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, 2021

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

PROGENITY, 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: (855) 293-2639

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	PROG	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. ☐

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, 2021, was approximately $125,774,520.

The number of shares of Registrant's Common Stock outstanding as of March 15, 2022 was 184,125,819.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its 2022 Annual Meeting of Stockholders, to be held on or about June 15, 2022, are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. Such proxy statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

Table of Contents

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:

- the ongoing COVID-19 pandemic and related matters;
- our plans and ability to successfully research, develop and commercialize new products and product candidates;
- the size and growth potential of the markets for our products under development, and our ability to serve those markets;
- the rate and degree of market acceptance and clinical utility of our products under development, if approved;
- coverage and reimbursement for our products under development;
- the performance of third parties in connection with the development of our products under development, including third-party contract research organizations and suppliers;
- regulatory developments in the United States and foreign countries;
- our ability to obtain and maintain regulatory approval or clearance of our products under development on expected timelines;
- the development, regulatory approval, efficacy, and commercialization of competing products;
- the outcome of pending investigations and legal proceedings;
- the loss or retirement of key scientific or management personnel;
- our ability to develop and maintain our corporate infrastructure, including maintaining effective internal control;
- our estimates regarding expenses, future revenue, capital requirements, and needs for additional financing; and
- our expectations regarding our ability to obtain and maintain intellectual property protection for our products, as well as our ability to operate our business without infringing the intellectual property rights of others.

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

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

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

PART I

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

Item 1. Business.

Overview

Progenity, Inc. is a biotechnology company developing oral biotherapeutics. Our drug-device combinations could enable new treatment approaches in the delivery of therapeutics in two main areas:

- Targeted delivery of therapeutics to the site of disease in the gastrointestinal ("GI") tract, which are designed to improve outcomes for patients with Inflammatory Bowel Disease ("IBD"); and
- Systemic delivery of biotherapeutics, which are designed to replace injection with needle-free, oral delivery technology.

We are also developing diagnostics devices to help characterize the GI tract and diagnose GI diseases like Small Intestine Bacterial Overgrowth ("SIBO") through the development of innovative technologies that are designed to diagnose at the site of the disease. Using these platforms, we intend to develop therapeutics and diagnostic solutions for a broad range of disorders.

We commenced operations in 2010 and our corporate office is located in San Diego, California. Our historical operations included a licensed Clinical License Improvement Amendment and College of American Pathologists certified laboratory located in Michigan specializing in the molecular testing markets serving women's health providers in the obstetric, gynecological, fertility, and maternal fetal medicine specialty areas in the United States. Historically, our core business was focused on the prenatal carrier screening and noninvasive prenatal test market, targeting preconception planning and routine pregnancy management for genetic disease risk assessment. Through our prior affiliation with Mattison Pathology, LLP ("Mattison"), 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 the Progenity genetics lab in Ann Arbor, Michigan and the sale of our Avero laboratory business in December 2021, together referred to as the Laboratory Operations. We have excluded from continuing operations for all periods presented in this report revenues and expenses associated with its Laboratory Operations, which are reported as discontinued operations in the consolidated financial statements. See Note 4 to our audited consolidated financial statements for additional information on the Laboratory Operations.

