders of 136,961 shares of Series X Preferred Stock were represented in person or by proxy. Immediately prior to the special meeting, all 86,210 shares of Series X Preferred Stock that were not voted were redeemed. The remaining 136,961 outstanding shares of Series X Preferred Stock were redeemed automatically upon the effectiveness of the Certificate of Amendment on January 3, 2023.

Note 12. Stock-Based Compensation

In February 2018, the Company adopted the 2018 Equity Incentive Plan (“2018 Plan”). The 2018 Plan is the successor to and continuation of the Second Amended and Restated 2012 Stock Plan (“2012 Plan”) and is administered with either stock options or restricted stock units. The Board of Directors administers the plans. Upon adoption of the 2018 Plan, no new stock options or awards are issuable under the 2012 Plan, as amended. The 2018 Plan also provides for other types of equity to issue awards, which at this time the Company does not plan to utilize.

On May 5, 2021, holders of a majority of the outstanding common stock executed a written consent approving the Fourth Amended and Restated 2018 Equity Incentive Plan ("2018 Fourth Amended Plan"), which provides for an automatic annual increase in the number of shares of common stock reserved for issuance. As of December 31, 2022 there were 450,941 shares available for issuance under the 2018 Fourth Amended Plan.

On November 3, 2021, the Company's board of directors approved and adopted the Company’s 2021 Inducement Plan ("2021 Inducement Plan") to provide for the reservation of 260,000 shares of the Company’s common stock to be used exclusively for the grant of awards to individuals not previously an employee or non-employee director of the Company. As of December 31, 2022, 110,799 shares were available for grant under the 2021 Inducement Plan.

Stock Options

The following table summarizes stock option activity, which includes Performance Awards, under the Second Amended and Restated 2012 Stock Plan, the 2018 Fourth Amended Plan and the 2021 Inducement Plan during the year ended December 31, 2022:

	Stock Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Balance at December 31, 2021	344,713	$ 118.03		
Options granted	357,798	$ 20.90		
Options exercised	—	$ —		
Options forfeited/cancelled	(119,954)	$ 110.67		
Balance at December 31, 2022	582,557	$ 59.89	8.25	$ —
Vested and expected to vest at December 31, 2022	582,557	$ 59.89	8.25	$ —
Vested and exercisable at December 31, 2022	164,576	$ 113.99	6.17	$ —

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 granted during the years ended December 31, 2022 and 2021:

	Year ended December 31,	
	2022	2021
Risk-free interest rate	2.0% - 4.2%	0.6% - 1.4%
Expected volatility	90.7% - 101.3%	52.9% - 77.0%
Expected dividend yield	—	—
Expected life (years)	5.5 - 6.3	3.0 - 6.3

The weighted-average grant date fair value of options granted during the years ended December 31, 2022 and 2021 was $19.09 per option and $53.28 per option, respectively.

Restricted Stock Units

The following table summarizes RSU activity for the year ended December 31, 2022:

	Number of Shares	Weighted-Average Grant Date Fair Value
Balance at December 31, 2021	155,153	$ 95.32
Granted	213,066	$ 20.87
Vested	(45,336)	$ 99.70
Forfeited/cancelled	(44,771)	$ 86.73
Balance at December 31, 2022	278,112	$ 38.95

2020 Employee Stock Purchase Plan

In June 2020, the Company's board of directors adopted the ESPP with 20,400 shares of common stock reserved for future issuance under the ESPP. The ESPP also provides for automatic annual increases in the number of shares of common stock reserved for issuance. As of December 31, 2022 there were 47,450 total shares of common stock reserved for future issuance. The ESPP was suspended on November 6, 2022. All employee payroll withholdings related to the ESPP were either reimbursed or shares were purchased subsequent to the suspension of the program.

Stock-Based Compensation Expense

The following table presents total stock-based compensation expense included in each functional line item in the accompanying consolidated statements of operations (in thousands):

	Year Ended December 31,	
	2022	2021
Research and development	2,626	3,584
Selling, general and administrative	5,178	8,378
Discontinued operations	—	1,594
Total stock-based compensation expense	$ 7,804	$ 13,556

At December 31, 2022 there was $10.5 million of compensation cost related to unvested stock options expected to be recognized over a remaining weighted average vesting period of 2.82 years and $9.4 million of compensation cost related to unvested RSUs expected to be recognized over a remaining weighted average vesting period of 2.99 years.

Note 13. Income Taxes

The provision for income taxes consists of the following (in thousands):

	Year Ended December 31,	
	2022	2021
Current provision:		
Federal	$ (546)	$ —
State	(347)	—
Foreign	126	—
	(767)	—
Deferred expense:		
Federal	347	(119)
State	—	—
	347	(119)
Net income tax provision	$ (420)	$ (119)

The components of income tax benefit from continuing operations relate to the following (in thousands):

	Year Ended December 31,	
	2022	2021
Income tax benefit at U.S. federal statutory rate	$ (10,343)	$ (37,514)
Federal research and development credit	—	2,978
Convertible debt and warrant liabilities	(4,390)	12,225
Stock-based compensation	1,504	1,700
Tax refunds	(900)	—
Change in valuation allowance	13,004	18,211
Other	705	2,281
Total income tax benefit	$ (420)	$ (119)

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. Significant components of the Company's deferred tax assets and deferred tax liabilities as of December 31, 2022 and 2021 are presented below (in thousands):

	December 31, 2022	December 31, 2021
Deferred tax assets:		
Net operating losses and carryforwards	$ 137,149	$ 124,230
Section 174 Capitalization	4,027	—
Reserves	949	3,454
Intangible assets	—	1,571
Accrued expenses	527	1,447
Lease liability	343	—
Stock-based compensation	2,591	2,603
Other, net	101	112
Total deferred tax assets	145,687	133,417
Deferred tax liabilities:		
Fixed assets	(726)	(864)
Intangible assets	(1,201)	—
Investment in Enumera	(1,317)	—
ROU asset	(340)	—
Prepaid expenses	(743)	(1,123)
Adoption of ASC 606	—	(1,341)
Convertible debt	(552)	(677)
Other, net	—	(33)
Total deferred tax liabilities	(4,879)	(4,038)
Net deferred tax assets	140,808	129,379
Less: valuation allowance	(141,155)	(129,379)
Net deferred tax liabilities	$ (347)	$ —

The Company has established a valuation allowance against net deferred tax assets due to the uncertainty that such assets will be realized. The Company periodically evaluates the recoverability of the deferred assets. At such time as it is determined that it is more likely than not that the deferred tax asset will be realized, the valuation allowance will be reduced. The change in the valuation allowance for the year ended December 31, 2022 was an increase of $11.8 million.

At December 31, 2022, the Company had federal and state income tax net operating loss (“NOL”) carryforwards of approximately $504.9 million and $246.3 million, respectively. The U.S. federal net operating losses will be carried forward indefinitely and state net operating losses will begin to expire in various years, depending on the applicable jurisdiction. Federal net operating loss carryforwards generated post 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 of approximately $8.7 million and $1.4 million, respectively, as of December 31, 2022. The federal research and expenditure credit will begin to expire after 2033 if unused and the state research and expenditure credit may be carried forward indefinitely.

Pursuant to Section 382 and Section 383 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 performed a formal study through the date of the IPO and determined future utilization of tax attribute carryforwards are not limited per Section 382 of the Internal Revenue Code. The Company has not updated their 382 study since the IPO offering 2020. Any future changes may limit future utilization of tax attribute carryforwards. Due to the existence of the valuation allowance, limitations created by future ownership changes, if any, will not impact the Company's effective tax rate.

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, 2022.

The Company is subject to taxation in the United States, various U.S. state jurisdictions. Multiple tax years remain open to examination depending on the applicable jurisdiction. The Company’s policy is to recognize interest and penalties related to income tax matters in the provision for income taxes. At December 31, 2022, there were no interest and penalties related to uncertain tax positions.

Note 14. Net 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,	
	2022	2021
Stock options to purchase common stock	582,557	344,713
Restricted stock units	278,112	155,153
Common stock warrant	2,331,597	1,047,352
Common stock issuable upon conversion of Convertible Notes	1,623,547	1,623,547
Total	4,815,813	3,170,765

Note 15. Employee Benefit Plan

The Company has a qualified 401(k) employee savings plan for the benefit of its employees ("401(k) Plan"). Substantially all employees are eligible to participate in the 401(k) Plan. Under the 401(k) Plan, employees can contribute and defer taxes on compensation contributed. The Company has the option to make discretionary profit-sharing contributions to the 401(k) Plan. The Company made employer contributions to the 401(k) Plan of $0.5 million and $2.4 million for the years ended December 31, 2022 and 2021, respectively.

Note 16. Quarterly Financial Data (Unaudited)

The following tables present selected quarterly financial data for the years presented (in thousands, except per share data):

	Three Months Ended			
2022	**December 31,**	**September 30,**	**June 30,**	**March 31,**
Revenues	$ 14	$ 80	$ 104	$ 107
Loss from continuing operations	(13,469)	(14,874)	(5,997)	(14,490)
(Loss) gain from discontinued operations	(253)	9,760	484	682
Net loss	(13,722)	(5,114)	(5,513)	(13,808)
Net loss per share, basic and diluted	(1.64)	(0.68)	(0.75)	(1.88)

2021				
Revenues	$ 435	$ 182	$ 463	$ 167
Loss from continuing operations	(82,787)	(36,874)	(41,400)	(17,460)
Loss from discontinued operations	(10,087)	(6,870)	(37,131)	(14,803)
Net loss	(92,874)	(43,744)	(78,531)	(32,263)
Net loss per share, basic and diluted	(13.98)	(11.41)	(30.70)	(14.03)

Note 17. Subsequent Events

From January 1, 2023 through February 16, 2023, the Company received net proceeds of $12.6 million, after deducting commissions and other offering expenses, from the sale of 2,853,109 shares under the ATM Sale Agreement. The Company sold such shares at a weighted average purchase price of $4.69 per share.

On January 12, 2023, the Company issued warrants to purchase 90,000 shares of common stock to an institutional investor in exchange for the investor's agreement to waive the lockup provisions contained in the November 2022 Offering securities purchase agreement. The warrant has an exercise price of $8.22, is exercisable beginning on May 9, 2023 and expires on May 9, 2028.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Management's Evaluation of Disclosure Controls and Procedures

As of December 31, 2022, our management, with the participation and supervision of our principal executive officer and our principal financial officer, evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost benefit relationship of possible controls and procedures. Based on this evaluation, our principal executive officer and our principal financial officer concluded that our disclosure controls and procedures were effective as of December 31, 2022 to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and our principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

No changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the quarter ended December 31, 2022 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) under the Exchange Act). Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our principal executive officer and our principal financial officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States.

As of December 31, 2022, our management assessed the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework. Based on this assessment, our management concluded that our internal control over financial reporting was effective as of December 31, 2022.

Attestation Report of Registered Public Accounting Firm

As an emerging growth company, we are not required to provide an attestation report on our internal control over financial reporting issued by the Company's independent registered public accounting firm.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information required by this item will be contained in our definitive proxy statement to be filed with the SEC on Schedule 14A within 120 days after December 31, 2022, and is incorporated herein by reference, including under the heading "Directors, Executive Officers, and Corporate Governance."

We have adopted a Code of Ethics that applies to all of our directors, officers and employees, including our principal executive, principal financial and principal accounting officers, or persons performing similar functions. Our Code of Ethics is posted on our website located at www.investors.bioratherapeutics.com. We intend to disclose future amendments to certain provisions of the Code of Ethics, and waivers of the Code of Ethics granted to executive officers and directors, on the website within four business days following the date of the amendment or waiver.

Item 11. Executive Compensation.

Information required by this item will be contained in our definitive proxy statement to be filed with the SEC on Schedule 14A within 120 days after December 31, 2022, and is incorporated herein by reference, including under the headings "Executive Compensation" and "Directors, Executive Officers and Corporate Governance."

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Information required by this item will be contained in our definitive proxy statement to be filed with the SEC on Schedule 14A within 120 days after December 31, 2022, and is incorporated herein by reference, including under the headings "Security Ownership of Certain Beneficial Owners and Management" and "Executive Compensation-Securities Authorized for Issuance Under Equity Compensation Plans."

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Information required by this item will be contained in our definitive proxy statement to be filed with the SEC on Schedule 14A within 120 days after December 31, 2022, and is incorporated herein by reference, including under the headings "Directors, Executive Officers and Corporate Governance" and "Certain Relationships and Related Party Transactions."

Item 14. Principal Accountant Fees and Services.

Our independent registered public accounting firm is KPMG LLP, San Diego, CA, Auditor Firm ID: 185.

Information required by this item will be contained in our definitive proxy statement to be filed with the SEC on Schedule 14A within 120 days after December 31, 2022, and is incorporated herein by reference, including under heading "Ratification of Selection of Independent Registered Public Accounting Firm."

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) 1. FINANCIAL STATEMENTS

Reference is made to the Index to Financial Statements under Item 8, Part II hereof.

2. FINANCIAL STATEMENT SCHEDULES

The financial statement schedules have been omitted either because they are not required or because the information has been included in the consolidated financial statements or the notes thereto included in this annual report.

