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, 2023

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, 2023, was approximately $38,960,310.

The number of shares of registrant's Common Stock outstanding as of March 20, 2024 was 30,313,428.

DOCUMENTS INCORPORATED BY REFERENCE

None

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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 effected 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 continue operations in view of our limited capital resources as disclosed in this Annual Report and our ability to maintain compliance with the continued listing requirements of the Nasdaq Global Market ("Nasdaq");
- the beneficial characteristics, safety, efficacy and therapeutic effects of our product candidates;
- our plans and ability to successfully research, develop and commercialize new products and product candidates;
- the success, cost and timing of our preclinical and clinical development activities and planned clinical trials;
- 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 product candidates 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 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 controls;
- 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.

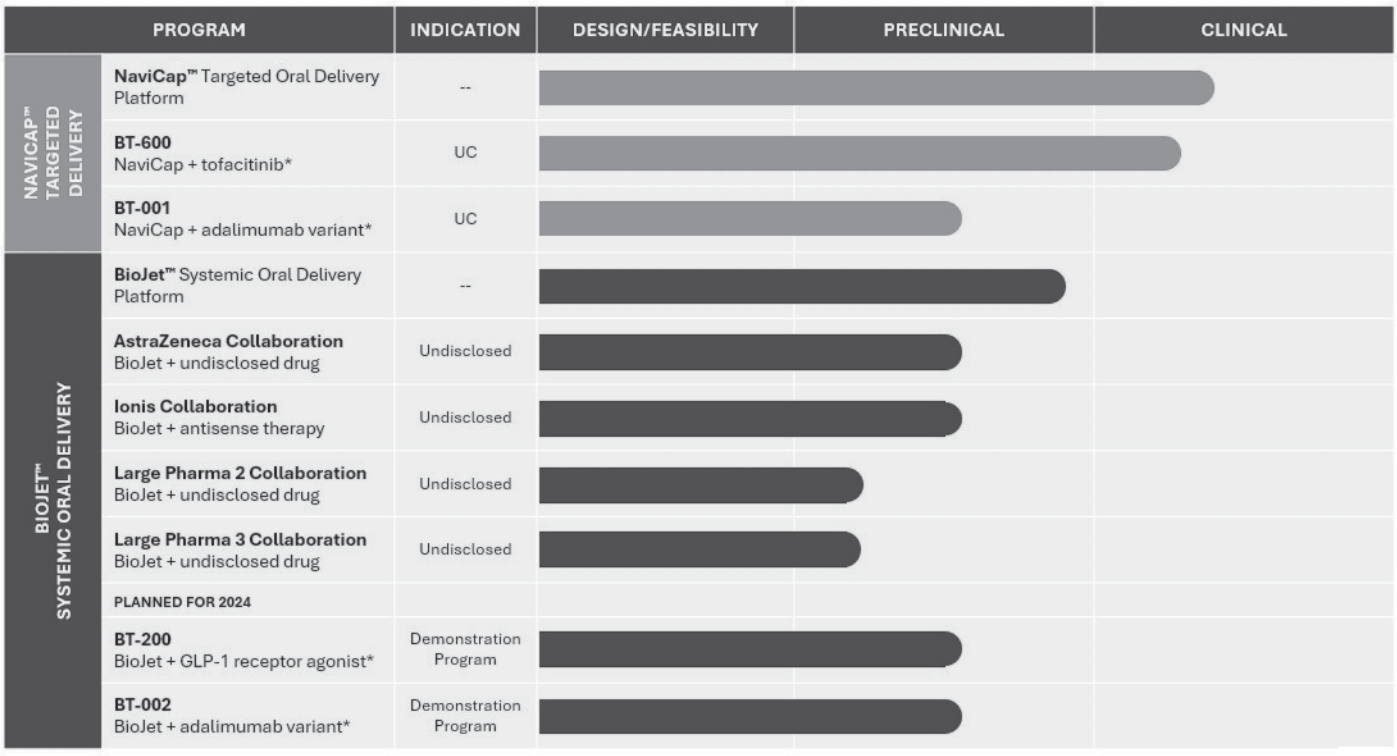
Item 1. Business.

Overview

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

- **NaviCap™ Targeted Oral Delivery Platform**: 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**: Designed to replace injection with needle-free, oral delivery of large molecules for better management of chronic diseases.

Our mission is to reimagine therapeutics and their delivery. By creating innovative smart pills designed for targeted drug delivery to the GI tract and systemic, needle-free delivery of biotherapeutics, we are developing therapies intended to improve patients' lives. Our therapeutic pipeline is shown below.



*Biora's own molecules

NaviCap™ Targeted Oral Delivery Platform

Overview

Our NaviCap platform is an ingestible smart capsule designed to deliver drugs to the site of disease in the GI tract to improve treatment of IBD. The NaviCap platform utilizes a novel therapeutic approach that is designed to overcome the limitations of current treatments by maximizing the available dose at the site of disease while reducing systemic toxicity.

Using this platform, we are developing a pipeline of investigational drug-device combinations that utilize an ingestible smart capsule for targeted delivery of therapeutics in the GI tract. We have two programs, BT-600 (NaviCap + tofacitinib) and BT-001 (NaviCap + variant of adalimumab). Both tofacitinib and adalimumab have been approved for the treatment of ulcerative colitis ("UC"), a type of

IBD, but are dose limited by safety concerns at higher doses. Existing research, including research we have generated, suggests that efficacy may be limited by insufficient drug reaching diseased tissue in the colon.

We believe our technology has the potential to:

(1) achieve sufficient therapeutic amounts of these drugs through local delivery to the site of inflammation in the GI tract, potentially improving outcomes for patients suffering from UC;

(2) enable administration of lower doses of drug, potentially reducing the severe adverse event profiles seen with some of these therapeutics; and

(3) enable the use of combination therapy in IBD, by reducing systemic drug exposure and improving safety, in order to target multiple pathways of disease.

Unmet Need

Inflammatory Bowel Disease

IBD is a heterogeneous group of inflammatory disorders of the GI tract, and broadly includes two major disorders: Crohn's disease and UC. According to the Crohn's & Colitis Foundation ("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 immune system, which normally protects the body from external invaders like bacteria and viruses, becomes dysregulated in patients with IBD, causing 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.

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. We estimate the IBD therapeutics market to be in excess of $15 billion.

Ulcerative Colitis

The CCF estimates that UC affects nearly one million Americans. UC is characterized by inflammation and ulceration of the mucosal lining of the colon. The typical symptoms include diarrhea, bleeding and abdominal pain. In more severe cases, there can be large amounts of blood loss, which can be life-threatening and may require emergency surgery.

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 remain poor, with few patients achieving long-term remission. Data suggests that only 15 to 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 conjunction with our academic collaborators, we presented 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.

NaviCap Targeted Oral Delivery Device

The NaviCap device is an investigational, clinical-stage, single-use ingestible device that has a drug capacity of up to 500µL with an outer casing made of inert material. The device is approximately the size of a fish-oil capsule and is rounded for ease of swallowing. Once swallowed, the device is designed to autonomously identify specific locations in the GI tract and release a therapeutic dose at a determined location that can act locally in the GI tract, thereby potentially limiting systemic absorption and the associated toxicity effects.

NaviCap device

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 within 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.

Clinical Device Function Studies

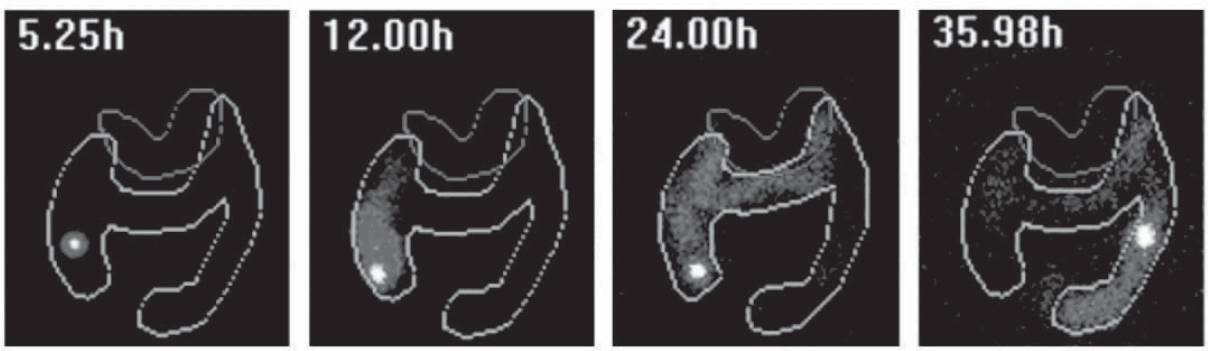
We have conducted four separate clinical device function studies to evaluate the function of the NaviCap device in humans, with approximately 50 study participants receiving over 80 NaviCap devices. The NaviCap device has demonstrated a favorable safety profile and high accuracy rate in identifying entry into the colon in both normal healthy volunteers and in patients with active UC.

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

We conducted a clinical device function 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.

PM-602 Device function study in patients with active UC

In this clinical device function 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 its liquid payload and achieved distribution across the colon. The scintigraphic images below are taken from a subject in the study. They demonstrate release in the first part of the colon and eventual distribution of the radioisotope to the entire colon. This study was funded in part by the CCF.



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

In this clinical device function 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. All analyzed devices (39/39) successfully identified entry to the colon in all fasted/fed schedules, and 97.4% of analyzed devices (38/39) activated the payload release function. This study confirmed that the potential effect of food on the function of the NaviCap device is minimal.

BT-603 Device function study in healthy volunteers – fasted state

In this clinical device function study, we evaluated the performance in healthy volunteers of the NaviCap device that we intend to use in a Phase 1 trial using scintigraphic imaging. Results indicated that 94% of devices (15/16) accurately identified entry into the colon, triggered release of its liquid payload, and achieved distribution across the entire colon.

NaviCap Programs

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

Our lead program for the NaviCap platform is BT-600 (formerly known as PGN-600). We are developing BT-600 as a drug-device combination product that includes an orally delivered liquid formulation of tofacitinib for the treatment of UC. Tofacitinib is approved for the treatment of UC and is dose-limited based on safety concerns, making it an ideal therapy for targeted delivery.

Clinical Trials

In 2023, we submitted an Investigational New Drug (IND) application for BT-600 to the U.S. Food and Drug Administration ("FDA"), and the FDA cleared our IND application in late 2023. In January 2024, we initiated a Phase 1 trial of BT-600 in healthy volunteers.

The objectives of this Phase 1 randomized, double-blind, placebo-controlled, single and multiple ascending dose clinical trial are to evaluate the safety, pharmacokinetics ("PK") and pharmacodynamics, including effects on colon tissue, of BT-600 when administered orally in healthy adult volunteers. The trial, which is being conducted in the United States, consists of two parts. The first is a single-dose ascending cohort comprised of 24 participants receiving BT-600 with tofacitinib at 5 mg and 10 mg doses or placebo. The second is a multiple-dose ascending cohort comprised of 24 participants receiving BT-600 with tofacitinib at 5 mg and 10 mg doses or placebo.

The clinical trial is currently in progress, and results will be presented upon completion of the trial. The single ascending dose cohort was completed in February 2024, and we shared key results from the interim analysis in the Company's 8-K filed on March 26, 2024. Based on what has been observed preclinically, we anticipate increased colonic tissue drug levels and reduced systemic levels compared with conventional oral tofacitinib. Given the known efficacy of the currently approved doses of tofacitinib, BT-600 has the potential to improve the management of UC in patients.

Preclinical Studies

Our data generated in animal models of colitis demonstrated 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 the NaviCap device. 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.

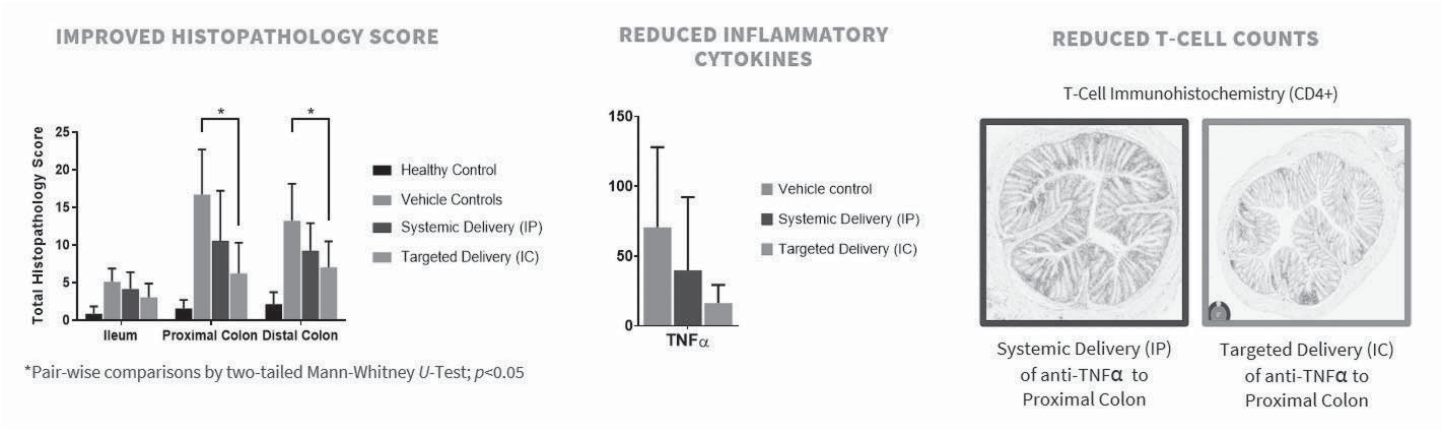
Results of the study demonstrated that BT-600 was well tolerated with a favorable safety profile and that when tofacitinib was delivered to the colon, drug levels in blood were reduced compared to oral tofacitinib tablets. In addition, tissue drug levels were at least 25 times higher along the length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

To support our IND filing for BT-600, we subsequently completed a 14-day preclinical toxicology study of BT-600 in a canine model comparing 14-day daily administration of 10 mg of liquid formulation of tofacitinib delivered via NaviCap (BT-600) versus placebo delivered via NaviCap. Over 600 devices were administered and no safety signals were observed.

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.

BioJet Systemic Oral Delivery Platform

The BioJet systemic oral delivery platform is a novel platform for needle-free delivery of therapeutics that would otherwise require injection. Biora's novel approach to oral delivery of large molecules uses an ingestible capsule designed for needle-free, liquid jet injection of a liquid drug formulation into the tissue of the small intestine where it can be absorbed systemically.

The BioJet platform includes drug-device combination programs designed to achieve systemic bioavailability and replace injection for better management of chronic diseases. This technology has the potential to deliver a range of molecules, including proteins, peptides, and nucleic acids.

We believe oral, systemic delivery of large molecules has the potential to:

(1) improve patient convenience and therefore patient compliance through the more desirable oral route of administration, thus improving healthcare outcomes;

(2) improve drug efficacy and safety through more frequent administration of lower doses, compared to current weekly or monthly injection regimens; and

(3) help biotherapeutics become more competitive with small molecules, expanding the market for these drugs across a range of chronic use indications.

Unmet Need

Over the past two decades, biologic drugs have become the standard of care for a variety of diseases, including rheumatoid arthritis, psoriasis, diabetes, obesity, Crohn's disease, UC and a range of cancers. To reduce injections, many biologics have been developed for less frequent dosing, such as weekly or monthly injections; however, this means larger amounts of the 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.

There is also 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 glucagon-like-peptide 1 ("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.

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 achieve limited bioavailability, with less than 1% achieved in commercial products.

The BioJet Systemic Oral Delivery Device

The BioJet platform uses an ingestible device designed to transit through the digestive system and activate in the small intestine, where liquid jets deliver drug directly into small intestinal tissue for uptake into systemic circulation.

The BioJet device is a mechanical device that is designed for economical production at scale. The device is approximately the size of a multivitamin and is shaped like a standard capsule for ease of swallowing. It is made of an inert, biocompatible material with a liquid reservoir that can hold 300-400µL with low retained volume (less than 10µL), which protects the drug from stomach acids and proteolytic enzymes. The large payload provides the ability to dose in multi-milligram concentrations, and the use of liquid formulation reduces or eliminates the need for reformulation, making the platform broadly applicable to a wide range of molecules.

Upon reaching the small intestine, an enteric trigger degrades, activating the liquid jet formation and delivery. The device uses liquid jet delivery to deliver the liquid drug into the submucosal layer of the small intestine, where it can be rapidly taken up into systemic circulation.

BioJet Systemic Oral Delivery Device

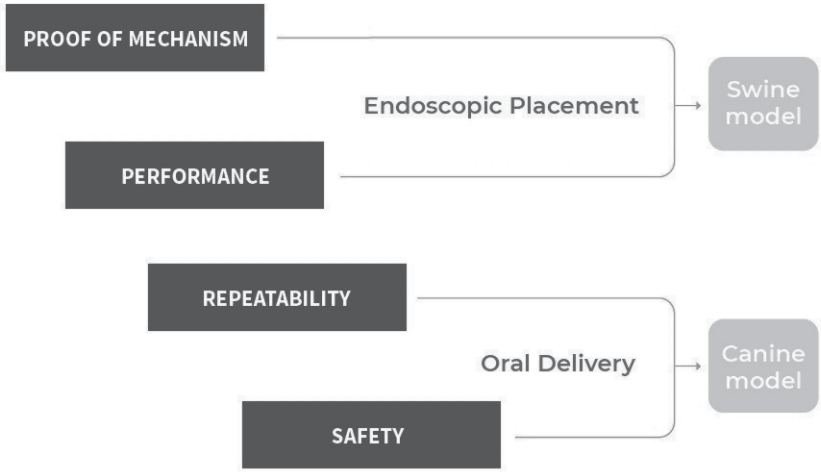
Preclinical Model Selection for Translational Research

We utilize two different animal models for translational research with the BioJet platform: canine and swine.

Although the canine is a preferred model for oral therapeutic evaluation, anatomical differences between the canine and human small intestine make the canine model suboptimal for the evaluation of liquid jet injection to the small intestine (*e.g.*, determining drug bioavailability). Instead, due to the canine's similar GI transit and motility to human, its consistent and controllable gastric emptying, and the ease of oral dosing, the canine model is used specifically for evaluation of safety and oral delivery functionality, including consistency and repeatability.

A swine model was chosen to better represent the PK properties of submucosal injection in humans, due to its similar anatomical and histological features in the small intestine. The anatomy of the swine stomach requires endoscopic placement of the device, which, once released, can naturally transit, autonomously trigger and deploy.

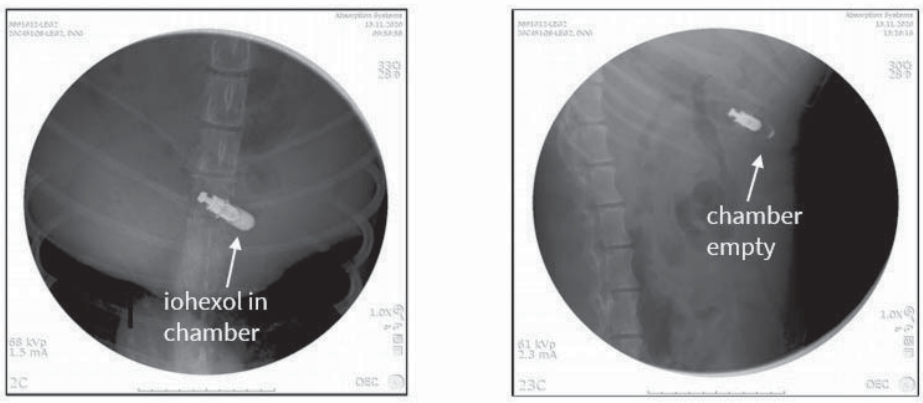
Our preclinical model selection is depicted in the diagram below.



Preclinical Device Function Studies

In 2022, we conducted a preclinical study to evaluate the performance and assess the autonomous trigger function of the BioJet device in a canine model, which was presented as a poster at the Parenteral Drug Association Universe of Pre-Filled Syringes and Injection Devices Conference in October 2022. The study was a single-dose study evaluating safety and tolerability of the device in addition to the ability of the device to autonomously actuate in the small intestine. We evaluated device function by loading BioJet devices with a contrast agent (iohexal) and sequentially imaged post-administration as the device transited through the body to show device deployment time and location in the intestine.

This study demonstrated that the BioJet device can reliably deploy in the small intestine, which supports oral administration of the device. 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.



Research Collaborations

Our strategy is to partner with third parties to 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 multiple ongoing research collaborations with pharmaceutical

companies. As we advance development of the BioJet platform, we intend to expand our existing collaborations and pursue additional partnership opportunities with pharmaceutical companies.

AstraZeneca

We have an ongoing research collaboration with AstraZeneca, which was previously referred to as "Large Pharma 1." In January 2024, we announced that the BioJet platform met key performance milestones as part this research collaboration using AstraZeneca's undisclosed molecule. In a preclinical study, we assessed the bioavailability of the molecule when delivered via the BioJet platform in a porcine model, with comparison to subcutaneous administration. BioJet devices were administered endoscopically, which is typical in a porcine model, and released for autonomous actuation. The results met performance targets set by us and our collaborator of (i) greater than 25% bioavailability compared to subcutaneous delivery and (ii) less than 50% coefficient of variation.

Ionis Pharmaceuticals

We have been conducting preclinical research under a research collaboration agreement that provides funding to test the BioJet platform's ability to deliver antisense oligonucleotides. A key interest with this molecule type is the ability to demonstrate the potential of the BioJet platform to achieve uptake of large molecules into the liver. Many disease targets reside in the liver, and it is a key area of focus for RNA-based therapeutics, which include antisense oligonucelotides as well as siRNA-based therapeutics. These large molecules must typically be delivered via intravenous ("IV") or subcutaneous injection; however, the majority of the drug is metabolized before reaching the liver.

The BioJet platform uses liquid jet injection into the small intestine, which is an optimal delivery pathway to the liver, via the hepatic portal system. Results of this research, which have not been released, indicate the BioJet platform's potential to provide a unique advantage for liver-targeted, oral delivery of large molecules.

Other Research Collaborations

We also have research collaborations with two other undisclosed large pharmaceutical companies. We refer to these collaborators as Large Pharma 2 and Large Pharma 3. These research collaborations provide funding to test the BioJet platform's ability to achieve bioavailability through oral delivery of the collaborators' molecules via liquid jet delivery to the small intestine in animal models.

Demonstration Programs

We have two demonstration drug-device combination programs for the BioJet platform, BT-200 (GLP-1 receptor agonist) and BT-002 (adalimumab variant).

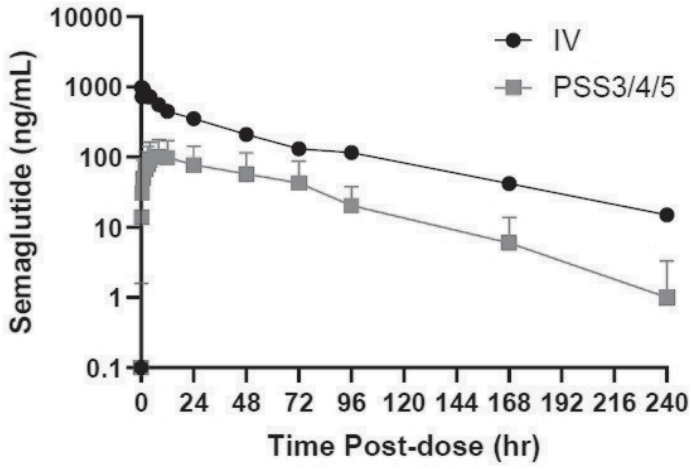
BT-200: Liquid formulation of a GLP-1 receptor agonist delivered via BioJet for the treatment of type 2 diabetes

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. GLP-1 receptor agonists stimulate insulin secretion and suppress glucagon release. We believe oral GLP-1 receptor agonists will be preferred by patients to injectables, resulting in a significant market opportunity.

In October 2023, we presented data at the European Association for the Study of Diabetes from three preclinical studies to assess the bioavailability of semaglutide when delivered via liquid jet technology in a porcine model. Semaglutide is a GLP-1 receptor agonist currently used to treat type 2 diabetes and for weight management via subcutaneous injection or taken orally. The studies included single, approximately 1 mg doses of semaglutide in a liquid formulation delivered via the BioJet device. Devices were administered endoscopically, and then released for autonomous activation. Blood sampling was performed from zero to 240 hours post-dose, with comparison to a control animal with drug administered intravenously.

Across the three studies, 96% of animals showed semaglutide in systemic circulation at clinically relevant levels for up to ten days following administration. Among the 22 animals dosed with semaglutide, oral bioavailability averaged 20.5% ± 15.3%, compared to IV control.

The PK data obtained across the three studies (PSS3, PSS4, and PSS5) is shown compared to IV administration in the graph below.

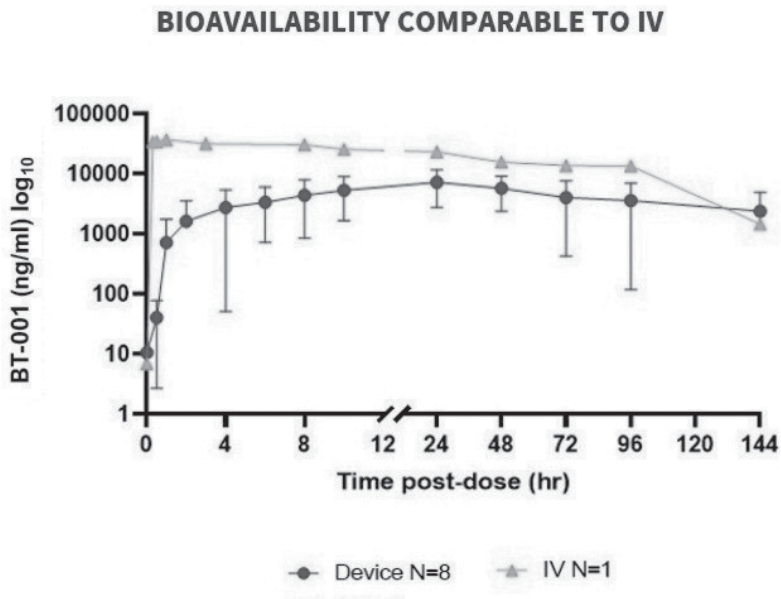


BT-002: Liquid formulation of adalimumab delivered via BioJet for the treatment of autoimmune conditions

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. 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. We estimate the market for monoclonal antibodies to be over $100 billion alone. An oral variant of adalimumab may represent a significant market opportunity due to the many patients who would like to avoid painful injections. BT-002 is currently in preclinical development with a liquid formulation of adalimumab that we have developed and scaled to GMP-grade material.

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. Using the BioJet device, 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. 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.

The PK data obtained with BT-002 is illustrated in the graph below.



GI Sampling and Diagnostics

We have previously developed two additional ingestible devices focused on GI sampling and diagnostics. These platforms use our GItrac™ autonomous location technology, which is also part of the NaviCap platform, which is designed to autonomously identify key regions of the GI tract. GItrac is based on a proprietary LED light and photodetector sensor array that detects reflected light within the GI tract and uses a proprietary algorithm to determine anatomical locations of interest, such as the pyloric and ileocecal transition.

Our **Recoverable Sampling System** ("RSS") platform is an ingestible 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** platform is an ingestible 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.

The RSS and PIL Dx platforms are not in active development, but we 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.

NaviCap Platform 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, including, but not limited to, AbbVie, Eli Lilly, Galapagos, Gilead, J&J, Pfizer, Protagonist, Roche, Takeda, and UCB.

BioJet Platform 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 an in-house, 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, which enables us to leverage existing knowledge to solve new challenges. Our R&D team is comprised of over 35 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 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 over 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 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 seek opportunities to increase market penetration, such as expanding the portion of the population that can be treated, because our targeted therapeutics may have lower systemic toxicity and may provoke lower immunogenicity.
- ***Develop and commercialize a disruptive pipeline of drug-device combination products***. Leveraging our novel technologies and platforms, we are developing drug-device combinations that address the unmet medical needs of patients with GI disorders and beyond. 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 initially pursue only 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 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 create sustainable and scalable platforms for development of 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 paradigms 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 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 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 products we are currently developing or may develop in the future. 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 ingestible product candidates 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 (the "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. The 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 the 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 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. The 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, the 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 certain 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, 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 civil penalties and/or 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. For certain medical devices, the transition period was extended, ending between December, 31, 2026 and December 31, 2028, depending on the class of the device and the fulfillment of certain additional conditions. (Regulation (EU) 2023/607). 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.

Drugs and biologics are regulated under the FD&C Act and, for biologics, the Public Health Service Act ("PHSA"). Generally, a new drug may be marketed in the United States only if the 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") regulations, 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;
- manufacture of the proposed drug or biologic candidate in accordance with current good manufacturing practice ("cGMP");
- performance of adequate and well-controlled clinical trials in accordance with the FDA's GCP requirements and other applicable regulations to establish the safety, purity and potency of the proposed biologic, and the safety and efficacy of the proposed drug for each indication;
- preparation of and submission to the FDA of a BLA or NDA after successful completion of all pivotal clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of an NDA or BLA to file the application for substantive review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product candidate is produced to assess cGMP and to assure that the facilities, methods and controls are adequate for manufacturing of the drug or biologic according to its specifications; and
- FDA review and approval of the BLA or NDA prior to any commercial marketing or sale of the biologic or drug product in the United States.

Preclinical Testing

Before testing any compound or biologic in human subjects in the United States, we must generate extensive preclinical data. Preclinical testing generally includes laboratory evaluation of product chemistry and formulation, as well as toxicological and

pharmacological studies in several animal species to assess the quality and safety of the product candidate. Certain animal studies must be performed in compliance with the FDA's GLP regulations and the U.S. Department of Agriculture's Animal Welfare Act.

IND Submission

Human clinical trials for drugs or biologics in the United States cannot commence until an IND is submitted and becomes effective. A company must submit preclinical testing results, together with manufacturing information and analytical data, to the FDA as part of the IND, and the FDA must evaluate whether there is an adequate basis for testing the drug in initial clinical studies in human volunteers. The sponsor will also include a protocol detailing, among other things, the objectives of the initial clinical trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated, if the initial clinical trial lends itself to an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to the proposed clinical studies. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before clinical studies can begin. Once human clinical trials have commenced, the FDA may stop the clinical trials by placing them on partial or full "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.

A sponsor may choose, but is not required, to conduct a foreign clinical study under an IND. When a foreign clinical study is conducted under an IND, all IND requirements must be met unless waived. When the foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with certain FDA regulatory requirements in order to use the study as support for an IND or application for marketing approval or licensure, including that the study was conducted in accordance with GCP, including review and approval by an independent ethics committee and use of proper procedures for obtaining informed consent from subjects, and the FDA is able to validate the data from the study through an onsite inspection if the FDA deems such inspection necessary. The GCP requirements encompass both ethical and data integrity standards for clinical studies.

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 data 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 there is evidence that it would be 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. Under the Food and Drug Omnibus Reform Act of 2022, the FDA may require, as appropriate, that such studies be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated 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. The FDA also has increased authority for expedited procedures to withdraw approval of a product or indication approved under accelerated approval if the sponsor fails to conduct the required post-marketing studies or if such studies fail to verify the predicted clinical benefit. 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"), and is equivalent to the RLD with respect to the active ingredients, the route of administration, the dosage form, quality and performance characteristics, the strength of the drug, and intended use. 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 (the "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.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 ("CTIS"). The CTR includes a three-year transition period. Member states will work in CTIS immediately after the system has gone live. Since January 31, 2023, submission of initial clinical trial applications via CTIS is mandatory, and by January 31, 2025, all ongoing trials approved under the former Clinical Trials Directive will need to comply with the CTR and must be transitioned to CTIS.

The requirements and process governing the conduct of clinical trials, product licensing, pricing, and reimbursement may 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.

The 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, the 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, the 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 the FDA approval of a combination product. In December 2020, the FDA issued final guidance on how sponsors of combination products can obtain feedback from the FDA on scientific and regulatory questions pertaining to the combination product. In January 2022, FDA issued a final guidance document on principles for premarket pathways for combination products. FDA has issued, and will continue to issue, guidance documents on the premarket and postmarket regulatory requirements applicable to combination products.

After issuing marketing authorizations, the FDA has discretion in determining post-approval compliance requirements for combination products and could thus require compliance with certain cGMP requirements as well as QSR requirements for device components of a combination product. Other post-market requirements analogous to those described above for medical devices and

drugs/biologics will also apply, depending on the application type and center overseeing regulation of the combination product, including:

- post-market adverse event and medical device reporting requirements;
- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label uses;
- advertising and promotion requirements;
- restrictions on sale, distribution or use of the product;
- requirements for recalls being conducted and recall reporting;
- product tracking requirements;
- post-market surveillance or clinical trials; and
- other record-keeping requirements.