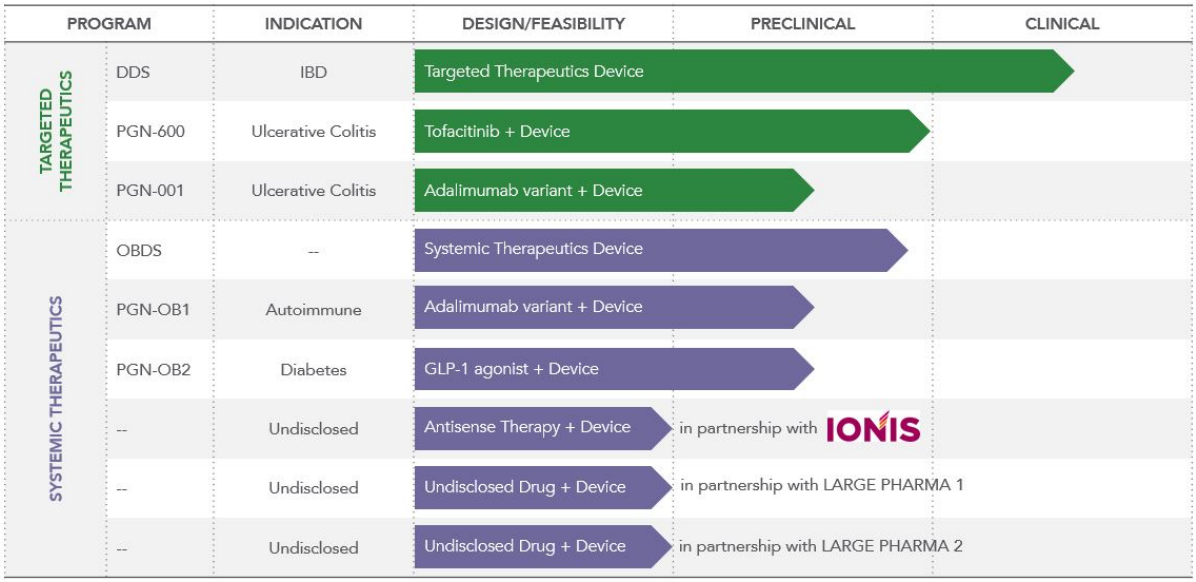
Product Candidate Overview

Our current research and development pipeline consists of the following product candidate categories:

Therapeutics

Our therapeutics pipeline is divided into two therapeutic delivery mechanisms: targeted oral delivery of biotherapeutics and systemic oral delivery of biotherapeutics.

THERAPEUTICS PIPELINE



Targeted Therapeutics

Our Targeted Therapeutics program uses an ingestible smart capsule ("Drug Delivery System" or “DDS”) designed for targeted delivery of therapeutics in the GI tract to improve treatment of IBD. Once swallowed, the capsule is designed to autonomously identify specific locations in the GI tract and release a therapeutic dose at the site of disease. The DDS is about the size of a “000” capsule, or approximately the size of a fish oil capsule, and has a drug capacity of up to 500µL. To date, the DDS capsule has demonstrated a favorable safety profile and high accuracy rate in identifying entry into the colon in normal healthy volunteers. We were a recipient of the Crohn’s and Colitis Foundation IBD Ventures development grant to support development and further clinical evaluation of the Targeted Therapeutics program.

Of the 1.6 million patients in the United States who suffer from IBD, only approximately 20% of patients achieve remission of symptoms after treatment with existing approved therapies, likely due to challenges in safely achieving therapeutic drug levels in the affected tissues. Our Targeted Therapeutics platform utilizes a novel therapeutic approach that has the potential to improve IBD patient outcomes by maximizing the available dose at the site of disease while reducing systemic toxicity. By reducing systemic drug levels, this approach may also enable combination therapy.

PGN-600: Liquid formulation of tofacitinib delivered with the DDS for the treatment of ulcerative colitis

We are developing PGN-600 as an orally delivered liquid formulation of tofacitinib for the treatment of ulcerative colitis. We have shown preclinically that targeted delivery using PGN-600 can lead to reduced drug levels in blood and to reduced levels in tissue at least 25 times higher along the length of the colon as compared to the equivalent standard oral dose. We plan to initiate a Phase 1 clinical trial of PGN-600 in late 2022.

PGN-001: Liquid formulation of Anti-TNF-alpha monoclonal antibody delivered with the DDS for the treatment of ulcerative colitis

We are developing PGN-001 as an orally-delivered variant of adalimumab for the treatment of ulcerative colitis. We have conducted a series of preclinical studies demonstrating the potential of locally delivered anti-TNF-alpha antibodies to reduce disease burden in ulcerative colitis models. We have developed our own anti-TNF-alpha antibody formulation for use in further development.

Systemic Therapeutics

Our Systemic Therapeutics program uses an ingestible capsule ("Oral Biotherapeutics Delivery System" or “OBDS”) designed for needle-free, oral delivery of large molecules to achieve high systemic exposure. The OBDS is approximately the size of a multivitamin. Our technology has the potential to deliver a range of molecules including monoclonal antibodies, peptides, and nucleic acids. These substances cannot survive stomach acids and are too large to be absorbed in the intestine and, therefore, are currently delivered by injection. However, there is significant aversion to injections among patients, with approximately 20% of adults affected

by fear of needles. For example, diabetes patients initiating treatment with an injectable GLP-1 agonist reported 71% higher discontinuation rate as compared to those starting oral therapy and 42% of patients failed to maintain treatment due to injection concerns.