3. EXHIBITS

EXHIBIT NO.	DESCRIPTION
3.1	Eighth Amended and Restated Certificate of Incorporation of the registrant (filed with the SEC as Exhibit 3.1 to the registrant's Form 8-K filed on June 26, 2020).
3.2	Certificate of Amendment of the Eighth Amended and Restated Certificate of Incorporation of the registrant, effective April 26, 2022 (filed with the SEC as Exhibit 3.1 to the registrant's Form 8-K filed on April 27, 2022).
3.3	Second Certificate of Amendment of the Eighth Amended and Restated Certificate of Incorporation of registrant (filed with the SEC as Exhibit 3.1 to the registrant's Form 8-K filed on December 30, 2022).
3.4	Certificate of Designation for Series X Preferred Stock (filed with the SEC as Exhibit 3.1 to the registrant's Form 8-K filed on November 28, 2022).
3.5	Certificate of Elimination of Series X Preferred Stock (filed with the SEC as Exhibit 3.1 to the registrant's Form 8-K filed on January 9, 2023).
3.6	Third Amended and Restated Bylaws of the registrant (filed with the SEC as Exhibit 3.2 to the registrant's Form 8-K filed on November 28, 2022).
4.1	Form of common stock certificate of the registrant (filed with the SEC as Exhibit 4.1 to the registrant's Form S-1/A filed on June 4, 2020).
4.2	Fourth Amended and Restated Investors' Rights Agreement, dated as of August 27, 2019, by and among Progenity, Inc. and certain of its stockholders (filed with the SEC as Exhibit 4.5 to the registrant's Form S-1 filed on May 27, 2020).
4.3	Amendment No. 1 to Fourth Amended and Restated Investors' Rights Agreement, dated as of November 10, 2020, by and among Progenity, Inc., and certain of its stockholders (filed with the SEC as Exhibit 4.6 to the registrant's Form S-1 filed on November 30, 2020).
4.4	Amendment No. 2 to Fourth Amended and Restated Investors' Rights Agreement, dated as of December 7, 2020, by and among Progenity, Inc., and certain of its stockholders (filed with the SEC as Exhibit 4.7 to the registrant's Form 10-K filed on March 18, 2021).
4.5	Amendment No. 3 to Fourth Amended and Restated Investors' Rights Agreement, dated as of May 31, 2021, by and among Progenity, Inc., and certain of its stockholders (filed with the SEC as Exhibit 4.3 to the registrant's Form 10-Q filed on August 12, 2021).
4.6	Indenture, dated as of December 7, 2020, between Progenity, Inc. and The Bank of New York Mellon Trust Company, N.A., as trustee (filed with the SEC as Exhibit 4.1 to the registrant's Form 8-K filed on December 7, 2020).
4.7	Form of certificate representing the 7.25% Convertible Senior Notes due 2025 (filed with the SEC as Exhibit 4.1 to the registrant's Form 8-K filed on December 7, 2020).
4.8	Form of Warrant (filed with the SEC as Exhibit 4.1 to the registrant's Form 8-K filed on February 25, 2021).
4.9	Form of Warrant (filed with the SEC as Exhibit 4.1 to the registrant's Form 8-K filed on June 14, 2021).
4.10	Form of Warrant (filed with the SEC as Exhibit 4.1 to the registrant's Form 8-K filed on August 23, 2021).
4.11	Form of Pre-Funded Warrant (filed with the SEC as Exhibit 4.2 to the registrant's Form 8-K filed on June 14, 2021).
4.12	Form of Warrant (filed with the SEC as Exhibit 10.2 to the registrant's Form 8-K on November 9, 2022).
4.13	Form of Amended Warrant (filed with the SEC as Exhibit 10.3 to the registrant's Form 8-K filed on November 9, 2022).
4.14	Form of Amended Warrant (filed with the SEC as Exhibit 10.4 to the registrant's Form 8-K filed on November 9, 2022).
4.15	Form of Warrant (filed with the SEC as Exhibit 10.1 to the registrant's Form S-3 filed on January 27, 2023).
4.16	Description of Securities (filed with the SEC as Exhibit 4.11 to the registrant's Form 10-K filed on March 18, 2021).

10.1	Form of Indemnification Agreement for directors and executive officers (filed with the SEC as Exhibit 10.1 to the registrant's Form S-1/A filed on June 4, 2020).
10.2+*	Second Amended and Restated 2012 Stock Plan.
10.3+*	Fourth Amended and Restated 2018 Equity Incentive Plan.
10.4+*	2020 Employee Stock Purchase Plan.
10.5+*	2021 Inducement Plan.
10.6+*	Form of 2021 Inducement Plan Stock Option Grant Notice.
10.7+*	Form of Inducement Plan Stock Option Award Agreement.
10.8+*	Form of Inducement Plan RSU Grant Notice.
10.9+*	Form of 2021 Inducement Plan RSU Award Agreement.
10.10+	Offer Letter by and between Progenity, Inc. and Eric d'Esparbes, dated as of May 1, 2019 (filed with the SEC as Exhibit 10.7 to the registrant's Form S-1 filed on May 27, 2020).
10.11+	Offer Letter by and between Progenity, Inc. and Clarke Neumann, dated as of August 26, 2014 (filed with the SEC as Exhibit 10.10 to the registrant's Form S-1 filed on May 27, 2020).
10.12+	Offer Letter by and between Progenity, Inc. and Adi Mohanty, dated as of October 30, 2021 (filed with the SEC as Exhibit 10.1 to the registrant's Form 8-K filed on November 9, 2021).
10.13+	Severance Plan (filed with the SEC as Exhibit 10.14 to the registrant's Form S-1/A filed on June 4, 2020).
10.14	Stipulation and Order of Settlement and Dismissal, effective July 23, 2020, among the U.S. Department of Justice through the U.S. Attorney's Office for the Southern District of New York, and on behalf of the Office of Inspector General of the Department of Health and Human Services, and with the relator named therein and Progenity, Inc. (filed with the SEC as Exhibit 10.1 to the registrant's Form 8-K filed on July 24, 2020).
10.15	Settlement Agreement, effective July 23, 2020, among the United States of America, acting through the U.S. Department of Justice through the U.S. Attorney's Office for the Southern District of California, and on behalf of the Defense Health Agency, the Tricare Program and the Office of Personnel Management, which administers the Federal Employees Health Benefits Program, and Progenity, Inc. (filed with the SEC as Exhibit 10.2 to the registrant's Form 8-K filed on July 24, 2020).
10.16	Promissory Note issued pursuant to the Settlement Agreement, dated July 21, 2020, among the United States of America, acting through the U.S. Department of Justice through the U.S. Attorney's Office for the Southern District of California, and on behalf of the Defense Health Agency, the Tricare Program and the Office of Personnel Management, which administers the Federal Employees Health Benefits Program, and Progenity, Inc. (filed with the SEC as Exhibit 10.3 to the registrant's Form 8-K filed on July 24, 2020).
10.17	Non-Prosecution Agreement, effective July 21, 2020, between the U.S. Attorney's Office for the Southern District of California and Progenity, Inc. (filed with the SEC as Exhibit 10.4 to the registrant's Form 8-K filed on July 24, 2020).
10.18	Corporate Integrity Agreement, effective July 21, 2020, between the Office of Inspector General of the Department of Health and Human Services and Progenity, Inc. (filed with the SEC as Exhibit 10.5 to the registrant's Form 8-K filed on July 24, 2020).
10.19	Securities Purchase Agreement, dated February 22, 2021, by and between Progenity, Inc. and the Purchasers signatory therein (filed with the SEC as Exhibit 10.1 to the registrant's Form 8-K filed on February 25, 2021).
10.20	Securities Purchase Agreement, dated June 9, 2021, by and between Progenity, Inc. and the Purchasers signatory thereto (filed with the SEC as Exhibit 10.1 to the registrant's Form 8-K filed on June 14, 2021).
10.21	Separation Agreement and General Release, dated September 1, 2021, by and between the registrant and Harry Stylli, Ph.D. (filed with the SEC as Exhibit 10.1 to the registrant's Form 8-K filed on September 1, 2021).
10.22	At Market Issuance Sales Agreement, dated November 22, 2021, by and among Progenity, Inc., B. Riley Securities, Inc., BTIG, LLC, and H.C. Wainwright & Co. LLC (filed with the SEC as Exhibit 1.1 to the registrant's Form 8-K filed on November 22, 2021).
10.23	Securities Purchase Agreement dated November 6, 2022, by and between Biora Therapeutics, Inc. and the Purchasers signatory therein (filed with the SEC as Exhibit 10.1 to the registrant's Form 8-K filed on November 9, 2022).
10.24	Letter Agreement, dated November 21, 2022, by and between the Company and SDNY (filed with the SEC as Exhibit 10.1 to the registrant's Form 8-K filed on November 23, 2022).
21.1*	List of subsidiaries.
23.1*	Consent of Independent Registered Public Accounting Firm.

31.1*	Certification of principal executive officer pursuant to Rule 13a-14(A) promulgated under the Securities Exchange Act of 1934.
31.2*	Certification of principal financial officer pursuant to Rule 13a-14(A) promulgated under the Securities Exchange Act of 1934.
32.1†	Certification of principal executive officer and principal financial officer pursuant to 18 U.S.C. Section 1350 and Rule 13a-14(B) promulgated under the Securities Exchange Act of 1934.
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.
\+ 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.
† Furnished herewith and not deemed to be "filed" for purposes of Section 18 of the Exchange Act, and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

Biora Therapeutics, Inc.

Date: March 30, 2023

By: /s/ Aditya P. Mohanty
Aditya P. Mohanty
Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each individual whose signature appears below hereby constitutes and appoints Eric d'Esparbes and Clarke W. Neumann, and each of them, the true and lawful attorneys-in-fact and agents of the undersigned, with full power of substitution and resubstitution, for and in the name, place and stead of the undersigned, to sign in any and all capacities (including, without limitation, the capacities listed below), with respect to this Annual Report on Form 10-K, and any and all amendments thereto, and to file the same, with all exhibits thereto, and all other documents in connection therewith, with the U.S. Securities and Exchange Commission, or the SEC, and hereby grants to such attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and anything necessary to be done to enable Biora Therapeutics, Inc. to comply with the provisions of the Securities Exchange Act of 1934 and all the requirements of the SEC, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitute, or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Aditya P. Mohanty **Aditya P. Mohanty**	Chief Executive Officer (principal executive officer)	March 30, 2023
/s/ Eric d'Esparbes **Eric d'Esparbes**	Chief Financial Officer (principal financial and accounting officer)	March 30, 2023
/s/ Jeffrey Alter **Jeffrey Alter**	Director	March 30, 2023
/s/ Jeffrey Ferrell **Jeffrey Ferrell**	Director	March 30, 2023
/s/ Jill Howe **Jill Howe**	Director	March 30, 2023
/s/ Dr. Brian L. Kotzin **Dr. Brian L. Kotzin**	Director	March 30, 2023
/s/ Lynne Powell **Lynne Powell**	Director	March 30, 2023
/s/ Surbhi Sarna **Surbhi Sarna**	Director	March 30, 2023

Exhibit 10.2

SECOND AMENDED AND RESTATED BIORA THERAPEUTICS, INC.
2012 STOCK PLAN

1. **ESTABLISHMENT, PURPOSE AND TERM OF PLAN.**

1.1 **Establishment**. The Biora Therapeutics, Inc. 2012 Stock Plan was originally established effective as of January 1, 2012 (the "***Prior Plan***"). The Prior Plan was amended and restated effective as of June 12, 2013, the date upon which it was approved by the Board and stockholders, and was further amended and restated on August 21, 2013 to reflect the name change set forth above, such name change effective August 1, 2013, and to reflect an increased share reserve based upon a 10 for 1 stock split approved by the Board and stockholders on August 21, 2013, and is now in the form of the Second Amended and Restated Biora Therapeutics, Inc. 2012 Stock Plan (the "***Plan***") set forth herein. Capitalized terms used in this Section 1 shall have the meanings set forth below in Section 2.1.

1.2 **Purpose**. The purpose of the Plan is to advance the interests of the Participating Company Group and its stockholders by providing an incentive to attract, retain and reward persons performing services for the Participating Company Group and by motivating such persons to contribute to the growth and profitability of the Participating Company Group. The Company intends that Awards granted pursuant to the Plan be exempt from or comply with Section 409A of the Code (including any amendments or replacements of such section), and the Plan shall be so construed.

1.3 **Term of Plan**. The Plan shall continue in effect until its termination by the Board; provided, however, that all Awards shall be granted, if at all, within ten (10) years from the earlier of the date the Plan is adopted by the Board or the date the Plan is duly approved by the stockholders of the Company.

2. **DEFINITIONS AND CONSTRUCTION**.

2.1 **Definitions**. Whenever used herein, the following terms shall have their respective meanings set forth below:

(a) "***Award***" means an Option, Restricted Stock Purchase Right or Restricted Stock Bonus granted under the Plan.

(b) "***Award Agreement***" means a written or electronic agreement between the Company and a Participant setting forth the terms, conditions and restrictions of the Award granted to the Participant.

(c) "***Board***" means the Board of Directors of the Company. If one or more Committees have been appointed by the Board to administer the Plan, "***Board***" also means such Committee(s).

(d) "***Cause***" means, unless such term or an equivalent term is otherwise defined with respect to an Award by the Participant's Award Agreement or written contract of employment or service, any of the following: (i) the Participant's theft, dishonesty, willful misconduct, breach of fiduciary duty for personal profit, or falsification of any Participating Company documents or records; (ii) the Participant's material failure to abide by a Participating Company's code of conduct or other policies (including, without limitation, policies relating to confidentiality and reasonable workplace conduct); (iii) the Participant's unauthorized use, misappropriation, destruction or diversion of any tangible or intangible asset or corporate opportunity of a Participating Company (including, without limitation, the Participant's improper use or disclosure of a Participating Company's confidential or proprietary information); (iv) any intentional act by the Participant which has a material detrimental effect on a Participating Company's reputation or business; (v) the Participant's repeated failure or inability to perform any reasonable assigned duties after written notice from a Participating Company of, and a reasonable opportunity to cure, such failure or inability; (vi) any material breach by the Participant of any employment or service agreement between the Participant and a Participating Company, which breach is not cured pursuant to the terms of such agreement; or

(vii) the Participant's conviction (including any plea of guilty or *nolo contendere)* of any criminal act involving fraud, dishonesty, misappropriation or moral turpitude, or which impairs the Participant's ability to perform his or her duties with a Participating Company.

(e) "***Change in Control***" means, unless such term or an equivalent term is otherwise defined with respect to an Award by the Participant's Award Agreement or written contract of employment or service, the occurrence of any of the following:

(i) an Ownership Change Event or a series of related Ownership Change Events (collectively, a *"**Transaction**")* in which the stockholders of the Company immediately before the Transaction do not retain immediately after the Transaction direct or indirect beneficial ownership of more than fifty percent (50%) of the total combined voting power of the outstanding securities entitled to vote generally in the election of Directors or, in the case of an Ownership Change Event described in Section 2.1(v)(iii), the entity to which the assets of the Company were transferred (the *"**Transferee**")*, as the case may be; or

(ii) the liquidation or dissolution of the Company.