Patent Term Restoration

Some of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND or IDE and the submission date of an NDA, BLA, or PMA, plus the time between the submission date and the approval of that application. Only one patent applicable to an approved product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. Thus, for each approved product, we may apply for restoration of patent term for one of our related owned or licensed patents to add patent life beyond the original expiration date, depending on the expected length of the clinical studies and other factors involved in the filing of the relevant NDA, BLA or PMA.

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 and collaborators. 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, 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.

Moreover, various state and non-U.S. laws and regulations, such as California's Confidentiality of Medical Information Act, the California Consumer Privacy Act of 2018 (the "CCPA"), as amended by the California Privacy Rights Act of 2020 (the "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 California's Confidentiality of Medical Information Act, or may be jurisdictionally limited), can result in investigations, proceedings, or in the imposition of significant civil and/or criminal penalties, private litigation and injunctive restrictions on data processing. Privacy and security laws, regulations, and other obligations are constantly evolving, and we could be exposed to additional obligations, further complicating compliance efforts.

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, (the "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.

There has been increased attention to privacy and data protection issues in the EU as well, 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. 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. Regarding data transfers to the United States, the European Commission published an adequacy decision and the new EU-U.S. Data Privacy Framework entered into force on June 10, 2023. However, the adequacy decision only covers data transfers to U.S. companies which are certified under the EU-U.S. Data Privacy Framework.

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, 2023, we had 58 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 ("CLIA") and College of American Pathologists ("CAP") certified laboratory located in Michigan specializing in the molecular testing markets serving women's health providers in the obstetric, gynecological, fertility, and maternal fetal medicine specialty areas in the United States. Previously, this core laboratory 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 affiliated Avero laboratory business in December 2021, together referred to as the Laboratory Operations. We have reported all revenues and expenses associated with our Laboratory Operations as discontinued operations in the consolidated financial statements. See Note 3 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. In November 2022, we licensed the Preecludia™ test to Northwest Pathology, doing business as Avero Diagnostics 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. In May 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 and subsequently, in March 2024 we sold that minority ownership stake.

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 2022 and 2023 in connection with the reimbursement for tests that were run prior to the closure of our Ann Arbor lab through September 2022.

Discontinued Laboratory Operations Payor Dispute

On November 16, 2020, we received a letter from Anthem, Inc. ("Anthem"), informing us that Anthem was 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 disputed 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, and during the year ended December 31, 2023 for the remainder 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, expect to incur losses in the future, have limited capital resources as disclosed in this Annual Report, and may not be able to continue operations or 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. An adverse judgment and/or significant damage award against us resulting from our pending litigation matters that we are currently defending would negatively impact our financial position and our ability to raise additional capital. 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.
- New 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.
- We may fail to qualify for continued listing on Nasdaq , which could make it more difficult for our stockholders to sell their shares.

Risks Related to Our Business and Industry

We have incurred losses in the past, expect to incur losses in the future, have limited capital resources as disclosed in this Annual Report, and may not be able to continue operations or 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 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, and expect to incur losses in the future. 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 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.

Given our limited capital resources as disclosed elsewhere in the Annual Report, if we are not able to raise additional capital or generate revenue to fund our operations, we may not be able to continue operations or 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. An adverse judgment and/or significant damage award against us resulting from our pending litigation matters that are currently defending would negatively impact our financial position and our ability to raise additional capital. 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 substantially eliminated. 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 sales and marketing efforts;
- pending and potential litigation and any resulting adverse judgments, damages, awards or liabilities, potential payor recoupments of reimbursement amounts as related to our historical testing business, 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. Our ability to raise capital in the public capital markets, including through “at the market” offerings pursuant to our At Market Issuance Sales Agreement with B. Riley Securities, Inc., BTIG, LLC, and H.C. Wainwright & Co. LLC (the "ATM Facility"), may be limited by, among other things, SEC rules and regulations impacting the eligibility of smaller companies to use Form S-3 for primary offerings of securities. Although alternative public and private transaction structures may be available, these may require additional time and cost, may impose operational restrictions on us, and may not be available on attractive terms.

Furthermore, any additional capital raised through the sale of equity or equity-linked securities, including through our ATM Facility, 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 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.

In May 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, in November 2022, we announced that we had signed an agreement to license our Preecludia™ rule-out test for preeclampsia to Northwest Pathology, doing business as Avero Diagnostics ("Northwest") for commercial development in exchange for commercial milestone payments and royalties on net sales. There is no assurance that Northwest 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 R&D 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 R&D 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. For more information on our current R&D efforts, see Part I, Item 1. "Business."

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 R&D 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 two therapeutic platforms that use ingestible drug-device combination products. However, medical device and related 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.

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, 2023, we had a face value of approximately $51.1 million of convertible notes outstanding. Certain of our debt agreements contain various restrictive covenants.

The indentures for our Convertible Notes prohibit us and 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 subordinated indebtedness for borrowed money that, in an aggregate principal amount (or accredited value, as applicable), does not exceed $10.0 million at any time outstanding.

Accordingly, we may incur 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, such as California's Confidentiality of Medical Information Act, 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, depending on the information at issue, comprehensive state privacy laws may apply as well, such as 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. Various state data breach laws may require additional notification requirements in the event of a breach, as well, depending on the types of information accessed without authorization.

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 now discontinued 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, R&D 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, personal 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 R&D activities, develop and commercialize products, collect, process and prepare company financial information, provide information about products, 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 personal 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 R&D 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 with respect to 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 preclinical research and 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 R&D 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
- 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 product 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.

Disruptions at the FDA, the SEC and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review regulatory filings and our ability to commence human clinical trials can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC, and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for the review and approval of INDs, which would adversely affect our business. For example, in recent years, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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 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 conflicts between Russia and Ukraine and among Israel and surrounding areas) 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, 2023, we had net operating loss ("NOL") carryforwards of approximately $500.3 million for federal income tax purposes, and $218.6 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 9 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, after the closure of our Laboratory Operations, we received several managed Medicaid payor recoupment requests aggregating to $1.1 million, which we dispute. 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/or patient specimens 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 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 or our potential partners are unable to obtain or maintain coverage or adequate reimbursement from, or achieve in-network status with, third-party payors for our future products, our ability to generate revenues will be limited. For example, healthcare providers

may be reluctant to prescribe our 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 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 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 Note 9 to our consolidated financial statements included elsewhere in this Annual Report. 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. For example, 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.

Our internal information technology systems, or those of any of our third party service providers, or potential future collaborators, may fail or suffer security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations.

In the ordinary course of our business, we and the third parties upon which we rely collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) proprietary, confidential, and sensitive data, including personal data, intellectual property, trade secrets, and other sensitive data (collectively, sensitive information). We may implement a variety of security measures designed to protect systems that store our information, given their size and complexity and the increasing amounts of information maintained on our internal information technology systems and those of our third-party service providers and supply chain companies, and consultants, these systems are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners and/or other third parties, or from cyber-attacks by malicious third parties, which may compromise our system infrastructure or lead to the loss, destruction, alteration or dissemination of, or damage to, our data.

Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, and the third parties upon which we rely, may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services. In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

To the extent that any disruption or security breach were to result in loss, destruction, unavailability, alteration or dissemination of, or damage to, our data or applications, or for it to be believed or reported that any of these occurred, we could incur liability and reputational damage and the development and commercialization of our programs could be delayed. Further, our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption in, or failure or security breach of, our systems or third-party systems where information important to our business operations or commercial development is stored.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We may be unable in the future to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences.

We rely on third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may cause stakeholders (including investors and potential customers) to stop supporting our platform, deter new customers from products, and negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

Risks Related to Our Intellectual Property

New 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, 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 Note 9 to our consolidated financial statements included elsewhere in this Annual Report for more information regarding a patent infringement suit filed by Ravgen, Inc. related to our discontinued historical 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 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 judgment 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, pharmaceutical or medical device 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:

- 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 Nasdaq, which could make it more difficult for our stockholders to sell their shares.

We are required to satisfy the continued listing requirements of Nasdaq to maintain such listing, including, among other things, the maintenance of a market value of our common stock of at least $50 million.

For example, on December 11, 2023, we received formal notice from Nasdaq indicating that we no longer satisfy the $50 million market value of listed securities requirement for continued listing on Nasdaq (the "MVLS Rule"). In accordance with Nasdaq Listing Rule 5810(c)(3)(C), we will have 180 calendar days, or until June 10, 2024 (the "Compliance Date"), to regain compliance with the MVLS Rule. To regain compliance with the MVLS Rule, our MVLS must equal or exceed $50 million for a minimum of ten consecutive business days at any time prior to the Compliance Date. If we regain compliance with the MVLS Rule, Nasdaq will provide us with written confirmation and will close the matter.

If we do not regain compliance with the MVLS Rule by the Compliance Date, we will receive written notification that our securities are subject to delisting. At that time, we may appeal the delisting determination to a Hearings Panel or we may be eligible to transfer the listing of our securities to The Nasdaq Capital Market (provided that we then satisfy the requirements for continued listing on that market).

There can be no assurance that we will be able to regain 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 meet the standards for continued listing on Nasdaq within the compliance period. In the event that we do not regain compliance with the Nasdaq Listing Rules, 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;
- an adverse effect on the market price of our common stock;
- loss of confidence from stakeholders, employees, and potential business partners;
- 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 indentures governing our outstanding Convertible Notes could delay or prevent an otherwise beneficial takeover of us.

Certain provisions in our Convertible Notes and the indentures 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 indentures 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 indentures 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 indentures 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 indentures 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 indentures 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 further increase our reported diluted loss per share.

Furthermore, the conversion features in our Convertible Notes are accounted for as free-standing embedded derivatives bifurcated from the principal balance of the Convertible Notes. The embedded derivative liabilities are 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, 2023, 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, as related to our historical testing business prior to our Strategic Transformation, 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 1C. Cybersecurity

In the ordinary course of our business, we collect, use, store, and transmit digitally large amounts of confidential, sensitive, proprietary, personal, and protected health information. The secure maintenance of this information and our information technology systems is important to our operations and business strategy. To this end, we have implemented processes designed to assess, identify, and manage risks from potential unauthorized occurrences on or through our information technology systems that may result in adverse effects on the confidentiality, integrity, and availability of these systems and the data residing therein. These processes are managed and monitored by our information technology department, which is led by our Director of Information Technology, and include mechanisms, controls, technologies, systems, and other processes designed to prevent or mitigate data loss, theft, misuse, or other security incidents or vulnerabilities affecting the data and maintain a stable information technology environment. For example, we conduct vulnerability testing, data recovery testing, security audits, and ongoing risk assessments, including due diligence on our key technology vendors, and other contractors and suppliers. We also conduct regular employee training on cyber and information security, among other topics. In addition, we consult with outside advisors and experts, when appropriate, to assist with assessing, identifying, and managing cybersecurity risks, including to anticipate future threats and trends, and their impact on the Company's risk environment.

Our Director of Information Technology, who has over 15 years of experience managing information technology and cybersecurity matters and holds a Master's Degree in computer science with a concentration in cybersecurity, together with our senior leadership team, is responsible for assessing and managing cybersecurity risks. We consider cybersecurity, along with other significant risks that we face, within our overall enterprise risk management framework. We have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected us, but we face certain ongoing cybersecurity risks threats that, if realized, are reasonably likely to materially affect us. Additional information on cybersecurity risks we face is discussed in Part I, Item 1A, "Risk Factors," under the heading "Our internal information technology systems, or those of any of our third party service providers, or potential future collaborators, may fail or suffer security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations."

Our Board of Directors, as a whole and at the committee level, has oversight of the most significant risks facing us and our processes to identify, prioritize, assess, manage, and mitigate those risks. Our Audit Committee, which is comprised solely of independent directors, oversees our cybersecurity risks. The Audit Committee receives regular updates on cybersecurity and information technology matters and related risk exposures from our Director of Information Technology as well as other members of the senior leadership team. The Board also receives updates from management and the Audit Committee on cybersecurity risks on at least an annual basis.

Item 2. Properties.

We currently lease approximately 15,400 square feet of office space in San Diego, California under a lease agreement that expires in June 2025. 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 lease approximately 4,500 square feet of office and laboratory space in Dallas, Texas under a lease agreement that expires in August 2026. We believe our existing facilities will be sufficient for our needs for the foreseeable future.

Item 3. Legal Proceedings.

The information in Note 9, "Commitments and Contingencies" to the audited financial statements included in this Annual Report on Form 10-K is incorporated herein by reference. There are no matters which constitute material pending legal proceedings to which we are a party other than those incorporated into this item by reference to Note 9 to the consolidated financial statements for the year ended December 31, 2023.

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 Nasdaq under the symbol "BIOR".

Holders

As of March 20, 2024, 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 and 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 clinical-stage biotechnology company developing oral biotherapeutics that could enable new treatment approaches in the delivery of therapeutics. Our pipeline includes two therapeutic delivery platforms:

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

Our mission is to reimagine therapeutics and their delivery. By creating innovative smart pills designed for targeted drug delivery to the GI tract and systemic, needle-free delivery of biotherapeutics, we are developing therapies intended to improve patients' lives.

Our historical operations included a licensed Clinical Laboratory Improvement Amendments 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 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, 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 have been retroactively adjusted to reflect the stock split.

Factors Affecting Our Performance

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. 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 research and development 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 targeted therapeutics and systemic 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 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 flat in 2024 as we continue clinical trials for our 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.

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 communications, 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 Note 9, "Commitments and Contingencies" in this Annual Report are included. We expect our selling, general and administrative expenses to decrease in 2024.

Interest Expense, Net

Interest expense, net is primarily attributable to borrowings under our credit and security agreements, lease agreements and interest income earned from our cash and cash equivalents.

Gain on Warrant Liabilities

Gain on warrant liabilities consists of losses on warrant issuances and changes in the fair value of our liability-classified warrants to purchase common stock.

Other (Expense) Income, Net

Other (expense) income, net primarily consists of changes in the fair value of our derivative liabilities related to the 2028 Convertible Notes, inducement loss and extinguishment loss on the Convertible Notes, gains and losses on investments, impairment of property and equipment, and loss on disposals of property and equipment.

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 the Years Ended December 31, 2023 and 2022

	Year Ended December 31,		
	2023	2022	Change
	(in thousands)		
Statement of Operations Data:			
Revenues	$ 4	$ 305	$ (301)
Operating expenses:			
Research and development	29,838	24,049	5,789
Selling, general and administrative	37,309	38,037	(728)
Total operating expenses	67,147	62,086	5,061
Loss from operations	(67,143)	(61,781)	(5,362)
Interest expense, net	(9,815)	(10,990)	1,175
Gain on warrant liabilities	18,004	20,904	(2,900)
Other (expense) income, net	(65,470)	2,617	(68,087)
Loss before income taxes	(124,424)	(49,250)	(75,174)
Income tax benefit	(90)	(420)	330
Loss from continuing operations	(124,334)	(48,830)	(75,504)
Gain from discontinued operations	219	10,673	(10,454)
Net loss	$ (124,115)	$ (38,157)	$ (85,958)

Research and Development Expenses

Research and development expenses increased by $5.8 million for the year ended December 31, 2023 compared to the year ended December 31, 2022, primarily attributable to an increase in salary and benefits, consulting and professional fees, clinical trial expenses and supplies costs, offset by a decrease in facilities costs.

Selling, General and Administrative Expenses

Selling, general and administrative expenses decreased by $0.7 million for the year ended December 31, 2023 compared to the year ended December 31, 2022, primarily attributable to an increase in salary and benefits and consulting and professional fees, offset by a decrease in software costs, business insurance and facilities costs.

Interest Expense, Net

Interest expense, net decreased by $1.2 million for the year ended December 31, 2023 compared to the year ended December 31, 2022, primarily due to a decrease in the balance of 2025 Convertible Notes from the September and December note exchanges.

Gain on Warrant Liabilities

Gain on warrant liabilities decreased by $2.9 million for the year ended December 31, 2023 compared to the year ended December 31, 2022, due to the loss on issuance of new warrants during the year and the change in fair value of the warrant liabilities for outstanding warrants.

Other (Expense) Income, Net

Other (expense) income, net decreased by $68.1 million for the year ended December 31, 2023 compared to the year ended December 31, 2022, primarily due to an inducement loss of $53.2 million, the remaining impact is due to an extinguishment loss on our 2025 Convertible Notes, a loss on the change in fair value of the derivative liabilities for the 2028 Convertible Notes, impairment on investment in Enumera Molecular, Inc. ("Enumera") and a gain on investment in Enumera for the year ended December 31, 2022 that did not reoccur for the year ended December 31, 2023.

Income Tax Benefit

Income tax benefit decreased by $0.3 million for the year ended December 31, 2023 compared to the year ended December 31, 2022, primarily due to prior year federal and state income tax refunds that did no reoccur for the year ended December 31, 2023.

Discontinued Operations

Gain from discontinued operations decreased by $10.5 million for the year ended December 31, 2023 compared to the year ended December 31, 2022 due to the closure of our Laboratory Operations during 2021. See Note 3 to our consolidated financial statements included elsewhere in this Annual Report for additional information regarding discontinued operations.

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 our Convertible Notes.

As of December 31, 2023, we had $15.0 million of cash and cash equivalents, $0.2 million of restricted cash and a working capital deficit. The face value of Convertible Notes outstanding was $51.1 million and our accumulated deficit as of December 31, 2023, was $951.0 million. For the year ended December 31, 2023, we had a net loss of $124.1 million and cash used in operations of $48.5 million. Our primary requirements for liquidity have been to fund our working capital needs, capital expenditures, research and development, and general corporate needs.

Based on our planned operations, we do not expect that our current cash and cash equivalents will be sufficient to fund our operations for at least 12 months from the issuance date of the consolidated financial statements for the year ended December 31, 2023, and we 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, 2023. 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

See Note 7 “Convertible Notes” to the consolidated financial statements included in this Annual Report for information on our Convertible Notes.

Equity Financings

See Note 10 “Stockholders' Equity” to the consolidated financial statements included in this Annual Report for information on our equity financings.

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 our research and development expenses to remain flat as we continue to focus on developing our therapeutics product candidates, through preclinical studies and clinical trials. 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,	
	2023	2022
Cash used in operating activities	$ (48,499)	$ (64,417)
Cash provided by (used in) investing activities	2,443	(792)
Cash provided by financing activities	30,781	7,298

Operating Activities

Net cash used in operating activities in the year ended December 31, 2023 was primarily attributable to a $124.1 million net loss, adjusted for non-cash charges, primarily driven by a $53.2 million inducement loss, $16.5 million of stock-based compensation

expense, $6.4 million loss on extinguishment of convertible notes, $3.9 million change in fair value of derivative liabilities, $3.0 million loss on investment in Enumera, $1.6 million of debt discount amortization and non-cash interest and $0.6 million of depreciation and amortization, partially offset by a $18.0 million change in fair value of warrant liabilities. The net cash inflow from changes in operating assets and liabilities was attributable to a $10.7 million increase in accrued expenses and a $1.0 million decrease in prepaid and other current assets, offset by a $1.2 million decrease in accounts payable and a $1.9 million decrease in other long-term liabilities.

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 a $5.7 million gain on investment in Enumera, offset by $7.8 million of stock-based compensation expense, a $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.

Investing Activities

Net cash provided by investing activities during the year ended December 31, 2023 was primarily attributable to $2.5 million from discontinued operations, offset by $0.1 million in purchases of property and equipment. Net cash used in investing for the year ended December 31, 2022 was attributable to $0.8 million in purchases of property and equipment.

Financing Activities

Net cash provided by financing activities during the year ended December 31, 2023 was primarily attributable to $18.1 million in proceeds from the issuance of common stock, $10.0 million from the issuance of senior secured convertible notes and $8.0 million in proceeds from the issuance of common stock warrants, partially offset by $2.3 million in payments for insurance financing, $2.0 million in tax payments to settle RSUs and $1.1 million in payments of offering costs. 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.

Other Contractual Obligations and Commitments

See Note 9 to our consolidated financial statements included elsewhere in this Annual Report for additional information.

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 revenues and expenses for the genetics laboratory as discontinued operations and all remaining assets as held for sale.

Common Stock Warrant Liabilities

We account for common stock warrants 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, 2023 and December 31, 2022, the fair value of our warrant liabilities of $40.8 million and $3.5 million, respectively, was estimated using the Black-Scholes Model with the following inputs and assumptions:

	As of December 31,	
	2023	2022
Risk-free interest rate	3.8% - 4.1%	4.0%
Expected volatility	95.6% - 101.8%	106.2% - 107.1%
Stock price	$1.35	$3.30
Expected life (years)	2.5 - 5.0	3.6 - 5.4

Embedded Derivatives Related to Convertible Notes

In December 2023, we issued Convertible Notes due in December 2028 that have conversion options which required bifurcation upon issuance and remeasurement to fair value separately as embedded derivatives. The conversion options include redemption features, interest rate features and conversion features. We utilized a binomial pricing 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 features are remeasured to fair value at each balance sheet date, 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. At December 31, 2023, the fair value of our embedded derivative liabilities of $22.9 million was estimated using a binomial pricing model with the following inputs and assumptions:

	As of December 31, 2023
Risk-free interest rate	3.8% - 4.3%
Expected volatility	84.3% - 95.7%
Stock price	$1.35
Discount Rate	28.7% - 28.9%

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,	
	2023	2022
Risk-free interest rate	3.5% - 4.7%	2.0% - 4.2%
Expected volatility	97.6% - 102.7%	90.7% - 101.3%
Expected dividend yield	—	—
Expected life (years)	5.5 - 6.3	5.5 - 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, 2023 or December 31, 2022.

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, 2023 and 2022, 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, 2023 and 2022, 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 a working capital deficit and an accumulated deficit that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. 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
April 1, 2024

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

	December 31,	
	2023	2022
Assets		
Current assets:		
Cash, cash equivalents and restricted cash	$ 15,211	$ 30,486
Income tax receivable	830	828
Prepaid expenses and other current assets	3,030	4,199
Current assets of disposal group held for sale	—	2,603
Total current assets	19,071	38,116
Property and equipment, net	1,156	1,654
Right-of-use assets	1,614	1,482
Other assets	3,302	6,201
Goodwill	6,072	6,072
Total assets	$ 31,215	$ 53,525
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 2,843	$ 3,606
Accrued expenses and other current liabilities	17,319	16,161
Warrant liabilities	40,834	3,538
Related party senior secured convertible notes, current portion	1,976	—
Total current liabilities	62,972	23,305
Convertible notes, net of unamortized discount of $259 and $4,914 as of December 31, 2023 and December 31, 2022, respectively	9,966	127,811
Senior secured convertible notes, net of unamortized discount of $11,066 and $0 as of December 31, 2023 and December 31, 2022, respectively (Note 7)	14,591	—
Related party senior secured convertible notes net of unamortized discount of $7,951 and $0 as of December 31, 2023 and December 31, 2022, respectively (including future interest of $9,747 and $0 as of December 31, 2023 and December 31, 2022, respectively) (Note 7)	19,179	—
Derivative liabilities	22,899	—
Other long-term liabilities	3,029	4,696
Total liabilities	$ 132,636	$ 155,812
Commitments and contingencies (Note 9)		
Stockholders' deficit:		
Common stock – $0.001 par value. 164,000,000 shares authorized as of December 31, 2023 and December 31, 2022; 28,574,918 and 9,098,844 shares issued as of December 31, 2023 and December 31, 2022, respectively; 27,837,563 and 8,928,498 shares outstanding as of December 31, 2023 and December 31, 2022, respectively	25	8
Additional paid-in capital	868,591	743,626
Accumulated deficit	(950,958)	(826,843)
Treasury stock – at cost; 737,355 and 170,346 shares of common stock as of December 31, 2023 and December 31, 2022, respectively	(19,079)	(19,078)
Total stockholders' deficit	(101,421)	(102,287)
Total liabilities and stockholders' deficit	$ 31,215	$ 53,525

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,	
	2023	2022
Revenues	$ 4	$ 305
Operating expenses:		
Research and development	29,838	24,049
Selling, general and administrative	37,309	38,037
Total operating expenses	67,147	62,086
Loss from operations	(67,143)	(61,781)
Interest expense, net	(9,815)	(10,990)
Gain on warrant liabilities	18,004	20,904
Other (expense) income, net	(65,470)	2,617
Loss before income taxes	(124,424)	(49,250)
Income tax benefit	(90)	(420)
Loss from continuing operations	(124,334)	(48,830)
Gain from discontinued operations	219	10,673
Net loss	$ (124,115)	$ (38,157)
Net loss per share from continuing operations, basic and diluted	$ (7.88)	$ (6.40)
Net gain per share from discontinued operations, basic and diluted	$ 0.01	$ 1.40
Net loss per share, basic and diluted	$ (7.87)	$ (5.00)
Weighted average shares outstanding, basic and diluted	15,773,297	7,635,107

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, 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)**
Issuance of common stock, net	8,245,273	6	17,482	—	—	—	17,488
Issuance of common stock upon vesting of restricted stock units	1,370,520	1	(1,960)	—	(567,009)	(1)	(1,960)
Issuance of common stock upon conversion of debt, net	9,860,281	10	67,421	—	—	—	67,431
Related party troubled debt restructuring	—	—	25,547	—	—	—	25,547
Stock-based compensation expense	—	—	16,475	—	—	—	16,475
Net loss	—	—	—	(124,115)	—	—	(124,115)
Balance at December 31, 2023	**28,574,918**	**$ 25**	**$ 868,591**	**$ (950,958)**	**(737,355)**	**$ (19,079)**	**$ (101,421)**

See notes to consolidated financial statements.

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

	Year Ended December 31,	
	2023	2022
Operating Activities:		
Net loss	$ (124,115)	$ (38,157)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain from discontinued operations	(219)	(10,673)
Depreciation and amortization	555	907
Stock-based compensation expense	16,475	7,804
Loss on extinguishment of convertible notes and accrued interest	6,363	2,722
Amortization of debt discount	1,601	1,419
Inducement loss on convertible notes	53,198	—
Loss on disposal of property and equipment	15	543
Impairment of property and equipment	100	545
Change in fair value of derivative liabilities	3,915	—
Change in fair value of warrant liabilities	(18,004)	(20,904)
Loss (gain) on investment in Enumera Molecular, Inc.	3,000	(5,731)
Changes in operating assets and liabilities:		
Income tax receivable	(2)	(828)
Prepaid expenses and other current assets	998	3,387
Accounts payable	(1,172)	(5,072)
Accrued expenses and other liabilities	10,677	(417)
Other long-term liabilities	(1,884)	(1,720)
Net cash used in operating activities - continuing operations	(48,499)	(66,175)
Net cash provided by operating activities - discontinued operations	—	1,758
Net cash used in operating activities	(48,499)	(64,417)
Investing Activities:		
Purchases of property and equipment	(103)	(792)
Proceeds from sale of property and equipment	11	—
Net cash used in investing activities - continuing operations	(92)	(792)
Net cash provided by investing activities - discontinued operations	2,535	—
Net cash provided by (used in) investing activities	2,443	(792)
Financing Activities:		
Proceeds from issuance of common stock	18,137	9,014
Proceeds from issuance of common stock warrants	8,000	3,318
Tax payments to settle restricted stock units	(1,960)	—
Proceeds from issuance of common stock under employee stock purchase plan	—	98
Proceeds from issuance of senior secured convertible notes	10,000	—
Payments for financing of insurance premiums	(2,264)	(5,120)
Payments for offering costs	(1,132)	—
Principal payments on capital lease obligations	—	(12)
Net cash provided by financing activities	30,781	7,298
Net decrease in cash, cash equivalents and restricted cash	(15,275)	(57,911)
Cash, cash equivalents and restricted cash at beginning of period	30,486	88,397
Cash, cash equivalents and restricted cash at end of period	$ 15,211	$ 30,486

See notes to consolidated financial statements.

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

	Year Ended December 31,	
	2023	2022
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 2,277	$ 5,871
Cash paid for income taxes	$ 18	$ 31
Supplemental schedule of non-cash investing and financing activities:		
Conversion of convertible notes to common stock and warrants	$ 51,000	$ —
Related party troubled debt restructuring	$ 25,547	$ —
Exchange of convertible notes for senior secured convertible notes and warrants	$ 18,000	$ —
Conversion of accrued interest in exchange for senior secured convertible notes	$ 6,953	$ —
Investment in Enumera Molecular Inc. in exchange for assets	$ —	$ 6,000
Issuance of common stock and re-priced warrants upon settlement of accrued interest	$ —	$ 3,929
Issuance of warrants upon settlement of accrued interest	$ —	$ 2,300
Leased assets obtained in exchange for operating lease liabilities	$ 1,344	$ 2,922
Change in fair value of re-priced equity classified warrants	$ —	$ 619
Equity financing issuance costs incurred but not paid	$ 49	$ 116
Debt issuance costs incurred but not paid	$ 350	$ —
Issuance of common stock in settlement of accrued expenses	$ —	$ 98
Purchases of property and equipment in accounts payable	$ 12	$ 86

See notes to consolidated financial statements.

Note 1. Organization and Description of Business

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

- NaviCap™ Targeted Oral Delivery Platform: 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: Designed to replace injection 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, a Texas limited liability partnership doing business as Avero Diagnostics (“Avero”), the Company’s operations also included anatomic and molecular pathology testing products.

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 and in December 2021, the Company sold Avero, together referred to as the Laboratory Operations. The Company has reported all revenues and expenses associated with its Laboratory Operations as discontinued operations; see Note 3 for additional information.

In April 2022, the Company announced that it would rebrand to better reflect the current focus on its therapeutics pipeline, and changed its name to Biora Therapeutics, Inc.

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, 2023, the Company had cash and cash equivalents of $15.0 million, restricted cash of $0.2 million and a working capital deficit. The Company had an accumulated deficit of $951.0 million as of December 31, 2023. For the year ended December 31, 2023, the Company reported a net loss of $124.1 million and cash used in operating activities of $48.5 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, 2023, the Company had a face value of $40.9 million of 11.00%/13.00% convertible senior secured notes due 2028 ("2028 Convertible Notes") outstanding and a face value of $10.2 million of 7.25% convertible senior notes due 2025 ("2025 Convertible Notes" and together with the 2028 Convertible Notes, the "Convertible Notes") outstanding (see Note 7). 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, 2023, 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, 2023.

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 and notes thereto give retrospective effect, where applicable, to the Reverse Stock Split for all periods presented. All common stock, options exercisable for common stock, restricted stock units ("RSUs"), 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.

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 valuation of stock options, the valuation of goodwill, the valuation of the derivative liabilities associated with the 2028 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 3.

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.

Restricted Cash

Restricted cash consists of collateral required for the Company's bank-issued credit cards with balances of $0.2 million and $0 as of December 31, 2023 and December 31, 2022, respectively.

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*. The Company accounts for impairment of investments in equity securities by reviewing these assets for impairment whenever events or changes in circumstances indicate that the fair value of the security is less than its carrying amount.

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

Leasehold improvements are amortized on a straight-line basis over the shorter of the lease term or the useful life of the asset.

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, 2023 or December 31, 2022.

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 $0.1 million and $0.5 million during the years ended December 31, 2023 and December 31, 2022, respectively.

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 6).

Embedded Derivatives Related to Convertible Notes

In December 2023, the Company issued the 2028 Convertible Notes with embedded derivatives that are 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 derivatives are recorded to other income, net in the consolidated statements of operations.

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.

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.

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, conferences, and professional fees of audit, legal, and recruiting services. Selling, general and administrative expenses are expensed as incurred.

Stock-Based Compensation

Stock-based compensation related to stock options, 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 June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses*, which requires the measurement of expected credit losses for financial instruments carried at amortized cost, such as accounts receivable, held at the reporting date based on historical experience, current conditions and reasonable forecasts. The main objective of this standard is to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. In November 2018, the FASB issued ASU No. 2018-19, *Codification Improvements to Topic 326, Financing Instruments–Credit Losses*, which included an amendment of the effective date. The Company adopted this standard on January 1, 2023, and it did not have a material impact on the consolidated financial statements.

Recent Accounting Pronouncements Not Yet Adopted

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 Company adopted this standard on January 1, 2024, and it did not have a material impact on the consolidated financial statements.

In December 2023, the FASB issued ASU No. 2023-09*, Improvements to Income Tax Disclosures*, which introduces new and enhanced income tax disclosure requirements. The standard is effective for the Company for annual reporting periods beginning after December 15, 2025. The Company is currently evaluating the impact the adoption of this standard may have on its consolidated financial statements and related disclosures.

Note 3. Strategic Transformation

Assets Held for Sale and Discontinued Operations

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 represented 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. Additionally, the remaining assets are reported as assets held for sale in the Company's consolidated balance sheets as of December 31, 2022 and there are no remaining assets as of December 31, 2023.