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

The OBDS platform is designed to enable delivery of liquid drug, reducing or eliminating the need for reformulation, and allowing for industry-leading dosing of up to 400 µL. This makes the technology potentially broadly applicable for large molecule candidates. With more frequent administration, oral delivery has the potential to improve drug efficacy and safety as compared to current injection regimens. We have conducted a series of preclinical studies demonstrating the ability of the OBDS to trigger and release payload and achieve bioavailability of up to 67% with an average of 23% bioavailability in animals where drug was detected in blood in our most recent study.

PGN-OB1: liquid formulation of Anti-TNF-alpha monoclonal antibody delivered with the OBDS for the treatment of autoimmune conditions

We are developing PGN-OB1 as a combination product of a variant of adalimumab and the OBDS for the treatment of inflammatory conditions. Several anti-TNF-alpha antibodies have been approved to treat a range of inflammatory conditions. However, all require either intravenous or subcutaneous injection. An oral anti-TNF-alpha antibody may represent a significant market opportunity. We have developed our own anti-TNF-alpha antibody formulation and we are currently conducting preclinical studies of PGN-OB1.

PGN-OB2: liquid formulation of a GLP-1 receptor agonist delivered with the OBDS for the treatment of Type 2 diabetes

We are developing PGN-OB2 as a combination product of a GLP-1 receptor agonist and the OBDS for the treatment of Type 2 diabetes. We believe oral GLP-1RAs will be preferred by patients to injectables resulting in a significant market opportunity.

In addition to our internal pipeline, we have partnered with Ionis Pharmaceuticals to evaluate the OBDS for delivery of antisense oligonucleotides, and we have two other partnerships with leading pharmaceutical companies to evaluate delivery of their proprietary drugs via the OBDS platform. We intend to pursue additional partnership opportunities with large pharmaceutical companies for the OBDS technology.

GI Sampling and Diagnostics

We are also developing two other smart capsule platforms for GI sampling and diagnostics.

RSS

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

PIL Dx

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

We plan to advance next-generation designs of both the RSS and PIL Dx capsules.

Preeclampsia

We have 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 have deprioritized this project and discontinued further investment in its development. An advisory firm has been engaged to manage the process of transferring this asset to potential commercial development partners.

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 have deprioritized this project and discontinued further investment in its development. An advisory firm has been engaged to manage the process of transferring this asset to potential commercial development partners.

Our Strengths

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

Our strengths include:

- ***Breadth and depth of R&D capabilities driving breakthrough innovation***. We have built a first class research and development ("R&D") organization capable of harnessing and translating novel technologies into innovative platforms and product solutions as we strive to remain at the forefront of patient needs. Our technical expertise along the product development spectrum includes medical device, therapeutics and diagnostic expertise, and enables us to leverage existing knowledge to solve new challenges. Our targeted therapeutics and systemic biotherapeutics team is comprised of over 25 full-time, experienced drug developers, engineers, researchers, and innovators working to create solutions to improve patient outcomes. In addition to our full-time staff, our team is augmented by more than 50 contract researchers, manufacturers, and consultants.
- ***Drug-device combination platforms targeting large, underserved markets***. We are developing multiple therapeutics with a platform approach based on innovative drug-device combinations, which could represent a paradigm shift from existing therapeutics approaches. We believe these platforms have the potential to address significant unmet medical needs.
- ***Comprehensive intellectual property portfolio***. We hold the rights to approximately 350 issued patents and pending patent applications that include claims that are directed to a range of therapeutic and device methods, systems, and compositions surrounding our suite of current and future products. In addition, we believe that our trade secrets and other know-how provide additional barriers to entry.
- ***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 research and development efforts on technologies that have the potential to disrupt current treatment paradigms and transform how healthcare is provided, thereby improving the lives of patients. We intend to target diseases with large markets and where current treatments have limited efficacy and very high morbidity, such as IBD. In addition to prioritizing diseases with high unmet need, we will look for the potential to expand the portion of the population that can be treated as our targeted therapeutics may have lower systemic toxicity, lower immunogenicity, and increase market penetration.
- ***Develop and commercialize a disruptive pipeline of drug device combination products***. Our platform is focused on addressing unmet medical needs of patients with GI disorders and beyond. Leveraging our capsule technologies and platforms, we are developing investigational devices and drug/device combinations designed for both diagnostic and therapeutic purposes. We believe our product candidates, if successfully developed and approved or cleared, could transform patient management. Ultimately, we intend to pursue commercialization of such product candidates ourselves or via strategic partnership.
- ***Opportunistic approach to drug candidate selection***. Using our platforms, we are developing potentially improved versions of existing drugs with established mechanisms of action. We intend to only pursue mature and approved drugs with expiring patents that we believe are biologically suited to address the target disease. We believe this strategy of