For purposes of the preceding sentence, indirect beneficial ownership shall include, without limitation, an interest resulting from ownership of the voting securities of one or more corporations or other business entities which own the Company or the Transferee, as the case may be, either directly or through one or more subsidiary corporations or other business entities. The Board shall have the right to determine whether multiple sales or exchanges of the voting securities of the Company or multiple Ownership Change Events are related, and its determination shall be final, binding and conclusive.

(f) "***Code***" means the Internal Revenue Code of 1986, as amended, and any applicable regulations and administrative guidelines promulgated thereunder.

(g) "***Committee***" means the compensation committee or other committee or subcommittee of the Board duly appointed to administer the Plan and having such powers as shall be specified by the Board. Unless the powers of the Committee have been specifically limited, the Committee shall have all of the powers of the Board granted herein, including, without limitation, the power to amend or terminate the Plan at any time, subject to the terms of the Plan and any applicable limitations imposed by law.

(h) "***Company***" means Biora Therapeutics, Inc., a Delaware corporation, or any successor corporation thereto.

(i) "***Consultant***" means a person or entity engaged to provide consulting or advisory services (other than as an Employee or a Director) to a Participating Company, provided that (i) if the Consultant is a person, the identity of such person, the nature of such services or the entity to which such services are provided would not preclude the Company from offering or selling securities to such person pursuant to the Plan in reliance on either the exemption from registration provided by Rule 701 under the Securities Act or, if the Company is required to file reports pursuant to Section 13 or 15(d) of the Exchange Act, registration on a Form S-8 Registration Statement under the Securities Act, and (ii) if the Consultant is an entity would not preclude the Company from offering or selling securities to such an entity pursuant to the Plan in reliance on Section 4(2) of the Securities Act.

(j) "***Director***" means a member of the Board.

(k) "***Disability***" means the inability of the Participant, in the opinion of a qualified physician acceptable to the Company, to perform the major duties of the Participant's position with the Participating Company Group because of the sickness or injury of the Participant.

(l) "***Employee***" means any person treated as an employee (including an Officer or a Director who is also treated as an employee) in the records of a Participating Company and, with respect to any Incentive Stock Option granted to such person, who is an employee for purposes of Section 422 of the Code; provided,

however, that neither service as a Director nor payment of a director's fee shall be sufficient to constitute employment for purposes of the Plan. The Company shall determine in good faith and in the exercise of its discretion whether an individual has become or has ceased to be an Employee and the effective date of such individual's employment or termination of employment, as the case may be. For purposes of an individual's rights, if any, under the terms of the Plan as of the time of the Company's determination of whether or not the individual is an Employee, all such determinations by the Company shall be final, binding and conclusive as to such rights, if any, notwithstanding that the Company or any court of law or governmental agency subsequently makes a contrary determination as to such individual's status as an Employee.

(m) "***Exchange Act***" means the Securities Exchange Act of 1934, as amended.

(n) "***Fair Market Value***" means, as of any date, the value of a share of Stock or other property as determined by the Board, in its discretion, or by the Company, in its discretion, if such determination is expressly allocated to the Company herein, subject to the following:

(i) If, on such date, the Stock is listed on a national or regional securities exchange or market system, the Fair Market Value of a share of Stock shall be the closing price of a share of Stock as quoted on the national or regional securities exchange or market system constituting the primary market for the Stock, as reported in The Wall Street Journal or such other source as the Company deems reliable. If the relevant date does not fall on a day on which the Stock has traded on such securities exchange or market system, the date on which the Fair Market Value shall be established shall be the last day on which the Stock was so traded prior to the relevant date, or such other appropriate day as shall be determined by the Board, in its discretion.

(ii) If, on such date, the Stock is not listed on a national or regional securities exchange or market system, the Fair Market Value of a share of Stock shall be as determined by the Board in good faith without regard to any restriction other than a restriction which, by its terms, will never lapse, and in a manner consistent with the requirements of Section 409A of the Code.

(o) "***Incentive Stock Option***" means an Option intended to be (as set forth in the Award Agreement) and which qualifies as an incentive stock option within the meaning of Section 422(b) of the Code.

(p) "***Insider***" means an Officer, a Director or other person whose transactions in Stock are subject to Section 16 of the Exchange Act.

(q) "***Insider Trading Policy***" means the written policy of the Company pertaining to the purchase, sale, transfer or other disposition of the Company's equity securities by Directors, Officers, Employees or other service providers who may possess material, nonpublic information regarding the Company or its securities.

(r) "***Net-Exercise***" means a procedure by which the Participant will be issued a number of whole shares of Stock upon the exercise of an Option determined in accordance with the following formula:

N = X(A-B)/A, where

"N" = the number of shares of Stock to be issued to the Participant upon exercise of the Option;

"X" = the total number of shares with respect to which the Participant has elected to exercise the Option;

"A" = the Fair Market Value of one (1) share of Stock determined on the exercise date; and

"B" = the exercise price per share (as defined in the Participant's Award Agreement).

(s) "***Nonstatutory Stock Option***" means an Option not intended to be (as set forth in the Award Agreement) or which does not qualify as an Incentive Stock Option.

(t) "***Officer***" means any person designated by the Board as an officer of the Company.

(u) "***Option***" means an Incentive Stock Option or a Nonstatutory Stock Option granted pursuant to the Plan.

(v) "***Ownership Change Event***" means the occurrence of any of the following with respect to the Company: (i) the direct or indirect sale or exchange in a single or series of related transactions by the stockholders of the Company of more than fifty percent (50%) of the voting stock of the Company; (ii) a merger or consolidation in which the Company is a party; or (iii) the sale, exchange, or transfer of all or substantially all of the assets of the Company (other than a sale, exchange or transfer to one or more subsidiaries of the Company).

(w) "***Parent Corporation***" means any present or future "parent corporation" of the Company, as defined in Section 424(e) of the Code.

(x) "***Participant***" means any eligible person who has been granted one or more Awards.

(y) "***Participating Company***" means the Company or any Parent Corporation or Subsidiary Corporation.

(z) "***Participating Company Group***" means, at any point in time, all entities collectively which are then Participating Companies.

(aa) "***Restricted Stock Award***" means an Award of a Restricted Stock Bonus or a Restricted Stock Purchase Right.

(bb) "***Restricted Stock Bonus***" means Stock granted to a Participant pursuant to Section 7.

(cc) "***Restricted Stock Purchase Right***" means a right to purchase Stock granted to a Participant pursuant to Section 7.

(dd) "***Rule 16b-3***" means Rule **16b-3** under the Exchange Act, as amended from time to time, or any successor rule or regulation.

(ee) "***Securities Act***" means the Securities Act of 1933, as amended.

(ff) "***Service***" means a Participant's employment or service with the Participating Company Group, whether in the capacity of an Employee, a Director or a Consultant. Unless otherwise provided by the Board, a Participant's Service shall not be deemed to have terminated merely because of a change in the capacity in which the Participant renders such Service or a change in the Participating Company for which the Participant renders such Service, provided that there is no interruption or termination of the Participant's Service. Furthermore, a Participant's Service shall not be deemed to have terminated if the Participant takes any military leave, sick leave, or other bona fide leave of absence approved by the Company. However, unless otherwise provided by the Board, if any such leave taken by a Participant exceeds ninety (90) days, then on the ninety-first (91st) day following the commencement of such leave the Participant's Service shall be deemed to have terminated, unless the Participant's right to return to Service is guaranteed by statute or contract. Notwithstanding the foregoing, unless otherwise established by the Company or required by law, an unpaid leave of absence shall not be treated as Service for purposes of determining vesting under the Participant's Award Agreement. Except as otherwise provided by the Board, in its discretion, the Participant's Service shall be deemed to have terminated either upon an actual termination of Service or upon the business entity for which the Participant performs Service ceasing to be a Participating Company. Subject

to the foregoing, the Company, in its discretion, shall determine whether the Participant's Service has terminated and the effective date of and reason for such termination.

(gg) "***Stock***" means the common stock of the Company, as adjusted from time to time in accordance with Section 4.2.

(hh) "***Subsidiary Corporation***" means any present or future "subsidiary corporation" of the Company, as defined in Section 424(f) of the Code.

(ii) "***Ten Percent Stockholder***" means a person who, at the time an Award is granted to such person, owns stock possessing more than ten percent (10%) of the total combined voting power of all classes of stock of a Participating Company within the meaning of Section 422(b)(6) of the Code.

(jj) "***Vesting Conditions***" mean those conditions established in accordance with the Plan prior to the satisfaction of which shares subject to an Award remain subject to forfeiture or a repurchase option in favor of the Company exercisable for the Participant's monetary purchase price, if any, for such shares upon the Participant's termination of Service.

2.2 **Construction**. Captions and titles contained herein are for convenience only and shall not affect the meaning or interpretation of any provision of the Plan. Except when otherwise indicated by the context, the singular shall include the plural and the plural shall include the singular. Use of the term "or" is not intended to be exclusive, unless the context clearly requires otherwise.

3. ADMINISTRATION.

3.1 **Administration by the Board**. The Plan shall be administered by the Board. All questions of interpretation of the Plan, of any Award Agreement or of any other form of agreement or other document employed by the Company in the administration of the Plan or of any Award shall be determined by the Board, and such determinations shall be final, binding and conclusive upon all persons having an interest in the Plan or such Award, unless fraudulent or made in bad faith. Any and all actions, decisions and determinations taken or made by the Board in the exercise of its discretion pursuant to the Plan or Award Agreement or other agreement thereunder (other than determining questions of interpretation pursuant to the preceding sentence) shall be final, binding and conclusive upon all persons having an interest therein.

3.2 **Authority of Officers**. Any Officer shall have the authority to act on behalf of the Company with respect to any matter, right, obligation, determination or election which is the responsibility of or which is allocated to the Company herein, provided the Officer has apparent authority with respect to such matter, right, obligation, determination or election.

3.3 **Powers of the Board**. In addition to any other powers set forth in the Plan and subject to the provisions of the Plan, the Board shall have the full and final power and authority, in its discretion:

(a) to determine the persons to whom, and the time or times at which, Awards shall be granted and the number of shares of Stock to be subject to each Award;

(b) to determine the type of Award granted;

(c) to determine the Fair Market Value of shares of Stock or other property;

(d) to determine the terms, conditions and restrictions applicable to each Award (which need not be identical) and any shares acquired pursuant thereto, including, without limitation, (i) the exercise or purchase price of shares pursuant to any Award, (ii) the method of payment for shares purchased pursuant to any Award, (iii) 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 Stock, (iv) the timing, terms and conditions of the exercisability or vesting of any Award or shares acquired pursuant thereto, (v) the time of expiration of any Award, (vi) the effect of any Participant's termination of Service on any of the foregoing, and (vii) all other terms, conditions and restrictions applicable to any Award or shares acquired pursuant thereto not inconsistent with the terms of the Plan;

(e) to approve one or more forms of Award Agreement;

(f) to amend, modify, extend, cancel or renew any Award or to waive any restrictions or conditions applicable to any Award or any shares acquired pursuant thereto;

(g) to 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;

(h) to prescribe, amend or rescind rules, guidelines and policies relating to the Plan, or to adopt sub-plans or supplements to, or alternative versions of, the Plan, including, without limitation, as the Board deems necessary or desirable to comply with the laws of, or to accommodate the tax policy, accounting principles or custom of, foreign jurisdictions whose citizens may be granted Awards; and

(i) to correct any defect, supply any omission or reconcile any inconsistency in the Plan or any Award Agreement and to make all other determinations and take such other actions with respect to the Plan or any Award as the Board may deem advisable to the extent not inconsistent with the provisions of the Plan or applicable law.

3.4 **Administration with Respect to Insiders**. With respect to participation by Insiders in the Plan, at any time that any class of equity security of the Company is registered pursuant to Section 12 of the Exchange Act, the Plan shall be administered in compliance with the requirements, if any, of Rule 16b-3.

3.5 **Indemnification**. In addition to such other rights of indemnification as they may have as members of the Board or as officers or employees of the Participating Company Group, members of the Board and any officers or employees of the Participating Company Group to whom authority to act for the Board or the Company is delegated 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 hereunder, and against all amounts paid by them in settlement thereof (provided such settlement is approved by independent legal counsel selected by the Company) 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.

4. SHARES SUBJECT TO PLAN.

4.1 **Maximum Number of Shares Issuable**. Subject to adjustment as provided in Section 4.2, the maximum aggregate number of shares of Stock that may be issued under the Plan shall be 1,200,000 and shall consist of authorized but unissued or reacquired shares of Stock or any combination thereof. The aggregate number of shares of Stock issued pursuant to Awards under this Plan at any time shall equal only the number of shares of Stock actually issued upon grant, exercise or settlement of an Award. If an outstanding Award for any reason expires or is terminated or canceled or if shares of Stock are acquired pursuant to an Award subject to forfeiture or repurchase and are forfeited or repurchased by the Company for an amount not greater than the Participant's exercise or purchase price, the shares of Stock allocable to the terminated portion of such Award or such forfeited or repurchased shares of Stock shall again be available for issuance under the Plan.