The following table presents the results of discontinued operations of the Laboratory Operations for the years ended December 31, 2023 and December 31, 2022 (in thousands):

	Years Ended December 31,	
	2023	2022
Revenues [1]	$ 1,219	$ 11,848
Operating expenses:		
Selling, general and administrative [2]	1,000	1,175
Total operating expenses	1,000	1,175
Net income from discontinued operations	$ 219	$ 10,673

(1) Refer to Note 9 for further discussion regarding the reversal of a previously established accrual related to a third-party claim of recoupment.
(2) Refer to Note 9 for further discussion regarding the accrual of amounts related to the IPO litigation.

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

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

In October 2023, the Company entered into a purchase and sale agreement to sell the building located in Ann Arbor, Michigan included in current assets held for sale. The transaction closed in October 2023 and the Company received gross proceeds of $2.8 million, incurred closing expenses of $0.2 million. As of December 31, 2023 assets held for sale was zero.

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 concluded, based on a technical evaluation of the facts, that Enumera is not a variable interest entity. 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. The Company recognized a gain of $5.7 million on the investment during the year ended December 31, 2022 included in other (expense) income, net on the consolidated statements of operations. The Company determined the fair value was less than carrying value as of December 31, 2023 based on their negative cash flows from operations and for the year ended December 31, 2023 recorded a $3.0 million impairment loss on its investment, included in other (expense) income, net on the consolidated statements of operations. In March 2024, the Company entered into a stock purchase agreement, pursuant to which it sold its Series A-1 preferred shares for $3.0 million.

Licensing Agreements

In November 2022, the Company entered into a license agreement with Northwest Pathology, doing business as Avero Diagnostics ("Northwest"), pursuant to which the Company licensed 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 received the rights to assets and intellectual property related to the Preecludia test and the Company will receive commercial milestone payments and royalties on net sales.

In June 2023, the Company entered into a purchase and license agreement with a diagnostics company pursuant to which the Company sold certain assets and licensed intellectual property related to preeclampsia for research and development (the "Preeclampsia Agreement"). Under the terms of the Preeclampsia Agreement, the Company received a one-time payment for the sale of assets, including the sale of rights to certain antibody sequences, during the year ended December 31, 2023 and recorded $1.5 million of other income.

In May 2023, the Company entered into a professional services agreement with an affiliate of Enumera, a related party. Pursuant to the agreement, the affiliate will assist in selling legacy assets. The Company incurred $0.4 million in other expenses in connection with the agreement.

Note 4. Revenues

The Company's current revenue is related to license and collaboration agreements. Revenues historically were derived from contracts with healthcare insurers, government payors, laboratory partners and patients related to tests provided to patients. The Company evaluated its contracts 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 billed for its products. The amount of revenue recognized reflected the transaction price and considered the effects of variable consideration. 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 were accounted for as reductions in revenues in the statement of operations as an element of variable consideration.

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 of revenue for the year ended December 31, 2022 and zero for the year ended December 31, 2023. 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 9.

Note 5. Balance Sheet Components

Prepaid Expenses and Other Current Assets

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

	December 31,	
	2023	2022
Prepaid expenses	$ 2,443	$ 3,634
Other current assets	587	565
Total	$ 3,030	$ 4,199

Property and Equipment, Net

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

	December 31,	
	2023	2022
Computers and software	$ 1,193	$ 2,715
Building and leasehold improvements	803	750
Laboratory equipment	423	958
Furniture, fixtures, and office equipment	799	1,138
Construction in progress	45	92
Total property and equipment	3,263	5,653
Less accumulated depreciation and amortization	(2,107)	(3,999)
Property and equipment, net	$ 1,156	$ 1,654

Depreciation expense included in continuing operations was $0.6 million and $0.9 million for the years ended December 31, 2023 and 2022, respectively.

Other Assets

Other assets consisted of the following (in thousands):

	December 31,	
	2023	2022
Investment in Enumera	$ 3,000	$ 6,000
Other	302	201
Total	$ 3,302	$ 6,201

Accrued Expenses and Other Current Liabilities

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

	December 31,	
	2023	2022
Accrual for reimbursement claims and legal settlements, current [1]	$ 6,337	$ 8,372
Commissions and bonuses	2,469	1,433
Vacation and payroll benefits	1,367	1,724
Accrued professional services	2,914	307
Accrued interest	173	890
Lease liabilities, current	896	893
Insurance financing	401	445
Contract liabilities	542	47
Other [2]	2,220	2,050
Total	$ 17,319	$ 16,161

(1) Revenues related to Laboratory Operations have all 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 is responsible for that were expensed in discontinued operations in 2021.

Other Long-term Liabilities

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

	December 31,	
	2023	2022
Lease liabilities, net of current portion	818	601
Other [1]	2,211	4,095
Total	$ 3,029	$ 4,696

(1) Included in this amount are contracts that the Company is responsible for that were expensed in discontinued operations in 2021.

Note 6. 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, 2023 and 2022.

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, 2023			
Derivative liabilities	$ —	$ —	$ 22,899
Warrant liabilities	$ —	$ —	$ 40,834
December 31, 2022			
Money market funds [1]	$ 5	$ —	$ —
Warrant liabilities	$ —	$ —	$ 3,538

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

The Company issued 2028 Convertible Notes (see Note 7) that contain conversion features that are required to be bifurcated and recorded as embedded derivative liabilities in the consolidated balance sheet. The Company utilized a binomial pricing model to determine the fair value of the conversion features, which utilizes significant unobservable inputs. The fair value of the embedded derivatives as of December 31, 2023 was estimated using a binomial pricing model with the following inputs and assumptions:

	As of December 31, 2023
Risk-free interest rate	3.8% - 4.3%
Expected volatility	84.3% - 95.7%
Stock price	$1.35
Discount Rate	28.7% - 28.9%

The Company's Level 3 liabilities consist of the warrant liabilities resulting from equity financings (see Note 10) and the Convertible Note exchanges (see Note 7). 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 warrant liabilities includes 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, 2023 and 2022, the fair value of the warrant liabilities were estimated using the Black-Scholes Model with the following inputs and assumptions:

	As of December 31,	
	2023	2022
Risk-free interest rate	3.8% - 4.1%	4.0%
Expected volatility	95.6% - 101.8%	106.2% - 107.1%
Stock price	$1.35	$3.30
Expected life (years)	2.5 - 5.0	3.6 - 5.4

A summary of the changes in the Level 3 classified liabilities is presented below (in thousands):

	Warrant Liabilities	Derivative Liabilities
Balance at December 31, 2021	$ 18,731	$ —
Recognition of new warrant liabilities	2,990	—
Change in fair value	(18,183)	—
Balance at December 31, 2022	$ 3,538	$ —
Recognition of new warrant liabilities	63,393	—
Recognition of derivative liabilities	—	18,984
Change in fair value	(26,097)	3,915
Balance at December 31, 2023	$ 40,834	$ 22,899

Note 7. Convertible Notes

The following table summarizes significant terms of the Company's Convertible Notes at December 31, 2023 (in thousands):

	December 31, 2023				
	Face Value	Carrying Value	Fair Value [1]	Stated Interest Rate	Effective Interest Rate
2028 Convertible Notes	$ 23,500	$ 14,591	$ 14,846	11-13%	48.9%
Related Party 2028 Convertible Notes	$ 17,383	$ 21,155	$ 10,982	11-13%	(22.0)%
2025 Convertible Notes	$ 10,225	$ 9,966	$ 5,984	7.25%	8.7%

(1) To estimate the fair value of the 2028 Convertible Notes, the Company used a binomial pricing model. Including the derivative liabilities of $22.9 million, the 2028 Convertible Notes fair value using the with method is $48.7 million. To estimate the fair value of the 2025 Convertible Notes, the Company used unadjusted quoted prices in the active market obtained from third-party pricing services.

The following table summarizes significant terms of the Company's Convertible Notes at December 31, 2022 (in thousands):

	December 31, 2022				
	Face Value	Carrying Value	Fair Value [2]	Stated Interest Rate	Effective Interest Rate
2025 Convertible Notes	$ 132,725	$ 127,811	$ 71,790	7.25%	8.7%

(2) The Company used unadjusted quoted prices in the active market obtained from third-party pricing services to determine the fair value of the 2025 Convertible Notes.

The carrying value of the Convertible Notes does not approximate their fair values because the carrying values reflect the balance of unamortized discount related to the derivative liabilities associated with the value of the conversion features assessed at inception. The Company amortizes the debt discount using the effective interest method over the term of the Convertible Notes. As of December 31, 2023 and 2022, the unamortized debt discount on the 2025 Convertible Notes was $0.3 million and $4.9 million, respectively, and the amortization of the debt discount was $1.3 million and $1.4 million, respectively, and is included in interest expense, net in the consolidated statements of operations. As of December 31, 2023, the unamortized debt discount on the 2028 Convertible Notes was $19.0 million and the amortization of the debt discount was $0.3 million and is included in interest expense, net in the consolidated statements of operations.

2025 Convertible Notes

In December 2020, the Company issued a total of $168.5 million principal amount of 2025 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 2025 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 2025 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. During the years ended December 31, 2023 and 2022, the Company recognized interest expense on the 2025 Convertible Notes of $8.4 million and $9.6 million, respectively.

The 2025 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 2025 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 2025 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 2025 Convertible Notes, which represents an initial conversion price of approximately $89.92 per share of common stock. Noteholders that converted their 2025 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 2025 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 2025 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 2025 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 2025 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 2025 Convertible Notes have customary provisions relating to the occurrence of "Events of Default" (as defined in the Indenture). As of December 31, 2023 and December 31, 2022, the Company was in compliance with all such covenants.

The 2025 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 feature was bifurcated and recorded separately as an embedded derivative remeasured at fair value each reporting period with changes in fair value recorded in the consolidated statement of operations. As of December 31, 2022, the conversion option expired and there was no longer a derivative liability.

Note Exchanges

In September 2023, certain related-party holders of 2025 Convertible Notes exchanged an aggregate of $50.0 million principal amount for a combination of 9,235,281 shares of the Company's common stock, 7,399,226 pre-funded warrants at an exercise price of $0.001 per share and warrants to purchase up to 16,634,507 shares of common stock at an exercise price of $3.01 per share. The warrants are exercisable on or after September 18, 2023 until September 18, 2026 and the pre-funded warrants have no expiration date. The pre-funded warrants and the warrants (together, the "September Warrants") are subject to certain exercise limitations, including a limitation on the ability to exercise if the holder's beneficial ownership would exceed 49.9%. As the 2025 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 $53.2 million, included in other (expense) income, net in the consolidated statements of operations. Pursuant to ASC 815, the Company deemed the September Warrants to be classified as a liability at fair value initially with subsequent changes in fair value recorded in earnings. The September Warrants were recorded at a fair value of $35.1 million determined using the Black-Scholes Model.

In December 2023, the Company entered into Exchange Agreements (the "Note Exchange Agreements") with certain holders of 2025 Convertible Notes to exchange an aggregate of $72.5 million principal amount for a combination of (i) $23.9 million in principal amount of 2028 Convertible Notes (ii) 625,000 shares of the Company's common stock, (iii) warrants to purchase 5,039,236 shares of common stock (the "Exchange Warrants"), and (iv) accrued and unpaid interest on the 2025 Convertible Notes. The Company also entered into Note Purchase Agreements (the "Note Purchase Agreements"), with certain investors (the "Purchasers") to purchase $17.0 million in principal amount of additional 2028 Convertible Notes from the Company for cash at par value. The Purchasers were granted warrants to purchase 5,084,613 shares of common stock (the "Additional Warrants") and certain Purchasers were also granted warrants to purchase 7,352,941 shares of common stock (the "Commitment Warrants"). In connection with the Note Exchange Agreements and the Note Purchase Agreements, the Company has agreed to allow certain of the parties to designate one board observer.

2028 Convertible Notes

The 2028 Convertible Notes were issued pursuant to, and are governed by, an indenture (the "2028 Convertible Notes Indenture"), dated December 19, 2023, by and between the Company and GLAS Trust Company LLC, as trustee (the "Trustee"). The 2028 Convertible Notes will mature on the earlier of December 19, 2028 and the date that is 90 days prior to the maturity of the Convertible Notes solely to the extent there are Convertible Notes outstanding in a principal amount equal to or greater than $5.0 million as of such date, unless earlier repurchased, redeemed or converted. The Notes will accrue interest at a rate of 11.0% per annum in the case of cash payment and 13.0% in the case of blended payments or payments-in-kind, payable semi-annually in arrears on June 1 and December 1 of each year, with the initial payment on June 1, 2024. During the year ended December 31, 2023 the Company recognized interest expense on the 2028 Convertible Notes of $0.1 million.

The 2028 Convertible Notes are the Company's senior secured obligations, and are secured by substantially all of the Company's and its subsidiaries' assets. The 2028 Convertible Notes are (i) senior in right of payment to the Company's existing and

future senior, unsecured indebtedness to the extent of the value of the collateral; and (ii) senior in right of payment to the Company's existing and future indebtedness that is expressly subordinated to the 2028 Convertible Notes.

At any time, noteholders may convert their 2028 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 641.02564 shares of common stock per $1,000 principal amount of 2028 Convertible Notes, which represents an initial conversion price of approximately $1.56 per share of common stock. Noteholders that convert their 2028 Convertible Notes will be entitled to an additional premium payment representing the amount of certain of the remaining interest payments on the 2028 Convertible Notes as specified in the 2023 Indenture. The conversion rate and conversion price will be subject to customary adjustments upon the occurrence of certain events.

The 2028 Convertible Notes are redeemable, in whole and not in part, at the Company's option at any time on or after December 19, 2024, and in some circumstances prior to that date, at a cash redemption price equal to the principal amount of the 2028 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 150% 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.

If certain corporate events that constitute a "Fundamental Change" (as defined in the Indenture) occur, then noteholders may require the Company to repurchase their Notes at a cash repurchase price equal to the principal amount of the 2028 Convertible Notes to be repurchased, plus accrued and unpaid interest, if any, to, but excluding, the fundamental change repurchase date. The definition of Fundamental Change includes certain business combination transactions involving the Company and certain de-listing events with respect to the Company's common stock.

The 2028 Indenture contains covenants restricting the Company's ability to incur indebtedness, incur liens, make restricted payments, make asset sales and engage in transactions with affiliates, subject to certain baskets. The 2028 Convertible Notes Indenture requires the Company to maintain minimum liquidity of $4.0 million and to add future assets to the collateral under the Security Agreement (as defined below) and to add future subsidiaries as guarantors under the Security Agreement. The 2028 Convertible Notes have customary provision relating to the occurrence of "Events of Default" (as defined in the Indenture). As of December 31, 2023, the Company was in compliance with all such covenants.

The 2028 Convertible Notes have several conversion features which are required to be bifurcated upon issuance and periodically remeasured to fair value separately as an embedded derivative. The conversion features were bifurcated and recorded separately as an embedded derivative remeasured at fair value each reporting period with changes in fair value recorded in other (expense) income, net in the consolidated statement of operations.

The note exchange with one holder of 2025 Convertible Notes constitutes a troubled debt restructuring ("TDR") under ASC 470, because the Company is experiencing financial difficulty and a concession has been granted by the holder. As the holder is a related party, the Company recorded the restructuring gain as a capital contribution resulting in $25.5 million of restructuring gain recorded within additional paid-in-capital as of December 31, 2023. Following the TDR guidance under ASC 470, future interest payments of approximately $11.7 million were also included in the carrying value of the restructured senior secured convertible notes.

The note exchange with the other holders of 2025 Convertible Notes is considered a debt extinguishment under ASC 470. As a result, the Company recorded a loss on debt extinguishment of $6.4 million, which is the difference between the fair value of the 2028 Convertible Notes combined with the fair value of the warrants, derivative liabilities and common stock and the net carrying value of the 2025 Convertible Notes, which included $0.5 million of unamortized debt discount and third-party fees of $0.3 million.

The Exchange Warrants have an exercise price of $5.50 per share, the Commitment Warrants have an exercise price of $1.36 per share and are exercisable at any time on or after June 19, 2024 and the Additional Warrants have an exercise price of $5.00 per share. Each of the Exchange Warrants, the Commitment Warrants and the Additional Warrants (together the "December Warrants") are subject to certain exercise limitations, including a limitation on the ability to exercise if the holder's beneficial ownership of common stock would exceed specified levels. Pursuant to ASC 815, the Company deemed the December Warrants to be classified as a liability at fair value initially with subsequent changes in fair value recorded in earnings.

Note 8. Related Party Transactions

In November 2022, the Company entered into a securities purchase agreement with affiliates of Athyrium Capital Management, LP (“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 became exercisable 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 the 2025 Convertible Notes 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. Athyrium also held $103.5 million aggregate principal amount of 2025 Convertible Notes as of December 31, 2022. As of December 31, 2022 the accrued interest expense related to the 2025 Convertible Notes held by Athyrium was $0.6 million.

In September 2023, Athyrium exchanged an aggregate of $50.0 million principal amount of 2025 Convertible Notes for a combination of 9,235,281 shares of the Company's common stock, 7,399,226 pre-funded warrants and warrants to purchase up to 16,634,507 shares of common stock at an exercise price of $3.01 (see Note 7).

In December 2023, Athyrium exchanged an aggregate of $53.5 million principal amount of 2025 Convertible Notes for $10.4 million of 2028 Convertible Notes and warrants to purchase up to 5,039,236 shares of common stock at an exercise price of $5.50 per share. Additionally, Athyrium purchased $7.0 million of 2028 Convertible Notes with an in-kind payment in the form of a waiver of the Company’s cash interest payment obligation on the Convertible Notes and was granted warrants to purchase up to 2,085,372 shares of common stock at an exercise price of $5.00 per share (see Note 7).

As of December 31, 2023 Athyrium held $17.4 million aggregate principal amount of 2028 Convertible Notes. Athyrium also held 10,929,763 shares, or 39.3%, of the Company's common stock outstanding, 7,399,226 pre-funded warrants and warrants to purchase up to 24,583,231 shares of common stock at exercise prices ranging from of $3.01 to $8.22 as of December 31, 2023.

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 10). 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 November 2022 Offering (as defined below) securities purchase agreement. As of March 31, 2023 this institutional investor held less than 5% of the Company's outstanding common stock and is no longer considered a related party.

In June 2023, the Company entered into a securities purchase agreement with certain institutional and accredited investors relating to the offering and sale of 1,509,434 shares of common stock in a registered direct offering at an offering price of $5.30 per share. In addition, in a concurrent private placement, the Company issued unregistered warrants to purchase 3,018,868 shares of common stock (see Note 10) to the same investors. Following this transaction, the institutional and accredited investors became related parties due to greater than 5% ownership. As of September 30, 2023 the institutional and accredited investors held less than 5% of the Company's outstanding common stock and are no longer considered related parties.

Note 9. Commitments and Contingencies

Operating Leases

The Company has entered into various non-cancelable operating lease agreements, primarily for office space, laboratory space, and equipment. In March 2023, the Company signed an amended lease agreement for certain office space in San Diego, California to decrease the office space and extend the term to June 2025. In August 2023, the Company signed a 36-month lease agreement for laboratory space in Dallas, Texas.

The components of lease expense were as follows (in thousands):

	Year Ended December 31,	
	2023	2022
Operating lease costs	$ 1,369	$ 1,531
Cash paid for operating leases	$ 1,281	$ 1,609

Supplemental weighted-average information related to operating leases is as follows:

	December 31,	
	2023	2022
Weighted-average remaining lease term (years)	2.2	2.3
Weighted-average discount rate	9.7%	7.8%

As of December 31, 2023, future lease payments under the non-cancelable operating leases were as follows (in thousands):

Year ending December 31,	Minimum Operating Lease Payments
2024	$ 1,022
2025	590
2026	264
2027	18
2028 and thereafter	—
Total minimum lease payments	1,894
Less: interest	(180)
Present value of lease liabilities	$ 1,714

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. 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. The Company did not make any payments during the year ended December 31, 2022. In July 2023, the Company made payments of $1.7 million and entered into agreements to extend the deadline for the remaining payments to the following:

- approximately $2.8 million on or before January 1, 2024; and
- approximately $2.6 million on or before July 1, 2024.

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, 2023, the Company's accrual consisted of $5.3 million in accrued expenses and other current liabilities. In January 2024, the Company paid $2.8 million.

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, 2023 and 2022.

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 NIPT, particularly those with a nexus to California patients. The OAG alleged that the Company violated California Business and Professions Code sections 17200 et seq. and 17500 et seq., in a complaint filed September 12, 2023 in the Superior Court of the State of California (case no. 23CV008397) for injunctive and other relief. The Company and OAG settled the matter via a stipulated entry of Final Judgment and Permanent Injunction that was entered and ordered by the Court on September 25, 2023. Pursuant to the order, the Company paid civil penalties in the total amount of $0.2 million.

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 discontinued legacy billing practices involving the implementation of a new Current Procedure Terminology code for reimbursement for the Company's former Preparent expanded carrier screening tests. 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. During the year ended December 31, 2023, the Company

reversed the remaining accrual for this 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 rejected several managed Medicaid payor recoupment requests that it received in 2022 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 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 related to payors and the Company's ceased laboratory operations, individually or in the aggregate, should not 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. 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. The case is currently scheduled for trial in October 2024. Given the uncertainty of 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 this matter, 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 filed a motion to dismiss the third amended complaint with prejudice on March 20, 2023, which the court granted on July 12, 2023. Lead Plaintiffs filed a notice of appeal on August 11, 2023 and the appeal is currently before the United States Court of Appeals for the Ninth Circuit (Case No: 23-55716) with appellate briefing concluded and submitted by the parties in March 2024. Subject to a reservation of rights, the Company is advancing expenses subject to indemnification to the underwriters of the IPO. In March 2024, the Company and plaintiffs agreed to settle the litigation, subject to negotiation and entry into

definitive and binding agreements and court approval, for an amount of $1.0 million. The Company has accrued this amount in accrued expenses in the balance sheet as of December 31, 2023. The expense of $1.0 million was recorded in selling, general and administrative expenses from discontinued operations for the year ended December 31, 2023.

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 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 resolution of the appeal 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 10. 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 the consolidated financial statements, reduced the authorized shares of the Company to 164,000,000 and did not change the par value of the Company's common stock.

Registered Offerings

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. Pursuant to ASC 815, the Company deemed the 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. 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 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.

Additionally, as part of the November 2022 Offering, the Company agreed with certain institutional investors to amend outstanding warrants previously issued to purchase up to 104,895 shares of common stock with an exercise price of $171.50 per share and 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, were not exercisable until May 9, 2023 and (iii) extend the original expiration date of such existing warrants to May 9, 2028. 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.

In January 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 warrants have an exercise price of $8.22, were exercisable beginning on May 9, 2023. Pursuant to ASC 815, the

Company deemed the warrants to be classified as a liability at fair value initially with subsequent changes in fair value recorded in earnings.

In June 2023, the Company entered into a securities purchase agreement with certain institutional and accredited investors relating to the offering and sale of 1,509,434 shares of common stock in a registered direct offering at an offering price of $5.30 per share (the "June 2023 Offering"). In addition, in a concurrent private placement with the same investors, the Company issued unregistered warrants to purchase 3,018,868 shares of common stock. The warrants have an exercise price of $5.05 per share and are exercisable at any time. The Company received approximately $7.3 million in net proceeds, after deducting placement agent fees and offering expenses. Pursuant to ASC 815, the Company deemed the 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 $9.0 million, as the total fair value of the warrant liability exceeds the gross proceeds of $8.0 million, the Company recorded a loss of the $1.0 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 as part of this transaction. The Company incurred a total of $0.7 million in issuance costs, which were allocated between the warrants and common stock on a relative fair value basis.

In October 2023, the Company issued warrants to purchase up to 1,000,000 shares and 4,278,074 shares of the Company's common stock, with exercise prices of $1.93 per share and $1.87 per share, respectively, to accredited investors in private placement transactions. The warrants are exercisable in April 2024, six months following the dates of issuance. The investors may from time to time agree to acquire, and the Company may agree to sell, up to an aggregate of $9.9 million of common stock at any time prior to January 31, 2024. The warrants will vest in proportion to issuances described in the preceding sentence. Pursuant to ASC 815, the Company deemed the 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 $6.7 million and the Company recorded a loss of the $6.7 million excess to gain (loss) on warrant liabilities in the consolidated statements of operations.

Common stock warrants

As of December 31, 2023, the Company had the following warrants outstanding to acquire shares of its common stock:

Expiration Date	Shares of common stock issuable upon exercise of warrants	Exercise Price per share
Held by Related Parties		
N/A	7,399,226	$ 0.001
September 2026	16,634,507	$ 3.01
May 2028	824,116	$ 8.22
December 2028	2,085,372	$ 5.00
December 2028	5,039,236	$ 5.50
Related Parties Total	31,982,457	
Held by non-affiliates		
February 2026	69,930	$ 171.50
June 2026	3,018,868	$ 5.05
August 2026	452,635	$ 25.00
April 2027	826,816	$ 1.87
April 2027	698,107	$ 1.93
May 2028	1,074,916	$ 8.22
December 2028	7,352,941	$ 1.36
December 2028	2,999,241	$ 5.00
Non-affiliate Total	16,493,454	
Total	48,475,911	

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. The Company further reduced the aggregate offering price to $12.0 million in connection with the June 2023 Offering. As of October 9, 2023, the aggregate offering price was increased to $37.6 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. The following table provides information on the shares sold under the ATM Sale Agreement for the three months and year ended December 31, 2023 and 2022.

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Net proceeds (in millions)	$ 4.9	$ 0.6	$ 17.7	$ 7.1
Number of shares	3,799,814	52,620	6,735,839	317,155
Weighted average purchase price	$ 1.37	$ 10.93	$ 3.66	$ 30.27

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.

On January 9, 2023, the Company filed a Certificate of Elimination of Series X Preferred Stock with the Secretary of State of the State of Delaware, which, effective immediately upon filing, eliminated all matters set forth in the Certificate of Designation of Series X Preferred Stock filed with the Secretary of State of the State of Delaware on November 21, 2022.

Note 11. 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 RSUs. 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 June 14, 2023, the Company's stockholders approved the Fifth Amended and Restated 2018 Equity Incentive Plan ("2018 Fifth Amended Plan"), which included an increase of 5,500,000 shares of common stock reserved for issuance. As of December 31, 2023 there were 3,302,136 shares available for issuance under the 2018 Fifth 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, 2023, 63,964 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 2012 Stock Plan, the 2018 Fifth Amended Plan and the 2021 Inducement Plan during the year ended December 31, 2023:

	Stock Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Balance at December 31, 2022	582,557	$ 59.89		
Options granted	265,000	$ 3.54		
Options exercised	—	$ —		
Options forfeited/cancelled	(84,545)	$ 96.78		
Balance at December 31, 2023	763,012	$ 36.23	8.0	$ 0.2
Vested and expected to vest at December 31, 2023	763,012	$ 36.23	8.0	$ 0.2
Vested and exercisable at December 31, 2023	269,718	$ 66.98	7.3	$ —

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, 2023 and 2022:

	Year ended December 31,	
	2023	2022
Risk-free interest rate	3.5% - 4.7%	2.0% - 4.2%
Expected volatility	97.6% - 102.7%	90.7% - 101.3%
Expected dividend yield	—	—
Expected life (years)	5.5 - 6.3	5.5 - 6.3

The weighted-average grant date fair value of options granted during the years ended December 31, 2023 and 2022 was $2.49 per option and $19.09 per option, respectively.

Restricted Stock Units

The following table summarizes RSU activity for the year ended December 31, 2023:

	Number of Shares	Weighted-Average Grant Date Fair Value
Balance at December 31, 2022	278,112	$ 38.95
Granted	3,703,321	$ 3.09
Vested	(1,370,520)	$ 9.70
Forfeited/cancelled	(73,556)	$ 7.96
Balance at December 31, 2023	2,537,357	$ 3.31

In August 2023, the Board of Directors approved the acceleration of vesting of all unvested, outstanding RSUs. As a result of this modification, an additional $7.9 million of stock-based compensation expense was recognized for the year ended December 31, 2023.

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, 2023 there were 71,450 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,	
	2023	2022
Research and development	6,979	2,626
Selling, general and administrative	9,496	5,178
Total stock-based compensation expense	$ 16,475	$ 7,804

At December 31, 2023 there was $6.6 million of compensation cost related to unvested stock options expected to be recognized over a remaining weighted average vesting period of 2.5 years and $7.5 million of compensation cost related to unvested RSUs expected to be recognized over a remaining weighted average vesting period of 3.6 years.

Note 12. Income Taxes

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

	Year Ended December 31,	
	2023	2022
Current provision:		
Federal	$ —	$ (546)
State	(15)	(347)
Foreign	—	126
	(15)	(767)
Deferred expense:		
Federal	(75)	347
State	—	—
	(75)	347
Net income tax provision	$ (90)	$ (420)

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

	Year Ended December 31,	
	2023	2022
Income tax benefit at U.S. federal statutory rate	$ (26,129)	$ (10,343)
Cancellation of debt	8,161	—
Inducement loss	11,172	—
Extinguishment loss	1,336	—
Convertible debt and warrant liabilities	(3,781)	(4,390)
Derivative Liability	822	—
Stock-based compensation	2,687	1,504
Tax refunds	(35)	(900)
Change in valuation allowance	5,556	13,004
Other	121	705
Total income tax benefit	$ (90)	$ (420)

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, 2023 and 2022 are presented below (in thousands):

	December 31, 2023	December 31, 2022
Deferred tax assets:		
Net operating losses and carryforwards	$ 139,735	$ 137,149
Section 174 Capitalization	7,536	4,027
Reserves	656	949
Accrued expenses	1,159	527
Lease liability	360	343
Stock-based compensation	1,460	2,591
Other, net	—	101
Total deferred tax assets	150,906	145,687
Deferred tax liabilities:		
Fixed assets	(222)	(726)
Intangible assets	(1,110)	(1,201)
Investment in Enumera	(574)	(1,317)
ROU asset	(339)	(340)
Prepaid expenses	(271)	(743)
Convertible debt	—	(552)
Total deferred tax liabilities	(2,516)	(4,879)
Net deferred tax assets	148,390	140,808
Less: valuation allowance	(148,649)	(141,155)
Net deferred tax liabilities	$ (259)	$ (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, 2023 was an increase of $7.5 million.

At December 31, 2023, the Company had federal and state income tax net operating loss (“NOL”) carryforwards of approximately $500.3 million and $218.6 million, respectively. The U.S. federal NOLs will be carried forward indefinitely and state NOLs will begin to expire in various years, depending on the applicable jurisdiction. Federal NOL carryforwards generated post the Tax Cuts and Jobs Act of 2017 may be carried forward indefinitely, subject to the 80% taxable income limitation on the utilization of the carryforwards. In addition, the Company has federal and state research and expenditure credit carryforwards of approximately $8.5 million and $1.9 million, respectively, as of December 31, 2023. The federal research and expenditure credit will begin to expire after 2033 unless otherwise utilized 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 NOL 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, 2023.

The Company is subject to taxation in the United States and 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, 2023, there were no interest and penalties related to uncertain tax positions.

Note 13. Net Loss Per Share

The table below provides potentially dilutive securities in equivalent shares of common stock not included in the Company's calculation of diluted loss per share because to do so would be antidilutive:

	Year Ended December 31,	
	2023	2022
Stock options to purchase common stock	763,012	582,557
Restricted stock units	2,537,357	278,112
Common stock warrant	48,475,911	2,331,597
Common stock issuable upon conversion of Convertible Notes	26,332,126	1,623,547
Total	78,108,406	4,815,813

Note 14. 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 for both of the years ended December 31, 2023 and 2022.

Note 15. Subsequent Events

From January 1, 2024 through March 27, 2024, the Company received net proceeds of $2.8 million, after deducting commissions and other offering expenses, from the sale of 2,591,662 shares under the ATM Sale Agreement. The Company sold such shares at a weighted average purchase price of $1.13 per share.

On March 8, 2024 the Company entered into an exchange agreement with a holder of the Company's 2025 Convertible Notes, pursuant to which the Company agreed to acquire an aggregate of $5.6 million of 2025 Convertible Notes from the holder in exchange for (i) $3.8 million in aggregate principal amount of 2028 Convertible Notes, and (ii) accrued and unpaid interest on the 2025 Convertible Notes exchanged. The Company also entered into a note purchase agreement with the investor to purchase $2.8 million in aggregate principal amount of 2028 Convertible Notes from the Company for cash at par value. Additionally, as part of the agreements, the investor was granted warrants to purchase 2,000,000 shares of common stock.