starting with an approved therapeutic is core to operating drug development programs in a scalable and capital efficient manner. By starting with approved drugs with known mechanisms of action, we believe we can efficiently and cost-effectively evaluate opportunities that we believe are the most promising, and very quickly discontinue programs that do not meet performance thresholds. We believe this will enable us to develop a sustainable and scalable platform to develop multiple drug/device candidates.

- ***Leverage our robust R&D capabilities to drive breakthrough innovation***. We continually strive to innovate in ways that will allow us to disrupt current treatment paradigms. Through our robust research and development pipeline, we seek to unlock novel approaches in the oral delivery of biotherapeutics. Our drug-device combinations could enable new treatment approaches in the areas of (1) delivery of therapeutics to the site of disease in the GI tract, which are designed to improve outcomes for patients with IBD, and (2) systemic delivery of biotherapeutics, which are designed to replace injection with needle free, oral capsules.
- ***Focus on maximizing value generation through partnerships and licensing***. Following our strategic transformation in June 2021, our initial focus and 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 partnerships with pharmaceutical companies as part of our strategy to continue the development of our targeted and systemic drug delivery products.

Targeted Therapeutics for GI-Related Disorders

Targeted Therapeutics Market

Inflammatory Bowel Diseases

IBDs are a heterogeneous group of inflammatory disorders of the GI tract, and broadly include two major groups: Crohn's disease and ulcerative colitis. According to the Crohn's and 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 body's immune system which normally protects the body from external invaders like bacteria and viruses becomes dysregulated in patients with IBD and this causes the immune system to attack the body's own tissues. Although IBD has no known cause, there is strong evidence that genetics, a dysregulated immune system, the environment and the gut microbiome all play a role initially in causing the disease, and then perpetuating the inflammation. We estimate the IBD therapeutics market to be in excess of $15 billion.

Ulcerative Colitis

The CCF estimates that Ulcerative colitis ("UC") may affect as many as 907,000 Americans. UC is characterized by inflammation and ulceration of the mucosal lining of the colon. The typical symptoms include diarrhea, bleeding and often abdominal pain. In the more severe cases, there can be large amount of blood loss, which can be life-threatening and require emergency surgery. The goal of medical treatment for all forms of IBD is to reduce the inflammation and induce remission initially with medication, followed by the administration of maintenance medication to prevent a relapse of the disease. Treatment for UC depends on the severity of the disease, complications, and response to previous treatment. Most patients with mild to moderate UC will first be treated with aminosalicylates. For patients with moderate to severe UC who do not respond to aminosalicylates, more potent systemic therapies such as infliximab and adalimumab are used. Despite multiple therapeutics being approved for ulcerative colitis that work through a range of mechanisms, outcomes for these patients remains poor with few patients achieving long-term remission. Data suggests only approximately 20% of moderate to severe UC patients achieve remission of symptoms after treatment. Many of these therapies have side effects that limit dosing, which leads to insufficient drug levels in diseased tissue. There is growing data that suggests the amount of drug in tissue is a key driver of patient outcomes. For anti-TNF-alphas such as infliximab and adalimumab, clinical studies have shown that the tissue TNF-alpha level far exceeds the amount of drug reaching the actively inflamed tissue in patients with active IBD. We believe that current approaches to drug delivery are inadequate to suppress the inflammatory response. In addition, we recently presented, in conjunction with our academic collaborators, compelling evidence to support the importance of drug levels in tissue at the 17th Congress of the European Crohn's and Colitis Organization and 34th edition of the Belgian Week of Gastroenterology in February 2022. Material presented included data from patients with moderate to severe UC taking commercial formulations of tofacitinib. GI tissue biopsies were obtained from these patients, which identified a clear correlation between higher concentrations of drug in the tissue and improved outcomes.