4.2 **Adjustments for Changes in Capital Structure**. Subject to any required action by the stockholders of the Company and the requirements of Sections 409A and 424 of the Code to the extent applicable, in the event of any change in the Stock effected without receipt of consideration by the Company, whether through merger, consolidation, reorganization, reincorporation, recapitalization, reclassification, stock dividend, stock split, reverse stock split, split-up, split-off, spin-off, combination of shares, exchange of shares, or similar change in the capital structure of the Company, or in the event of payment of a dividend or distribution to the stockholders of the Company in a form other than Stock (excepting normal cash dividends) that has a material effect on the Fair Market Value of shares of Stock, appropriate and proportionate adjustments shall be made in the number and kind of shares subject to the Plan and to any outstanding Awards, in the ISO Share Limit set forth in Section 5.3(a), and in the exercise or purchase price per share of any outstanding Awards in order to prevent dilution or enlargement of Participants' rights under the Plan. For purposes of the foregoing, conversion of any convertible securities of the Company shall not be treated as "effected without receipt of consideration by the Company." If a majority of the shares which are of the same class as the shares that are subject to outstanding Awards are exchanged for, converted into, or otherwise become (whether or not pursuant to an Ownership Change Event) shares of another corporation (the *"**New Shares**")*, the Board may unilaterally amend the outstanding Awards to provide that such Awards are for New Shares. In the event of any such amendment, the number of shares subject to, and the exercise or purchase price per share of, the outstanding Awards shall be adjusted in a fair and equitable manner as determined by the Board, in its discretion. Any fractional share resulting from an adjustment pursuant to this Section shall be rounded down to the nearest whole number, and the exercise price per share shall be rounded up to the nearest whole cent. In no event may the exercise or purchase price, if any, under any Award be decreased to an amount less than the par value, if any, of the stock subject to the Award. Such adjustments shall be determined by the Board, and its determination shall be final, binding and conclusive.

5. **ELIGIBILITY AND OPTION LIMITATIONS**.

5.1 **Persons Eligible for Awards**. Awards may be granted only to Employees, Consultants and Directors.

5.2 **Participation in the Plan**. Awards are granted solely at the discretion of the Board. Eligible persons may be granted more than one Award. However, eligibility in accordance with this Section shall not entitle any person to be granted an Award, or, having been granted an Award, to be granted an additional Award.

5.3 **Incentive Stock Option Limitations**.

(a) **Maximum Number of Shares Issuable Pursuant to Incentive Stock Options**. Subject to Section 4.1 and adjustment as provided in Section 4.2, the maximum aggregate number of shares of Stock that may be issued under the Plan pursuant to the exercise of Incentive Stock Options shall not exceed 1,200,000 shares (the *"**ISO Share Limit**")*. The maximum aggregate number of shares of Stock that may be issued under the Plan pursuant to all Awards other than Incentive Stock Options shall be the number of shares determined in accordance with Section 4.1, subject to adjustment as provided in Section 4.2.

(b) **Persons Eligible**. An Incentive Stock Option may be granted only to a person who, on the effective date of grant, is an Employee. Any person who is not an Employee on the effective date of the grant of an Option to such person may be granted only a Nonstatutory Stock Option.

(c) **Fair Market Value Limitation**. To the extent that Options designated as Incentive Stock Options (granted under all stock plans of the Participating Company Group, including the Plan) become exercisable by a Participant for the first time during any calendar year for Stock having a Fair Market Value greater than One Hundred Thousand Dollars ($100,000), the portions of such Options which exceed such amount shall be treated as Nonstatutory Stock Options. For purposes of this Section 5.3, Options designated as Incentive Stock Options shall be taken into account in the order in which they were granted, and the Fair Market Value of Stock shall be determined as of the time the Option with respect to such Stock is granted. If the Code is amended to provide for a limitation different from that set forth in this Section, such different limitation shall be deemed incorporated herein effective as of the date and with respect to such Options as required or permitted by such amendment to the Code. If

an Option is treated as an Incentive Stock Option in part and as a Nonstatutory Stock Option in part by reason of the limitation set forth in this Section, the Participant may designate which portion of such Option the Participant is exercising. In the absence of such designation, the Participant shall be deemed to have exercised the Incentive Stock Option portion of the Option first. Upon exercise of the Option, shares of Stock issued pursuant to each such portion shall be separately identified.

6. **STOCK OPTIONS**.

Options shall be evidenced by Award Agreements specifying the number of shares of Stock covered thereby, in such form as the Board shall from time to time establish. Award Agreements shall set forth the terms and conditions upon which Stock Options may be exercised. Such Award Agreements may incorporate all or any of the terms of the Plan by reference and shall comply with and be subject to the following terms and conditions:

6.1 **Exercise Price**. The exercise price for each Option shall be established in the discretion of the Board; provided, however, that (a) the exercise price per share for an Option shall be not less than the Fair Market Value of a share of Stock on the effective date of grant of the Option and (b) no Incentive Stock Option granted to a Ten Percent Stockholder shall have an exercise price per share less than one hundred ten percent (110%) of the Fair Market Value of a share of Stock on the effective date of grant of the Option. Notwithstanding the foregoing, an Option (whether an Incentive Stock Option or a Nonstatutory Stock Option) may be granted with an exercise price lower than the minimum exercise price set forth above if such Option is granted pursuant to an assumption or substitution for another option in a manner qualifying under the provisions of Section 424(a) of the Code.

6.2 **Exercisability and Term of Options**. Options shall be exercisable at such time or times, or upon such event or events, and subject to such terms, conditions, performance criteria and restrictions as shall be determined by the Board and set forth in the Award Agreement evidencing such Option; provided, however, that (a) no Option shall be exercisable after the expiration of ten (10) years after the effective date of grant of such Option and (b) no Incentive Stock Option granted to a Ten Percent Stockholder shall be exercisable after the expiration of five (5) years after the effective date of grant of such Option. Subject to the foregoing, unless otherwise specified by the Board in the grant of an Option, any Option granted hereunder shall terminate ten (10) years after the effective date of grant of the Option, unless earlier terminated in accordance with its provisions.

6.3 **Payment of Exercise Price**.

(a) **Forms of Consideration Authorized**. Except as otherwise provided below, payment of the exercise price for the number of shares of Stock being purchased pursuant to any Option shall be made (i) in cash, by check or in cash equivalent, (ii) by tender to the Company, or attestation to the ownership, of shares of Stock owned by the Participant having a Fair Market Value not less than the exercise price, (iii) by delivery of a properly executed notice of exercise together with irrevocable instructions to a broker providing for the assignment to the Company of the proceeds of a sale or loan with respect to some or all of the shares being acquired upon the exercise of the Option (including, without limitation, through an exercise complying with the provisions of Regulation T as promulgated from time to time by the Board of Governors of the Federal Reserve System) (a ***"Cashless Exercise"***), (iv) by delivery of a properly executed notice electing a Net-Exercise, (v) by such other consideration as may be approved by the Board from time to time to the extent permitted by applicable law, or (vi) by any combination thereof. The Board may at any time or from time to time grant Options which do not permit all of the foregoing forms of consideration to be used in payment of the exercise price or which otherwise restrict one or more forms of consideration.

(b) **Limitations on Forms of Consideration**.

(i) **Tender of Stock**. Notwithstanding the foregoing, an Option may not be exercised by tender to the Company, or attestation to the ownership, of shares of Stock to the extent such tender or attestation would constitute a violation of the provisions of any law, regulation or agreement restricting the redemption of the Company's stock. Unless otherwise provided by the Board, an Option may not be exercised by tender to the Company, or attestation to the ownership, of shares of Stock unless such shares either have been owned by the

Participant for more than six (6) months or such other period, if any, required by the Company (and were not used for another Option exercise by attestation during such period) or were not acquired, directly or indirectly, from the Company.

(ii) **Cashless Exercise**. The Company reserves, at any and all times, the right, in the Company's sole and absolute discretion, to establish, decline to approve or terminate any program or procedures for the exercise of Options by means of a Cashless Exercise, including with respect to one or more Participants specified by the Company notwithstanding that such program or procedures may be available to other Participants.

6.4 **Effect of Termination of Service**.

(a) **Option Exercisability**. Subject to earlier termination of the Option as otherwise provided by this Plan, an Option shall terminate immediately upon the Participant's termination of Service to the extent that it is then unvested and shall be exercisable after the Participant's termination of Service to the extent it is then vested only during the applicable time period determined in accordance with the Award Agreement evidencing the Option. To the extent required by applicable law, vested Options shall be exercisable for a minimum period of six (6) months following termination of the Participant's Service due to Disability or death and thirty (30) days following any other termination of Service (other than a termination due to Cause). Except as otherwise provided in an Award Agreement, if the Participant's Service is terminated for Cause, the Option shall terminate in its entirety and cease to be exercisable immediately upon such termination of Service. Notwithstanding the foregoing, no Option shall be exercisable later than the date of expiration of the Option's term as set forth in the Award Agreement evidencing the Option (the *"**Option Expiration Date**").*

(b) **Extension if Exercise Prevented by Law**. Notwithstanding the foregoing and other than with respect to a termination of Service for Cause, if the exercise of an Option within the applicable time periods set forth in the Award Agreement is prevented by the provisions of Section 11 below, the Option shall remain exercisable until the later of (i) thirty (30) days after the date such exercise first would no longer be prevented by such provisions or (ii) the end of the applicable time period set forth in the Award Agreement, but in any event no later than the Option Expiration Date.

6.5 **Transferability of Options**. During the lifetime of the Participant, an Option shall be exercisable only by the Participant or the Participant's guardian or legal representative. An Option shall not be subject in any manner to anticipation, alienation, sale, exchange, transfer, assignment, pledge, encumbrance, or garnishment by creditors of the Participant or the Participant's beneficiary, except transfer by will or by the laws of descent and distribution. Notwithstanding the foregoing, to the extent permitted by the Board, in its discretion, and set forth in the Award Agreement evidencing such Option, a Nonstatutory Stock Option shall be assignable or transferable subject to the applicable limitations, if any, described in Rule 701 under the Securities Act, and the General Instructions to the Form S-8 Registration Statement under the Securities Act.

7. **RESTRICTED STOCK AWARDS**.

Restricted Stock Awards shall be evidenced by Award Agreements specifying whether the Award is a Restricted Stock Bonus or a Restricted Stock Purchase Right and the number of shares of Stock subject to the Award, in such form as the Board shall from time to time establish. Award Agreements evidencing Restricted Stock Awards may incorporate all or any of the terms of the Plan by reference and shall comply with and be subject to the following terms and conditions:

7.1 **Types of Restricted Stock Awards Authorized**. Restricted Stock Awards may be granted in the form of either a Restricted Stock Bonus or a Restricted Stock Purchase Right. Restricted Stock Awards may be granted upon such conditions as the Board shall determine, including, without limitation, upon the attainment of one or more performance goals.

7.2 **Purchase Price**. The purchase price for shares of Stock issuable under each Restricted Stock Purchase Right shall be established by the Board in its discretion. No monetary payment (other than applicable tax

withholding) shall be required as a condition of receiving shares of Stock pursuant to a Restricted Stock Bonus, the consideration for which shall be services actually rendered to a Participating Company or for its benefit. Notwithstanding the foregoing, if required by applicable state corporate law, the Participant shall furnish consideration in the form of cash or past services rendered to a Participating Company or for its benefit having a value not less than the par value of the shares of Stock subject to a Restricted Stock Award.

7.3 **Purchase Period**. A Restricted Stock Purchase Right shall be exercisable within a period established by the Board, which shall in no event exceed thirty (30) days from the effective date of the grant of the Restricted Stock Purchase Right.

7.4 **Payment of Purchase Price**. Except as otherwise provided below, payment of the purchase price for the number of shares of Stock being purchased pursuant to any Restricted Stock Purchase Right shall be made (a) in cash, by check or in cash equivalent, (b) by such other consideration as may be approved by the Board from time to time to the extent permitted by applicable law, or (c) by any combination thereof.

7.5 **Vesting and Restrictions on Transfer**. Shares issued pursuant to any Restricted Stock Award may (but need not) be made subject to Vesting Conditions based upon the satisfaction of such Service requirements, conditions, restrictions or performance criteria, as shall be established by the Board and set forth in the Award Agreement evidencing such Award. During any period in which shares acquired pursuant to a Restricted Stock Award remain subject to Vesting Conditions, such shares may not be sold, exchanged, transferred, pledged, assigned or otherwise disposed of other than pursuant to an Ownership Change Event or as provided in Section 7.8. The Board, in its discretion, may provide in any Award Agreement evidencing a Restricted Stock Award that, if the satisfaction of Vesting Conditions with respect to any shares subject to such Restricted Stock Award would otherwise occur on a day on which the sale of such shares would violate the provisions of the Insider Trading Policy, then satisfaction of the Vesting Conditions automatically shall be determined on the next trading day on which the sale of such shares would not violate the Insider Trading Policy. Upon request by the Company, each Participant shall execute any agreement evidencing such transfer restrictions prior to the receipt of shares of Stock hereunder and shall promptly present to the Company any and all certificates representing shares of Stock acquired hereunder for the placement on such certificates of appropriate legends evidencing any such transfer restrictions.

7.6 **Voting Rights; Dividends and Distributions**. Except as provided in this Section, Section 7.5 and any Award Agreement, during any period in which shares acquired pursuant to a Restricted Stock Award remain subject to Vesting Conditions, the Participant shall have all of the rights of a stockholder of the Company holding shares of Stock, including the right to vote such shares and to receive all dividends and other distributions paid with respect to such shares. However, in the event of a dividend or distribution paid in shares of Stock or other property or any other adjustment made upon a change in the capital structure of the Company as described in Section 4.2, any and all new, substituted or additional securities or other property (other than normal cash dividends) to which the Participant is entitled by reason of the Participant's Restricted Stock Award shall be immediately subject to the same Vesting Conditions as the shares subject to the Restricted Stock Award with respect to which such dividends or distributions were paid or adjustments were made.

7.7 **Effect of Termination of Service**. Unless otherwise provided by the Board in the Award Agreement evidencing a Restricted Stock Award, if a Participant's Service terminates for any reason, whether voluntary or involuntary (including the Participant's death or disability), then (a) the Company shall have the option to repurchase for the purchase price paid by the Participant any shares acquired by the Participant pursuant to a Restricted Stock Purchase Right which remain subject to Vesting Conditions as of the date of the Participant's termination of Service and (b) the Participant shall forfeit to the Company any shares acquired by the Participant pursuant to a Restricted Stock Bonus which remain subject to Vesting Conditions as of the date of the Participant's termination of Service. The Company shall have the right to assign at any time any repurchase right it may have, whether or not such right is then exercisable, to one or more persons as may be selected by the Company.