On March 31, 2024, the Company entered into a securities purchase agreement with certain institutional and accredited investors relating to (1) the offering and sale of an aggregate of 5,454,548 shares of the Company's common stock at an offering price of $1.10 per share in a registered direct offering (the "Offering") and (2) the issuance of unregistered warrants to purchase up to 5,454,548 shares of Common Stock with an exercise price of $1.10 to certain accredited investors in a concurrent private placement (the "Private Placement"). The Offering and the Private Placement are expected to close on April 3, 2024. The Company expects to receive gross proceeds from the Offering of approximately $6 million before deducting placement agent fees and estimated offering expenses.

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, 2023, 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, 2023 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, 2023 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, 2023, 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, 2023.

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.

Directors and Executive Officers

Biographical and other information regarding our executive officers and directors is set forth below. There are no family relationships among any of our directors or executive officers.

Name	Age	Position
Executive Officers		
Adi Mohanty	57	Chief Executive Officer and Director
Eric d'Esparbes	56	Chief Financial Officer
Clarke Neumann	60	SVP, General Counsel and Secretary
Non-Employee Directors		
Jeffrey D. Alter (1)(3)	61	Independent Chairman of the Board
Jeffrey A. Ferrell (2)(3)	49	Independent Director
Jill Howe (1)(3)	48	Independent Director
Brian L. Kotzin, M.D. (2)	75	Independent Director
Lynne Powell (1)	57	Independent Director

(1) Member of the Audit Committee
(2) Member of the Compensation Committee
(3) Member of the Nominating & Corporate Governance Committee (the "Nominating Committee")

Executive Officers

Adi Mohanty. Mr. Mohanty has served as our Chief Executive Officer and a member of our Board since November 2021. Prior to joining the Company, Mr. Mohanty founded EnCellX, Inc., a functional cell selection company, and he served as its Chief Executive Officer from December 2019 to November 2021. From 2014 to September 2018, he served as Chief Executive Officer, President and a member of the board of directors of BioTime (now Lineage Cell Therapeutics, Inc. (NYSE: LCTX)), a biotechnology company. Prior to BioTime, Mr. Mohanty served in various leadership roles at Transkaryotic Therapies, Inc., a biopharmaceutical company, and then at Shire PLC following its acquisition of Transkaryotic Therapies. Mr. Mohanty held several executive positions at Shire spanning global technical operations, product development and commercial operations. He was responsible for a global franchise in rare diseases with over $600 million in sales and operations in over 50 countries. His most recent role at Shire was as President of Regenerative Medicine, a full vertically integrated business unit of Shire with commercial and clinical products. Earlier in his career, Mr. Mohanty held a variety of management positions in the bioscience division of Baxter International Inc. (NYSE: BAX), a healthcare company. Mr. Mohanty previously served on the board of directors of Oncocyte Corp. (Nasdaq: OCX), a molecular diagnostics company, from 2015 to 2020 and Asterias Biotherapeutics, Inc., a cell therapy company, from 2015 to 2018. Mr. Mohanty earned his M.S. in Chemical Engineering from Clarkson University and his M.B.A. from Saint Mary's College, California.

We believe Mr. Mohanty is qualified to serve on our Board because of his extensive leadership experience in the biotechnology industry.

Eric d'Esparbes. Mr. d'Esparbes has served as our Chief Financial Officer since May 2019 and he served as our interim Chief Executive Officer from September 2021 to November 2021. With a focus on establishing strong financial controls and resolving legacy company challenges, Mr. d'Esparbes led the effort to bring the Company public in 2020, raising capital to support the Company's key innovation programs. He was also one of the leading forces behind its transformation into a highly focused biotherapeutics company. From 2014 to August 2018, Mr. d'Esparbes served as Chief Financial Officer of Innoviva, Inc. (Nasdaq: INVA), a publicly traded biotechnology company managing a portfolio of drug-device combination medicines for the treatment of asthma and chronic obstructive pulmonary disease, which are sold globally by GlaxoSmithKline, where he was responsible for all aspects of the finance function including financial accounting, capital planning, audit, tax and investor relations. Mr. d'Esparbes also served as the interim Principal Executive Officer of Innoviva from February 2018 to June 2018. Prior to this, Mr. d'Esparbes held leadership positions as Chief Financial Officer for Joule Unlimited, Vice President of Finance for global energy company AEI, Inc. and Chief Financial Officer for Meiya Power Company (now CNG New Energy), where he collaborated with large private equity investors to raise and optimize capital. In his previous CFO roles, he was responsible for profit and loss management of up to $3.5 billion annual global sales. Mr. d'Esparbes earned his bachelor's degree from Hautes Études Commercial in Montréal, Canada.

Clarke Neumann, J.D. Mr. Neumann has served as our General Counsel and Secretary since September 2014. Previously, Mr. Neumann served as Vice President, Associate General Counsel and Assistant Secretary of Sequenom, Inc., a molecular diagnostic testing and genetics analysis company, from 2012 to 2014, as Vice President, General Counsel and Assistant Secretary from 2001 to

2012 and as Corporate Counsel from 1999 to 2001. From 1993 to 1999, Mr. Neumann was an attorney at Lyon & Lyon, LLP, specializing in intellectual property litigation, strategic counseling, business litigation and transactional matters. Mr. Neumann earned his B.S. in Chemical Engineering from Pennsylvania State University and his J.D. from Loyola Law School, Los Angeles.

Non-employee Directors

Jeffrey D. Alter. Mr. Alter has served as a member of our Board since January 2019 and as the Chairman of our Board since November 2021. Mr. Alter has served as Chief Executive Officer and as a member of the board of directors of Sound Inpatient Physicians, Inc., a multi-specialty physician practice, since September 2023. Mr. Alter served as Chief Executive Officer and as a member of the board of directors of Summit Health, a healthcare network, from October 2021 to January 2023. Prior to joining Summit Health, Mr. Alter served as the Executive Vice President of IngenioRX and Anthem Health Solutions, at Anthem, Inc. (NYSE: ANTM), a health benefits company, from September 2020 to October 2021. From July 2018 to September 2020, Mr. Alter served as President of Arcturus One Consulting, LLC, a consulting company. From 2004 to June 2018, he served in various executive leadership positions at UnitedHealthcare Inc., a health plan business, including as Chief Executive Officer of its commercial group from 2014 to June 2018, as Chief Executive Officer of its employer and individual business from 2011 to 2014, as Chief Executive Officer of the Northeast Region from 2008 to 2011, as Chief Operating Officer from 2005 to 2008 and as Chief Financial Officer of the Northeast Region from 2004 to 2005. Mr. Alter earned both his B.S. in Marketing and his M.B.A. in Finance from Saint John's University, New York.

We believe Mr. Alter is qualified to serve on our Board because of his extensive leadership experience in the healthcare industry and finance experience.

Jeffrey A. Ferrell. Mr. Ferrell has served as a member of our Board since June 2014. Mr. Ferrell has served as the Managing Partner of Athyrium Capital Management, LP, a life sciences focused investment and advisory company, since 2008. Prior to Athyrium Capital, Mr. Ferrell served in a number of roles at Lehman Brothers Holdings Inc., a former financial services firm, including as Senior Vice President from 2005 to 2008 and as Vice President in its private equity division from 2002 to 2005. From 1997 to 2001, Mr. Ferrell served as a principal at Schroder Ventures Life Sciences, a healthcare fund. Mr. Ferrell previously served as a director of Lpath, Inc., a biotechnology company, from 2007 to 2016. Mr. Ferrell earned his A.B. in Biochemical Sciences from Harvard University.

We believe Mr. Ferrell is qualified to serve on our Board because of his extensive experience investing in and guiding early stage life sciences companies.

Jill Howe. Ms. Howe has served as a member of our Board since November 2021. Ms. Howe has served as Chief Financial Officer of Lineage Cell Therapeutics, Inc. (NYSE: LCTX), a biotechnology company, since November 2022. Prior to joining Lineage Cell Therapeutics, she served as Chief Financial Officer at DTx Pharma, Inc., a biotechnology company, from June 2021 to July 2022. Previously, Ms. Howe served as Treasurer and Vice President of Finance at Gossamer Bio, Inc. (Nasdaq: GOSS), a clinical-stage biopharmaceutical company, from January 2018 to June 2021, where she was the internal project lead for the company's initial public offering, follow-on offering and debt offerings, and oversaw finance for 18 subsidiaries across the U.S. and Ireland. Prior to Gossamer Bio, she served as Controller of Amplyx Pharmaceuticals, Inc., a biopharmaceutical company, from 2016 to December 2017. She previously held positions, including as Controller and Director of Finance, at Receptos, Inc., a biotechnology company, and at Somaxon Pharmaceuticals, Inc., a specialty pharmaceutical company. Ms. Howe has served on the board of directors at Codagenix, Inc., a clinical stage synthetic biology company, since 2021. Ms. Howe earned a B.S. in Accountancy from San Diego State University.

We believe Ms. Howe is qualified to serve on our Board because of her financial expertise in the biotechnology industry.

Brian L. Kotzin, M.D. Dr. Kotzin has served as a member of our Board since June 2019. Dr. Kotzin has served as Chief Executive Officer of BL Kotzin, Inc., a consulting services company, since 2015. Dr. Kotzin served as Chief Medical Officer, Senior Vice President of Clinical Development and Head of Immunology at Nektar Therapeutics (Nasdaq: NKTR), a biopharmaceutical company, from April 2022 to June 2023, and has previously held various other leadership positions at Nektar, including serving as Senior Vice President of Clinical Development and Head of Immunology from September 2021 to April 2022, as Chief Medical Officer and Head of Clinical Development from January 2021 to September 2021 and as Senior Vice President of Clinical Development since April 2017. Prior to Nektar, from 2004 to 2015, Dr. Kotzin served as Vice President of Global Clinical Development and Head of the Inflammation Therapeutic Area at Amgen Inc. (Nasdaq: AMGN), a biopharmaceutical company. During his employment at Amgen, he also served as Vice President of Translational Sciences and Head of Medical Sciences from 2006 to 2011. From 1981 to 2004, Dr. Kotzin served as a faculty member in the Division of Rheumatology of the Department of Medicine and Department of Immunology at the University of Colorado Health Sciences Center in Denver, Colorado. During this time, he also served as Head of Clinical Immunology in the Department of Medicine and as director of the Autoimmunity Center of Excellence from 1998 to 2004. Dr. Kotzin has been elected as a Master of the American College of Rheumatology and is an elected

Member of the American Society of Clinical Investigation and the Association of American Physicians. He has served as a member of the board of directors of Kyverna Therapeutics, Inc., a cell therapy company, since 2019, Rigel Pharmaceuticals, Inc. (Nasdaq: RIGL), a biotechnology company, since 2017, and Genascence, Inc., a gene therapy biotechnology company, since 2022. Dr. Kotzin previously served as a member of the board of directors of Vera Therapeutics, Inc. (Nasdaq: VERA), a clinical stage biotechnology company, in 2020. Dr. Kotzin earned his M.D. from Stanford University and his B.S. in Mathematics from the University of Southern California.

We believe Dr. Kotzin is qualified to serve on our Board because of his extensive academic research experience in immunology and experience as a senior executive and board member for life sciences companies

Lynne Powell. Ms. Powell has served as a member of our Board since February 2019. Since September 2019 and October 2019, Ms. Powell has served as Chief Executive Officer and as a member of the board of directors, respectively, of Tavanta Therapeutics (formerly known as Druggability Technologies Holdings Ltd prior to a reorganization), a specialty pharmaceutical company. Prior to joining Tavanta, Ms. Powell served as Senior Vice President and Chief Commercial Officer of BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX), a biotherapeutics company, from 2015 to July 2019. From 2010 to 2014, Ms. Powell served as Senior Vice President of North American Commercial Operations at CSL Behring, a biotherapeutics company. She earned her B.S. in Applied Biology, Pharmacology & Toxicology from the University of East London and her M.B.A. from Monash University (Australia) and Warwick University (UK).

We believe Ms. Powell is qualified to serve on our Board because of her extensive experience as a senior executive and board member in the pharmaceutical industry.

Code of Business Conduct and Ethics

Our Board has adopted a Code of Business Conduct and Ethics that establishes the standards of ethical conduct applicable to all our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. It addresses, among other matters, compliance with laws and policies, conflicts of interest, corporate opportunities, regulatory reporting, external communications, confidentiality requirements, insider trading, proper use of assets and how to report compliance concerns. A copy of the code is available on our website at https://investors.bioratherapeutics.com/, under "Governance." We intend to disclose any amendments to the code, or any waivers of its requirements, on our website to the extent required by applicable rules. Our Board is responsible for applying and interpreting the code in situations where questions are presented to it.

Audit Committee and Audit Committee Financial Expert

Our Board has a separately designated Audit Committee. The members of our Audit Committee are Mr. Alter, Ms. Howe, and Ms. Powell, each of whom qualifies as an "independent" director for audit committee purposes, as defined under Nasdaq listing rules and the rules and regulations established by the SEC. Ms. Howe qualifies as an "audit committee financial expert," as that term is defined in the rules and regulations established by the SEC, and all members of the Audit Committee are "financially literate" under Nasdaq listing rules.

Item 11. Executive Compensation.

Our named executive officers ("NEOs") for 2023, which consist of our principal executive officer and the next two most highly-compensated executives who served during the year ended December 31, 2023, are:

- Adi Mohanty, our Chief Executive Officer, or CEO;
- Eric d'Esparbes, our Chief Financial Officer and former interim CEO; and
- Clarke Neumann, our SVP, General Counsel and Secretary.

2023 Summary Compensation Table

The following table summarizes the compensation awarded to, earned by, or paid to our NEOs for 2023 and 2022.

Name and Principal Position	Year	Salary ($)	Stock Awards ($)[1]	Option Awards ($)[1]	Non-Equity Incentive Plan Compensation ($)[2]	All Other Compensation ($)[3]	Total ($)
Adi Mohanty	2023	574,141	2,154,881	—	388,125	21,870	3,139,017
Chief Executive Officer	2022	550,000	1,171,875	1,492,015	288,750	20,070	3,522,710
Eric d'Esparbes	2023	500,816	848,997	—	225,573	21,870	1,597,256
Chief Financial Officer	2022	486,130	450,998	576,680	146,003	19,773	1,679,584
Clarke Neumann	2023	483,034	808,302	—	217,641	23,940	1,532,917
SVP, General Counsel and Secretary	2022	464,550	364,815	466,527	139,514	20,070	1,455,476

(1) Amounts shown in this column represent the aggregate grant date fair value (calculated in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718) of stock awards and stock options granted during the year. A description of the methodologies and assumptions we use to value equity awards and the manner in which we recognize the related expense are described in Note 11 to our consolidated financial statements, Stock-Based Compensation. These amounts may not correspond to the actual value eventually realized by each NEO because the value depends on the market value of our common stock at the time the award vests or is exercised.

(2) On January 30, 2024, the Compensation Committee approved the non-equity incentive plan compensation earned in respect of 2023 as shown in the 2023 Summary Compensation Table for Eric d'Esparbes and Clarke Neumann and on February 6, 2024 the Board of Directors approved the non-equity incentive plan compensation earned in respect of 2023 as shown in the 2023 Summary Compensation Table for Adi Mohanty. Such bonuses are expected to be paid no later than June 30, 2024.

(3) For each NEO, the amounts shown in this column represent the value of life insurance premiums paid by the Company and the value of 401(k) contributions made by the Company.

Outstanding Equity Awards at 2023 Fiscal-Year End Table

The following table sets forth information regarding outstanding equity awards as of December 31, 2023 for each of our NEOs.

	Option Awards					Stock Awards	
Name	Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)
Adi Mohanty	11/8/2021[1]	43,476	39,999	88.50	11/8/2031	—	—
	5/15/2022[2]	39,506	60,310	18.75	5/15/2032	—	—
	8/15/2023[10]	—	—	—	—	559,450	755,258
Eric d'Esparbes	1/9/2020[3]	1,136	—	247.25	1/9/2030	—	—
	1/15/2020[4]	3,568	76	247.25	1/15/2030	—	—
	3/4/2020	311	—	244.00	3/4/2030	—	—
	8/15/2020[5]	2,522	431	192.75	8/15/2030	—	—
	3/15/2021	2,718	—	118.25	3/15/2031	—	—
	4/15/2021[6]	4,834	2,197	85.25	4/15/2031	—	—
	4/15/2022[7]	6,562	8,438	25.00	4/15/2032	—	—
	5/15/2022[8]	7,874	11,025	18.75	5/15/2032	—	—
	8/15/2023[10]	—	—	—	—	219,650	296,528
Clarke Neumann	9/10/2014	1,035	—	162.18	9/10/2024	—	—
	2/1/2015	388	—	268.75	2/1/2025	—	—
	2/24/2016	388	—	313.53	2/24/2026	—	—
	1/9/2020[3]	1,810	—	247.25	1/9/2030	—	—
	3/4/2020[9]	1,334	58	244.00	3/4/2030	—	—
	3/4/2020	257	—	244.00	3/4/2030	—	—
	8/15/2020[5]	1,437	246	192.75	8/15/2030	—	—
	3/15/2021	3,565	—	118.25	3/15/2031	—	—
	4/15/2021[6]	5,039	2,290	85.25	4/15/2031	—	—
	4/15/2022[7]	5,235	6,732	25.00	4/15/2032	—	—
	5/15/2022[8]	6,460	9,049	18.75	5/15/2032	—	—
	8/15/2023[10]	—	—	—	—	210,175	283,736

(1) The stock options granted on November 8, 2021 vest over a four-year period, with 25% vesting on the one-year anniversary of the date of grant and then in equal monthly installments thereafter.
(2) The stock options granted on May 15, 2022 vest over a four-year period, with 25% vesting on the one-year anniversary of the date of grant and then in equal monthly installments thereafter.
(3) On January 9, 2020, our Board and stockholders approved the reduction of the exercise price of the stock options to $247.25 to reflect the current fair market value of our common stock on such date.
(4) The stock options granted on January 15, 2020 vest over a four-year period, with 25% vesting on the one-year anniversary of the date of grant and then in equal monthly installments thereafter.
(5) The stock options granted on August 15, 2020 vest over a four-year period, in equal monthly installments ending on July 15, 2024.
(6) The stock options granted on April 15, 2021 vest over a four-year period in equal monthly installments ending on March 15, 2025.
(7) The stock options granted on April 15, 2022 vest over a four-year period in equal monthly installments ending on April 15, 2026.
(8) The stock options granted on May 15, 2022 vest over a four-year period in equal monthly installments ending on May 15, 2026.
(9) The stock options granted on March 4, 2020 vested over a four-year period in equal monthly installments ending on February 4, 2024.
(10) The RSUs granted on August 15, 2023 vest 25% on August 15, 2024 and thereafter in semi-annual installments beginning on February 15, 2025 and ending on August 15, 2027.

Employment Agreements

We do not have employment agreements with any of our NEOs at this time, but, in connection with Messrs. Mohanty's, d'Esparbes' and Neumann's commencement of employment, we extended offer letters to each of them that provide for base salary, participation in benefit plans and eligibility to earn an annual bonus. In addition, the offer letters provided for the grant of stock options and, in some cases, restricted stock units ("RSUs"), to each NEO, which are reflected in the Outstanding Equity Awards at 2023 Fiscal-Year End Table above. The offer letters also included a brief protection of confidential information commitment and related representations.

Base Salary

Messrs. Mohanty's, d'Esparbes' and Neumann's base salaries for 2023 were $575,000, $501,275 and $483,647, respectively, and such amounts represent ordinary course increases from the prior year equal to 4.5%, 3% and 4%, respectively. At the beginning of fiscal year 2024, the Compensation Committee approved ordinary course increases in base salary for Messrs. Mohanty, d'Esparbes and Neumann equal to 4.0%, 2.7% and 2.3%, respectively, resulting in base salaries equal to $598,000, $515,000 and $495,000, respectively.

Incentive Compensation

Annual Incentive. For fiscal 2023 our NEOs were eligible to receive an annual incentive bonus determined as a percentage of base salary based upon the achievement of pre-established corporate performance goals, which for 2023 included NaviCap Phase 1 IND submission weighted at 15%, NaviCap Phase 1 first patient in weighted at 15%, NaviCap Phase 1 last patient out weighted at 20%, NaviCap Functional DDS3 prototype device (performance demonstrated on benchtop) weighted at 10%, BioJet Preclinical PK data that supports further development with collaborator agreement weighted at 10%, sign broader Pharma partnership for BioJet (contingent on preclinical data) weighted at 10%, manage corporate spend within budget weighted at 10%, financing activities to support operations weighted at 10%, and stretch goal to optimize capital structure (reduce/remove debt) weighted at 10%. For 2023, the target award opportunities were 75%, 50% and 50% of base salary for each of Messrs. Mohanty, d'Esparbes and Neumann, respectively. Performance was measured at fiscal year-end and the Compensation Committee and the Board of Directors determined that the corporate goals were achieved at 90% and as a result decided to award bonuses as reported in the 2023 Summary Compensation Table for Messrs. Mohanty, d'Esparbes and Neumann.

Equity Incentive. We maintain our 2018 Equity Incentive Plan (as amended, the "2018 Plan") pursuant to which we currently grant stock option and RSU awards to eligible participants. We also maintain our 2021 Inducement Plan (the "2021 Plan"), pursuant to which we granted equity awards to Mr. Mohanty as a material inducement to his entry into employment with us in 2021. In March and August of 2023, each NEO received equity awards under the 2018 Plan in the form of RSUs, subject to our standard four-year vesting schedule. The equity awards were awarded in two tranches due to limited available shares in our 2018 Plan prior to approval by our stockholders in June 2023 to increase the number of shares authorized under our 2018 Plan.

Post-Employment Compensation and Change in Control Payments and Benefits

In December 2019, our Board adopted the Biora Therapeutics, Inc. Severance Plan (the "Severance Plan"), pursuant to which certain senior employees, including our NEOs, may become eligible to receive compensation and benefits upon certain qualifying terminations of employment. In the event that an NEO is terminated by the company without cause or voluntarily terminates employment with good reason (with "cause" and "good reason" each as defined in the Severance Plan), in either case more than three months prior to or 13 months or more following a change in control (as defined in the Severance Plan), subject to execution of a general release of claims in favor of the company and compliance with various standard restrictive covenants (such as protection of confidential information and non-disparagement commitments), the NEO is entitled to receive: (i) continued payment of base salary (for a period of 12 months, in the case of our CEO and Mr. d'Esparbes, and for a period of nine months, in the case of Mr. Neumann); and (ii) payment of the before-tax cost of the NEO's premiums to continue coverage (the "Continued Coverage") for the NEO and the NEO's eligible dependents, if any, under the company's health, vision and/or dental benefit plans to the extent such NEO (and eligible dependents, if applicable) were enrolled prior to such termination (for a period of 12 months, in the case of our CEO and Mr. d'Esparbes, and for a period of nine months, in the case of Mr. Neumann) ((i) and (ii) collectively, the "Non-Change in Control Benefits"). In the event that an NEO is terminated by the company without cause or voluntarily terminates employment with good reason, in either case within the period that is three months prior to or 13 months following a change in control, subject to execution of a general release of claims in favor of the company, the NEO is entitled to receive: (i) a lump sum payment within 30 days of the change in control equal to 24 months of base salary for the CEO and Mr. d'Esparbes and 18 months of base salary for Mr. Neumann; (ii) a lump sum payment within 30 days of the change in control equal to the NEO's average cash incentive bonus earned for the two most recently completed fiscal years multiplied by 2, in the case of the CEO and Mr. d'Esparbes, and by 1.5, in the case of Mr. Neumann; (iii) the Continued Coverage for a period of 24 months (or such shorter period as required by law), in the case of the CEO and Mr. d'Esparbes, and 18 months, in the case of Mr. Neumann; and (iv) all unvested time-based equity awards will accelerate in full and all unvested performance-based equity awards that are outstanding as of the termination date will vest, if at all, based on actual performance for the portion of the performance period ending shortly prior to the occurrence of the change in control as if such partial performance period were the entire performance period.

401(k) Plan

We offer our eligible full-time employees, including our NEOs, the opportunity to participate in our tax-qualified 401(k) plan. Employees can contribute 1% to 85% of their eligible earnings up to the Internal Revenue Service's annual limits, which is generally $23,000 for 2024. We provide a match of 60% of the first 10% contributed. The matches we provided to our NEOs in 2023 are reflected in the "All Other Compensation" column of the 2023 Summary Compensation Table above. The matching funds that we provide are 100% vested after the completion of one year of service.

Other Benefits

We do not maintain any defined benefit pension plans or any nonqualified deferred compensation plans. We previously maintained an Employee Stock Purchase Plan in order to enable eligible employees, including our eligible NEOs, to purchase shares of our common stock at a discount, but that plan was suspended in 2022.

Clawback Policy

Effective as of October 2, 2023, we adopted a clawback policy intended to comply with the requirements of Nasdaq Listing Standard 5608 implementing Rule 10D-1 under the Exchange Act. In the event the Company is required to prepare an accounting restatement of the Company's financial statements due to material non-compliance with any financial reporting requirement under the federal securities laws, the Company will recover, on a reasonably prompt basis, the excess incentive-based compensation received by any covered executive, including the NEOs, during the prior three fiscal years that exceeds the amount that the executive otherwise would have received had the incentive-based compensation been determined based on the restated financial statements.

Director Compensation

Outside Director Compensation Policy

We adopted a policy for compensating our non-employee directors with a combination of cash and equity, with such equity awards being subject to the terms and conditions of our 2018 Plan and the RSU Agreement and Stock Option Agreement thereunder, and related forms of grant notices approved by the Board.

Cash Compensation. Each of our non-employee directors is eligible to receive a $50,000 ($90,000 for our Chairman, Jeffrey D. Alter) annual cash retainer for serving as a member of the Board as well as the following additional annual cash retainers for their committee service:

	Chair	Member
Audit Committee	$ 20,000	$ 8,000
Compensation Committee	15,000	6,000
Nominating Committee	10,000	5,000

Each annual cash retainer and additional annual fee is paid quarterly in advance on a prorated basis. In addition, we reimburse all of our directors for their reasonable out-of-pocket expenses, including travel, food and lodging, incurred by them in connection with attendance at Board and committee meetings.

Equity Compensation. New non-employee directors are entitled to receive an initial equity grant of 30,000 RSUs and 30,000 stock options. Subject to the director's continued service, such initial equity awards vest in equal annual installments over a three-year period following the date of grant. In addition, in 2023 each non-employee director was entitled to receive an annual equity grant of 12,500 RSUs and 12,500 stock options vesting, subject to continued service through such date, on the earlier of (i) the one-year anniversary of the date of grant or (ii) the date of the following year's annual meeting of stockholders.

Fiscal Year 2023 Outside Director Compensation Table

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)[1]	Option Awards ($)[1]	All Other Compensation ($)	Total ($)
Jeffrey D. Alter	$ 103,000	58,688	46,424	—	208,112
Jeffrey A. Ferrell	—	—	—	—	—
Jill Howe	75,000	58,688	46,424	—	180,112
Brian L. Kotzin, M.D.	65,000	58,688	46,424	15,000 [3]	185,112
Lynne Powell	58,000	58,688	46,424	—	163,112
Surbhi Sarna [4]	28,000	—	—	—	28,000

(1) Amounts shown in this column represent the aggregate grant date fair value (calculated in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718 "*Compensation—Stock Compensation*") of stock awards and stock options granted during the year. A description of the methodologies and assumptions we use to value equity awards and the manner in which we recognize the related expense are described in Note 11 to our consolidated financial statements, Stock-Based Compensation. These amounts may not correspond to the actual value eventually realized by each director because the value depends on the market value of our common stock at the time the award vests or is exercised. As of December 31, 2023, Mr. Alter held 12,500 RSUs and 21,679 stock options, Mr. Ferrell held no RSUs and no stock options, Ms. Howe held 14,035 RSUs and 21,767 stock options, Dr. Kotzin held 12,500 RSUs and 21,679 stock options, Ms. Powell held 12,500 RSUs and 21,679 stock options, and Ms. Sarna held no RSUs and no stock options.

(2) Mr. Ferrell elected not to receive any compensation from us for his services in 2023.

(3) Represents amounts received pursuant to a consulting agreement between the Company and Dr. Kotzin.

(4) Ms. Sarna served as a director until the 2023 Annual Meeting of Stockholders.

Mr. Mohanty did not receive any additional compensation for his 2023 Board service. The compensation received by Mr. Mohanty for his services to us as our Chief Executive Officer is presented in the 2023 Summary Compensation Table below.

Indemnification Agreements

We have entered into indemnification agreements with our officers and directors. The indemnification agreements and our Bylaws require us to indemnify these individuals to the fullest extent permitted by Delaware law.

Compensation Committee Interlocks

None of the members of our Compensation Committee has at any time during the prior three years been one of our officers or employees. None of our executive officers currently serves, or in the past fiscal year has served, as a member of the board or compensation committee of any entity that has one or more executive officers serving on our Board or Compensation Committee. For more information regarding transactions involving entities affiliated with certain members of the Compensation Committee, please see transactions described under "Certain Relationships and Transactions" in Item 13. Certain Relationships and Related Transactions, and Director Independence.

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

Security Ownership of Certain Beneficial Owners and Management

Unless otherwise specified below, the following table presents information regarding beneficial ownership of our common stock as of March 1, 2024 by:

- each stockholder or group of stockholders known by us to be the beneficial owner of more than 5% of our outstanding common stock;
- each of our directors;
- each of our NEOs; and
- all of our current directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC, and thus represents voting or investment power with respect to our securities. Under such rules, beneficial ownership includes any shares over which the individual has sole or shared voting power or investment power as well as any shares that the individual has the right to acquire within 60 days after the date of this table. To our knowledge and subject to applicable community property rules, and except as otherwise indicated below, the persons and entities named in the table have sole voting and sole investment power with respect to all shares beneficially owned.

The percentage ownership information shown in the column titled "Percentage of Shares Beneficially Owned" in the table below is based on 29,336,364 shares of our common stock outstanding as of March 1, 2024 (plus any shares such person has the right to acquire within 60 days after the date of this table). Unless otherwise indicated, the address of each individual listed in this table is the Company's address set forth on the cover of this Annual Report on Form 10-K.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
Greater than 5% Holders		
Entities affiliated with Athyrium Capital Management, LP[1]	18,333,122	49.90%
Entities affiliated with Davidson Kempner Capital Management[2]	12,687,978	30.19%
Entities affiliated with Highbridge Tactical[3]	6,000,365	17.29%
Named Executive Officers and Directors		
Adi Mohanty[4]	259,296	*
Jeffrey D. Alter[5]	15,725	*
Jeffrey A. Ferrell[1]	18,333,122	49.90%
Jill Howe[6]	12,989	*
Brian L. Kotzin, M.D.[7]	14,925	*
Lynne Powell[8]	14,925	*
Eric d'Esparbes[9]	92,267	*
Clarke Neumann[10]	82,062	*
All current directors and executive officers as a group (8 persons)[11]	18,852,311	50.97%

* Represents beneficial ownership of less than one percent.

(1) Based solely on certain Company records and a Schedule 13D/A filed on December 20, 2023 and includes shares of common stock, shares of common stock issuable upon conversion of the 11.00% / 13.00% Convertible Senior Secured Notes due 2028 (the "11.00% / 13.00% Convertible Notes") and shares underlying certain warrants held by certain affiliates of Athyrium Capital Management, LP ("Athyrium"), and excludes shares underlying the 11.00% / 13.00% Convertible Notes and certain warrants that are subject to certain limitations on the ability on the ability of the holders of such notes or warrants to convert or exercise, applicable, if the holders' beneficial ownership of common stock (together with its affiliates and certain attribution parties) would exceed 49.9% of the outstanding shares of common stock. Consists of (a) 12,958,820 shares of common stock owned by Athyrium Opportunities III Co-Invest 1 LP ("Co-Invest LP"), (b) 671,917 shares of common stock owned by Athyrium Opportunities III Acquisition LP ("Acquisition LP"), (c) 4,519,052 shares of common stock owned by Athyrium Opportunities III Acquisition 2 LP ("Acquisition 2 LP" and, together with Acquisition LP, the "AOIII Acquisition Funds") and (d) 183,333 shares of common stock owned by Athyrium Opportunities 2020 LP ("2020 LP" and, together with Co-Invest LP and the AOIII Acquisition Funds, the "Funds"). Voting and investment power with respect to the shares of the Company's common stock held by the Funds may be deemed to be shared by certain affiliated entities. Athyrium Opportunities Associates III LP ("Associates III LP") is the General Partner of the AOIII Acquisition Funds and 2020 LP. Athyrium Opportunities Associates III GP LLC ("Associates III GP") is the General Partner of Associates III LP. Athyrium Opportunities Associates Co-Invest LLC ("Associates Co-Invest") is the General Partner of Co-Invest LP. Athyrium Funds GP Holdings LLC ("GP Holdings") is the Managing Member of Associates Co-Invest and Associates III GP. Jeffrey A. Ferrell, a member of the Company's Board, serves as the Managing Member of GP Holdings and the President of Associates III GP and Associates Co-Invest, and in his capacity as such, may be deemed to exercise shared voting and investment power over the shares owned by the Funds. Mr. Ferrell and each of the foregoing entities disclaim beneficial ownership of such shares except to the extent of his or its pecuniary interest therein. The business address of each of the above entities and Mr. Ferrell is c/o Athyrium Capital Management, LP, 505 Fifth Avenue, Floor 18, New York, New York 10017.