7.8 **Nontransferability of Restricted Stock Award Rights**. Rights to acquire shares of Stock pursuant to a Restricted Stock Award shall not be subject in any manner to anticipation, alienation, sale, exchange, transfer, assignment, pledge, encumbrance or garnishment by creditors of the Participant or the Participant's beneficiary, except transfer by will or the laws of descent and distribution. All rights with respect to a Restricted

Stock Award granted to a Participant hereunder shall be exercisable during his or her lifetime only by such Participant or the Participant's guardian or legal representative.

8. **STANDARD FORMS OF AWARD AGREEMENTS**.

8.1 **Award Agreements**. Each Award shall comply with and be subject to the terms and conditions set forth in the appropriate form of Award Agreement approved by the Board and as amended from time to time. No Award or purported Award shall be a valid and binding obligation of the Company unless evidenced by a fully executed Award Agreement. Any Award Agreement may consist of an appropriate form of Notice of Grant and a form of Agreement incorporated therein by reference, or such other form or forms, including electronic media, as the Board may approve from time to time.

8.2 **Authority to Vary Terms**. The Board shall have the authority from time to time to vary the terms of any standard form of Award Agreement either in connection with the grant or amendment of an individual Award or in connection with the authorization of a new standard form or forms; provided, however, that the terms and conditions of any such new, revised or amended standard form or forms of Award Agreement are not inconsistent with the terms of the Plan or applicable law.

9. **CHANGE IN CONTROL**.

9.1 **Effect of Change in Control on Awards**. 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:

(a) **Accelerated Vesting**. The Board may, in its discretion, provide in any Award Agreement or, in the event of a Change in Control, may take such actions as it deems appropriate to provide for the acceleration of the exercisability and/or vesting in connection with such Change in Control of each or any outstanding Award or portion thereof and shares acquired pursuant thereto upon such conditions, including termination of the Participant's Service prior to, upon, or following such Change in Control, to such extent as the Board shall determine.

(b) **Assumption, Continuation or Substitution of Awards**. In the event of a Change in Control, the surviving, continuing, successor, or purchasing corporation or other business entity or parent thereof, as the case may be (the *"**Acquiror**")*, may, without the consent of any Participant, assume or continue the Company's rights and obligations under each or any Award or portion thereof outstanding immediately prior to the Change in Control or substitute for each or any such outstanding Award or portion thereof a substantially equivalent award with respect to the Acquiror's stock. For purposes of this Section, if so determined by the Board, in its discretion, an Award or any portion thereof shall be deemed assumed if, following the Change in Control, the Award confers the right to receive, subject to the terms and conditions of the Plan and the applicable Award Agreement, for each share of Stock subject to such portion of the Award immediately prior to the Change in Control, the consideration (whether stock, cash, other securities or property or a combination thereof) to which a holder of a share of Stock on the effective date of the Change in Control was entitled; provided, however, that if such consideration is not solely common stock of the Acquiror, the Board may, with the consent of the Acquiror, provide for the consideration to be received upon the exercise of the Award for each share of Stock to consist solely of common stock of the Acquiror equal in Fair Market Value to the per share consideration received by holders of Stock pursuant to the Change in Control. If any portion of such consideration may be received by holders of Stock pursuant to the Change in Control on a contingent or delayed basis, the Board may, in its discretion, determine such Fair Market Value per share as of the time of the Change in Control on the basis of the Board's good faith estimate of the present value of the probable future payment of such consideration. Except as otherwise provided in an Award Agreement, if the Acquiror does not assume or continue any Award, then any Award or portion thereof which is not assumed or continued by the Acquiror in connection with the Change in Control and which is not exercised as of the time of consummation of the Change in Control shall terminate and cease to be outstanding effective as of the time of consummation of the Change in Control. Notwithstanding the foregoing, shares acquired upon exercise of an Award prior to the Change in Control and any consideration received pursuant to the Change in Control with respect to such shares shall continue to be subject to all applicable provisions of the Award Agreement evidencing such Award except as otherwise provided in such Award Agreement.

(c) **Cash-Out of Outstanding Awards**. Notwithstanding anything in this Plan to the contrary, the Board may, in its discretion and without the consent of any Participant, determine that, upon the occurrence of a Change in Control, each or any Award or portion thereof outstanding immediately prior to the Change in Control shall be canceled in exchange for a payment with respect to each vested share (and each unvested share, if so determined by the Board) of Stock subject to such canceled Award in (i) cash, (ii) stock of the Company or of a corporation or other business entity a party to the Change in Control, or (iii) other property which, in any such case, shall be in an amount having a Fair Market Value equal to the Fair Market Value of the consideration to be paid per share of Stock in the Change in Control, reduced by the exercise or purchase price per share, if any, under such Award. If any portion of such consideration may be received by holders of Stock pursuant to the Change in Control on a contingent or delayed basis, the Board may, in its sole discretion, determine such Fair Market Value per share as of the time of the Change in Control on the basis of the Board's good faith estimate of the present value of the probable future payment of such consideration. In the event such determination is made by the Board, the amount of such payment (reduced by applicable withholding taxes, if any) shall be paid to Participants in respect of the vested portions of their canceled Awards as soon as practicable following the date of the Change in Control and in respect of the unvested portions of their canceled Awards in accordance with the vesting schedules applicable to such Awards.

9.2 **Federal Excise Tax Under Section 4999 of the Code**.

(a) If at any time or from time to time, it shall be determined by independent tax professionals selected by the Company ("Tax Professional") that any acceleration of vesting pursuant to an Award and any other payment or benefit received or to be received by a Participant, whether or not pursuant to an Award granted under the Plan, would subject the Participant to any excise tax pursuant to Section 4999 of the Code (or any similar tax payable under any state, local, foreign or other law, but expressly excluding any income taxes and penalties or interest imposed pursuant to Section 409A of the Code ("Excise Taxes"), due to the characterization of such acceleration of vesting, payment or benefit as an "excess parachute payment" under Section 280G of the Code ("Potential Parachute Payment"), then Participant's Potential Parachute Payment shall be either (a) provided to Executive in full, or (b) provided to Participant as to such lesser extent which would result in no portion of such benefits being subject to the Excise Taxes, whichever of the foregoing amounts, after taking into account applicable federal, state, local and foreign income and employment taxes, the Excise Tax, and any other applicable taxes, results in the receipt by Participant, on an after-tax basis, of the greatest amount of benefits, notwithstanding that all or some portion of such benefits may be taxable under the Excise Taxes ("Payments").

(b) Implementation of Any Benefit Reduction. In the event of a reduction of benefits pursuant to paragraph 9.2(a), the Tax Professional shall determine which benefits shall be reduced so as to achieve the principle set forth in paragraph 9.2(a). For purposes of making the calculations required by paragraph 9.2(a), the Tax Professional may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of the Code and other applicable legal authority. The Company and the Participant shall furnish to the Tax Professional such information and documents as the Tax Professional may reasonably request in order to make a determination under paragraph 9.2(a). The Company shall bear all costs the Tax Professional may reasonably incur in connection with any calculations contemplated by paragraph 9.2(a).

(c) Potential Subsequent Adjustments.

(i) If, notwithstanding any calculations performed or reduction in benefits imposed as described in paragraph 9.2(a), the IRS determines that Participant is liable for Excise Taxes as a result of the receipt of any payments characterized as "parachute payments" within the meaning of Section 280G of the Code, then the Participant shall be obligated to pay back to the Company, within thirty (30) days after a final IRS determination or in the event that the Participant challenges the final IRS determination, a final judicial determination, a portion of the Payments equal to the "Repayment Amount." The Repayment Amount shall be the smallest such amount, if any, as shall be required to be paid to the Company so that the Participant's net after-tax proceeds with respect to the Payments (after taking into account the payment of the Excise Taxes and all other applicable taxes imposed on such benefits) shall be maximized. The Repayment Amount shall be zero if a Repayment Amount of more than zero would not result in Executive's net after-tax proceeds with respect to the Payments being maximized. If the Excise Taxes are not eliminated pursuant to this paragraph 9.2(c), Executive shall pay the Excise Taxes.

(ii) Notwithstanding any other provision of this Section 9.2, if (A) there is a reduction in the payments to the Participant as described above in this Section 9.2, (B) the IRS later determines that the Participant is liable for Excise Taxes, the payment of which would result in the maximization of the Participant's net after-tax proceeds (calculated based on the full amount of the Participant's parachute payments and as if the Participant's benefits had not previously been reduced), and (C) the Participant pays the Excise Tax, then the Company shall pay to the Participant those payments which were reduced pursuant to the application of the previous provisions of this Section 9.2 as soon as administratively possible after the Participant pays the Excise Taxes to the extent that the Participant's net after-tax proceeds with respect to the payment of the Payments are maximized.

10. TAX WITHHOLDING.

10.1 **Tax Withholding in General**. The Company shall have the right to deduct from any and all payments made under the Plan, or to require the Participant, through payroll withholding, cash payment or otherwise, including by means of a Cashless Exercise of an Option, to make adequate provision for, the federal, state, local and foreign taxes (including any social insurance tax), if any, required by law to be withheld by the Participating Company Group with respect to an Award or the shares acquired pursuant thereto. The Company shall have no obligation to deliver shares of Stock or to release shares of Stock from an escrow established pursuant to an Award Agreement until the Participating Company Group's tax withholding obligations have been satisfied by the Participant.

10.2 **Withholding in Shares**. The Company shall have the right, but not the obligation, to deduct from the shares of Stock issuable to a Participant upon the exercise of an Award, or to accept from the Participant the tender of, a number of whole shares of Stock having a Fair Market Value, as determined by the Company, equal to all or any part of the tax withholding obligations of the Participating Company Group. The Fair Market Value of any shares of Stock withheld or tendered to satisfy any such tax withholding obligations shall not exceed the amount determined by the applicable minimum statutory withholding rates.

11. COMPLIANCE WITH SECURITIES LAW.

The grant of Awards and the issuance of shares of Stock pursuant to any Award shall be subject to compliance with all applicable requirements of federal, state and foreign law with respect to such securities and the requirements of any stock exchange or market system upon which the Stock may then be listed. In addition, no Award may be exercised or shares 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 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 inability of the Company to obtain from any regulatory body having jurisdiction the authority, if any, deemed by the Company's legal counsel to be necessary to the lawful issuance and sale of any shares hereunder shall relieve the Company of any liability in respect of the failure to issue or sell such shares as to which such requisite authority shall not have been obtained. As a condition to issuance of any Stock, the Company may require the Participant to satisfy any qualifications that may be necessary or appropriate, to evidence compliance with any applicable law or regulation and to make any representation or warranty with respect thereto as may be requested by the Company.

12. AMENDMENT OR TERMINATION OF PLAN.

The Board may amend, suspend or terminate the Plan at any time. However, without the approval of the Company's stockholders, there shall be (a) no increase in the maximum aggregate number of shares of Stock that may be issued under the Plan (except by operation of the provisions of Section 4.2), (b) no change in the class of persons eligible to receive Incentive Stock Options, and (c) no other amendment of the Plan that would require approval of the Company's stockholders under any applicable law, regulation or rule, including the rules of any stock exchange or market system upon which the Stock may then be listed. No amendment, suspension or termination of the Plan shall affect any then outstanding Award unless expressly provided by the Board. Except as provided by the next sentence, no amendment, suspension or termination of the Plan may materially adversely affect any then outstanding Award without the consent of the Participant. Notwithstanding any other provision of the Plan or any Award Agreement to the contrary, the Board may, in its sole and absolute discretion and without the consent of any Participant, amend the Plan or any Award Agreement, to take effect retroactively or otherwise, as it deems necessary

or advisable for the purpose of conforming the Plan or such Award Agreement to any present or future law, regulation or rule applicable to the Plan, including, but not limited to, Section 409A of the Code.

13. MISCELLANEOUS PROVISIONS.

13.1 **Repurchase Rights**. Shares of Stock issued under the Plan may be subject to a right of first refusal, one or more repurchase options, 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 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 Stock hereunder and shall promptly present to the Company any and all certificates representing shares of 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 Stock issued under the Plan will be required to enter into such agreement upon acquiring such shares of Stock.

13.2 **Provision of Information**. At least annually, copies of the Company's balance sheet and income statement for the just completed fiscal year shall be made available to each Participant and purchaser of shares of Stock upon the exercise of an Award; provided, however, that this requirement shall not apply if all offers and sales of securities pursuant to the Plan comply with all applicable conditions of Rule 701 under the Securities Act. The Company shall not be required to provide such information to key persons whose duties in connection with the Company assure them access to equivalent information. The Company shall deliver to each Participant such disclosures as are required in accordance with Rule 701 under the Securities Act.

13.3 **Rights as Employee, Consultant or Director**. No person, even though eligible pursuant to Section 5, shall have a right to be selected as a Participant, or, having been so selected, to be selected again as a Participant. Nothing in the Plan or any Award granted under the Plan shall confer on any Participant a right to remain an Employee, Consultant or Director or interfere with or limit in any way any right of a Participating Company to terminate the Participant's Service at any time. To the extent that an Employee of a Participating Company other than the Company, receives an Award under the Plan, that Award shall in no event be understood or interpreted to mean that the Company is the Employee's employer or that the Employee has an employment relationship with the Company.

13.4 **Rights as a Stockholder**. A Participant shall have no rights as a stockholder with respect to any shares covered by an Award until the date of the issuance of such shares (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company). No adjustment shall be made for dividends, distributions or other rights for which the record date is prior to the date such shares are issued, except as provided in Section 4.2 or another provision of the Plan.

13.5 **Delivery of Title to Shares**. Subject to any governing rules or regulations, the Company shall issue or cause to be issued the shares of Stock acquired pursuant to an Award and shall deliver such shares to or for the benefit of the Participant by means of one or more of the following: (a) by delivering to the Participant evidence of book entry shares of Stock credited to the account of the Participant, (b) by depositing such shares of Stock for the benefit of the Participant with any broker with which the Participant has an account relationship, (c) by delivering such shares of Stock to the Participant in certificate form, or (d) by delivering such shares to an escrow agent who shall hold such shares in accordance with the terms of a form of escrow agreement established by the Company in order to ensure compliance with the terms of the Plan, the Award Agreement under which the right to receive such shares of Stock were granted, and any other conditions, restrictions or terms of other agreement to which such shares of Stock are subject upon their issuance.

13.6 **Fractional Shares**. The Company shall not be required to issue fractional shares upon the exercise or settlement of any Award.

13.7 **Retirement and Welfare Plans**. Neither Awards made under this Plan nor shares of Stock or cash paid pursuant to such Awards shall be included as "compensation" for purposes of computing the benefits payable to any Participant under any Participating Company's retirement plans (both qualified and non-qualified) or welfare benefit plans unless such other plan expressly provides that such compensation shall be taken into account in computing such benefits.

13.8 **Severability**. If any one or more of the provisions (or any part thereof) of this Plan shall be held invalid, illegal or unenforceable in any respect, such provision shall be modified so as to make it valid, legal and enforceable, and the validity, legality and enforceability of the remaining provisions (or any part thereof) of the Plan shall not in any way be affected or impaired thereby.

13.9 **No Constraint on Corporate Action**. Nothing in this Plan shall be construed to: (a) limit, impair, or otherwise affect the Company's or another Participating Company's right or power to make adjustments, reclassifications, reorganizations, or changes of its capital or business structure, or to merge or consolidate, or dissolve, liquidate, sell, or transfer all or any part of its business or assets; or (b) limit the right or power of the Company or another Participating Company to take any action which such entity deems to be necessary or appropriate.

13.10 **Choice of Law**. Except to the extent governed by applicable federal law, the validity, interpretation, construction and performance of the Plan and each Award Agreement shall be governed by the laws of the State of California, without regard to its conflict of law rules.

13.11 **Stockholder Approval**. The Plan or any increase in the maximum aggregate number of shares of Stock issuable thereunder as provided in Section 4.1 (the ***"Authorized Shares")*** shall be approved by a majority of the outstanding securities of the Company entitled to vote by the later of (a) a period beginning twelve (12) months before and ending twelve (12) months after the date of adoption thereof by the Board or (b) the first issuance of any security pursuant to the Plan in the State of California (within the meaning of Section 25008 of the California Corporations Code). Awards granted prior to security holder approval of the Plan or in excess of the Authorized Shares previously approved by the security holders shall become exercisable no earlier than the date of security holder approval of the Plan or such increase in the Authorized Shares, as the case may be, and such Awards shall be rescinded if such security holder approval is not received in the manner described in the preceding sentence.

PLAN HISTORY

February 23, 2012	Board adopts Ascendant MDx, Inc. 2012 Stock Plan, with an initial reserve of 1,250,000 shares.
February 23, 2012	Stockholders of the Company approve Ascendant MDx, Inc. 2012 Stock Plan.
June 12, 2013	Board adopts Amended and Restated Ascendant MDx, Inc. 2012 Stock Plan with a reserve of 3,000,000 shares.
June 12, 2013	Stockholders of the Company approve Amended and Restated Ascendant MDx, Inc. 2012 Stock Plan.
August 21, 2013	Board and Stockholders adopt and approve a 10 for 1 stock split (and corresponding Second Amended and Restated Progenity, Inc. 2012 Stock Plan with a reserve of 30,000,0000 shares, reflecting the stock split)
January 3, 2023	Board and Stockholders adopt and approve a 1 for 25 reverse stock split

BIORA THERAPEUTICS, INC.

2018 EQUITY INCENTIVE PLAN (FOURTH AMENDED & RESTATED)

ADOPTED BY THE BOARD: FEBRUARY 22, 2018 (FIRST AMENDMENT MARCH 6, 2019, SECOND AMENDMENT DECEMBER 5, 2019, THIRD AMENDMENT MARCH 4, 2020, FOURTH AMENDMENT MAY 5, 2021)

APPROVED BY THE STOCKHOLDERS: FEBRUARY 22, 2018 (FIRST AMENDMENT MARCH 6, 2019, SECOND AMENDMENT DECEMBER 5, 2019, THIRD AMENDMENT MARCH 4, 2020, FOURTH AMENDMENT MAY 5, 2021)

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 February 22, 2018 (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, as aggregated from time to time, will be seven hundred ninety-four thousand one hundred thirty-six (794,136) shares of Common Stock (the "**Share Reserve**").

(ii) The Share Reserve will automatically increase on January 1st of each year, during the term of the Plan, commencing on January 1, 2022 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 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 seven hundred ninety-four thousand one hundred thirty-six (794,136) 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 Biora Therapeutics, 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 Biora Therapeutics, Inc. (Fourth 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

BIORA THERAPEUTICS, 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 Biora Therapeutics, 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 is less than the Offering Price 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 twenty thousand four hundred (20,400) 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) twenty-four thousand (24,000) 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.

BIORA THERAPEUTICS, INC.

2021 INDUCEMENT PLAN

ADOPTED BY THE BOARD OF DIRECTORS ON NOVEMBER 3, 2021

1. GENERAL.

(a) **Eligible Award Recipients**. New Employees are eligible to receive Awards as a material inducement to the commencement of employment within the meaning of the Listing Rule.

(b) **Available Awards**. The Plan provides for the grant of the following Awards: (i) Nonstatutory Stock Options; (ii) Stock Appreciation Rights; (iii) Restricted Stock Awards; (iv) Restricted Stock Unit Awards; (v) Performance Stock Awards; and (vi) Other Stock Awards.

(c) **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 (which Awards shall be intended as a material inducement to the individual becoming an Employee); (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. In accordance with the Listing Rule, any exercise of the Board's authority under this Section 2(b)(i) must be exercised solely by the Board's independent Directors within the meaning of Rule 5605(a)(2) of the Nasdaq Listing Rules.

(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, 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 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 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 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. 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 clarify the manner of exemption from, or to bring the Award into compliance with, Section 409A of the Code, or (B) 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, except that the Board's authority under Section 2(b)(i) above may only be delegated to the Compensation Committee of the Board. 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 (or a Committee, if within the scope of the Committee's delegated authority) may delegate to one (1) or more Officers the day to day administration of the Plan, and such administrator(s) may have the authority to execute and distribute agreements or other documents evidencing or relating to Awards granted under this Plan, to maintain records relating to the grant, vesting, exercise, forfeiture or expiration of Awards, to process or oversee the issuance of shares of Common Stock upon the exercise, vesting and/or settlement of an Award, to interpret the terms of Awards and to take such other actions as the Board may specify.

(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 two hundred sixty thousand (260,000) shares of Common Stock (the "**Share Reserve**").

(ii) 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.

(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 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, whether or not 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. Under all circumstances, the Share Reserve shall only be reduced upon the issuance of shares covered by a Stock Award.

(c) **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.

Awards under the Plan may be granted only to New Employees who satisfy the standards for inducement grants under the Listing Rule, and only when the Award is an inducement material to the individual's entering into employment with the Company within the meaning of the Listing Rule.

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 granted as Nonstatutory Stock Options. 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**. 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**. 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) 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.

(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 or (B) 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) 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 equal to or greater 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) **Provision of Information**. To the extent required by applicable law, the Company will provide information to Participants regarding the Company.

(b) **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.

(c) **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.

(d) **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.

(e) **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 the Participant's employment or other service for any reason or no reason, with or without notice and with or without cause, including, but not limited to, Cause.

(f) **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.

(g) **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.

(h) **Withholding Obligations**. Unless prohibited or restricted 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.

(i) **Electronic Delivery or Notice**. Any reference herein to a "written" agreement, document or notice will include any agreement, document or notice delivered electronically (including via the website of a designated broker), 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).

(j) **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.

(k) **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.

(l) **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) and (ii) 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 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.

(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) "**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.

(f) "**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.

(g) "**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.

(h) "**Code**" means the U.S. Internal Revenue Code of 1986, as amended, including any applicable regulations and guidance thereunder.

(i) "**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).

(j) "**Common Stock**" means the common stock of the Company.

(k) "**Company**" means Biora Therapeutics, Inc., a Delaware corporation.

(l) "**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, 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.

(m) "**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.

(n) "**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).

(o) "**Director**" means a member of the Board.

(p) "**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.

(q) "**Effective Date**" means November 3, 2021.

(r) "**Employee**" means any person providing services as an employee of the Company or an Affiliate. For the avoidance of doubt, service solely as a Director or Consultant, or payment of a fee for such services, will not cause a Director to be considered an "Employee" for purposes of the Plan. Notwithstanding the foregoing, a person who already is serving as a Director prior to becoming an Employee will not be eligible to be granted an Award under the Plan unless permitted under the Listing Rule.

(s) "**Entity**" means a corporation, partnership, limited liability company or other entity.

(t) "**Exchange Act**" means the U.S. Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

(u) "**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 Affiliate of the Company, (ii) any employee benefit plan of the Company or any Affiliate of the Company or any trustee or other fiduciary holding securities under an employee benefit plan of the Company or any Affiliate 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.

(v) "**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. 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.

(w) "**Listing Rule**" means Rule 5635(c)(4) of the Nasdaq Listing Rules.

(x) "**New Employee**" means an Employee who commenced employment with the Company or any of its Affiliates on terms and conditions consistent with the Listing Rule.

(y) "**Nonstatutory Stock Option**" means any option granted pursuant to Section 5 of the Plan that is not intended to be, and that does not qualify as, an "incentive stock option" within the meaning of Section 422 of the Code.

(z) "**Officer**" means a person who is an officer of the Company within the meaning of Section 16 of the Exchange Act.

(aa) "**Option**" means a Nonstatutory Stock Option to purchase shares of Common Stock granted pursuant to the Plan.

(bb) "**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.

(cc) "**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.

(dd) "**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).

(ee) "**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.

(ff) "**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.

(gg) "**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.

(hh) "**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. Performance Periods may be of varying and overlapping duration, at the sole discretion of the Board.

(ii) "**Performance Stock Award**" means a Stock Award granted under the terms and conditions of Section 6(c)(i).

(jj) "**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.

(kk) "**Plan**" means this Biora Therapeutics, Inc. 2021 Inducement Plan.

(ll) "**Restricted Stock Award**" means an award of shares of Common Stock that is granted pursuant to the terms and conditions of Section 6(a).

(mm) "**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.

(nn) "**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).

(oo) "**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.

(pp) "**Securities Act**" means the U.S. Securities Act of 1933, as amended.

(qq) "**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.

(rr) "**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.

(ss) "**Stock Award**" means any right to receive shares of Common Stock granted under the Plan, including 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".

(tt) "**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.

END OF DOCUMENT

Exhibit 10.6

BIORA THERAPEUTICS, INC.

NEW HIRE EMPLOYEE NOTICE OF GRANT OF STOCK OPTION
(2021 Inducement Plan)

The Participant has been granted an option (the "***Option***") to purchase certain shares of stock of Biora Therapeutics, Inc. (the "***Company***") pursuant to the Biora Therapeutics, Inc. 2021 Inducement Plan (the "***Plan***"), as follows:

Participant:	
Date of Grant:	
Grant Number:	
Number of Options:	
Exercise Price:	
Vesting Commencement Date:	One year after the Date of Grant above
Option Expiration Date:	The date ten (10) years after the Date of Grant
Tax Status of Option:	Nonstatutory Stock Option
Vesting Schedule:	Except as provided in the Stock Option Agreement, the number of Vested Options (disregarding any resulting fractional share) as of any date is determined as follows: Subject to Participant's Continuous Service, 12/48 (25%) vests and becomes exercisable on the Vesting Commencement Date, and 1/48 vests and becomes exercisable each calendar month thereafter for the next 36 months.

By acknowledging and agreeing to the terms of your online grant package, the Company and the Participant agree that the Option is governed by this Grant Notice, the provisions of the Plan and the Stock Option Agreement, which are attached to and made a part of this Grant Notice. The Participant: (a) acknowledges receipt of, and represents that the Participant has read and is familiar with the terms and conditions of, this Grant Notice, the Stock Option Agreement and the Plan, (b) acknowledges and agrees to all of the terms and conditions of the Option as set forth in this Grant Notice, the Stock Option Agreement and the Plan, including the tax withholding provisions set forth at Section 3.4 of the Stock Option Agreement, and hereby authorizes the Company to withhold from the Participant's compensation in accordance with Section 3.4(b), (c) agrees to accept as binding, conclusive and final all decisions or interpretations of the Board upon any questions arising under this Grant Notice, the Stock Option Agreement or the Plan, and (d) consents to receive such documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

If you have any questions, please contact the Company by e-mail at stock.administration@bioratherapeutics.com.

STOCK OPTION AGREEMENT

Biora Therapeutics, Inc. (the "***Company***") has granted to the Participant named in the *Notice of Grant of Stock Option* (the "***Grant Notice***") to which this Stock Option Agreement (this "***Option Agreement***") is attached an option (the "***Option***") to purchase certain shares of Common Stock upon the terms and conditions set forth in the Grant Notice and this Option Agreement. The Option has been granted pursuant to and shall in all respects be subject to the terms and conditions of the Biora Therapeutics, Inc. 2021 Inducement Plan (the "***Plan***"), the provisions of which are incorporated herein by reference. By accepting the grant, the Participant: (a) acknowledges receipt of, and represents that the Participant has read and is familiar with the terms and conditions of, the Grant Notice, this Option Agreement and the Plan, (b) acknowledges and agrees to all of the terms and conditions of the Option as set forth in the Grant Notice, this Option Agreement and the Plan, and agrees to accept as binding, conclusive and final all decisions or interpretations of the Board upon any questions arising under the Grant Notice, this Option Agreement or the Plan.

1. **DEFINITIONS AND CONSTRUCTION.**

1.1 **Definitions.** Unless otherwise defined herein, capitalized terms shall have the meanings assigned to such terms in the Grant Notice or the Plan.

1.2 **Construction.** Captions and titles contained herein are for convenience only and shall not affect the meaning or interpretation of any provision of this Option Agreement. Except when otherwise indicated by the context, the singular shall include the plural and the plural shall include the singular. Use of the term "or" is not intended to be exclusive, unless the context clearly requires otherwise.

2. **INDUCEMENT AWARD.** This Option is granted to Participant as a material inducement to the commencement of employment within the meaning of the Listing Rule. This Option is not intended to qualify as an Incentive Stock Option and shall be regarded as a Nonstatutory Stock Option.