(2) Based solely on certain Company records. Consists of (a) 1,993,991 shares of common stock underlying certain exercisable warrants and 10,334,820 shares of common stock issuable upon the conversion of the 11.00% / 13.00% Convertible Notes held by Davidson Kempner Arbitrage, Equities and Relative Value LP and (b) 58,090 shares of common stock underlying certain exercisable warrants and 301,077 shares of common stock issuable upon the conversion of the 11.00% / 13.00% Convertible Notes held by M.H Davidson & Co. The business address of such affiliates of Davidson Kempner Capital Management is 520 Madison Avenue, 30th Floor, New York, New York 10022.

(3) Based solely on certain Company records. Consists of (a) 500,000 shares of common stock, 757,728 shares of common stock underlying certain exercisable warrants and 3,542,307 shares of common stock issuable upon the conversion of the 11.00% / 13.00% Convertible Notes held by certain affiliates of Highbridge Tactical Credit Master Fund, L.P and (b) 125,000 shares of common stock, 189,432 shares of common stock underlying certain exercisable warrants and 885,898 shares of common stock issuable upon the conversion of the 11.00% / 13.00% Convertible Notes held by certain affiliates of Highbridge Tactical Credit Institutional Fund, Ltd . The business address of such affiliates of Highbridge Tactical is 277 Park Ave, 23rd Floor, New York, New York, 10172.

(4) Consists of (a) 161,042 shares of common stock and (b) 98,254 shares of common stock underlying options that are exercisable as of the date of this table or will become exercisable within 60 days after such date.

(5) Consists of (a) 6,546 shares of common stock and (b) 9,179 shares of common stock underlying options that are exercisable as of the date of this table or will become exercisable within 60 days after such date.

(6) Consists of (a) 5,381 shares of common stock and (b) 7,608 shares of common stock underlying options that are exercisable as of the date of this table or will become exercisable within 60 days after such date.

(7) Consists of (a) 5,746 shares of common stock and (b) 9,179 shares of common stock underlying options that are exercisable as of the date of this table or will become exercisable within 60 days after such date.

(8) Consists of (a) 5,746 shares of common stock and (b) 9,179 shares of common stock underlying options that are exercisable as of the date of this table or will become exercisable within 60 days after such date.

(9) Consists of (a) 59,012 shares of common stock and (b) 33,255 shares of common stock underlying options that are exercisable as of the date of this table or will become exercisable within 60 days after such date.

(10) Consists of (a) 52,018 shares of common stock and (b) 30,044 shares of common stock underlying options that are exercisable as of the date of this table or will become exercisable within 60 days after such date.

(11) Consists of those shares described in footnotes (1) and (4) through (10) above.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table contains information about our equity compensation plans as of December 31, 2023. As of such date, we had outstanding awards under six equity compensation plans: our 2011 Incentive Stock Plan (the "2011 Plan"),Second Amended and Restated 2012 Stock Plan (the :2012 Plan"), our 2015 Consultant Stock Plan (the "2015 Plan"), our 2018 Plan, our 2020 Employee Stock Purchase Plan ("the "ESPP") and our 2021 Plan.

Plan Category	Number of Securities to Be Issued Upon Exercise of Outstanding Options, Warrants and Rights		Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance under Equity Compensation Plans (Excluding Securities Reflected in Column (a))	
	(a)		(b)[1]	(c)	
Equity compensation plans approved by security holders	3,136,913	(2)	$29.16	3,397,586	(3)
Equity compensation plans not approved by security holders	163,456	(4)	$60.13	63,964	(5)
Total	3,300,369		$36.23	3,461,550	

(1) The weighted-average exercise price does not take into account the shares issuable upon vesting of outstanding RSU awards, which have no exercise price.

(2) Consists of stock options to purchase 634,556 shares of our common stock and 2,502,357 RSUs granted under our 2018 Plan, our 2011 Plan, our 2012 Plan and our 2015 Plan.

(3) Represents 3,302,136 shares of our common stock reserved for future grants under our 2018 Plan and 95,450 shares reserved for issuance under our ESPP. Excludes 4,237,838 that were added to our 2018 Plan on January 1, 2024 pursuant to the evergreen provisions thereunder that provide for automatic annual increases on January 1 of each year until January 1, 2030 equal to 4% of our outstanding shares as of the preceding December 31 (or such lesser amounts as approved by the Board). Our ESPP was suspended effective November 6, 2022.

(4) Consists of stock options to purchase 128,456 shares of our common stock and 35,000 RSUs granted under our 2021 Plan.

(5) Represents shares of our common stock reserved for future grants under our 2021 Plan.

Material Features of the 2021 Inducement Plan

On November 3, 2021, the Board approved and adopted the 2021 Plan for the grant of awards to individuals not previously an employee or non-employee director of the Company (or following a bona fide period of non-employment with the Company), as an inducement material to the individual's entry into employment with the Company within the meaning of Rule 5635(c)(4) of the Nasdaq Listing Rules ("Rule 5635(c)(4)"). The Inducement Plan was approved by the independent directors of the Board without stockholder approval pursuant to Rule 5635(c)(4). The Inducement Plan was established with the purpose of helping 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 our common stock. Subject to adjustment for certain changes in our capitalization, the maximum aggregate number of shares that may be issued under the Inducement Plan is 260,000. The Inducement Plan permits the grant of non-statutory stock options, stock appreciation rights, restricted stock, RSUs, performance stock awards and other awards based in whole or part by reference to shares of our common stock.

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

The following is a summary of each transaction or series of similar transactions since January 1, 2022, or any currently proposed transaction, to which we were or are a party in which:

- the amount involved exceeds $120,000; and
- any related person (including our directors, executive officers, beneficial owners of more than 5% of our common stock, and any members of their immediate family) had or will have a direct or indirect material interest, other than compensation and other arrangements that are described under the section titled "Executive Compensation" or that were approved by our Compensation Committee.

Beneficial ownership of securities is determined in accordance with the rules of the SEC.

Related Party Transactions

Convertible Notes, Securities Purchase Agreement and Warrants

In November 2022, we 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 $3.75 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 $3.75 million due on our 7.25% Convertible Senior Notes due 2025 (the 7.25% Convertible Notes") 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 "Amended Warrants"). The Amended 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.

In September 2023, we entered into a convertible notes exchange agreement for common stock and warrants (the "September 2023 Exchange Agreement") with certain affiliates of Athyrium, pursuant to which $50,000,000 aggregate principal amount of the 7.25% Convertible Notes was exchanged for (1) an aggregate of 9,235,281 shares of common stock, (2) pre-funded warrants to purchase an aggregate of 7,399,226 shares of common stock ("September 2023 Pre-Funded Warrants"), (3) warrants to purchase an aggregate of 16,634,507 shares of common stock ("September 2023 Warrants"), and (4) accrued and unpaid interest paid in cash on the 7.25% Convertible Notes exchanged to, but excluding, the closing date. The September 2023 Pre-Funded Warrants have an exercise price of $0.001 per share and are exercisable at any time on or after September 18, 2023 until such September 2023 Pre-Funded Warrants have been fully exercised in accordance with their terms. The September 2023 Warrants have an exercise price of $3.01 per share and are exercisable at any time on or after September 18, 2023 until September 18, 2026. Each of the September 2023 Pre-Funded Warrants and the September 2023 Warrants are subject to certain exercise limitations, including a limitation on the ability to exercise if the holder's beneficial ownership of common stock (together with its affiliates and certain attribution parties) would exceed 49.9% of the outstanding common stock.

In December 2023, we entered into a convertible notes purchase agreement (the "December 2023 Purchase Agreement") with certain affiliates of Athyrium, pursuant to which such affiliates of Athyrium purchased $6,953,000 aggregate principal amount of the 11.00% / 13.00% Convertible Notes and warrants to purchase an aggregate of 2,085,372 shares of common stock (such warrants, "December 2023 Additional Warrants"), which warrants were issued to and are directly held by such affiliates of Athyrium pursuant to the terms of the December 2023 Purchase Agreement, from the Company in exchange for an aggregate of $6,953,000 in interest that had accrued but not yet been paid to such affiliates of Athyrium under the 7.25% Convertible Notes.

In December 2023, we entered into a convertible notes exchange agreement for new notes and warrants (the "December 2023 Exchange Agreement") with certain affiliates of Athyrium, pursuant to which such affiliates of Athyrium exchanged (1) $13,906,000 aggregate principal amount of 7.25% Convertible Notes for $10,430,000 aggregate principal amount of 11.00% / 13.00% Convertible Notes, together with accrued and unpaid interest on the 7.25% Convertible Notes exchanged, and (2) $39,594,000 aggregate principal amount of 7.25% Convertible Notes for warrants to purchase an aggregate of 5,039,236 shares of common stock ("December 2023 Exchange Warrants"), which warrants were issued to and are directly held by such affiliates of Athyrium pursuant to the terms of the December 2023 Exchange Agreement, together with accrued and unpaid interest on the 7.25% Convertible Notes exchanged. All accrued and unpaid interest on 7.25% Convertible Notes exchanged pursuant to the December 2023 Exchange Agreement was used to pay the purchase price owing pursuant to the December 2023 Purchase Agreement. The 11.00% / 13.00% Convertible Notes are subject to certain limitations on conversion, and limitations on the Company's ability to issue common stock to satisfy obligations under the 11.00% / 13.00% Convertible Notes, including a limitation on the ability of the holder to convert or the Company to issue common stock if the holder's beneficial ownership of common stock (together with its affiliates and certain attribution parties) would, in the case of Acquisition LP and Co-Invest LP, exceed 49.9% of the outstanding common stock. The December 2023 Additional Warrants have an exercise price of $5.00 per share and are exercisable at any time on or after December 19, 2023 until December 19, 2028. The December 2023 Exchange Warrants have an exercise price of $5.50 per share and are exercisable at any time on or after December 19, 2023 until December 19, 2028. Each of the December 2023 Additional Warrants and the December 2023 Exchange Warrants are subject to certain exercise limitations, including a limitation on the ability to exercise if the holder's beneficial ownership of common stock (together with its affiliates and certain attribution parties) would exceed 49.9% of the outstanding common stock.

In December 2023, we entered into a convertible notes purchase agreement with entities affiliated with Davidson Kempner Capital Management ("DK"), pursuant to which DK purchased $6,842,000 aggregate principal amount of the 11.00% / 13.00% Convertible Notes, Additional Warrants to purchase an aggregate of 2,052,081 shares of common stock and warrants to purchase an aggregate of 5,030,882 shares of common stock (such warrants, "December 2023 Commitment Warrants"). The December 2023 Commitment Warrants have an exercise price of $1.36 per share and are exercisable at any time on or after December 19, 2023 until December 19, 2028. Additionally, as part of the December 2023 Exchange Agreement, we entered into the agreement with certain

affiliates of DK, pursuant to which such affiliates of DK exchanged $13,000,000 aggregate principal amount of 7.25% Convertible Notes for $9,750,000 aggregate principal amount of 11.00% / 13.00% Convertible Notes.

In December 2023, we entered into a convertible notes purchase agreement with entities affiliated with Highbridge Tactical ("Highbridge"), pursuant to which Highbridge purchased $3,158,000 aggregate principal amount of the 11.00% / 13.00% Convertible Notes, December 2023 Additional Warrants to purchase an aggregate of 947,160 shares of common stock and December 2023 Commitment Warrants to purchase an aggregate of 2,322,059 shares of common stock. Additionally, as part of the December 2023 Exchange Agreement, we entered into the agreement with certain affiliates of Highbridge, pursuant to which such affiliates of Highbridge exchanged $6,000,000 aggregate principal amount of 7.25% Convertible Notes for (1) $3,750,000 aggregate principal amount of 11.00% / 13.00% Convertible Notes and (2) 625,000 shares of common stock.

In November 2022, we entered into a securities purchase agreement with Armistice Capital Master Fund Ltd. (together with its affiliates, "Armistice") 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. Following this transaction, Armistice 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 Armistice in exchange for Armistice'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.

Fourth Amended and Restated Investors' Rights Agreement

We are party to a fourth amended and restated investors' rights agreement, effective as of August 27, 2019, as amended, which provides certain holders of our capital stock, including funds managed by Athyrium, with certain registration rights, including the right to demand that we file a registration statement or request that their shares be covered by a registration statement that we are otherwise filing. The registration of shares of the Company's common stock pursuant to the exercise of registration rights described below would enable holders to sell these shares without restriction under the Securities Act of 1933, as amended (the "Securities Act") when the registration statement is declared effective. We will pay all expenses related to any demand, piggyback, or Form S-3 registration described below, with the exception of underwriting discounts and commissions. The registration rights described below will expire (i) five years after the completion of the Company's initial public offering, (ii) with respect to any particular holder, at the time that such holder can sell all its registrable securities under Rule 144 or another similar exemption under the Securities Act without limitation during a three-month period without registration or (iii) upon termination of the fourth amended and restated investors' rights agreement.

Demand Registration Rights

At any time beginning on January 14, 2021, the holders of 50% or more of the registrable securities then outstanding may make a written request that we register all or a portion of their shares, subject to certain specified exceptions. Such request for registration must cover securities with an aggregate offering price, net of underwriting discounts and commissions, of at least $20,000,000. We will prepare and file a registration statement as requested, unless, in the good faith judgment of the Board, such registration would be seriously detrimental to the Company and its stockholders and filing should be deferred. We may defer only once in any 12-month period, and such deferral shall not exceed 120 days after receipt of the request. In addition, we are not obligated to effect more than two of these registrations within any 12-month period or if the holders' proposed registered securities may be immediately registered on Form S-3.

Piggyback Registration Rights

Subject to certain specified exceptions, if we propose to register any of the Company's securities under the Securities Act either for the Company's own account or for the account of other stockholders, the holders of shares having registration rights are entitled to written notice and certain "piggyback" registration rights allowing them to include their shares in the Company's registration statement. These registration rights are subject to specified conditions and limitations, including the right of the underwriters, in their sole discretion, to limit the number of shares included in any such offering under certain circumstances, but not below 15% of the total amount of securities included in such offering, unless all other securities, other than the Company's securities, are entirely excluded from the offering.

Form S-3 Registration Rights

At any time after we are qualified to file a registration statement on Form S-3, and subject to limitations and conditions, the holders of 50% or more of the registrable securities then outstanding are entitled to written notice of such registration and may make a written request that we prepare and file a registration statement on Form S-3 under the Securities Act covering their shares, so long as the aggregate price to the public, net of the underwriters' discounts and commissions, is at least $10,000,000. We will prepare and file the Form S-3 registration as requested, unless, in the good faith judgment of the Board, such registration would be seriously

detrimental to the Company and its stockholders and filing should be deferred. We may defer only once in any 12-month period, and such deferral shall not exceed 120 days after receipt of the request. In addition, we are not obligated to prepare or file any of these registration statements: (i) within 180 days after the effective date of a registration statement pursuant to demand or piggyback registration rights or (ii) if two of these registrations have been completed within any 12-month period.

Registration Rights for Shares of Common Stock Issuable Upon Conversion of Notes

In connection with the issuance of the 7.25% Convertible Notes, we entered into an amendment to the registration rights agreement with certain entities affiliated with Athyrium pursuant to which certain entities affiliated with Athyrium acquired rights to cause us to register the resale of shares of common stock issuable upon conversion of the 7.25% Convertible Notes.

Investment in Enumera Molecular, Inc.

In May 2022, we completed the divesture of our single-molecule detection platform. Under the terms of the agreements, we 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. Enumera was formed by and is affiliated with Dr. Matthew Cooper, our former Chief Scientific Officer, who owned approximately 10% of the equity interests of Enumera on a fully diluted basis immediately following the consummation of the transaction. Upon the consummation of the transaction, the Company received 6,000,000 shares of Series A-1 preferred stock of Enumera with an estimated value of $6.0 million in exchange for the contributed assets, representing 25% minority ownership in Enumera on a fully-diluted basis. In March 2024 we sold all of our ownership interest in Enumera.

Related Party Transaction Policy

We have adopted a written related party transaction policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related person transactions. For purposes of our policy, a related person transaction is a transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we and any related person (as defined above) are, were or will be participants in which the amount involved exceeds $100,000. Transactions involving compensation for services provided to us as an employee or director, among other limited exceptions, are deemed to have standing pre-approval by the Audit Committee but may be specifically reviewed if appropriate in light of the facts and circumstances.

Under the policy, if a transaction has been identified as a related party transaction, including any transaction that was not a related party transaction when originally consummated or any transaction that was not initially identified as a related party transaction prior to consummation, our management must present information regarding the related party transaction to our Audit Committee for review, consideration and approval or ratification. The presentation must include a description of, among other matters, the material facts, the interests, direct and indirect, of the related persons, the benefits to us of the transaction and whether the transaction is on terms that are comparable to the terms available to or from, as the case may be, an unrelated third party or to or from employees generally. Under the policy, we will collect information that we deem reasonably necessary from each director, executive officer and, to the extent feasible, significant stockholder to enable us to identify any existing or potential related party transactions and to effectuate the terms of the policy. In addition, under our Code of Business Conduct and Ethics, our employees and directors have an affirmative responsibility to disclose any transaction or relationship that reasonably could be expected to give rise to a conflict of interest. In considering related party transactions, our Audit Committee will take into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;
- the impact on a director's independence in the event that the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties or to or from employees generally.

The policy requires that, in determining whether to approve, ratify, or reject a related party transaction, our Audit Committee consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, our best interests and those of our stockholders, as our Audit Committee determines in the good faith exercise of its discretion.

Certain related party transactions described above were consummated prior to our adoption of the formal, written policy described above, and, accordingly, the foregoing policies and procedures were not followed with respect to these transactions. However, we believe that the terms obtained or consideration that we paid or received, as applicable, in connection with the

transactions described below were comparable to terms available or the amounts that would be paid or received, as applicable, in arm's-length transactions at such time.

Director Independence

Nasdaq listing rules require a majority of a listed company's board of directors to be comprised of independent directors who, in the opinion of the board of directors, do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. Subject to specified exceptions, each member of a listed company's audit, compensation and nominating committees must be independent, and audit and compensation committee members must satisfy additional independence criteria under the Securities Exchange Act of 1934, as amended (the "Exchange Act").

Our Board undertook a review of its composition and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including the beneficial ownership of our capital stock by each non-employee director, our Board has determined that Messrs. Alter and Ferrell, Dr. Kotzin and Mses. Howe and Powell qualify as "independent directors" as defined by the Nasdaq listing rules. Surbhi Sarna, our former director, was determined to be independent during the period she served on the Board in 2023. Mr. Mohanty is deemed not to be independent by virtue of his employment with the Company.

Our Board also determined that each of the directors currently serving on the Audit Committee and the Compensation Committee satisfy the additional independence criteria applicable to directors on such committees under Nasdaq listing rules and the rules and regulations established by the SEC.

In determining that Dr. Kotzin qualifies as an "independent director" as defined by the Nasdaq listing rules and satisfies the heightened independence standards for compensation committees, the Board took into consideration a consulting agreement between Dr. Kotzin and the Company pursuant to which Dr. Kotzin is eligible to receive up to $15,000 per year, which the Board determined did not affect his independence.

Item 14. Principal Accountant Fees and Services.

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

Audit Fees and Services

KPMG has served as our independent auditor since 2011. The following table summarizes the audit fees billed and expected to be billed by KPMG for the indicated fiscal years and the fees billed by KPMG for all other services rendered during the indicated fiscal years. All services associated with such fees were by our Audit Committee in accordance with the Policies and Procedures" described below.

	Year Ended December 31,	
Fee Category	**2023**	**2022**
Audit Fees[1]	$ 1,430,000	$ 1,450,000
Audit-Related Fees[2]	—	—
Tax Fees[3]	657,511	536,119
All Other Fees[4]	—	—
Total Fees	$ 2,087,511	$ 1,986,119

(1) Consists of aggregate fees billed for professional services related to the audit of our annual consolidated financial statements, review of our quarterly condensed consolidated financial statements and professional consultations with respect to accounting matters. Also includes services provided in connection with SEC filings, including consents and comment and comfort letters.
(2) Consists of fees for assurance and related services reasonably related to the performance of the audit or review of our financial statements.
(3) Consists of fees for professional services for tax compliance, tax advice and tax planning.
(4) Consists of fees for all other services.

Pre-Approval Policies and Procedures

Our Audit Committee has adopted procedures requiring the pre-approval of all audit and non-audit services performed by our independent auditor in order to assure that these services do not impair the auditor's independence. These procedures generally approve the performance of specific services subject to a cost limit for all such services. This general approval is reviewed, and if necessary modified, at least annually. Management must obtain the specific prior approval of the committee for each engagement of our auditor to perform other audit-related or other non-audit services. The committee does not delegate its responsibility to approve services performed by our auditor to any member of management. The committee has delegated authority to the committee chair to pre-approve any audit or non-audit service to be provided to us by our auditor provided that the fees for such services do not exceed $100,000. Any approval of services by the committee chair pursuant to this delegated authority must be reported to the committee at its next regularly scheduled meeting.

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 NUMBER	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	Amendment No. 4 to Fourth Amended and Restated Investors' Rights Agreement, dated September 18, 2023, by and among Biora Therapeutics, Inc., and certain of its stockholders (filed with the SEC as Exhibit 4.3 to the registrant's Form 8-K filed on September 19, 2023).
4.7	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).
4.8*	First Supplemental Indenture, dated as of December 19, 2023, between Biora Therapeutics, Inc. and The Bank of New York Mellon Trust Company, N.A., as trustee.
4.9*	Second Supplemental Indenture, dated as of March 12, 2024, between Biora Therapeutics, Inc. and The Bank of New York Mellon Trust Company, N.A., as trustee.
4.10	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).
4.11	Form of Warrant (filed with the SEC as Exhibit 4.1 to the registrant's Form 8-K filed on February 25, 2021).
4.12	Form of Warrant (filed with the SEC as Exhibit 4.1 to the registrant's Form 8-K filed on June 14, 2021).
4.13	Form of Warrant (filed with the SEC as Exhibit 4.1 to the registrant's Form 8-K filed on August 23, 2021).
4.14	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).
4.15	Form of Warrant (filed with the SEC as Exhibit 10.2 to the registrant's Form 8-K on November 9, 2022).
4.16	Form of Amended Warrant (filed with the SEC as Exhibit 10.3 to the registrant's Form 8-K filed on November 9, 2022).
4.17	Form of Amended Warrant (filed with the SEC as Exhibit 10.4 to the registrant's Form 8-K filed on November 9, 2022).

4.18	Form of Warrant (filed with the SEC as Exhibit 10.1 to the registrant's Form S-3 filed on January 27, 2023).
4.19	Form of Warrant (filed with the SEC as Exhibit 10.2 to the registrant's Form 8-K filed on June 14, 2023).
4.20	Form of Pre-Funded Warrant (filed with the SEC as Exhibit 4.1 to the registrant's Form 8-K filed on September 19, 2023).
4.21	Form of September 2023 Warrant (filed with the SEC as Exhibit 4.2 to the registrant's Form 8-K filed on September 19, 2023).
4.22	Form of October 2023 Private Placement Warrant (filed with the SEC as Exhibit 4.1 to the registrant's Form 8-K filed on October 11, 2023).
4.23*	Description of Securities.
4.24*	Indenture, dated as of December 19, 2023, between Biora Therapeutics, Inc. and GLAS Trust Company LLC.
4.25*	Supplemental Indenture, dated as of March 12, 2024, between Biora Therapeutics, Inc. and GLAS Trust Company LLC.
4.26	Form of Note (filed with the SEC as Exhibit 4.2 to the registrant's Form 8-K filed on December 18, 2023).
4.27	Form of Exchange Warrant (filed with the SEC as Exhibit 4.3 to the registrant's Form 8-K filed on December 18, 2023).
4.28	Form of Commitment Warrant (filed with the SEC as Exhibit 4.4 to the registrant's Form 8-K filed on December 18, 2023).
4.29	Form of Additional Warrant (filed with the SEC as Exhibit 4.5 to the registrant's Form 8-K filed on December 18, 2023).
4.30	Form of March 2024 Warrant (filed with the SEC as Exhibit 4.4 to the registrant's Form 8-K filed on March 11, 2024).
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 (filed with the SEC as Exhibit 10.2 to the registrant's Form 10-K filed on March 31, 2023).
10.3+	Fifth Amended and Restated 2018 Equity Incentive Plan (filed with the SEC as Exhibit 10.1 to the registrant's Form 8-K filed on June 15, 2023).
10.4+	2020 Employee Stock Purchase Plan (filed with the SEC as Exhibit 10.4 to the registrant's Form 10-K filed on March 31, 2023).
10.5+	2021 Inducement Plan (filed with the SEC as Exhibit 10.5 to the registrant's Form 10-K filed on March 31, 2023).
10.6+	Form of 2021 Inducement Plan Stock Option Grant Notice (filed with the SEC as Exhibit 10.6 to the registrant's Form 10-K filed on March 31, 2023).
10.7+	Form of Inducement Plan Stock Option Award Agreement (filed with the SEC as Exhibit 10.7 to the registrant's Form 10-K filed on March 31, 2023).
10.8+	Form of Inducement Plan RSU Grant Notice (filed with the SEC as Exhibit 10.8 to the registrant's Form 10-K filed on March 31, 2023).
10.9+	Form of 2021 Inducement Plan RSU Award Agreement (filed with the SEC as Exhibit 10.9 to the registrant's Form 10-K filed on March 31, 2023).
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	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).
10.22	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).
10.23	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).
10.24	Form of Securities Purchase Agreement (filed with the SEC as Exhibit 10.1 to the registrant's Form 8-K filed on June 14, 2023).
10.25	Convertible Notes Exchange Agreement for Common Stock and Warrants, dated September 18, 2023, by and among Biora Therapeutics, Inc., Athyrium Opportunities III Acquisition LP and Athyrium Opportunities III Co-Invest 1 LP (filed with the SEC as Exhibit 10.1 to the registrant's Form 8-K filed on September 19, 2023).
10.26	Purchase and Sale Agreement, dated October 6, 2023, by and among Biora Therapeutics, Inc. and Lynxdx, Inc (filed with the SEC as Exhibit 10.2 to the registrant's Form 10-Q filed on November 13, 2023).
10.27	Form of Note Exchange Agreement, dated December 18, 2023, between the Company and the holders named therein (filed with the SEC as Exhibit 10.1 to the registrant's Form 8-K filed on December 18, 2023).
10.28	Form of Note Purchase Agreement, dated December 18, 2023, between the Company and the purchasers named therein (filed with the SEC as Exhibit 10.2 to the registrant's Form 8-K filed on December 18, 2023).
10.29*	Security Agreement, dated as of December 19, 2023, between the Company, as issuer, subsidiaries of the Company, as guarantors, and GLAS Trust Company LLC, as Collateral Agent.
10.30	Form of Registration Rights Agreement, dated as of December 19, 2023, between the Company and the investors named therein (filed with the SEC as Exhibit 10.4 to the registrant's Form 8-K filed on December 18, 2023).
10.31	Form of Note Exchange Agreement, dated March 8, 2024, between the Company and the holder named therein (filed with the SEC as Exhibit 10.1 to the registrant's Form 8-K filed on March 11, 2024).
10.32	Form of Note Purchase Agreement, dated March 8, 2024, between the Company and the purchaser named therein (filed with the SEC as Exhibit 10.2 to the registrant's Form 8-K filed on March 11, 2024).
10.33	Form of Registration Rights Agreement, dated as of March 12, 2024, between the Company and the investor named therein (filed with the SEC as Exhibit 10.4 to the registrant's Form 8-K filed on March 11, 2024).
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.
97.1*	Biora Therapeutics, Inc. Compensation Recoupment (Clawback) Policy
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema with Embedded Linkbases Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.
\+ Indicates management contract or compensatory plan.
† 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: April 1, 2024

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)	April 1, 2024
/s/ Eric d'Esparbes **Eric d'Esparbes**	Chief Financial Officer (principal financial and accounting officer)	April 1, 2024
/s/ Jeffrey Alter **Jeffrey Alter**	Director	April 1, 2024
/s/ Jeffrey Ferrell **Jeffrey Ferrell**	Director	April 1, 2024
/s/ Jill Howe **Jill Howe**	Director	April 1, 2024
/s/ Dr. Brian L. Kotzin **Dr. Brian L. Kotzin**	Director	April 1, 2024
/s/ Lynne Powell **Lynne Powell**	Director	April 1, 2024

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4330 La Jolla Village Drive, Suite 300, San Diego, CA 92122

NOTICE OF THE 2024 ANNUAL MEETING OF STOCKHOLDERS
TO BE HELD ON JUNE 5, 2024

To the Stockholders of Biora Therapeutics:

Biora Therapeutics, Inc. (the "Company") will hold its 2024 Annual Meeting of Stockholders (the "Annual Meeting") on Wednesday, June 5, 2024, at 10:00 a.m. Pacific Time. The Annual Meeting will be a virtual meeting conducted exclusively online via live audio webcast at the unique link that will be emailed to you approximately one hour prior to the meeting after you register in advance at *www.proxydocs.com/BIOR*. The Annual Meeting will be held for the following purposes, as more fully described in the accompanying proxy statement (the "Proxy Statement"):

(1) To elect the six director nominees named in the Proxy Statement to serve until the 2025 Annual Meeting of Stockholders or until their successors are duly elected and qualified;

(2) To ratify the selection of KPMG LLP as the Company's independent registered public accounting firm for the year ending December 31, 2024;

(3) To approve an amendment to the Company's Certificate of Incorporation to increase the number of authorized shares of the Company's common stock, par value $0.001 per share (the "common stock"), from 164,000,000 to 300,000,000;

(4) To authorize, for purposes of complying with Nasdaq Listing Rule 5635(d), the issuance of shares of common stock underlying certain warrants issued by the Company pursuant to that certain Securities Purchase Agreement, dated as of March 31, 2024, by and among the Company and certain institutional and accredited investors, and those certain Warrant Amendment Agreements, dated as of March 31, 2024, by and between the Company and the institutional investors participating in the offering, in an amount equal to or in excess of 20% of the common stock outstanding immediately prior the issuance of such warrants; and

(5) To transact any other matters that may properly come before the Annual Meeting or any adjournments or postponements thereof.

The Board of Directors has fixed April 16, 2024 as the record date. Only stockholders of record at the close of business on that date will be entitled to notice of, and to vote at, the Annual Meeting or any adjournment or postponement thereof.

Instructions for accessing the virtual Annual Meeting are provided in the Proxy Statement. To attend the virtual Annual Meeting, stockholders must register by 5:00 p.m. Pacific Time on June 4, 2024. In the event of a technical malfunction or other situation that the meeting chair determines may affect the ability of the Annual Meeting to satisfy the requirements for a meeting of stockholders to be held by means of remote communication under the Delaware General Corporation Law, or that otherwise makes it advisable to adjourn the Annual Meeting, the meeting chair or secretary will convene the meeting at 11:00 a.m. Pacific Time on the date specified above and at the Company's address specified above solely for the purpose of adjourning the meeting to reconvene at a date, time and physical or virtual location announced by the meeting chair or secretary. Under either of the foregoing circumstances, we will post information regarding the announcement on the Investors page of the Company's website at *https://investors.bioratherapeutics.com/*.

By Order of the Board of Directors,

/s/ Adi Mohanty
Adi Mohanty
Chief Executive Officer and Director

San Diego, California
April 24, 2024

Whether or not you expect to participate in the virtual Annual Meeting, please vote as promptly as possible in order to ensure your representation at the Annual Meeting. You may vote online or, if you requested printed copies of the proxy materials, by telephone or by using the proxy card or voting instruction form provided with the printed proxy materials.

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LEGAL MATTERS

Important Notice Regarding the Availability of Proxy Materials for the 2024 Annual Meeting of Stockholders to Be Held on June 5, 2024. The Proxy Statement and Annual Report for the year ended December 31, 2023 are available at *www.proxydocs.com/BIOR*.