3. **EXERCISE OF THE OPTION.**

3.1 **Right to Exercise.** Except as otherwise provided herein, the Option shall be exercisable on and after the Vesting Commencement Date and prior to the termination of the Option (as provided in Section 4) in an amount not to exceed the number of Vested Options less the number of shares previously acquired upon exercise of the Option. In no event shall the Option be exercisable for more shares of Common Stock than the Number of Option Shares, as adjusted from time to time pursuant to Section 9 of the Plan.

3.2 **Method of Exercise.** Exercise of the Option shall be completed electronically by a method authorized by the Company. Exercise of the Option must be completed prior to the termination of the Option as set forth in Section 4 and must be accompanied by full payment of the aggregate Exercise Price for the number of shares of Common Stock being purchased in a manner consistent with Section 3.3. The Option shall be deemed to be exercised upon receipt by the Company of such electronic notice by the designated broker and the aggregate Exercise Price.

3.3 **Payment of Exercise Price. Forms of Consideration Authorized.** Except as otherwise provided below, payment of the aggregate Exercise Price for the number of shares of Common Stock for which the Option is being exercised shall be made (i) by cash, check, bank draft or money order payable to the Company, (ii) if established by the Company and permitted by the Company with respect to the Option, 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 the 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) if permitted by the Company, by delivery to the Company (either by actual delivery or attestation) of shares of Common Stock, (iv) if permitted by the Company, 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, (v) in any other form of legal consideration that the Board determines is a benefit to the Company, or (vi) by any combination of the foregoing that is permitted with respect to the Option.

3.4 **Tax Withholding.** The Company may, in its sole discretion, satisfy any U.S. federal, state, local, foreign or other tax withholding obligation relating to the exercise or any other event that triggers tax liability with respect to the Option by any of the following means or by a combination of such means: (a) causing the Participant to tender, or cause to have tendered, a cash payment, (b) withholding from the Participant's cash compensation from the Company after obtaining the authorization of the Participant, (c) withholding, or causing to have withheld, shares of Common Stock or other securities or other property from the shares of Common Stock, other securities or other property issued or otherwise issuable to the Participant in connection with the exercise of the Option (only up to the amount permitted that will not cause an adverse accounting consequence or cost), or (d) payment from any amounts otherwise payable to the Participant out of proceeds from the sale of shares of Common Stock issued upon the exercise of the Option under a program established by the Company. Unless otherwise provided by the Company through action of the Board or Committee or agreement with the Participant, the Company's withholding tax obligations shall generally be satisfied using the approach set forth under (c) or (d) above. None of the Company, its Affiliates, its representatives or agents, or any other person shall have any obligation to deliver shares of Common Stock or other securities or other property, until the tax withholding obligations of the Company have been fully satisfied by the Participant.

3.5 **Beneficial Ownership of Shares; Certificate Registration.** The Participant hereby authorizes the Company, in its sole discretion, to deposit for the benefit of the Participant with any broker selected by the Company, or with the concurrence of the Company, any broker with which the Participant has an account relationship of which the Company has notice any or all shares of Common Stock acquired by the Participant pursuant to the exercise of the Option. Except as provided by the preceding sentence, a certificate for the shares as to which the Option is exercised shall be registered in the name of the Participant, or, if applicable, in the names of the heirs of the Participant (or for any uncertificated shares, such entry shall be made in book- entry form).

3.6 **Fractional Shares.** The Company shall not be required to issue fractional shares upon the exercise of the Option.

4. **TERMINATION OF THE OPTION.**

The Option shall terminate and may no longer be exercised after the first to occur of (a) the close of business on the Option Expiration Date, (b) the close of business on the last date for exercising the Option following termination of the Participant's Continuous Service as described in Section 5, or (c) a Change in Control to the extent provided in Section 9 of the Plan.

5. **EFFECT OF TERMINATION OF CONTINUOUS SERVICE.**

5.1 **Option Exercisability.** The Option shall be exercisable after the Participant's termination of Continuous Service to the extent it is then vested and unexercised only during the applicable time period as determined below and thereafter shall terminate.

(a) **Disability.** If the Participant's Continuous Service terminates because of the Disability of the Participant, the Option, to the extent unexercised and exercisable for Vested Options on the date on which the Participant's Continuous Service terminated, may be exercised by the Participant (or the Participant's guardian or legal representative) at any time prior to the expiration of twelve (12) months after the date on which the Participant's Continuous Service terminated, but in any event no later than the Option Expiration Date.

(b) **Death.** If the Participant's Continuous Service terminates because of the death of the Participant, the Option, to the extent unexercised and exercisable for Vested Options on the date on which the Participant's Continuous Service terminated, may be exercised by the Participant's legal representative or other person who acquired the right to exercise the Option by reason of the Participant's death at any time prior to the expiration of eighteen (18) months after the date on which the Participant's Continuous Service terminated, but in any event no

later than the Option Expiration Date.

(c) **Termination for Cause.** Notwithstanding any other provision of this Option Agreement, if the Participant's Continuous Service is terminated for Cause, the Option 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 the Option 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 Participant's Continuous Service is suspended pending an investigation of the existence of Cause, all of the Participant's rights under the Option will also be suspended during the investigation period.

(d) **Other Termination of Service.** If the Participant's Continuous Service terminates for any reason, except Disability, death or Cause, the Option, to the extent unexercised and exercisable for shares by the Participant on the date on which the Participant's Continuous Service terminated, may be exercised by the Participant at any time prior to the expiration of three (3) months after the date on which the Participant's Continuous Service terminated, but in any event no later than the Option Expiration Date.

5.2 **Extension if Exercise Prevented by Law.** Notwithstanding the foregoing other than termination of Continuous Service for Cause, if the exercise of the Option within the applicable time periods set forth in Section 5.1 is prevented solely because the issuance of shares of Common Stock would violate any provision of applicable securities law, the Option shall remain exercisable until the earlier of (a) 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 would not be in violation of such provisions, and (b) the Option Expiration Date. If the sale of any Common Stock received upon exercise of the Option 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, then the Option 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 would not be in violation of the Insider Trading Policy or (ii) the Option Expiration Date.

6. **LEGENDS.**

The Company may at any time place legends referencing any applicable federal, state or foreign securities law restrictions and any other applicable restrictions on all certificates representing shares of stock subject to the provisions of this Option Agreement. The Participant shall, at the request of the Company, promptly present to the Company any and all certificates representing any shares acquired pursuant to the Option in the possession of the Participant in order to carry out the provisions of this Section.

7. **MISCELLANEOUS PROVISIONS.**

7.1 **Further Instruments.** The parties hereto agree to execute such further instruments and to take such further action as may reasonably be necessary to carry out the intent of this Option Agreement.

7.2 **Binding Effect.** Subject to the restrictions on transfer set forth herein, this Option Agreement shall inure to the benefit of and be binding upon the parties hereto and their respective heirs, executors, administrators, successors and assigns.

7.3 **Delivery of Documents and Notices.** Any document relating to participation in the Plan, or any notice required or permitted hereunder shall be given in writing and shall be deemed effectively given upon personal delivery or electronic delivery at the e-mail address, if any, provided by the Company or the Participant to the other party, or, upon deposit in the U.S. Post Office or foreign postal service, by registered or certified mail, or with a nationally recognized overnight courier service with postage and fees prepaid, addressed to the other party at the address of such party set forth in the Grant Notice or at such other address as such party may designate in writing from time to time to the other party. If the Participant does not affirmatively designate a different e-mail address and/or physical address, the Company may use the Participant's Company e-mail address and may rely upon the use of the

most recent address for the Participant in the Company's books and records.

(a) **Description of Electronic Delivery.** The Plan documents, which include the Plan, the Grant Notice, and this Option Agreement, as well as any reports of the Company provided generally to the Company's stockholders, may be delivered to the Participant electronically. In addition, if permitted by the Company, the Participant may deliver electronically the Grant Notice to the Company or to such third party involved in administering the Plan as the Company may designate from time to time. Such means of electronic delivery may include, but do not necessarily include, the delivery of a link to a Company intranet or the Internet site of a third party involved in administering the Plan, the delivery of the document via e-mail or such other means of electronic delivery specified by the Company.

(b) **Consent to Electronic Delivery.** The Participant acknowledges that the Participant has read Section 8(i) of the Plan ("***Electronic Delivery***") and consents to the electronic delivery of the Plan documents and, if permitted by the Company, the delivery of the Grant Notice, as described in Section 8(i) of the Plan. The Participant acknowledges that he or she may receive from the Company a paper copy of any documents delivered electronically at no cost to the Participant by contacting the Company by telephone or in writing. The Participant further acknowledges that the Participant will be provided with a paper copy of any documents if the attempted electronic delivery of such documents fails. Similarly, the Participant understands that the Participant must provide the Company or any designated third party administrator with a paper copy of any documents if the attempted electronic delivery of such documents fails. The Participant may revoke his or her consent to the electronic delivery of documents described in Section 8(i) of the Plan or may change the electronic mail address to which such documents are to be delivered (if Participant has provided an electronic mail address) at any time by notifying the Company at the e-mail address or physical address provided by the Company for this purpose of such revoked consent or revised e-mail address by postal service or electronic mail. Finally, the Participant understands that he or she is not required to consent to electronic delivery of documents described in Section 8(i) of the Plan.

7.4 **Integrated Agreement.** The Grant Notice, this Option Agreement and the Plan, together with any employment, service or other agreement between the Participant and the Company expressly referring to the Option, shall constitute the entire understanding and agreement of the Participant and the Company with respect to the subject matter contained herein or therein and supersede any prior agreements, understandings, restrictions, representations, or warranties between the Participant and the Company with respect to such subject matter. To the extent contemplated herein or therein, the provisions of the Grant Notice, the Option Agreement and the Plan shall survive any exercise of the Option and shall remain in full force and effect.

7.5 **Applicable Law.** The laws of the State of Delaware will govern all questions concerning the construction, validity and interpretation of this Option Agreement, without regard to that state's conflict of laws rules.

7.6 **Counterparts.** The Grant Notice may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

Exhibit 10.8

BIORA THERAPEUTICS, INC.

NEW HIRE EMPLOYEE NOTICE OF GRANT OF RESTRICTED STOCK UNITS
(2021 Inducement Plan)

The Participant has been granted an award of restricted stock units (the "***RSU Award***") to acquire certain shares of stock of Biora Therapeutics, Inc. (the "***Company***") upon settlement of the RSU Award, pursuant to the Biora Therapeutics, Inc. 2021 Inducement Plan (the "***Plan***"), as follows:

Participant:	
Date of Grant:	
Grant Number:	
Number of Shares Underlying RSU Award:	
Vesting Commencement Date:	The first February 15, May 15, August 15, or November 15 that occurs on or following the one-year anniversary of the Date of Grant.
Vesting Schedule:	25% of the shares of Common Stock subject to the RSU Award shall vest on the Vesting Commencement Date and the remaining 75% of the shares of Common Stock subject to the RSU Award shall vest in equal semi-annual installments of one-eighth (1/8th) of the shares of Common Stock subject to the RSU Award between the Vesting Commencement Date and on or about the fourth anniversary of the Date of Grant, subject to the Participant remaining in Continuous Service on each such date.

By acknowledging and agreeing to the terms of your online grant package, the Company and the Participant agree that the RSU Award is governed by this Grant Notice, the provisions of the Plan and the Restricted Stock Unit Agreement (the "***RSU Agreement***"), which are attached to and made a part of this Grant Notice. In addition, by acknowledging and agreeing to the terms of your online grant package, the Participant: (a) acknowledges receipt of, and represents that the Participant has read and is familiar with the terms and conditions of, this Grant Notice, the RSU Agreement and the Plan, including the tax withholding provisions set forth at Section 3.3 of the RSU Agreement, and hereby authorizes the Company to withhold from the Participant's compensation in accordance with Section 3.3(b), (b) acknowledges and agrees to all of the terms and conditions of the RSU Award as set forth in this Grant Notice, the RSU Agreement and the Plan, (c) agrees to accept as binding, conclusive and final all decisions or interpretations of the Board upon any questions arising under this Grant Notice, the RSU Agreement or the Plan and (d) consents to receive such documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

If you have any questions, please contact the Company by email at stock.administration@bioratherapeutics.com.

Exhibit 10.9

RESTRICTED STOCK UNIT AGREEMENT

Biora Therapeutics, Inc. (the "***Company***") has granted to the Participant named in the *Notice of Grant of Restricted Stock Units* (the "***Grant Notice***") to which this Restricted Stock Unit Agreement (this "***RSU Agreement***") is attached a Restricted Stock Unit Award to acquire a certain number of shares of Common Stock upon the vesting and settlement of such award as set forth in the Grant Notice and this RSU Agreement (the "***RSU Award***"). The RSU Award has been granted pursuant to and shall in all respects be subject to the terms and conditions of the Biora Therapeutics, Inc. 2021 Inducement Plan (the "***Plan***"), the provisions of which are incorporated herein by reference. By accepting the grant, the Participant: (a) acknowledges receipt of, and represents that the Participant has read and is familiar with the terms and conditions of, the Grant Notice, this RSU Agreement and the Plan, (b) acknowledges and agrees to all of the terms and conditions of the RSU Award as set forth in the Grant Notice, this RSU Agreement and the Plan, and (c) agrees to accept as binding, conclusive and final all decisions or interpretations of the Board upon any questions arising under the Grant Notice, this RSU Agreement or the Plan.

1. **DEFINITIONS AND CONSTRUCTION.**

1.1 **Definitions.** Unless otherwise defined herein, capitalized terms shall have the meanings assigned to such terms in the Grant Notice or the Plan.

1.2 **Construction.** Captions and titles contained herein are for convenience only and shall not affect the meaning or interpretation of any provision of this RSU Agreement. Except when otherwise indicated by the context, the singular shall include the plural and the plural shall include the singular. Use of the term "or" is not intended to be exclusive, unless the context clearly requires otherwise.

2. **INDUCEMENT AWARD.** This RSU Award is granted to Participant as a material inducement to the commencement of employment within the meaning of the Listing Rule.