Forward-Looking Statements. The Proxy Statement may contain "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, which statements are subject to substantial risks and uncertainties and are based on estimates and assumptions. All statements other than statements of historical fact included in the Proxy Statement are forward-looking statements, including statements about the Company's Board of Directors, corporate governance practices, executive compensation program and equity compensation utilization. In some cases, you can identify forward-looking statements by terms such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "design," "estimate," "predict," "potential," "plan" or the negative of these terms, and similar expressions intended to identify forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors that could cause our actual results to differ materially from the forward-looking statements expressed or implied in the Proxy Statement. Such risks, uncertainties and other factors include those risks described in "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in the Company's most recent Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission ("SEC") and other subsequent documents we file with the SEC. The Company expressly disclaims any obligation to update or alter any statements whether as a result of new information, future events or otherwise, except as required by law.

Website References. Website references throughout this document are inactive textual references and provided for convenience only, and the content on the referenced websites is not incorporated herein by reference and does not constitute a part of the Proxy Statement.

Use of Trademarks. Biora Therapeutics is the trademark of Biora Therapeutics, Inc. Other names and brands may be claimed as the property of others.

4330 La Jolla Village Drive, Suite 300, San Diego, CA 92122

PROXY STATEMENT
FOR THE 2024 ANNUAL MEETING OF STOCKHOLDERS

QUESTIONS AND ANSWERS ABOUT THE PROXY MATERIALS AND VOTING

What Is the Purpose of These Proxy Materials?

We are making these proxy materials available to you in connection with the solicitation of proxies by the Board of Directors (the "Board") of Biora Therapeutics, Inc. ("we," "us," "our" or the "Company") for use at the 2024 Annual Meeting of Stockholders (the "Annual Meeting") to be held virtually on June 5, 2024 at 10:00 a.m. Pacific Time, or at any other time following adjournment or postponement thereof. You are invited to participate in the Annual Meeting and to vote on the proposals described in this Proxy Statement. The proxy materials are first being made available to our stockholders on or about April 24, 2024.

Why Did I Receive a Notice of Internet Availability?

Pursuant to U.S. Securities and Exchange Commission ("SEC") rules, we are furnishing the proxy materials to our stockholders primarily via the Internet instead of mailing printed copies. This process allows us to expedite our stockholders' receipt of proxy materials, lower the costs of printing and mailing the proxy materials and reduce the environmental impact of our Annual Meeting. If you received a Notice of Internet Availability of Proxy Materials (the "Notice"), you will not receive a printed copy of the proxy materials unless you request one. The Notice provides instructions on how to access the proxy materials for the Annual Meeting via the Internet, how to request a printed set of proxy materials and how to vote your shares.

Why Are We Holding a Virtual Annual Meeting?

We have adopted a virtual meeting format for the Annual Meeting to provide a consistent experience to all stockholders regardless of geographic location. We believe this expands stockholder access, improves communications and lowers our costs while reducing the environmental impact of the meeting. In structuring our virtual Annual Meeting, our goal is to enhance rather than constrain stockholder participation in the meeting, and we have designed the meeting to provide stockholders with the same rights and opportunities to participate as they would have at an in-person meeting.

Who Can Vote?

Only stockholders of record at the close of business on April 16, 2024 (the "Record Date") are entitled to notice of the Annual Meeting and to vote on the proposals described in this Proxy Statement. At the close of business on the Record Date, 35,883,843 shares of our common stock, par value $0.001 per share (the "common stock"), were issued and outstanding.

What Is the Difference between Holding Shares as a Registered Stockholder and as a Beneficial Owner?

Registered Stockholder: Shares Registered in Your Name

If your shares of common stock are registered directly in your name with our transfer agent, Equiniti Trust Company, LLC, you are considered to be, with respect to those shares of common stock, the registered stockholder, and these proxy materials are being sent directly to you by us.

Beneficial Owner: Shares Registered in the Name of a Broker, Fiduciary or Custodian

If your shares of common stock are held by a broker, fiduciary or custodian, you are considered the beneficial owner of shares of common stock held in "street name," and these proxy materials are being forwarded to you from that broker, fiduciary or custodian.

How Can I Participate in the Virtual Annual Meeting?

Stockholders of record as of the close of business on the record date are entitled to participate in and vote at the Annual Meeting. To participate in the Annual Meeting, including to vote, ask questions and view the list of registered stockholders as of the Record Date during the meeting, stockholders will need to register in advance following the instructions below.

We will endeavor to answer as many stockholder-submitted questions as time permits that relate to the proposals to be voted on at the meeting and comply with the Annual Meeting rules of conduct. We reserve the right to edit profanity or other inappropriate language and to exclude questions regarding topics that are not pertinent to the proposals to be voted on. If we receive substantially similar questions, we may group such questions together and provide a single response to avoid repetition.

The meeting webcast will begin promptly at 10:00 a.m. Pacific Time. Online check-in will begin approximately 15 minutes before then, and we encourage you to allow ample time for check-in procedures. If you experience technical difficulties during the check-in process or during the meeting, please call the technical support number that will be included in the email containing your access link to the meeting. Additional information regarding the rules and procedures for participating in the Annual Meeting will be set forth in our meeting rules of conduct, which stockholders can view during the meeting at the meeting website.

Meeting Registration Process for Registered Stockholders

If your shares are registered directly in your name with our transfer agent, you can register for the Annual Meeting at *www.proxydocs.com/BIOR* by following the instructions on the website. You must register by 5:00 p.m. Pacific Time on June 4, 2024. As part of the registration process, you will be asked to enter the control number located on your proxy card or Notice. Upon completing your registration, you will receive further instructions via email, including a unique link that will allow you access to the Annual Meeting and vote and submit questions during the Annual Meeting.

Meeting Registration Process for Beneficial Owners

If your shares are held in street name, you can register for the Annual Meeting at *www.proxydocs.com/BIOR* by following the instructions on the website. You must register by 5:00 p.m. Pacific Time on June 4, 2024. You will need to provide the registered name on your account and the name of your broker, bank or other nominee as part of the registration process. In addition, it is important that you also follow the instructions you receive from your broker, bank or other nominee about participating in the Annual Meeting, which may include a requirement to obtain a "legal proxy" from them and submit a copy during the advance registration process for the meeting. As the process for requesting a "legal proxy" can take up to several days, we recommend starting this process at least five days before the deadline to register for the Annual Meeting.

What Am I Voting on?

The proposals to be voted on at the Annual Meeting are as follows:

(1) Election of the six director nominees to serve until the 2025 Annual Meeting of Stockholders ("Proposal 1");

(2) Ratification of the selection of KPMG LLP as the Company's independent auditor for 2024 ("Proposal 2");

(3) Approval of an amendment to the Company's Certificate of Incorporation to increase the total number of authorized shares of our common stock from 164,000,000 to 300,000,000 ("Proposal 3"); and

(4) Authorization, for purposes of complying with Nasdaq Listing Rule 5635(d), of the issuance of shares of common stock underlying certain warrants issued by the Company pursuant to that certain Securities Purchase Agreement, dated as of March 31, 2024, by and among the Company and certain institutional and accredited investors, and those certain Warrant Amendment Agreements, dated as of March 31, 2024, by and between the Company and the institutional investors participating in the offering, in an amount equal to or in excess of 20% of the common stock outstanding immediately prior the issuance of such warrants ("Proposal 4").

How Does the Board Recommend That I Vote?

The Board recommends that you vote your shares "FOR" each director nominee in Proposal 1 and "FOR" Proposals 2, 3 and 4.

What If Another Matter Is Properly Brought before the Annual Meeting?

As of the date of filing this Proxy Statement, the Board knows of no other matters that will be presented for consideration at the Annual Meeting. If any other matters are properly brought before the Annual Meeting, it is the intention of the persons named as proxies in the proxy card to vote on such matters in accordance with their best judgment.

How Many Votes Do I Have?

Each share of common stock is entitled to one vote on each proposal to be voted on at the Annual Meeting.

What Does It Mean If I Receive More Than One Set of Proxy Materials?

If you receive more than one set of proxy materials, your shares may be registered in more than one name or held in different accounts. Please cast your vote with respect to each set of proxy materials that you receive to ensure that all of your shares are voted.

How Do I Vote?

Even if you plan to attend the Annual Meeting, we recommend that you also submit your vote as early as possible in advance so that your vote will be counted if you later decide not to, or are unable to, virtually attend the Annual Meeting.

Registered Stockholder: Shares Registered in Your Name

If you are the registered stockholder, you may vote your shares online during the virtual Annual Meeting (see "How Can I Participate in the Virtual Annual Meeting?" above) or by proxy in advance of the Annual Meeting by Internet (at *www.proxypush.com/BIOR*) or, if you requested paper copies of the proxy materials, by completing and mailing a proxy card or by telephone (at 866-230-8395).

Beneficial Owner: Shares Registered in the Name of a Broker, Fiduciary or Custodian

If you are the beneficial owner, you may vote your shares online during the virtual Annual Meeting (see "How Can I Participate in the Virtual Annual Meeting?" above) or you may direct your broker, fiduciary or custodian how to vote in advance of the Annual Meeting by following the instructions they provide.

What Happens If I Do Not Vote?

Registered Stockholder: Shares Registered in Your Name

If you are the registered stockholder and do not vote in one of the ways described above, your shares will not be voted at the Annual Meeting and will not be counted toward the quorum requirement.

Beneficial Owner: Shares Registered in the Name of a Broker, Fiduciary or Custodian

If you are the beneficial owner and do not direct your broker, fiduciary or custodian how to vote your shares, your broker, fiduciary or custodian will only be able to vote your shares with respect to proposals considered to be "routine." Your broker, fiduciary or custodian is not entitled to vote your shares with respect to "non-routine" proposals, which we refer to as a "broker non-vote." Whether a proposal is considered routine or non-routine is subject to stock exchange rules and final determination by the stock exchange. Even with respect to routine matters, some brokers are choosing not to exercise discretionary voting authority. As a result, we urge you to direct your broker, fiduciary or custodian how to vote your shares on all proposals to ensure that your vote is counted.

What If I Sign and Return a Proxy Card or Otherwise Vote but Do Not Indicate Specific Choices?

Registered Stockholder: Shares Registered in Your Name

The shares represented by each signed and returned proxy will be voted at the Annual Meeting by the persons named as proxies in the proxy card in accordance with the instructions indicated on the proxy card. However, if you are the registered stockholder and sign and return your proxy card without giving specific instructions, the persons named as proxies in the proxy card will vote your shares in accordance with the recommendations of the Board. Your shares will be counted toward the quorum requirement.

Beneficial Owner: Shares Registered in the Name of a Broker, Fiduciary or Custodian

If you are the beneficial owner and do not direct your broker, fiduciary or custodian how to vote your shares, your broker, fiduciary or custodian will only be able to vote your shares with respect to proposals considered to be "routine." Your broker, fiduciary or custodian is not entitled to vote your shares with respect to "non-routine" proposals, resulting in a broker non-vote with respect to such proposals.

Can I Change My Vote after I Submit My Proxy?

Registered Stockholder: Shares Registered in Your Name

If you are the registered stockholder, you may revoke your proxy at any time before the final vote at the Annual Meeting in any one of the following ways:

(1) You may complete and submit a new proxy card, but it must bear a later date than the original proxy card;

(2) You may submit new proxy instructions via telephone or the Internet;

(3) You may send a timely written notice that you are revoking your proxy to our Corporate Secretary at the address set forth on the first page of this Proxy Statement; or

(4) You may vote by attending the Annual Meeting virtually. However, your virtual attendance at the Annual Meeting will not, by itself, revoke your proxy.

Your last submitted vote is the one that will be counted.

Beneficial Owner: Shares Registered in the Name of a Broker, Fiduciary or Custodian

If you are the beneficial owner, you must follow the instructions you receive from your broker, fiduciary or custodian with respect to changing your vote.

What Is the Quorum Requirement?

The holders of one-third of the voting power of the stock outstanding and entitled to vote at the Annual Meeting, including at least one-third of the outstanding shares of common stock, must be present at the Annual Meeting, either virtually or represented by proxy, to constitute a quorum. A quorum is required to transact business at the Annual Meeting.

Your shares will be counted toward the quorum only if you submit a valid proxy (or a valid proxy is submitted on your behalf by your broker, fiduciary or custodian) or if you attend the Annual Meeting virtually and vote. Abstentions and broker non-votes will be counted toward the quorum requirement. If there is no quorum, the meeting chair or the holders of a majority of the voting power of the stock virtually present at the Annual Meeting, either personally or by proxy, may adjourn the Annual Meeting to another time or date.

How Many Votes Are Required to Approve Each Proposal and How Are Votes Counted?

Votes will be counted by Mediant Communications, Inc., a BetaNxt company, and the Company's SVP, General Counsel and Secretary will serve as the Inspector of Elections appointed for the Annual Meeting.

Proposal 1: Election of Directors

A nominee will be elected as a director at the Annual Meeting if the nominee receives a plurality of the votes cast "FOR" his or her election. "Plurality" means that the individuals who receive the highest number of votes cast "FOR" are elected as directors. Broker non-votes, if any, and votes that are withheld will not be counted as votes cast on the matter and will have no effect on the outcome of the election. Stockholders do not have cumulative voting rights for the election of directors.

Proposal 2: Ratification of Independent Auditor Selection

The affirmative vote of a majority of the shares of common stock present or represented at the Annual Meeting and entitled to vote on the matter is required for the ratification of the appointment of KPMG LLP as our independent auditor. Abstentions will have the same effect as a vote "AGAINST" the matter. Broker non-votes, if any, will have no effect on the outcome of the matter.

Proposal 3: Approval of An Amendment to Our Certificate of Incorporation to Increase the Number of Authorized Shares

The affirmative vote of a majority of the votes cast on the matter at the Annual Meeting is required for the approval of the amendment to the Company's Certificate of Incorporation to increase the number of authorized shares. Abstentions and broker non-votes, if any, will have no effect on the outcome of the matter.

Proposal 4: Authorization of the Issuance of Shares of Common Stock Underlying Certain Warrants

The affirmative vote of a majority of the shares of common stock present or represented at the Annual Meeting and entitled to vote on the matter is required for the authorization of the issuance of shares of common

stock underlying certain warrants. Abstentions will have the same effect as a vote "AGAINST" the matter. Broker non-votes, if any, will have no effect on the outcome of the matter.

Who Is Paying for This Proxy Solicitation?

We will pay the costs associated with the solicitation of proxies, including the preparation, assembly, printing and mailing of the proxy materials. We may also reimburse brokers, fiduciaries or custodians for the cost of forwarding proxy materials to beneficial owners of shares of common stock held in "street name."

In addition, our employees, officers and directors may solicit proxies in person or via telephone or the Internet. We will not pay additional compensation for any of these services.

How Can I Find out the Voting Results?

We expect to announce preliminary voting results at the Annual Meeting. Final voting results will be published in a Current Report on Form 8-K to be filed with the SEC within four business days after the Annual Meeting.

PROPOSAL 1: ELECTION OF DIRECTORS

The Board currently consists of six directors. At the Annual Meeting, the stockholders will vote to elect the six director nominees named in this Proxy Statement to serve until the 2025 Annual Meeting of Stockholders, in all cases until their successors have been duly elected and qualified or until their earlier resignation or removal. Our Board has nominated each of Adi Mohanty, Jeffrey D. Alter, Jeffrey A. Ferrell, Jill Howe, Brian L. Kotzin, M.D. and Lynne Powell for election to our Board. Each of them was most recently elected by stockholders at the 2023 Annual Meeting of Stockholders.

Our director nominees have indicated that they are willing and able to serve as directors. However, if any of them becomes unable or, for good cause, unwilling to serve, proxies may be voted for the election of such other person as shall be designated by our Board, or the Board may decrease the size of the Board.

Information Regarding Director Nominees

Biographical and other information regarding our director nominees, including the primary skills and experiences considered by our Nominating/Corporate Governance Committee (the "Nominating Committee") in determining to recommend them as nominees, is set forth below.

Name	Age (as of April 24)	Position
Adi Mohanty	57	Chief Executive Officer and Director
Jeffrey D. Alter[1][3]	61	Independent Chairman of the Board
Jeffrey A. Ferrell[2][3]	49	Independent Director
Jill Howe[1][3]	48	Independent Director
Brian L. Kotzin, M.D.[2]	75	Independent Director
Lynne Powell[1]	57	Independent Director

(1) Member of the Audit Committee
(2) Member of the Compensation Committee
(3) Member of the Nominating Committee

Adi Mohanty. Mr. Mohanty has served as our Chief Executive Officer and a member of our Board since November 2021. Prior to joining the Company, Mr. Mohanty founded EnCellX, Inc., a functional cell selection company, and he served as its Chief Executive Officer from December 2019 to November 2021. From 2014 to September 2018, he served as Chief Executive Officer, President and a member of the board of directors of BioTime (now Lineage Cell Therapeutics, Inc. (NYSE: LCTX)), a biotechnology company. Prior to BioTime, Mr. Mohanty served in various leadership roles at Transkaryotic Therapies, Inc., a biopharmaceutical company, and then at Shire PLC following its acquisition of Transkaryotic Therapies. Mr. Mohanty held several executive positions at Shire spanning global technical operations, product development and commercial operations. He was responsible for a global franchise in rare diseases with over $600 million in sales and operations in over 50 countries. His most recent role at Shire was as President of Regenerative Medicine, a full vertically integrated business unit of Shire with commercial and clinical products. Earlier in his career, Mr. Mohanty held a variety of management positions in the bioscience division of Baxter International Inc. (NYSE: BAX), a healthcare company. Mr. Mohanty previously served on the board of directors of Oncocyte Corp. (Nasdaq: OCX), a molecular diagnostics company, from 2015 to 2020 and Asterias Biotherapeutics, Inc., a cell therapy company, from 2015 to 2018. Mr. Mohanty earned his M.S. in Chemical Engineering from Clarkson University and his M.B.A. from Saint Mary's College, California.

We believe Mr. Mohanty is qualified to serve on our Board because of his extensive leadership experience in the biotechnology industry.

Jeffrey D. Alter. Mr. Alter has served as a member of our Board since January 2019 and as the Chairman of our Board since November 2021. Mr. Alter has served as Chief Executive Officer and as a member of the board of directors of Sound Inpatient Physicians, Inc., a multi-specialty physician practice, since September 2023. Mr. Alter served as Chief Executive Officer and as a member of the board of directors of Summit Health, a healthcare network, from October 2021 to January 2023. Prior to joining Summit Health, Mr. Alter served as the Executive Vice President of IngenioRX and Anthem Health Solutions, at Anthem, Inc. (NYSE: ANTM), a health benefits company, from September 2020 to October 2021. From July 2018 to September 2020, Mr. Alter served as President of Arcturus One Consulting, LLC, a consulting company. From 2004 to June 2018, he served in various executive leadership positions at UnitedHealthcare Inc., a health plan business, including as Chief Executive Officer of its commercial group from 2014 to June 2018, as Chief Executive Officer of its employer and individual business from 2011 to 2014, as Chief Executive Officer of the Northeast Region from 2008 to 2011, as Chief Operating Officer from 2005 to 2008 and as Chief Financial Officer of the Northeast Region from 2004 to 2005. Mr. Alter earned both his B.S. in Marketing and his M.B.A. in Finance from Saint John's University, New York.

We believe Mr. Alter is qualified to serve on our Board because of his extensive leadership experience in the healthcare industry and finance experience.

Jeffrey A. Ferrell. Mr. Ferrell has served as a member of our Board since June 2014. Mr. Ferrell has served as the Managing Partner of Athyrium Capital Management, LP, a life sciences focused investment and advisory company, since 2008. Prior to Athyrium Capital, Mr. Ferrell served in a number of roles at Lehman Brothers Holdings Inc., a former financial services firm, including as Senior Vice President from 2005 to 2008 and as Vice President in its private equity division from 2002 to 2005. From 1997 to 2001, Mr. Ferrell served as a principal at Schroder Ventures Life Sciences, a healthcare fund. Mr. Ferrell previously served as a director of Lpath, Inc., a biotechnology company, from 2007 to 2016. Mr. Ferrell earned his A.B. in Biochemical Sciences from Harvard University.

We believe Mr. Ferrell is qualified to serve on our Board because of his extensive experience investing in and guiding early stage life sciences companies.

Jill Howe. Ms. Howe has served as a member of our Board since November 2021. Ms. Howe has served as Chief Financial Officer of Lineage Cell Therapeutics, Inc. (NYSE: LCTX), a biotechnology company, since November 2022. Prior to joining Lineage Cell Therapeutics, she served as Chief Financial Officer at DTx Pharma, Inc., a biotechnology company, from June 2021 to July 2022. Previously, Ms. Howe served as Treasurer and Vice President of Finance at Gossamer Bio, Inc. (Nasdaq: GOSS), a clinical-stage biopharmaceutical company, from January 2018 to June 2021, where she was the internal project lead for the company's initial public offering, follow-on offering and debt offerings, and oversaw finance for 18 subsidiaries across the U.S. and Ireland. Prior to Gossamer Bio, she served as Controller of Amplyx Pharmaceuticals, Inc., a biopharmaceutical company, from 2016 to December 2017. She previously held positions, including as Controller and Director of Finance, at Receptos, Inc., a biotechnology company, and at Somaxon Pharmaceuticals, Inc., a specialty pharmaceutical company. Ms. Howe has served on the board of directors at Codagenix, Inc., a clinical stage synthetic biology company, since 2021. Ms. Howe earned a B.S. in Accountancy from San Diego State University.

We believe Ms. Howe is qualified to serve on our Board because of her financial expertise in the biotechnology industry.

Brian L. Kotzin, M.D. Dr. Kotzin has served as a member of our Board since June 2019. Dr. Kotzin has served as Chief Executive Officer of BL Kotzin, Inc., a consulting services company, since 2015. Dr. Kotzin served as Chief Medical Officer, Senior Vice President of Clinical Development and Head of Immunology at Nektar Therapeutics (Nasdaq: NKTR), a biopharmaceutical company, from April 2022 to June 2023, and has previously held various other leadership positions at Nektar, including serving as Senior Vice President of

Clinical Development and Head of Immunology from September 2021 to April 2022, as Chief Medical Officer and Head of Clinical Development from January 2021 to September 2021 and as Senior Vice President of Clinical Development since April 2017. Prior to Nektar, from 2004 to 2015, Dr. Kotzin served as Vice President of Global Clinical Development and Head of the Inflammation Therapeutic Area at Amgen Inc. (Nasdaq: AMGN), a biopharmaceutical company. During his employment at Amgen, he also served as Vice President of Translational Sciences and Head of Medical Sciences from 2006 to 2011. From 1981 to 2004, Dr. Kotzin served as a faculty member in the Division of Rheumatology of the Department of Medicine and Department of Immunology at the University of Colorado Health Sciences Center in Denver, Colorado. During this time, he also served as Head of Clinical Immunology in the Department of Medicine and as director of the Autoimmunity Center of Excellence from 1998 to 2004. Dr. Kotzin has been elected as a Master of the American College of Rheumatology and is an elected Member of the American Society of Clinical Investigation and the Association of American Physicians. He has served as a member of the board of directors of Kyverna Therapeutics, Inc., a cell therapy company, since 2019, Rigel Pharmaceuticals, Inc. (Nasdaq: RIGL), a biotechnology company, since 2017, and Genascence, Inc., a gene therapy biotechnology company, since 2022. Dr. Kotzin previously served as a member of the board of directors of Vera Therapeutics, Inc. (Nasdaq: VERA), a clinical stage biotechnology company, in 2020. Dr. Kotzin earned his M.D. from Stanford University and his B.S. in Mathematics from the University of Southern California.

We believe Dr. Kotzin is qualified to serve on our Board because of his extensive academic research experience in immunology and experience as a senior executive and board member for life sciences companies.

Lynne Powell. Ms. Powell has served as a member of our Board since February 2019. Since September 2019 and October 2019, Ms. Powell has served as Chief Executive Officer and as a member of the board of directors, respectively, of Tavanta Therapeutics (formerly known as Druggability Technologies Holdings Ltd prior to a reorganization), a specialty pharmaceutical company. Prior to joining Tavanta, Ms. Powell served as Senior Vice President and Chief Commercial Officer of BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX), a biotherapeutics company, from 2015 to July 2019. From 2010 to 2014, Ms. Powell served as Senior Vice President of North American Commercial Operations at CSL Behring, a biotherapeutics company. She earned her B.S. in Applied Biology, Pharmacology & Toxicology from the University of East London and her M.B.A. from Monash University (Australia) and Warwick University (UK).

We believe Ms. Powell is qualified to serve on our Board because of her extensive experience as a senior executive and board member in the pharmaceutical industry.

Board Recommendation

The Board recommends a vote "**FOR**" the election of each of the director nominees set forth above.

PROPOSAL 2: RATIFICATION OF INDEPENDENT AUDITOR SELECTION

Our Audit Committee has selected KPMG LLP ("KPMG") as the Company's independent registered public accounting firm for the year ending December 31, 2024. In this Proposal 2, we are asking stockholders to vote to ratify this selection. Representatives of KPMG are expected to be present at the Annual Meeting. They will have the opportunity to make a statement, if they desire to do so, and are expected to be available to respond to appropriate questions from stockholders.

Stockholder ratification of the selection of KPMG as the Company's independent auditor is not required by law or our Bylaws. However, we are seeking stockholder ratification as a matter of good corporate governance. If our stockholders fail to ratify the selection, the committee will reconsider its selection. Even if the selection is ratified, the committee, in its discretion, may direct the selection of a different independent auditor at any time during the year if it determines that such a change would be in the best interests of the Company and our stockholders.

KPMG has served as our independent auditor since 2011. The following table summarizes the audit fees billed and expected to be billed by KPMG for the indicated fiscal years and the fees billed by KPMG for all other services rendered during the indicated fiscal years. All services associated with such fees were pre-approved by our Audit Committee in accordance with the "Pre-Approval Policies and Procedures" described below.

	Year Ended December 31,	
Fee Category	**2023**	**2022**
Audit Fees[1]	$1,430,000	$1,450,000
Audit-Related Fees[2]	—	—
Tax Fees[3]	657,511	536,119
All Other Fees[4]	—	—
Total Fees	$2,087,511	$1,986,119

(1) Consists of aggregate fees billed for professional services related to the audit of our annual consolidated financial statements, review of our quarterly condensed consolidated financial statements and professional consultations with respect to accounting matters. Also includes services provided in connection with SEC filings, including consents and comment and comfort letters.
(2) Consists of fees for assurance and related services reasonably related to the performance of the audit or review of our financial statements.
(3) Consists of fees for professional services for tax compliance, tax advice and tax planning.
(4) Consists of fees for all other services.

Pre-Approval Policies and Procedures

Our Audit Committee has adopted procedures requiring the pre-approval of all audit and non-audit services performed by our independent auditor in order to assure that these services do not impair the auditor's independence. These procedures generally approve the performance of specific services subject to a cost limit for all such services. This general approval is reviewed, and if necessary modified, at least annually. Management must obtain the specific prior approval of the committee for each engagement of our auditor to perform other audit-related or other non-audit services. The committee does not delegate its responsibility to approve services performed by our auditor to any member of management. The committee has delegated authority to the committee chair to pre-approve any audit or non-audit service to be provided to us by our auditor provided that the fees for such services do not exceed $100,000. Any approval of services by the committee chair pursuant to this delegated authority must be reported to the committee at its next regularly scheduled meeting.

Report of the Audit Committee

The Audit Committee has reviewed and discussed the audited financial statements for the year ended December 31, 2023 with the Company's management and with KPMG, the Company's independent registered public accounting firm. The Audit Committee has discussed with KPMG the matters required to be discussed by the applicable standards of the Public Company Accounting Oversight Board ("PCAOB") and the SEC. The Audit Committee has also received the written disclosures and the letter from KPMG pursuant to applicable PCAOB requirements regarding its communications with the Audit Committee concerning independence, and the Audit Committee has discussed with KPMG its independence. Based on the foregoing, the Audit Committee recommended to the Board that the audited financial statements be included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023 for filing with the SEC.

This report is provided by the following directors, who serve on the Audit Committee:

Jill Howe (Chair)
Jeffrey D. Alter
Lynne Powell

Board Recommendation

The Board recommends a vote "**FOR**" the ratification of the selection of KPMG to serve as our independent auditor.

PROPOSAL 3: APPROVAL OF AN AMENDMENT TO OUR CERTIFICATE OF INCORPORATION TO INCREASE THE NUMBER OF AUTHORIZED SHARES

We are asking stockholders to approve an amendment to the Company's Amended and Restated Certificate of Incorporation (the "Certificate of Incorporation") to increase the number of authorized shares of common stock, par value $0.001 per share, from 164,000,000 to 300,000,000, which would also have the effect of increasing the total number of authorized shares from 174,000,000 to 310,000,000 (the "Proposed Certificate Amendment"). Specifically, the Proposed Certificate Amendment, which our Board has approved and declared advisable, would amend Section 4.1(a) of Article IV of the Certificate of Incorporation as follows:

> "(a) Authorized Stock. The total number of shares which the Corporation shall have authority to issue is ~~174,000,000~~310,000,000, of which ~~164,000,000~~300,000,000 shall be designated as Common Stock, par value $0.001 per share (the "Common Stock"), and 10,000,000 shall be designated as Preferred Stock, par value $0.001 per share (the "Preferred Stock")."

Under the Proposed Certificate Amendment, the authorized number of shares of preferred stock would remain unchanged.

Purpose of the Proposed Certificate Amendment

As of April 16, 2024, the Record Date, our common stock share utilization was approximately as follows:

	Number of Shares of Common Stock
Authorized for issuance	164,000,000
Issued and outstanding	35,883,843
Reserved for issuance	92,604,850
• *Available for future grant under employee equity incentive plans**	4,893,643
• *Outstanding awards under our employee equity incentive plans**	6,015,041
• *Outstanding warrants*	51,178,040
• *Outstanding convertible notes*	30,518,126
Total share usage (issued and outstanding + reserved for issuance)	128,488,693
Total share usage as a percentage of authorized	78.35%

* *Includes our Second Amended and Restated 2012 Stock Plan, 2018 Plan, 2020 Employee Stock Purchase Plan and 2021 Plan.*

As a result, only approximately 35,511,307 shares of our common stock (or 21.65% of the total authorized) remain available for future use.

Our Board believes that the availability of additional authorized shares of common stock is needed to provide us with additional flexibility to issue common stock for a variety of general corporate purposes as the Board may determine to be desirable. This includes, but is not limited to, raising equity capital, including any future at-the-market equity programs, using our common stock as consideration for acquisitions, mergers, business combinations or other corporate transactions, adopting additional employee benefit plans or reserving additional shares for issuance under existing plans and implementing stock splits. Unless our stockholders approve the Proposed Certificate Amendment, we may not have sufficient unissued and unreserved authorized shares to engage in similar transactions in the future.

Having additional authorized shares of common stock available for future use will allow us to issue additional shares of common stock without the expense and delay of arranging a special meeting of stockholders. We may seek a further increase in authorized shares from time to time in the future as considered appropriate by our Board.

Effect of the Proposed Certificate Amendment

The Proposed Certificate Amendment would not change the number of shares of common stock outstanding, nor will it have any immediate dilutive effect. However, the issuance of additional shares of common stock authorized by the Proposed Certificate Amendment may occur at times or under circumstances as to have a dilutive effect on earnings per share, book value per share or the percentage voting or ownership interest of the present holders of our common stock, none of whom have preemptive rights under the Certificate of Incorporation to subscribe for additional securities that we may issue.

The Proposed Certificate Amendment has been prompted by business and financial considerations. The Board currently is not aware of any attempt by a third party to accumulate shares of our common stock or take control of the Company by means of a merger, tender offer or solicitation in opposition to management or the Board. Moreover, we currently have no plans to issue newly authorized shares of common stock to discourage third parties from attempting to take over the Company. However, the Proposed Certificate Amendment could, under certain circumstances, have an anti-takeover effect or delay or prevent a change in control of the Company by providing the Company the capability to engage in actions that would be dilutive to a potential acquiror, to pursue alternative transactions, or to otherwise increase the potential cost to acquire control of the Company. Thus, while we currently have no intent to use the additional authorized shares as an anti-takeover device, the Proposed Certificate Amendment may have the effect of discouraging future unsolicited takeover attempts.

Once the Proposed Certificate Amendment is approved, no further action by the stockholders would be necessary prior to the issuance of additional shares of common stock unless required by law or Nasdaq listing rules. Each of the newly authorized shares of common stock will have the same rights and privileges as currently authorized shares of common stock. Adoption of the Proposed Certificate Amendment will not affect the rights of the holders of currently outstanding common stock, nor will it change the par value of the common stock.

A complete copy of the existing Certificate of Incorporation is available as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 2023.

The Proposed Certificate Amendment is binding. If the Proposed Certificate Amendment is approved, we intend to file a Certificate of Amendment to our Certificate of Incorporation with the Secretary of State of the State of Delaware as soon as reasonably practicable after the Annual Meeting. The Proposed Certificate Amendment will become effective upon such filing.

Board Recommendation

The Board recommends a vote "**FOR**" the approval of an amendment to the Company's certificate of incorporation to increase the number of authorized shares.

PROPOSAL 4: AUTHORIZATION OF THE ISSUANCE OF SHARES OF COMMON STOCK UNDERLYING CERTAIN WARRANTS

We are asking stockholders to authorize, for purposes of complying with Nasdaq Listing Rule 5635(d), the issuance of shares of common stock underlying certain warrants issued by the Company pursuant to that certain Securities Purchase Agreement, dated as of March 31, 2024 (the "Purchase Agreement"), by and among the Company and certain institutional and accredited investors (the "Investors"), and those certain Warrant Amendment Agreements, dated as of March 31, 2024, by and between the Company and certain of the Investors (the "Warrant Amendment Agreements"), in an amount equal to or in excess of 20% of the common stock outstanding immediately prior the issuance of such warrants.

Purchase Agreement

On March 31, 2024, we entered into the Purchase Agreement relating to (1) the offering and sale of an aggregate of 5,454,548 shares (the "Shares") of common stock, at an offering price of $1.10 per share in a registered direct offering (the "Offering") and (2) the issuance of unregistered warrants to purchase up to 5,454,548 shares of common stock (the "Warrants") with an exercise price of $1.10 to certain accredited investors in a concurrent private placement (the "Private Placement"). The Offering and the Private Placement closed on April 3, 2024 (the "Closing Date").

The gross proceeds received by us from the Offering were approximately $6 million, before deducting the placement agent's fees and other offering expenses. We intend to use the net proceeds from the Offering to support our operations, complete our ongoing BT-600 clinical trial, make further investments in the development of our oral biotherapeutics platforms, and for working capital and general corporate purposes.

Warrant Amendment Agreements

In addition, on March 31, 2024, we entered into the Warrant Amendment Agreements with certain of the Investors to amend outstanding warrants previously issued in (i) February 2021 to purchase up to 104,895 shares of common stock with an exercise price of $6.86 per share, which were subsequently amended in November 2022 to lower the exercise price to $0.3288 per share and which were further adjusted to set the exercise price at $8.22 per share as a result of the Company's reverse stock split; (ii) June 2021 to purchase 80,000 shares of common stock with an exercise price of $2.84 per share, which were subsequently amended in November 2022 to lower the exercise price to $0.3288 per share and which were further adjusted to set the exercise price at $8.22 per share as a result of the Company's reverse stock split; (iii) November 2022 to purchase up to 800,000 shares of common stock with an exercise price of $0.3288 per share, which were adjusted to set the exercise price at $8.22 per share as a result of the Company's reverse stock split; (iv) January 2023 to purchase up to 90,000 shares of common stock with an exercise price of $8.22 per share; (v) June 2023 to purchase 3,018,868 shares of common stock with an exercise price of $5.05 per share; and (vi) December 2023 to purchase 2,322,059 shares of common stock with an exercise price of $1.36 per share (collectively, the "Existing Warrants").

Accordingly, we agreed to (i) lower the exercise price of the Existing Warrants to $1.10 per share, (ii) provide that the Existing Warrants, as amended, will not be exercisable until we receive stockholder approval of this Proposal 4 (such date, the "Stockholder Approval Date") and (iii) extend the original expiration date of the Existing Warrants to be five years following the Stockholder Approval Date (the Existing Warrants, as amended, are referred to as the "Amended Warrants"). These amendments became effective on March 31, 2024.

Warrants

The Warrants each have an initial exercise price of $1.10 per share, and are exercisable beginning on the Stockholder Approval Date. Each Warrant will expire on the five-year anniversary of the Stockholder Approval Date.

Voting Agreements

On the Closing Date, entities affiliated with Athyrium Capital Management, LP (solely in their respective capacities as Company stockholders) and all of the officers and directors of the Company entered into voting agreements (the "Voting Agreements") to vote all of their shares of common stock in favor of Proposal 4.

Further Information

The terms of the Purchase Agreement, the Warrants and the Voting Agreements are only briefly summarized above. For further information, please refer to the forms of the Purchase Agreement, the Warrants and the Voting Agreements, which were filed with the SEC as exhibits to our Current Report on Form 8-K, filed with the SEC on April 2, 2024. The discussion herein is qualified in its entirety by reference to the filed documents.

Reasons for the Warrant Exercise Proposal

Our common stock is listed on The Nasdaq Global Market and trades under the ticker symbol "BIOR." Nasdaq Listing Rule 5635(d) requires stockholder approval of transactions other than public offerings of greater than 20% of the outstanding common stock or voting power of the issuer prior to the transaction. In determining whether an offering qualifies as a public offering, Nasdaq considers all relevant factors, including the extent of any discount to market price. In determining discount, Nasdaq generally attributes a value of $0.125 for each warrant offered with a share of common stock, which value is generally deemed to be a discount. In order to ensure that the issuance of the Warrants and the amendment of the Existing Warrants qualified as a public offering under Rule 5635(d) due to the value attributable to the Warrants and the Amended Warrants, the Warrants and the Amended Warrants provide that they may not be exercised, and therefore have no value, until stockholder approval of their exercise is obtained.

Potential Consequences if Proposal 4 is Not Approved

The Board is not seeking the approval of our stockholders to authorize our entry into or consummation of the transactions contemplated by the Purchase Agreement and the Warrant Amendment Agreements, as the transactions have already been consummated and the Warrants and the Amended Warrants have already been issued. We are only asking for approval to issue the shares underlying the Warrants and the Amended Warrants upon exercise thereof.

The failure of our stockholders to approve this Proposal 4 will mean that: (i) we cannot permit the exercise of the Warrants and the Amended Warrants and (ii) may incur substantial additional costs and expenses.

Each Warrant and Amended Warrant has an initial exercise price of $1.10 per share. Accordingly, we would realize an aggregate of up to approximately $13 million in gross proceeds if all Warrants and Amended Warrants were exercised based on such value. If the Warrants and Amended Warrants cannot be exercised, we will not receive any such proceeds, which could adversely impact our ability to fund our operations.

In addition, in connection with the Private Placement and the issuance of Warrants, we agreed to seek stockholder approval every 90 days until our stockholders approve the issuance of the shares underlying the Warrants and the Amended Warrants. The costs and expenses associated with seeking such approval could materially adversely impact our ability to fund our operations and advance our clinical development plans.

Potential Adverse Effects of the Approval of Proposal 4

If this Proposal 4 is approved, existing stockholders will suffer dilution in their ownership interests in the future upon the issuance of shares of common stock upon exercise of the Warrants and Amended Warrants.

Assuming the full exercise of the Warrants and Amended Warrants, an aggregate of 11,870,370 additional shares of common stock will be outstanding, and the ownership interest of our existing stockholders would be correspondingly reduced. In addition, the sale into the public market of these shares also could materially and adversely affect the market price of our common stock.

Board Recommendation

The Board recommends a vote "FOR" the authorization, for purposes of complying with Nasdaq Listing Rule 5635(d), of the issuance of shares of common stock underlying certain warrants.

CORPORATE GOVERNANCE

Our business affairs are managed under the direction of our Board. Our Board has adopted a set of Principles of Corporate Governance as a framework for the governance of the Company, which is posted on our website at *https://investors.bioratherapeutics.com/documents-charters*, under "Governance Documents."

Board Composition

Director Nomination Process

The Nominating Committee is responsible for, among other things, overseeing succession planning for directors and building a qualified board to oversee management's execution of the Company's strategy and safeguard the long-term interests of stockholders. In this regard, the committee is charged with developing and recommending Board membership criteria to the Board for approval, evaluating the composition of the Board annually to assess the skills and experience that are currently represented on the Board and the skills and experience that the Board may find valuable in the future, and identifying, evaluating and recommending potential director candidates.

In identifying potential candidates for Board membership, the Nominating Committee considers recommendations from directors, stockholders, management and others, including, from time to time, third-party search firms to assist it in locating qualified candidates. Once potential director candidates are identified, the committee, with the assistance of management, undertakes a vetting process that considers each candidate's background, independence and fit with the Board's priorities. As part of this vetting process, the committee, as well as other members of the Board and the CEO, may conduct interviews with the candidates. If the committee determines that a potential candidate meets the needs of the Board and has the desired qualifications, it recommends the candidate to the full Board for appointment or nomination and to the stockholders for election at the annual meeting.

Criteria for Board Membership

In assessing potential candidates for Board membership and in assessing Board composition, the Nominating Committee considers a wide range of factors and generally seeks to balance the following skills, experiences and backgrounds on the Board:

- **Biotechnology Experience:** experience within the biotechnology industry, particularly in therapeutics, devices and diagnostics.
- **Corporate Governance:** experience, whether currently or in the past, serving on other public company boards of directors.
- **Diverse Background:** contribution to the diversity of personal backgrounds on the Board, including with respect to gender, race/ethnicity and sexual orientation.
- **Finance & Accounting:** experience or expertise in finance, accounting, investment analysis, financial reporting processes and capital markets.
- **Sales & Marketing:** experience overseeing and/or driving product sales, marketing and commercialization, particularly in therapeutics, devices and diagnostics.
- **Science & Research:** scientific knowledge related to biotechnology and life sciences (e.g., biology, chemistry, medicine) and experience in related research and clinical development.
- **Senior Leadership:** experience serving in a leadership role of an organization, including driving strategy execution, organizational growth and managing human capital.

In addition, the committee generally believes it is important for all Board members to possess the highest personal and professional ethics, integrity and values, an inquisitive and objective perspective, a sense for

priorities and balance, the ability and willingness to devote sufficient time and attention to Board matters, and a willingness to represent the long-term interests of all our stockholders.

Board Diversity

In addition to the factors discussed above, the Board and the Nominating Committee actively seek to achieve a diversity of occupational and personal backgrounds on the Board. The Nominating Committee considers a potential director candidate's ability to contribute to the diversity of personal backgrounds on the Board, including with respect to gender, race, ethnic and national background, geography, age and sexual orientation. The Nominating Committee assesses its effectiveness in balancing these considerations in connection with its annual evaluation of the composition of the Board. In this regard, our current Board of six directors includes two directors who self-identify as female (33%), one director who self-identifies as racially/ethnically diverse (17%) and one director who self-identifies as LGBTQ+ (17%).

In accordance with Nasdaq's board diversity listing standards, we are disclosing aggregated statistical information about our Board's self-identified gender and racial characteristics and LGBTQ+ status as voluntarily confirmed to us by each of our directors.

Board Diversity Matrix
(as of April 24)

Total number of directors – 6

Gender identity:	Female	Male	Non-Binary	Did Not Disclose Gender
Directors	2	4	—	—
Number of directors who identify in any of the categories below:				
African American or Black	—	—	—	—
Alaskan Native or Native American	—	—	—	—
Asian	—	1	—	—
Hispanic or Latinx	—	—	—	—
Native Hawaiian or Pacific Islander	—	—	—	—
White	2	3	—	—
Two or More Races or Ethnicities	—	—	—	—
LGBTQ+			1	
Did Not Disclose Demographic Background			—	

Stockholder Recommendations for Directors

It is the Nominating Committee's policy to consider written recommendations from stockholders for director candidates. The committee considers candidates recommended by our stockholders in the same manner as a candidate recommended by other sources. Any such recommendations should be submitted to the committee as described under "Stockholder Communications" and should include the same information required under our Bylaws for nominating a director, as described under "Stockholder Proposals and Director Nominations for Next Year's Annual Meeting."

Board Leadership Structure

Jeffrey D. Alter serves as our independent Chairman of the Board while Adi Mohanty serves as our Chief Executive Officer. Our Principles of Corporate Governance provide our Board with the flexibility to combine or separate the positions of Chairman and CEO. Currently, the Board believes that the roles of Chairman and CEO

should be separate and that the Chairman should be an independent director as this structure enables our independent Chairman to oversee corporate governance matters and our CEO to focus on leading the Company's business. At any time when the Chairman is not independent, the independent members of the Board may, upon the recommendation of the Nominating Committee, designate a non-management director to serve as the lead external director, or lead independent director if such external director is an independent director.

The independent directors have the opportunity to meet in executive sessions without management present at every regular Board meeting and at such other times as may be determined by the Chairman. The purpose of these executive sessions is to encourage and enhance communication among independent directors.

The Board believes that its programs for overseeing risk, as described under "Board Risk Oversight," would be effective under a variety of leadership frameworks. Accordingly, the Board's risk oversight function did not significantly impact its selection of the current leadership structure.

Director Independence

Nasdaq listing rules require a majority of a listed company's board of directors to be comprised of independent directors who, in the opinion of the board of directors, do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. Subject to specified exceptions, each member of a listed company's audit, compensation and nominating committees must be independent, and audit and compensation committee members must satisfy additional independence criteria under the Securities Exchange Act of 1934, as amended (the "Exchange Act").

Our Board undertook a review of its composition and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including the beneficial ownership of our capital stock by each non-employee director, our Board has determined that Messrs. Alter and Ferrell, Dr. Kotzin and Mses. Howe and Powell qualify as "independent directors" as defined by the Nasdaq listing rules. Surbhi Sarna, our former director, was determined to be independent during the period she served on the Board in 2023. Mr. Mohanty is deemed not to be independent by virtue of his employment with the Company.

Our Board also determined that each of the directors currently serving on the Audit Committee and the Compensation Committee satisfy the additional independence criteria applicable to directors on such committees under Nasdaq listing rules and the rules and regulations established by the SEC.

In determining that Dr. Kotzin qualifies as an "independent director" as defined by the Nasdaq listing rules and satisfies the heightened independence standards for compensation committees, the Board took into consideration a consulting agreement between Dr. Kotzin and the Company pursuant to which Dr. Kotzin is eligible to receive up to $15,000 per year, which the Board determined did not affect his independence.

Board Committees

Our Board has a separately designated Audit Committee, Compensation Committee and Nominating Committee, each of which is comprised solely of independent directors with the membership and responsibilities described below. Members serve on these committees until their resignation or until otherwise determined by our Board. Each of these committees is empowered to retain outside advisors as it deems appropriate, regularly reports its activities to the full Board and has a written charter. The charters of the Audit Committee, Compensation

Committee and Nominating Committee are posted on our website at *https://investors.bioratherapeutics.com/documents-charters*, under "Committee Charters."

Name	Audit Committee	Compensation Committee	Nominating Committee
Adi Mohanty			
Jeffrey D. Alter	X		X
Jeffrey A. Ferrell		X	Chair
Jill Howe	Chair		X
Brian L. Kotzin, M.D.		Chair	
Lynne Powell	X		
# of Meetings in 2023	4	4	1

Audit Committee. The primary responsibilities of our Audit Committee are to oversee the accounting and financial reporting processes of the Company and its subsidiaries, including the audits of the Company's financial statements, the integrity of the financial statements and the annual review of the performance, effectiveness and independence of the outside auditor. This includes reviewing the financial information provided to stockholders and others and the adequacy and effectiveness of the Company's internal controls. The committee also makes recommendations to the Board as to whether financial statements should be included in the Company's Annual Report on Form 10-K.

Ms. Howe qualifies as an "audit committee financial expert," as that term is defined in the rules and regulations established by the SEC, and all members of the Audit Committee are "financially literate" under Nasdaq listing rules.

Compensation Committee. The primary responsibilities of our Compensation Committee are to periodically review and approve the compensation and other benefits for our senior officers and directors. This includes reviewing and approving corporate goals and objectives relevant to the compensation of our senior officers, evaluating the performance of these officers in light of the goals and objectives and setting the officers' compensation based on those evaluations. The committee also administers and makes recommendations to the Board regarding equity incentive plans that are subject to the Board's approval and approves the grant of equity awards under the plans.

The Compensation Committee may delegate its authority to one or more subcommittees. The committee may also delegate authority to review and approve the compensation of our employees to certain of our executive officers. Even where the committee does not delegate authority, our executive officers will typically make recommendations to the committee regarding compensation to be paid to our employees and the size of equity awards under our equity incentive plans, but will not be present during voting or deliberations on their own compensation. The committee has the authority to engage outside advisors, such as compensation consultants, to assist it in carrying out its responsibilities. The committee engaged Compensia, Inc. ("Compensia") in 2023 to provide advice regarding the amount and form of executive and director compensation. The committee has determined that (1) Compensia satisfies applicable independence criteria, and (2) Compensia's work with the Company does not raise any conflict of interest, in each case under applicable Nasdaq listing rules and the rules and regulations established by the SEC.

Nominating Committee. The primary responsibilities of our Nominating Committee are to engage in succession planning for the Board, develop and recommend to the Board criteria for identifying and evaluating qualified director candidates, and make recommendations to the Board regarding candidates for election or reelection to the Board at each annual stockholders' meeting. In addition, the committee is responsible for overseeing our corporate governance practices and making recommendations to the Board concerning corporate governance matters. The committee is also responsible for making recommendations to the Board concerning the structure, composition and functioning of the Board and its committees.

Board Risk Oversight

We believe that risk management is an important part of establishing and executing on the Company's business strategy. Our Board, as a whole and at the committee level, focuses its oversight on the most significant risks facing the Company and on the Company's processes to identify, prioritize, assess, manage and mitigate those risks. The committees oversee specific risks within their purview, as follows:

- **The Audit Committee** has overall responsibility for overseeing the Company's practices with respect to risk assessment and management. Additionally, the committee is responsible for overseeing management of risks related to our accounting and financial reporting processes, compliance, and information technology and cybersecurity.
- **The Compensation Committee** is responsible for overseeing management of risks related to our compensation policies and programs.
- **The Nominating Committee** is responsible for overseeing management of risks related to director succession planning and our corporate governance practices.

Our Board and its committees receive regular reports from members of the Company's senior management on areas of material risk to the Company, including strategic, operational, financial, legal and regulatory risks. While our Board has an oversight role, management is principally tasked with direct responsibility for assessing and managing risks, including implementing processes and controls to mitigate their effects on the Company.

Other Corporate Governance Practices and Policies

Director Attendance

The Board met fifteen times during the year ended December 31, 2023. During 2023, each current member of the Board attended at least 75% of the aggregate number of meetings of the Board and the committees on which he or she served during the period in which he or she was on the Board or committee.

Directors are encouraged to attend the annual meeting of stockholders. Three directors then serving on the Board attended the 2023 Annual Meeting of Stockholders.

Stockholder Communications

Stockholders and other interested parties may communicate with our Board or a particular director by sending a letter addressed to the Board or a particular director to our Corporate Secretary at the address set forth on the first page of this Proxy Statement. These communications will be compiled and reviewed by our Corporate Secretary, who will determine whether the communication is appropriate for presentation to the Board or the particular director. The purpose of this screening is to allow the Board to avoid having to consider irrelevant or inappropriate communications (such as advertisements, solicitations and hostile communications).

To enable the Company to speak with a single voice, as a general matter, senior management serves as the primary spokesperson for the Company and is responsible for communicating with various constituencies, including stockholders, on behalf of the Company. Directors may participate in discussions with stockholders and other constituencies on issues where Board-level involvement is appropriate. In addition, the Board is kept informed by senior management of the Company's stockholder engagement efforts.

Code of Conduct

Our Board has adopted a Code of Business Conduct and Ethics that establishes the standards of ethical conduct applicable to all our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. It addresses, among other matters, compliance with laws and policies, conflicts of interest, corporate opportunities,

regulatory reporting, external communications, confidentiality requirements, insider trading, proper use of assets and how to report compliance concerns. A copy of the code is available on our website at *https://investors.bioratherapeutics.com/documents-charters*, under "Governance Documents." We intend to disclose any amendments to the code, or any waivers of its requirements, on our website to the extent required by applicable rules. Our Board is responsible for applying and interpreting the code in situations where questions are presented to it.

Anti-Hedging Policy

We have a policy that prohibits our employees, officers, directors and consultants from engaging in (a) short-term trading; (b) short sales; (c) transactions involving publicly traded options or other derivatives, such as trading in puts or calls with respect to Company securities; and (d) hedging transactions.

Compensation Committee Interlocks

None of the members of our Compensation Committee has at any time during the prior three years been one of our officers or employees. None of our executive officers currently serves, or in the past fiscal year has served, as a member of the board or compensation committee of any entity that has one or more executive officers serving on our Board or Compensation Committee. For more information regarding transactions involving entities affiliated with certain members of the Compensation Committee, please see transactions described under "Certain Relationships and Transactions" in this Proxy Statement.

Director Compensation

Outside Director Compensation Policy

We adopted a policy for compensating our non-employee directors with a combination of cash and equity, with such equity awards being subject to the terms and conditions of our 2018 Equity Incentive Plan (as amended, the "2018 Plan") and the Restricted Stock Unit ("RSU") Agreement and Stock Option Agreement thereunder, and related forms of grant notices approved by the Board.

Cash Compensation. Each of our non-employee directors is eligible to receive a $50,000 ($90,000 for our Chairman, Jeffrey D. Alter) annual cash retainer for serving as a member of the Board as well as the following additional annual cash retainers for their committee service:

	Chair	Member
Audit Committee	$20,000	$8,000
Compensation Committee	15,000	6,000
Nominating Committee	10,000	5,000

Each annual cash retainer and additional annual fee is paid quarterly in advance on a prorated basis. In addition, we reimburse all of our directors for their reasonable out-of-pocket expenses, including travel, food and lodging, incurred by them in connection with attendance at Board and committee meetings.

Equity Compensation. New non-employee directors are entitled to receive an initial equity grant of 30,000 RSUs and 30,000 stock options. Subject to the director's continued service, such initial equity awards vest in equal annual installments over a three-year period following the date of grant. In addition, in 2023, each non-employee director was entitled to receive an annual equity grant of 12,500 RSUs and 12,500 stock options vesting, subject to continued service through such date, on the earlier of (i) the one-year anniversary of the date of grant or (ii) the date of the following year's annual meeting of stockholders.

Fiscal Year 2023 Outside Director Compensation Table

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)[1]	Option Awards ($)[1]	All Other Compensation ($)	Total ($)
Jeffrey D. Alter	103,000	58,688	46,424	—	208,112
Jeffrey A. Ferrell[2]	—	—	—	—	—
Jill Howe	75,000	58,688	46,424	—	180,112
Brian L. Kotzin, M.D.	65,000	58,688	46,424	15,000[3]	185,112
Lynne Powell	58,000	58,688	46,424	—	163,112
Surbhi Sarna[4]	28,000	—	—	—	28,000

(1) Amounts shown in this column represent the aggregate grant date fair value (calculated in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718 "*Compensation—Stock Compensation*") of stock awards and stock options granted during the year. A description of the methodologies and assumptions we use to value equity awards and the manner in which we recognize the related expense are described in Note 11 to our consolidated financial statements, Stock-Based Compensation. These amounts may not correspond to the actual value eventually realized by each director because the value depends on the market value of our common stock at the time the award vests or is exercised. As of December 31, 2023, Mr. Alter held 12,500 RSUs and 21,679 stock options, Mr. Ferrell held no RSUs and no stock options, Ms. Howe held 14,035 RSUs and 21,767 stock options, Dr. Kotzin held 12,500 RSUs and 21,679 stock options, Ms. Powell held 12,500 RSUs and 21,679 stock options, and Ms. Sarna held no RSUs and no stock options.

(2) Mr. Ferrell elected not to receive any compensation from us for his services in 2023.

(3) Represents amounts received pursuant to a consulting agreement between the Company and Dr. Kotzin.

(4) Ms. Sarna served as a director until the 2023 Annual Meeting of Stockholders.

Mr. Mohanty did not receive any additional compensation for his 2023 Board service. The compensation received by Mr. Mohanty for his services to us as our Chief Executive Officer is presented in the 2023 Summary Compensation Table below.

Indemnification Agreements

We have entered into indemnification agreements with our officers and directors. The indemnification agreements and our Bylaws require us to indemnify these individuals to the fullest extent permitted by Delaware law.

EXECUTIVE OFFICERS

Biographical and other information regarding our executive officers is set forth below. There are no family relationships among any of our directors or executive officers.

Name	Age (as of April 24)	Position
Adi Mohanty[1]	57	Chief Executive Officer and Director
Eric d'Esparbes	56	Chief Financial Officer
Clarke Neumann	60	SVP, General Counsel and Secretary

(1) For Mr. Mohanty's biographical information, see "Information Regarding Director Nominees" above.

Eric d'Esparbes. Mr. d'Esparbes has served as our Chief Financial Officer since May 2019 and he served as our interim Chief Executive Officer from September 2021 to November 2021. With a focus on establishing strong financial controls and resolving legacy company challenges, Mr. d'Esparbes led the effort to bring the Company public in 2020, raising capital to support the Company's key innovation programs. He was also one of the leading forces behind its transformation into a highly focused biotherapeutics company. From 2014 to August 2018, Mr. d'Esparbes served as Chief Financial Officer of Innoviva, Inc. (Nasdaq: INVA), a publicly traded biotechnology company managing a portfolio of drug-device combination medicines for the treatment of asthma and chronic obstructive pulmonary disease, which are sold globally by GlaxoSmithKline, where he was responsible for all aspects of the finance function including financial accounting, capital planning, audit, tax and investor relations. Mr. d'Esparbes also served as the interim Principal Executive Officer of Innoviva from February 2018 to June 2018. Prior to this, Mr. d'Esparbes held leadership positions as Chief Financial Officer for Joule Unlimited, Vice President of Finance for global energy company AEI, Inc. and Chief Financial Officer for Meiya Power Company (now CNG New Energy), where he collaborated with large private equity investors to raise and optimize capital. In his previous CFO roles, he was responsible for profit and loss management of up to $3.5 billion annual global sales. Mr. d'Esparbes earned his bachelor's degree from Hautes Études Commercial in Montréal, Canada.

Clarke Neumann, J.D. Mr. Neumann has served as our General Counsel and Secretary since September 2014. Previously, Mr. Neumann served as Vice President, Associate General Counsel and Assistant Secretary of Sequenom, Inc., a molecular diagnostic testing and genetics analysis company, from 2012 to 2014, as Vice President, General Counsel and Assistant Secretary from 2001 to 2012 and as Corporate Counsel from 1999 to 2001. From 1993 to 1999, Mr. Neumann was an attorney at Lyon & Lyon, LLP, specializing in intellectual property litigation, strategic counseling, business litigation and transactional matters. Mr. Neumann earned his B.S. in Chemical Engineering from Pennsylvania State University and his J.D. from Loyola Law School, Los Angeles.

EXECUTIVE COMPENSATION

Our named executive officers ("NEOs") for 2023, which consist of our principal executive officer during 2023 and the next two most highly-compensated executives who served during the year ended December 31, 2023, are:

- Adi Mohanty, our Chief Executive Officer, or CEO;
- Eric d'Esparbes, our Chief Financial Officer and former interim CEO; and
- Clarke Neumann, our SVP, General Counsel and Secretary.

2023 Summary Compensation Table

The following table summarizes the compensation awarded to, earned by, or paid to our NEOs for 2023 and 2022.

Name and Principal Position	Year	Salary ($)	Stock Awards ($)[1]	Option Awards ($)[1]	Non-Equity Incentive Plan Compensation ($)[2]	All Other Compensation ($)[3]	Total ($)
Adi Mohanty	2023	574,141	2,154,881	—	388,125	21,870	3,139,017
Chief Executive Officer	2022	550,000	1,171,875	1,492,015	288,750	20,070	3,522,710
Eric d'Esparbes	2023	500,816	848,997	—	225,573	21,870	1,597,256
Chief Financial Officer	2022	486,130	450,998	576,680	146,003	19,773	1,679,584
Clarke Neumann	2023	483,034	808,302	—	217,641	23,940	1,532,917
SVP, General Counsel and Secretary	2022	464,550	364,815	466,527	139,514	20,070	1,455,476

(1) Amounts shown in this column represent the aggregate grant date fair value (calculated in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718) of stock awards and stock options granted during the year. A description of the methodologies and assumptions we use to value equity awards and the manner in which we recognize the related expense are described in Note 11 to our consolidated financial statements, Stock-Based Compensation. These amounts may not correspond to the actual value eventually realized by each NEO because the value depends on the market value of our common stock at the time the award vests or is exercised.

(2) On January 30, 2024, the Compensation Committee approved the non-equity incentive plan compensation earned in respect of 2023 as shown in the 2023 Summary Compensation Table for Eric d'Esparbes and Clarke Neumann and on February 6, 2024 the Board of Directors approved the non-equity incentive plan compensation earned in respect of 2023 as shown in the 2023 Summary Compensation Table for Adi Mohanty. Such bonuses are expected to be paid no later than June 30, 2024.

(3) For each NEO, the amounts shown in this column represent the value of life insurance premiums paid by the Company and the value of 401(k) contributions made by the Company.

Outstanding Equity Awards at 2023 Fiscal-Year End Table

The following table sets forth information regarding outstanding equity awards as of December 31, 2023 for each of our NEOs.

	Option Awards					Stock Awards	
Name	Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)
Adi Mohanty	11/8/2021[1]	43,476	39,999	88.50	11/8/2031	—	—
	5/15/2022[2]	39,506	60,310	18.75	5/15/2032	—	—
	8/15/2023[10]	—	—	—	—	559,450	755,258
Eric d'Esparbes	1/9/2020[3]	1,136	—	247.25	1/9/2030	—	—
	1/15/2020[4]	3,568	76	247.25	1/15/2030	—	—
	3/4/2020	311	—	244.00	3/4/2030	—	—
	8/15/2020[5]	2,522	431	192.75	8/15/2030	—	—
	3/15/2021	2,718	—	118.25	3/15/2031	—	—
	4/15/2021[6]	4,834	2,197	85.25	4/15/2031	—	—
	4/15/2022[7]	6,562	8,438	25.00	4/15/2032	—	—
	5/15/2022[8]	7,874	11,025	18.75	5/15/2032	—	—
	8/15/2023[10]	—	—	—	—	219,650	296,528
Clarke Neumann	9/10/2014	1,035	—	162.18	9/10/2024	—	—
	2/1/2015	388	—	268.75	2/1/2025	—	—
	2/24/2016	388	—	313.53	2/24/2026	—	—
	1/9/2020[3]	1,810	—	247.25	1/9/2030	—	—
	3/4/2020[9]	1,334	58	244.00	3/4/2030	—	—
	3/4/2020	257	—	244.00	3/4/2030	—	—
	8/15/2020[5]	1,437	246	192.75	8/15/2030	—	—
	3/15/2021	3,565	—	118.25	3/15/2031	—	—
	4/15/2021[6]	5,039	2,290	85.25	4/15/2031	—	—
	4/15/2022[7]	5,235	6,732	25.00	4/15/2032	—	—
	5/15/2022[8]	6,460	9,049	18.75	5/15/2032	—	—
	8/15/2023[10]	—	—	—	—	210,175	283,736

(1) The stock options granted on November 8, 2021 vest over a four-year period, with 25% vesting on the one-year anniversary of the date of grant and then in equal monthly installments thereafter.

(2) The stock options granted on May 15, 2022 vest over a four-year period, with 25% vesting on the one-year anniversary of the date of grant and then in equal monthly installments thereafter.

(3) On January 9, 2020, our Board and stockholders approved the reduction of the exercise price of the stock options to $247.25 to reflect the current fair market value of our common stock on such date.

(4) The stock options granted on January 15, 2020 vest over a four-year period, with 25% vesting on the one-year anniversary of the date of grant and then in equal monthly installments thereafter.

(5) The stock options granted on August 15, 2020 vest over a four-year period, in equal monthly installments ending on July 15, 2024.

(6) The stock options granted on April 15, 2021 vest over a four-year period in equal monthly installments ending on March 15, 2025.

(7) The stock options granted on April 15, 2022 vest over a four-year period in equal monthly installments ending on April 15, 2026.

(8) The stock options granted on May 15, 2022 vest over a four-year period in equal monthly installments ending on May 15, 2026.

(9) The stock options granted on March 4, 2020 vested over a four-year period in equal monthly installments ending on February 4, 2024.
(10) The RSUs granted on August 15, 2023 vest 25% on August 15, 2024 and thereafter in semi-annual installments beginning on February 15, 2025 and ending on August 15, 2027.

Employment Agreements

We do not have employment agreements with any of our NEOs at this time, but, in connection with Messrs. Mohanty's, d'Esparbes' and Neumann's commencement of employment, we extended offer letters to each of them that provide for base salary, participation in benefit plans and eligibility to earn an annual bonus. In addition, the offer letters provided for the grant of stock options and, in some cases, RSUs, to each NEO, which are reflected in the Outstanding Equity Awards at 2023 Fiscal-Year End Table above. The offer letters also included a brief protection of confidential information commitment and related representations.