3. **VESTING AND SETTLEMENT OF THE RSU AWARD.**

3.1 **General.** The RSU Award shall vest in accordance with the vesting schedule set forth in the Grant Notice. In the event that the vesting schedule applicable to the RSU Award results in the vesting of a fractional share of Common Stock, the vesting shall be rounded down to the nearest whole share of Common Stock, except at the time that Participant becomes fully vested in the RSU Award, the Participant shall become vested in all remaining unvested shares of Common Stock subject to the RSU Award. Each Restricted Stock Unit represents the right to receive payment on the date it vests in the form of one share of the Company's Common Stock. In no event shall the Participant receive such shares in respected of vested Restricted Stock Units any later than March 15th of the year subsequent to the year of vesting. Prior to actual payment of a share of Common Stock on any vested Restricted Stock Unit, such Restricted Stock Unit will represent an unsecured obligation of the Company, for which there is no trust and no obligation other than to issue shares of Common Stock as contemplated by this RSU Agreement and the Plan.

3.2 **Change in Control.** Upon a Change in Control that occurs while any portion of the RSU Award remains unvested, the RSU Award shall be assumed or an equivalent award substituted by the successor corporation (or a parent thereof) (the "***Acquiror***") and such award shall continue to be subject to the same vesting terms provided under the Grant Notice and this Agreement; provided, that the Participant shall be eligible to receive 100% of the shares of Common Stock then subject to the RSU Award if the Acquiror does not either assume the RSU Award or substitute an equivalent award for the RSU Award and the Board does not take other action provided for under Section 9(c) of the Plan.

3.3 **Tax Withholding.** The Company may, in its sole discretion, satisfy any U.S. federal, state, local, foreign or other tax withholding obligation relating to the vesting, settlement or any other event that triggers a tax liability with respect to the RSU Award by any of the following means or by a combination of such means: (a) causing the Participant to tender, or cause to have tendered, a cash payment, (b) withholding from the Participant's cash compensation from the Company after obtaining the authorization of the Participant, (c) withholding, or causing to have withheld, shares of Common Stock or other securities or other property from the shares of Common Stock, other securities or other property issued or otherwise issuable to the Participant in connection with the settlement of the RSU Award (only up to the amount permitted that will not cause an adverse accounting consequence or cost), or (d) payment from any amounts otherwise payable to the Participant out of proceeds from the sale of shares of Common Stock issued pursuant to the RSU Award under a program established by the Company. Unless otherwise provided by

the Company through action of the Board or Committee or agreement with the Participant, the Company's withholding tax obligations shall generally be satisfied using the approach set forth under (c) or (d) above. None of the Company, its Affiliates, its representatives or agents, or any other person shall have any obligation to deliver shares of Common Stock or other securities or other property, until the tax withholding obligations of the Company have been fully satisfied by the Participant.

3.4 **Beneficial Ownership of Shares; Certificate Registration.** The Participant hereby authorizes the Company, in its sole discretion, to deposit for the benefit of the Participant with any broker selected by the Company, or with the concurrence of the Company, any broker with which the Participant has an account relationship of which the Company has notice, any or all shares of Common Stock acquired by the Participant pursuant to the settlement of the RSU Award. Except as provided by the preceding sentence, a certificate for the shares as to which the RSU Award is settled shall be registered in the name of the Participant, or, if applicable, in the names of the heirs of the Participant (or for any uncertificated shares, such entry shall be made in book-entry form).

3.5 **Fractional Shares.** The Company shall not be required to issue fractional shares of Common Stock upon the settlement of the RSU Award.

3.6 **No Rights as a Stockholder; Spin-Off Participation.**

(a) The Participant shall not be deemed to be the holder of, or to have any of the rights of a holder with respect to, any share of Common Stock subject to the RSU Award, including but not limited to voting rights and rights to dividends and distributions that may become payable to the holders of Common Stock, prior to the time that (i) all vesting conditions set forth in the Grant Notice and this RSU Agreement have been satisfied (i.e., satisfaction of the required period of Continuous Service), (ii) such share of Common Stock has been issued by the Company, and (iii) such issuance of the share of Common Stock subject to the RSU Award has been entered into the books and records of the Company, unless expressly provided herein. Except as provided in Section 3.6(b) below, no dividends, distributions or dividend equivalents shall be credited in respect of shares of Common Stock covered by the RSU Award until the time that such shares of Common Stock have been issued and such issuance has been entered into the books and records of the Company.

(b) In the event that the holders of shares of Common Stock receive as a dividend securities of a subsidiary of the Company (such entity, "***SpinCo***") in a spin-off of all or substantially all of the equity securities of SpinCo held directly or indirectly by the Company (a "***Spin-Off***"), then the Participant shall be eligible to receive a number of shares of restricted common stock of SpinCo equal to (i) the number of shares of Common Stock subject to the portion of the RSU Award that has vested based on Continuous Service as of the effective date of the Spin- Off, *multiplied by* (ii) the number of securities of SpinCo that a holder of one share of Common Stock will receives in the Spin-Off (such restricted common stock of SpinCo, the "***SpinCo Restricted Shares***"). None of the Company, SpinCo or any other person shall have any obligation to settle the SpinCo Restricted Shares until the tax withholding obligations of the Company and/or SpinCo have been satisfied by the Participant. Notwithstanding the foregoing, the Company may, in its sole discretion, determine to provide, or cause to have provided, other equity securities or derivative securities of SpinCo of equivalent value (as determined by the Board) in lieu of the SpinCo Restricted Shares at the time of the Spin-Off. If the Company so determines, references in this RSU Agreement to SpinCo Restricted Shares shall mean such other equity securities or derivative securities of SpinCo.

4. EFFECT OF TERMINATION OF CONTINUOUS SERVICE.

4.1 The following terms shall govern the treatment of the RSU Award upon the Participant's termination of Continuous Service:

(a) **Termination for Cause.** Notwithstanding any other provision of this RSU Agreement, if the Participant's Continuous Service is terminated for Cause, the RSU Award shall terminate in its entirety upon such termination of Service.

(b) **Other Termination of Service.** If the Participant's Continuous Service terminates for any reason (other than for Cause), the Participant shall be eligible to receive the shares of Common Stock subject to the portion of the RSU Award that has vested based on Continuous Service as of the date on which the Participant's Continuous Service terminates. The portion of the RSU Award that remains unvested as of the date on which the Participant's Continuous Service terminates, shall be forfeited and become null and void.

5. **PROHIBITION ON TRANSFER**

The Participant shall not offer, sell, enter a contract to sell, pledge, hypothecate, grant any option to purchase or make any short sale of, or otherwise dispose of or transfer, or attempt to dispose of or transfer, the RSU Award (or any shares of Common Stock subject to the RSU Award) or any rights to acquire stock of the Company or any SpinCo under the RSU Award.

6. **LEGENDS AND PARTICIPANT REPRESENTATIONS.**

6.1 The Company may at any time place legends referencing any applicable federal, state or foreign securities law restrictions, and any other applicable restrictions on all certificates representing shares of stock subject to the provisions of this RSU Agreement. The Participant shall, at the request of the Company, promptly present to the Company any and all certificates representing any shares acquired pursuant to the RSU Award in the possession of the Participant in order to carry out the provisions of this Section.

6.2 **Representations of Participant.** In connection with the grant of the RSU Award hereunder, the Participant represents and warrants to and covenants with the Company as follows:

(a) The shares of Common Stock which are the subject of this RSU Agreement have been acquired by the Participant for investment and not with a view to, or in connection with, the sale or distribution thereof. No such sale or disposition may be effected without an effective registration statement related thereto or an opinion of counsel satisfactory to the company that such registration is not required under the Securities Act.

(b) The Participant has had an opportunity to ask questions and receive answers concerning the terms and conditions of the offering of the RSU Award and has had full access to such other relevant information concerning the Company as the Participant has reasonably requested or as may be legally required.

(c) This RSU Agreement constitutes a legal, valid and binding obligation of the Participant, enforceable as to the Participant in accordance with its terms, except as enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or other laws affecting creditors' rights generally and limitations on the availability of equitable remedies, and the execution, delivery, and performance of the Grant Notice and this RSU Agreement by the Participant does not and will not conflict with, violate, or cause a breach of any agreement, contract, or instrument to which the Participant is a party or any judgment, order, or decree to which the Participant is subject.

(d) The Participant represents that the Participant has not relied on the Company for (i) any representations or warranties, oral or written, by or on behalf of the Company not set forth herein, including any representations and warranties made by its officers, or other representatives or agents, relating to the future performance of the Company or the Common Stock or any Spin-Off, including any projections relating to the value thereof or the likelihood or timing of any Spin-Off, or (ii) any advice regarding the federal, state and local tax consequences of this RSU Agreement and has consulted, and has been fully advised by, the Participant's own tax advisor, regarding the federal, state and local tax consequences of this RSU Agreement and the receipt of the RSU Award.

7. **MISCELLANEOUS PROVISIONS.**

7.1 **Further Instruments.** The parties hereto agree to execute such further instruments and to take such further action as may reasonably be necessary to carry out the intent of this RSU Agreement.

7.2 **Binding Effect.** Subject to the restrictions on transfer set forth herein, this RSU Agreement shall inure to the benefit of and be binding upon the parties hereto and their respective heirs, executors, administrators, successors and assigns.

7.3 **Delivery of Documents and Notices.** Any document relating to participation in the Plan, or any notice required or permitted hereunder shall be given in writing and shall be deemed effectively given upon personal delivery or electronic delivery at the e-mail address, if any, provided by the Company or the Participant to the other party, or, upon deposit in the U.S. Post Office or foreign postal service, by registered or certified mail, or with a nationally recognized overnight courier service with postage and fees prepaid, addressed to the other party at the address of such party set forth in the Grant Notice or at such other address as such party may designate in writing from time to time to the other party. If the Participant does not affirmatively designate a different e-mail address and/or

physical address, the Company may use the Participant's Company e-mail address and may rely upon the use of the most recent address for the Participant in the Company's books and records.

(a) **Description of Electronic Delivery.** The Plan documents, which include the Plan, the Grant Notice, and this RSU Agreement, as well as any reports of the Company provided generally to the Company's stockholders, may be delivered to the Participant electronically. In addition, if permitted by the Company, the Participant may deliver electronically the Grant Notice to the Company or to such third party involved in administering the Plan as the Company may designate from time to time. Such means of electronic delivery may include, but do not necessarily include, the delivery of a link to a Company intranet or the Internet site of a third party involved in administering the Plan, the delivery of the document via e-mail or such other means of electronic delivery specified by the Company.

(b) **Consent to Electronic Delivery.** The Participant acknowledges that the Participant has read Section 8(i) of the Plan ("***Electronic Delivery***") and consents to the electronic delivery of the Plan documents and, if permitted by the Company, the delivery of the Grant Notice, as described in Section 8(i) of the Plan. The Participant acknowledges that he or she may receive from the Company a paper copy of any documents delivered electronically at no cost to the Participant by contacting the Company by telephone or in writing. The Participant further acknowledges that the Participant will be provided with a paper copy of any documents if the attempted electronic delivery of such documents fails. Similarly, the Participant understands that the Participant must provide the Company or any designated third party administrator with a paper copy of any documents if the attempted electronic delivery of such documents fails. The Participant may revoke his or her consent to the electronic delivery of documents described in Section 8(i) of the Plan or may change the electronic mail address to which such documents are to be delivered (if Participant has provided an electronic mail address) at any time by notifying the Company at the e- mail address or physical address provided by the Company for this purpose of such revoked consent or revised e-mail address by postal service or electronic mail. Finally, the Participant understands that he or she is not required to consent to electronic delivery of documents described in Section 8(i) of the Plan.

7.4 **Integrated Agreement.** The Grant Notice, this RSU Agreement and the Plan, together with any employment, service or other agreement between the Participant and Company expressly referring to the RSU Award, shall constitute the entire understanding and agreement of the Participant and the Company with respect to the subject matter contained herein or therein and supersede any prior agreements, understandings, restrictions, representations, or warranties between the Participant and the Company with respect to such subject matter. To the extent contemplated herein or therein, the provisions of the Grant Notice, the RSU Agreement and the Plan shall survive any settlement of the RSU Award and shall remain in full force and effect.

7.5 **Applicable Law.** The laws of the State of Delaware will govern all questions concerning the construction, validity, and interpretation of this RSU Agreement, without regard to that state's conflict of laws rules.

7.6 **Counterparts.** The Grant Notice may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

Exhibit 21.1

Subsidiaries of Biora Therapeutics, Inc.

Avero Laboratory Holdings LLC, a Delaware limited liability company

Biora Therapeutics UK Limited, a private limited company incorporated in the United Kingdom

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the registration statements (Nos. 333-246343 and 333-263911) on Form S-8, and in the registration statement (Nos. 333-258301 and 333-269446) on Form S-3, and in the registrations statements (Nos. 333-254471 and 333-257187) on Form S-1 of our report dated March 30, 2023, with respect to the consolidated financial statements of Biora Therapeutics, Inc. Our report contains an explanatory paragraph that states that the Company has suffered recurring losses from operations and has an accumulated deficit that raises 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
March 30, 2023

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Aditya P. Mohanty, certify that:

1. I have reviewed this Annual Report on Form 10-K of Biora Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 30, 2023

By: /s/ Aditya P. Mohanty

Aditya P. Mohanty, Chief Executive Officer
(principal executive officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Eric d'Esparbes, certify that:

1. I have reviewed this Annual Report on Form 10-K of Biora Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 30, 2023

By: /s/ Eric d'Esparbes

Eric d'Esparbes, Chief Financial Officer
(principal financial and accounting officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Biora Therapeutics, Inc. (the "Company") for the year ended December 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 30, 2023

By: /s/ Aditya P. Mohanty

Aditya P. Mohanty, Chief Executive Officer
(principal executive officer)

By: /s/ Eric d'Esparbes

Eric d'Esparbes, Chief Financial Officer
(principal financial and accounting officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. §1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Note: A signed original of this written statement required by §906 has been provided to Biora Therapeutics, Inc. and will be retained by Biora Therapeutics, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.