Base Salary

Messrs. Mohanty's, d'Esparbes' and Neumann's base salaries for 2023 were $575,000, $501,275 and $483,647, respectively, and such amounts represent ordinary course increases from the prior year equal to 4.5%, 3% and 4%, respectively. At the beginning of fiscal year 2024, the Compensation Committee approved ordinary course increases in base salary for Messrs. Mohanty, d'Esparbes and Neumann equal to 4.0%, 2.7% and 2.3%, respectively, resulting in base salaries equal to $598,000, $515,000 and $495,000, respectively.

Incentive Compensation

Annual Incentive. For fiscal 2023 our NEOs were eligible to receive an annual incentive bonus determined as a percentage of base salary based upon the achievement of pre-established corporate performance goals, which for 2023 included NaviCap Phase 1 IND submission weighted at 15%, NaviCap Phase 1 first patient in weighted at 15%, NaviCap Phase 1 last patient out weighted at 20%, NaviCap Functional DDS3 prototype device (performance demonstrated on benchtop) weighted at 10%, BioJet Preclinical PK data that supports further development with collaborator agreement weighted at 10%, sign broader Pharma partnership for BioJet (contingent on preclinical data) weighted at 10%, manage corporate spend within budget weighted at 10%, financing activities to support operations weighted at 10%, and stretch goal to optimize capital structure (reduce/ remove debt) weighted at 10%. For 2023, the target award opportunities were 75%, 50% and 50% of base salary for each of Messrs. Mohanty, d'Esparbes and Neumann, respectively. Performance was measured at fiscal year-end and the Compensation Committee and the Board of Directors determined that the corporate goals were achieved at 90% and as a result decided to award bonuses as reported in the 2023 Summary Compensation Table for Messrs. d'Esparbes, Neumann and Mohanty.

Equity Incentive. We maintain our 2018 Equity Incentive Plan (as amended, the "2018 Plan") pursuant to which we currently grant stock option and RSU awards to eligible participants. We also maintain our 2021 Inducement Plan (the "2021 Plan"), pursuant to which we granted equity awards to Mr. Mohanty as a material inducement to his entry into employment with us in 2021. In March and August of 2023, each NEO received equity awards under the 2018 Plan in the form of RSUs, subject to our standard four-year vesting schedule. The equity awards were awarded in two tranches due to limited available shares in our 2018 Plan prior to approval by our stockholders in June 2023 to increase the number of shares authorized under our 2018 Plan.

Post-Employment Compensation and Change in Control Payments and Benefits

In December 2019, our Board adopted the Biora Therapeutics, Inc. Severance Plan (the "Severance Plan"), pursuant to which certain senior employees, including our NEOs, may become eligible to receive compensation and benefits upon certain qualifying terminations of employment. In the event that an NEO is terminated by the company without cause or voluntarily terminates employment with good reason (with "cause" and "good reason"

each as defined in the Severance Plan), in either case more than three months prior to or 13 months or more following a change in control (as defined in the Severance Plan), subject to execution of a general release of claims in favor of the company and compliance with various standard restrictive covenants (such as protection of confidential information and non-disparagement commitments), the NEO is entitled to receive: (i) continued payment of base salary (for a period of 12 months, in the case of our CEO and Mr. d'Esparbes, and for a period of nine months, in the case of Mr. Neumann); and (ii) payment of the before-tax cost of the NEO's premiums to continue coverage (the "Continued Coverage") for the NEO and the NEO's eligible dependents, if any, under the company's health, vision and/or dental benefit plans to the extent such NEO (and eligible dependents, if applicable) were enrolled prior to such termination (for a period of 12 months, in the case of our CEO and Mr. d'Esparbes, and for a period of nine months, in the case of Mr. Neumann) ((i) and (ii) collectively, the "Non-Change in Control Benefits"). In the event that an NEO is terminated by the company without cause or voluntarily terminates employment with good reason, in either case within the period that is three months prior to or 13 months following a change in control, subject to execution of a general release of claims in favor of the company, the NEO is entitled to receive: (i) a lump sum payment within 30 days of the change in control equal to 24 months of base salary for the CEO and Mr. d'Esparbes and 18 months of base salary for Mr. Neumann; (ii) a lump sum payment within 30 days of the change in control equal to the NEO's average cash incentive bonus earned for the two most recently completed fiscal years multiplied by 2, in the case of the CEO and Mr. d'Esparbes, and by 1.5, in the case of Mr. Neumann; (iii) the Continued Coverage for a period of 24 months (or such shorter period as required by law), in the case of the CEO and Mr. d'Esparbes, and 18 months, in the case of Mr. Neumann; and (iv) all unvested time-based equity awards will accelerate in full and all unvested performance-based equity awards that are outstanding as of the termination date will vest, if at all, based on actual performance for the portion of the performance period ending shortly prior to the occurrence of the change in control as if such partial performance period were the entire performance period.

401(k) Plan

We offer our eligible full-time employees, including our NEOs, the opportunity to participate in our tax-qualified 401(k) plan. Employees can contribute 1% to 85% of their eligible earnings up to the Internal Revenue Service's annual limits, which is generally $23,000 for 2024. We provide a match of 60% of the first 10% contributed. The matches we provided to our NEOs in 2023 are reflected in the "All Other Compensation" column of the 2023 Summary Compensation Table above. The matching funds that we provide are 100% vested after the completion of one year of service.

Other Benefits

We do not maintain any defined benefit pension plans or any nonqualified deferred compensation plans. We previously maintained an Employee Stock Purchase Plan in order to enable eligible employees, including our eligible NEOs, to purchase shares of our common stock at a discount, but that plan was suspended in 2022.

Clawback Policy

Effective as of October 2, 2023, we adopted a clawback policy intended to comply with the requirements of Nasdaq Listing Standard 5608 implementing Rule 10D-1 under the Exchange Act. In the event the Company is required to prepare an accounting restatement of the Company's financial statements due to material non-compliance with any financial reporting requirement under the federal securities laws, the Company will recover, on a reasonably prompt basis, the excess incentive-based compensation received by any covered executive, including the NEOs, during the prior three fiscal years that exceeds the amount that the executive otherwise would have received had the incentive-based compensation been determined based on the restated financial statements.

CERTAIN INFORMATION ABOUT OUR COMMON STOCK

Security Ownership of Certain Beneficial Owners and Management

Unless otherwise specified below, the following table presents information regarding beneficial ownership of our common stock as of March 1, 2024 by:

- each stockholder or group of stockholders known by us to be the beneficial owner of more than 5% of our outstanding common stock;
- each of our directors and nominees;
- each of our NEOs; and
- all of our current directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC, and thus represents voting or investment power with respect to our securities. Under such rules, beneficial ownership includes any shares over which the individual has sole or shared voting power or investment power as well as any shares that the individual has the right to acquire within 60 days after the date of this table. To our knowledge and subject to applicable community property rules, and except as otherwise indicated below, the persons and entities named in the table have sole voting and sole investment power with respect to all shares beneficially owned.

The percentage ownership information shown in the column titled "Percentage of Shares Beneficially Owned" in the table below is based on 29,336,364 shares of our common stock outstanding as of the date of this table (plus any shares such person has the right to acquire within 60 days after the date of this table). Unless otherwise indicated, the address of each individual listed in this table is the Company's address set forth on the first page of this Proxy Statement.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
Greater than 5% Holders		
Entities affiliated with Athyrium Capital Management, LP[1]	18,333,122	49.90%
Entities affiliated with Davidson Kempner Capital Management[2]	12,687,978	30.19%
Entities affiliated with Highbridge Tactical[3]	6,000,365	17.29%
Named Executive Officers, Directors and Nominees		
Adi Mohanty[4]	259,296	*
Jeffrey D. Alter[5]	15,725	*
Jeffrey A. Ferrell[1]	18,333,122	49.90%
Jill Howe[6]	12,989	*
Brian L. Kotzin, M.D.[7]	14,925	*
Lynne Powell[8]	14,925	*
Eric d'Esparbes[9]	92,267	*
Clarke Neumann[10]	82,062	*
All current directors and executive officers as a group (8 persons)[11]	18,825,311	50.97%

* Represents beneficial ownership of less than one percent.

(1) Based solely on certain Company records and a Schedule 13D/A filed on December 20, 2023 and includes shares of common stock, shares of common stock issuable upon conversion of the 11.00% / 13.00%

Convertible Senior Secured Notes due 2028 (the "11.00% / 13.00% Convertible Notes") and shares underlying certain warrants held by certain affiliates of Athyrium Capital Management, LP ("Athyrium"), and excludes shares underlying the 11.00% / 13.00% Convertible Notes and certain warrants that are subject to certain limitations on the ability on the ability of the holders of such notes or warrants to convert or exercise, applicable, if the holders' beneficial ownership of common stock (together with its affiliates and certain attribution parties) would exceed 49.9% of the outstanding shares of common stock. Consists of (a) 12,958,820 shares of common stock owned by Athyrium Opportunities III Co-Invest 1 LP ("Co-Invest LP"), (b) 671,917 shares of common stock owned by Athyrium Opportunities III Acquisition LP ("Acquisition LP"), (c) 4,519,052 shares of common stock owned by Athyrium Opportunities III Acquisition 2 LP ("Acquisition 2 LP" and, together with Acquisition LP, the "AOIII Acquisition Funds") and (d) 183,333 shares of common stock owned by Athyrium Opportunities 2020 LP ("2020 LP" and, together with Co-Invest LP and the AOIII Acquisition Funds, the "Funds"). Voting and investment power with respect to the shares of the Company's common stock held by the Funds may be deemed to be shared by certain affiliated entities. Athyrium Opportunities Associates III LP ("Associates III LP") is the General Partner of the AOIII Acquisition Funds and 2020 LP. Athyrium Opportunities Associates III GP LLC ("Associates III GP") is the General Partner of Associates III LP. Athyrium Opportunities Associates Co-Invest LLC ("Associates Co-Invest") is the General Partner of Co-Invest LP. Athyrium Funds GP Holdings LLC ("GP Holdings") is the Managing Member of Associates Co-Invest and Associates III GP. Jeffrey A. Ferrell, a member of the Company's Board, serves as the Managing Member of GP Holdings and the President of Associates III GP and Associates Co-Invest, and in his capacity as such, may be deemed to exercise shared voting and investment power over the shares owned by the Funds. Mr. Ferrell and each of the foregoing entities disclaim beneficial ownership of such shares except to the extent of his or its pecuniary interest therein. The business address of each of the above entities and Mr. Ferrell is c/o Athyrium Capital Management, LP, 505 Fifth Avenue, Floor 18, New York, New York 10017.

(2) Based solely on certain Company records. Consists of (a) 1,993,991 shares of common stock underlying certain exercisable warrants and 10,334,820 shares of common stock issuable upon the conversion of the 11.00% / 13.00% Convertible Notes held by Davidson Kempner Arbitrage, Equities and Relative Value LP and (b) 58,090 shares of common stock underlying certain exercisable warrants and 301,077 shares of common stock issuable upon the conversion of the 11.00% / 13.00% Convertible Notes held by M.H Davidson & Co. Conversion of, and receipt of shares of common stock pursuant to the terms of, the 11.00% / 13.00% Convertible Notes and the exercise of the warrants by Davidson Kempner Capital Management LP is subject to a beneficial ownership limitation of 9.9%. The business address of such affiliates of Davidson Kempner Capital Management is 520 Madison Avenue, 30th Floor, New York, New York 10022.

(3) Based solely on certain Company records. Consists of (a) 500,000 shares of common stock, 757,728 shares of common stock underlying certain exercisable warrants and 3,542,307 shares of common stock issuable upon the conversion of the 11.00% / 13.00% Convertible Notes held by certain affiliates of Highbridge Tactical Credit Master Fund, L.P. and (b) 125,000 shares of common stock, 189,432 shares of common stock underlying certain exercisable warrants and 885,898 shares of common stock issuable upon the conversion of the 11.00% / 13.00% Convertible Notes held by certain affiliates of Highbridge Tactical Credit Institutional Fund, Ltd. Conversion of, and receipt of shares of common stock pursuant to the terms of, the 11.00% / 13.00% Convertible Notes and the exercise of the warrants by Highbridge Tactical is subject to a beneficial ownership limitation of 9.9%. The business address of such affiliates of Highbridge Tactical is 277 Park Ave, 23rd Floor, New York, New York, 10172.

(4) Consists of (a) 161,042 shares of common stock, and (b) 98,254 shares of common stock underlying options that are exercisable as of the date of this table or will become exercisable within 60 days after such date.

(5) Consists of (a) 6,546 shares of common stock and (b) 9,179 shares of common stock underlying options that are exercisable as of the date of this table or will become exercisable within 60 days after such date.

(6) Consists of (a) 5,381 shares of common stock and (b) 7,608 shares of common stock underlying options that are exercisable as of the date of this table or will become exercisable within 60 days after such date.

(7) Consists of (a) 5,746 shares of common stock and (b) 9,179 shares of common stock underlying options that are exercisable as of the date of this table or will become exercisable within 60 days after such date.

(8) Consists of (a) 5,746 shares of common stock and (b) 9,179 shares of common stock underlying options that are exercisable as of the date of this table or will become exercisable within 60 days after such date.
(9) Consists of (a) 59,012 shares of common stock and (b) 33,255 shares of common stock underlying options that are exercisable as of the date of this table or will become exercisable within 60 days after such date.
(10) Consists of (a) 52,018 shares of common stock and (b) 30,044 shares of common stock underlying options that are exercisable as of the date of this table or will become exercisable within 60 days after such date.
(11) Consists of those shares described in footnotes (1) and (4) through (10) above.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table contains information about our equity compensation plans as of December 31, 2023. As of such date, we had outstanding awards under six equity compensation plans: our Second Amended and Restated 2012 Stock Plan (the "2012 Plan"), our 2018 Plan, our 2020 Employee Stock Purchase Plan (the "ESPP") and our 2021 Plan.

Plan Category	Number of Securities to Be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted-average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance under Equity Compensation Plans (Excluding Securities Reflected in Column (a))
	(a)	(b)[1]	(c)
Equity compensation plans approved by security holders	3,136,913[2]	$29.16	3,397,586[3]
Equity compensation plans not approved by security holders	163,456[4]	$60.13	63,964[5]
Total	3,300,369	$36.23	3,461,550

(1) The weighted-average exercise price does not take into account the shares issuable upon vesting of outstanding RSU awards, which have no exercise price.
(2) Consists of stock options to purchase 634,556 shares of our common stock and 2,502,357 RSUs granted under our 2018 Plan and our 2012 Plan.
(3) Represents 3,302,136 shares of our common stock reserved for future grants under our 2018 Plan and 95,450 shares reserved for issuance under our ESPP. Excludes 4,237,838 that were added to our 2018 Plan on January 1, 2024 pursuant to the evergreen provisions thereunder that provide for automatic annual increases on January 1 of each year until January 1, 2030 equal to 4% of our outstanding shares as of the preceding December 31 (or such lesser amounts as approved by the Board). Our ESPP was suspended effective November 6, 2022.
(4) Consists of stock options to purchase 128,456 shares of our common stock and 35,000 RSUs granted under our 2021 Plan.
(5) Represents shares of our common stock reserved for future grants under our 2021 Plan.

Material Features of the 2021 Inducement Plan

On November 3, 2021, the Board approved and adopted the 2021 Plan for the grant of awards to individuals not previously an employee or non-employee director of the Company (or following a bona fide period of non-employment with the Company), as an inducement material to the individual's entry into employment with the Company within the meaning of Rule 5635(c)(4) of the Nasdaq Listing Rules ("Rule 5635(c)(4)"). The Inducement Plan was approved by the independent directors of the Board without stockholder approval pursuant to Rule 5635(c)(4). The Inducement Plan was established with the purpose of helping 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 our common stock. Subject to adjustment for certain changes in our capitalization, the maximum aggregate number of shares that may be issued under the Inducement Plan is 260,000. The Inducement Plan permits the grant of non-statutory stock options, stock appreciation rights, restricted stock, RSUs, performance stock awards and other awards based in whole or part by reference to shares of our common stock.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a summary of each transaction or series of similar transactions since January 1, 2022, or any currently proposed transaction, to which we were or are a party in which:

- the amount involved exceeds $120,000; and
- any related person (including our directors, executive officers, beneficial owners of more than 5% of our common stock, and any members of their immediate family) had or will have a direct or indirect material interest, other than compensation and other arrangements that are described under the section titled "Executive Compensation" or that were approved by our Compensation Committee.

Beneficial ownership of securities is determined in accordance with the rules of the SEC.

Related Party Transactions

Convertible Notes, Securities Purchase Agreement and Warrants

In November 2022, we entered into a securities purchase agreement with Armistice Capital Master Fund Ltd. (together with its affiliates, "Armistice") 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. Following this transaction, Armistice 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 Armistice in exchange for Armistice's agreement to waive the lockup provisions contained in the November 2022 offering securities purchase agreement. The warrants held by Armistice were amended by the Warrant Amendment Agreements in March 2024 and, as amended, have an exercise price of $1.10, will become exercisable on the Stockholder Approval Date and expire on the fifth anniversary of the Stockholder Approval Date.

In March 2024, we entered into the Purchase Agreement with Armistice relating to the offering and sale of an aggregate of 1,363,637 shares of common stock in the Offering and accompanying warrants to purchase 1,363,637 shares of common stock in the Private Placement, at a combined purchase price of $1.10 per share.

In November 2022, we 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 $3.75 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 $3.75 million due on our 7.25% Convertible Senior Notes due 2025 (the "7.25% Convertible Notes") 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 "Amended Warrants"). The Amended 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.

In September 2023, we entered into a convertible notes exchange agreement for common stock and warrants (the "September 2023 Exchange Agreement") with certain affiliates of Athyrium, pursuant to which $50,000,000 aggregate principal amount of the 7.25% Convertible Notes was exchanged for (1) an aggregate of 9,235,281 shares of common stock, (2) pre-funded warrants to purchase an aggregate of 7,399,226 shares of common stock ("September 2023 Pre-Funded Warrants"), (3) warrants to purchase an aggregate of 16,634,507 shares of common stock ("September 2023 Warrants"), and (4) accrued and unpaid interest paid in cash on the 7.25%

Convertible Notes exchanged to, but excluding, the closing date. The September 2023 Pre-Funded Warrants have an exercise price of $0.001 per share and are exercisable at any time on or after September 18, 2023 until such September 2023 Pre-Funded Warrants have been fully exercised in accordance with their terms. The September 2023 Warrants have an exercise price of $3.01 per share and are exercisable at any time on or after September 18, 2023 until September 18, 2026. Each of the September 2023 Pre-Funded Warrants and the September 2023 Warrants are subject to certain exercise limitations, including a limitation on the ability to exercise if the holder's beneficial ownership of common stock (together with its affiliates and certain attribution parties) would exceed 49.9% of the outstanding common stock.

In December 2023, we entered into a convertible notes purchase agreement (the "December 2023 Purchase Agreement") with certain affiliates of Athyrium, pursuant to which such affiliates of Athyrium purchased $6,953,000 aggregate principal amount of the 11.00% / 13.00% Convertible Notes and warrants to purchase an aggregate of 2,085,372 shares of common stock (such warrants, "December 2023 Additional Warrants"), which warrants were issued to and are directly held by such affiliates of Athyrium pursuant to the terms of the December 2023 Purchase Agreement, from the Company in exchange for an aggregate of $6,953,000 in interest that had accrued but not yet been paid to such affiliates of Athyrium under the 7.25% Convertible Notes

In December 2023, we entered into a convertible notes exchange agreement for new notes and warrants (the "December 2023 Exchange Agreement")with certain affiliates of Athyrium, pursuant to which such affiliates of Athyrium exchanged (1) $13,906,000 aggregate principal amount of 7.25% Convertible Notes for $10,430,000 aggregate principal amount of 11.00% / 13.00% Convertible Notes, together with accrued and unpaid interest on the 7.25% Convertible Notes exchanged, and (2) $39,594,000 aggregate principal amount of 7.25% Convertible Notes for warrants to purchase an aggregate of 5,039,236 shares of common stock ("December 2023 Exchange Warrants"), which warrants were issued to and are directly held by such affiliates of Athyrium pursuant to the terms of the December 2023 Exchange Agreement, together with accrued and unpaid interest on the 7.25% Convertible Notes exchanged. All accrued and unpaid interest on 7.25% Convertible Notes exchanged pursuant to the December 2023 Exchange Agreement was used to pay the purchase price owing pursuant to the December 2023 Purchase Agreement. The 11.00% / 13.00% Convertible Notes are subject to certain limitations on conversion, and limitations on the Company's ability to issue common stock to satisfy obligations under the 11.00% / 13.00% Convertible Notes, including a limitation on the ability of the holder to convert or the Company to issue common stock if the holder's beneficial ownership of common stock (together with its affiliates and certain attribution parties) would, in the case of Acquisition LP and Co-Invest LP, exceed 49.9% of the outstanding common stock. The December 2023 Additional Warrants have an exercise price of $5.00 per share and are exercisable at any time on or after December 19, 2023 until December 19, 2028. The December 2023 Exchange Warrants have an exercise price of $5.50 per share and are exercisable at any time on or after December 19, 2023 until December 19, 2028. Each of the December 2023 Additional Warrants and the December 2023 Exchange Warrants are subject to certain exercise limitations, including a limitation on the ability to exercise if the holder's beneficial ownership of common stock (together with its affiliates and certain attribution parties) would exceed 49.9% of the outstanding common stock.

In December 2023, we entered into a convertible notes purchase agreement with entities affiliated with Davidson Kempner Capital Management ("DK"), pursuant to which DK purchased $6,842,000 aggregate principal amount of the 11.00% / 13.00% Convertible Notes, Additional Warrants to purchase an aggregate of 2,052,081 shares of common stock and warrants to purchase an aggregate of 5,030,882 shares of common stock (such warrants, "December 2023 Commitment Warrants"). The December 2023 Commitment Warrants have an exercise price of $1.36 per share and are exercisable at any time on or after December 19, 2023 until December 19, 2028. Additionally, as part of the December 2023 Exchange Agreement, we entered into the agreement with certain affiliates of DK, pursuant to which such affiliates of DK exchanged $13,000,000 aggregate principal amount of 7.25% Convertible Notes for $9,750,000 aggregate principal amount of 11.00% / 13.00% Convertible Notes.

In December 2023, we entered into a convertible notes purchase agreement with entities affiliated with Highbridge Tactical ("Highbridge"), pursuant to which Highbridge purchased $3,158,000 aggregate principal

amount of the 11.00% / 13.00% Convertible Notes, December 2023 Additional Warrants to purchase an aggregate of 947,160 shares of common stock and December 2023 Commitment Warrants to purchase an aggregate of 2,322,059 shares of common stock. Additionally, as part of the December 2023 Exchange Agreement, we entered into the agreement with certain affiliates of Highbridge, pursuant to which such affiliates of Highbridge exchanged $6,000,000 aggregate principal amount of 7.25% Convertible Notes for (1) $3,750,000 aggregate principal amount of 11.00% / 13.00% Convertible Notes and (2) 625,000 shares of common stock. The warrants held by Highbridge were amended by the Warrant Amendment Agreements in March 2024 and, as amended, have an exercise price of $1.10, will become exercisable on the Stockholder Approval Date and expire on the fifth anniversary of the Stockholder Approval Date.

In March 2024, we entered into the Purchase Agreement with Highbridge relating to the offering and sale of an aggregate of 1,363,637 shares of common stock in the Offering and accompanying warrants to purchase 1,363,637 shares of common stock in the Private Placement, at a combined purchase price of $1.10 per share.

Fourth Amended and Restated Investors' Rights Agreement

We are party to a fourth amended and restated investors' rights agreement, effective as of August 27, 2019, as amended, which provides certain holders of our capital stock, including funds managed by Athyrium, with certain registration rights, including the right to demand that we file a registration statement or request that their shares be covered by a registration statement that we are otherwise filing. The registration of shares of the Company's common stock pursuant to the exercise of registration rights described below would enable holders to sell these shares without restriction under the Securities Act of 1933, as amended (the "Securities Act") when the registration statement is declared effective. We will pay all expenses related to any demand, piggyback, or Form S-3 registration described below, with the exception of underwriting discounts and commissions. The registration rights described below will expire (i) five years after the completion of the Company's initial public offering, (ii) with respect to any particular holder, at the time that such holder can sell all its registrable securities under Rule 144 or another similar exemption under the Securities Act without limitation during a three-month period without registration or (iii) upon termination of the fourth amended and restated investors' rights agreement.

Demand Registration Rights

At any time beginning on January 14, 2021, the holders of 50% or more of the registrable securities then outstanding may make a written request that we register all or a portion of their shares, subject to certain specified exceptions. Such request for registration must cover securities with an aggregate offering price, net of underwriting discounts and commissions, of at least $20,000,000. We will prepare and file a registration statement as requested, unless, in the good faith judgment of the Board, such registration would be seriously detrimental to the Company and its stockholders and filing should be deferred. We may defer only once in any 12-month period, and such deferral shall not exceed 120 days after receipt of the request. In addition, we are not obligated to effect more than two of these registrations within any 12-month period or if the holders' proposed registered securities may be immediately registered on Form S-3.

Piggyback Registration Rights

Subject to certain specified exceptions, if we propose to register any of the Company's securities under the Securities Act either for the Company's own account or for the account of other stockholders, the holders of shares having registration rights are entitled to written notice and certain "piggyback" registration rights allowing them to include their shares in the Company's registration statement. These registration rights are subject to specified conditions and limitations, including the right of the underwriters, in their sole discretion, to limit the number of shares included in any such offering under certain circumstances, but not below 15% of the total amount of securities included in such offering, unless all other securities, other than the Company's securities, are entirely excluded from the offering.

Form S-3 Registration Rights

At any time after we are qualified to file a registration statement on Form S-3, and subject to limitations and conditions, the holders of 50% or more of the registrable securities then outstanding are entitled to written notice of such registration and may make a written request that we prepare and file a registration statement on Form S-3 under the Securities Act covering their shares, so long as the aggregate price to the public, net of the underwriters' discounts and commissions, is at least $10,000,000. We will prepare and file the Form S-3 registration as requested, unless, in the good faith judgment of the Board, such registration would be seriously detrimental to the Company and its stockholders and filing should be deferred. We may defer only once in any 12-month period, and such deferral shall not exceed 120 days after receipt of the request. In addition, we are not obligated to prepare or file any of these registration statements: (i) within 180 days after the effective date of a registration statement pursuant to demand or piggyback registration rights or (ii) if two of these registrations have been completed within any 12-month period.

Registration Rights for Shares of Common Stock Issuable Upon Conversion of Notes

In connection with the issuance of the 7.25% Convertible Notes, we entered into an amendment to the registration rights agreement with certain entities affiliated with Athyrium pursuant to which certain entities affiliated with Athyrium acquired rights to cause us to register the resale of shares of common stock issuable upon conversion of the 7.25% Convertible Notes.

Investment in Enumera Molecular, Inc.

In May 2022, we completed the divesture of our single-molecule detection platform. Under the terms of the agreements, we 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. Enumera was formed by and is affiliated with Dr. Matthew Cooper, our former Chief Scientific Officer, who owned approximately 10% of the equity interests of Enumera on a fully diluted basis immediately following the consummation of the transaction. Upon the consummation of the transaction, the Company received 6,000,000 shares of Series A-1 preferred stock of Enumera with an estimated value of $6.0 million in exchange for the contributed assets, representing 25% minority ownership in Enumera on a fully-diluted basis. In March 2024, we sold all of our ownership interest in Enumera.

Related Party Transaction Policy

We have adopted a written related party transaction policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related person transactions. For purposes of our policy, a related person transaction is a transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we and any related person (as defined above) are, were or will be participants in which the amount involved exceeds $100,000. Transactions involving compensation for services provided to us as an employee or director, among other limited exceptions, are deemed to have standing pre-approval by the Audit Committee but may be specifically reviewed if appropriate in light of the facts and circumstances.

Under the policy, if a transaction has been identified as a related party transaction, including any transaction that was not a related party transaction when originally consummated or any transaction that was not initially identified as a related party transaction prior to consummation, our management must present information regarding the related party transaction to our Audit Committee for review, consideration and approval or ratification. The presentation must include a description of, among other matters, the material facts, the interests, direct and indirect, of the related persons, the benefits to us of the transaction and whether the transaction is on terms that are comparable to the terms available to or from, as the case may be, an unrelated third party or to or from employees generally. Under the policy, we will collect information that we deem reasonably necessary

from each director, executive officer and, to the extent feasible, significant stockholder to enable us to identify any existing or potential related party transactions and to effectuate the terms of the policy. In addition, under our Code of Business Conduct and Ethics, our employees and directors have an affirmative responsibility to disclose any transaction or relationship that reasonably could be expected to give rise to a conflict of interest. In considering related party transactions, our Audit Committee will take into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;
- the impact on a director's independence in the event that the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties or to or from employees generally.

The policy requires that, in determining whether to approve, ratify, or reject a related party transaction, our Audit Committee consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, our best interests and those of our stockholders, as our Audit Committee determines in the good faith exercise of its discretion.

Certain related party transactions described above were consummated prior to our adoption of the formal, written policy described above, and, accordingly, the foregoing policies and procedures were not followed with respect to these transactions. However, we believe that the terms obtained or consideration that we paid or received, as applicable, in connection with the transactions described below were comparable to terms available or the amounts that would be paid or received, as applicable, in arm's-length transactions at such time.

OTHER MATTERS

Stockholder Proposals and Director Nominations for Next Year's Annual Meeting

Pursuant to Rule 14a-8 of the Exchange Act, stockholders who wish to submit proposals for inclusion in the proxy statement for the 2025 Annual Meeting of Stockholders must send such proposals to our Corporate Secretary at the address set forth on the first page of this Proxy Statement. Such proposals must be received by us as of the close of business (6:00 p.m. Pacific Time) on December 25, 2024 and must comply with Rule 14a-8 of the Exchange Act. The submission of a stockholder proposal does not guarantee that it will be included in the proxy statement.

As set forth in our Bylaws, if a stockholder intends to make a nomination for director election or present a proposal for other business (other than pursuant to Rule 14a-8 of the Exchange Act) at the 2025 Annual Meeting of Stockholders, the stockholder's notice must be received by our Corporate Secretary at the address set forth on the first page of this Proxy Statement no earlier than the 120th day and no later than the close of business (6:00 p.m. Pacific Time) on the 90th day before the anniversary of the last annual meeting; provided, however, that if the date of the annual meeting is more than 30 days before or more than 60 days after such anniversary date, the stockholder's notice must be delivered no later than the 10th day after the first public announcement of the date of such annual meeting is made by the Company. Therefore, unless the 2025 Annual Meeting of Stockholders is more than 30 days before or more than 60 days after the anniversary of the Annual Meeting, notice of proposed nominations or proposals (other than pursuant to Rule 14a-8 of the Exchange Act) must be received by our Corporate Secretary no earlier than February 5, 2025 and no later than the close of business (6:00 p.m. Pacific Time) on March 7, 2025. Any such director nomination or stockholder proposal must be a proper matter for stockholder action and must comply with the terms and conditions set forth in our Bylaws. If a stockholder fails to meet these deadlines and fails to satisfy the requirements of Rule 14a-4 of the Exchange Act, we may exercise discretionary voting authority under proxies we solicit to vote on any such proposal as we determine appropriate. In addition to satisfying the deadlines in the advance notice provisions of our Bylaws, a stockholder who intends to solicit proxies in support of nominees submitted under these advance notice provisions for the 2025 Annual Meeting must provide the notice required under Rule 14a-19 of the Exchange Act to our Corporate Secretary in writing not later than the close of business (6:00 p.m. Pacific Time) on April 7, 2025. We reserve the right to reject, rule out of order or take other appropriate action with respect to any nomination or proposal that does not comply with these and other applicable requirements.

Delivery of Documents to Stockholders Sharing an Address

A number of brokerage firms have adopted a procedure approved by the SEC called "householding." Under this procedure, certain stockholders who have the same address and do not participate in electronic delivery of proxy materials will receive only one copy of the proxy materials, including this Proxy Statement, the Notice and our Annual Report on Form 10-K for the year ended December 31, 2023, until such time as one or more of these stockholders notifies us that they wish to receive individual copies. This procedure helps to reduce duplicate mailings and save printing costs and postage fees, as well as natural resources. If you received a "householding" mailing this year and would like to have additional copies of the proxy materials mailed to you, please send a written request to our Corporate Secretary at the address set forth on the first page of this Proxy Statement, or call (833) 727-2841, and we will promptly deliver the proxy materials to you. Please contact your broker if you received multiple copies of the proxy materials and would prefer to receive a single copy in the future, or if you would like to opt out of "householding" for future mailings.

Availability of Additional Information

We will provide, free of charge, a copy of our Annual Report on Form 10-K for the year ended December 31, 2023, including exhibits, upon the written or oral request of any stockholder of the Company. Please send a written request to our Corporate Secretary at the address set forth on the first page of this Proxy Statement or call the number above.