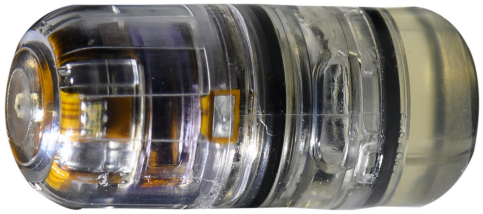
Our Solution: Targeted Therapeutics

We are developing a pipeline of investigational drug/device combinations that are designed to overcome the limitation of current treatments. Our products are designed to treat disease at its site in the GI tract and achieve high concentration in the affected tissues with the potential to drive efficacy and minimize systemic exposure and toxicity. Through preclinical studies we have shown that a

range of molecules including monoclonal antibodies targeting key pathways including TNF-alpha, integrins and interleukins were found in inflamed colonic tissue when given directly into the lumen of the colon. We have conducted preclinical studies which indicate that these molecules, given locally in animal models, can be efficacious. We believe delivering drugs locally at the site of inflammation will result in a higher concentration of drug in the intestinal tissues of patients with IBD, potentially leading to greater efficacy. We believe that local delivery at the site of disease will result in less systemic exposure and may require lower drug administration, potentially reducing the severe adverse event profiles seen with some of these therapeutics. We also believe that because this technology is designed to have lower systemic absorption, it may be ideal for use in combination therapy with the potential to boost efficacy without adversely affecting the active drug's safety profile.

Drug Delivery System

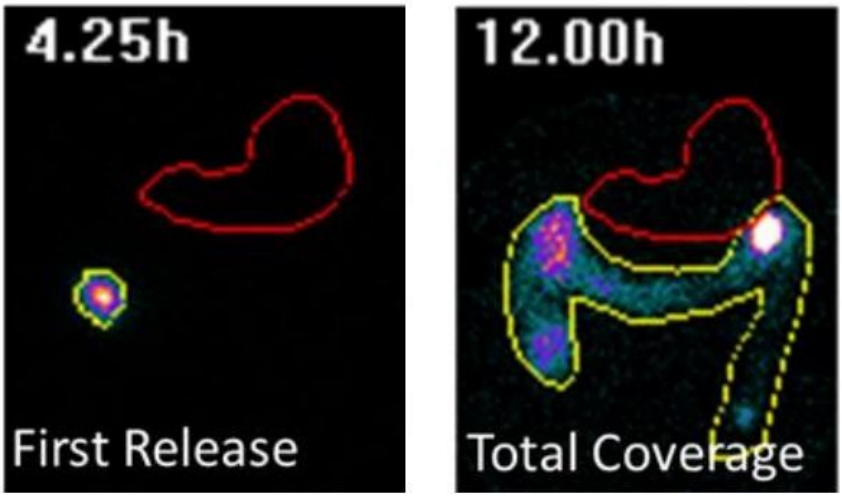
Our targeted therapeutics pipeline leverages our DDS capsule to deliver drugs to the site of disease in the GI tract. The DDS capsule is designed to autonomously identify the ileal/ileocecal region of the GI tract using our localization technology and deliver medication to that region. The autonomous localization technology is based on a proprietary LED light and photodetector sensor array that detects reflected light in the GI tract and uses a proprietary algorithm to determine anatomical locations of interest, such as the pyloric and ileocecal transition. Of note, this technology differs from other GI tract localization technologies that rely on pH levels and other physiological factors which are not specific and are highly variable, especially in patients with IBD. The localization technology was evaluated in 47 subjects across 3 clinical studies with 85% accurate detection of colon entry.



Drug Delivery System

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

We conducted a clinical study to evaluate the safety and tolerability of the device as well as the ability to identify entry into the colon and release payload. In the study, 12 normal healthy volunteers were enrolled and administered a single DDS 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 the DDS was well tolerated and 10/12 (83%) of devices accurately identified entry into the colon. The scintigraphic images below are taken from a subject in the study and demonstrate release in the first part of the colon and eventual total coverage of the colon by the radioisotope.



This study was in part funded by the CCF. Given the positive results of the study the CCF has continued to further fund the program. We plan to conduct a similar study in UC patients in the second quarter of 2022. If successful, this study will confirm the DDS is a robust platform to deliver a range of therapeutics to the colon in ulcerative colitis patients.

Lead Programs

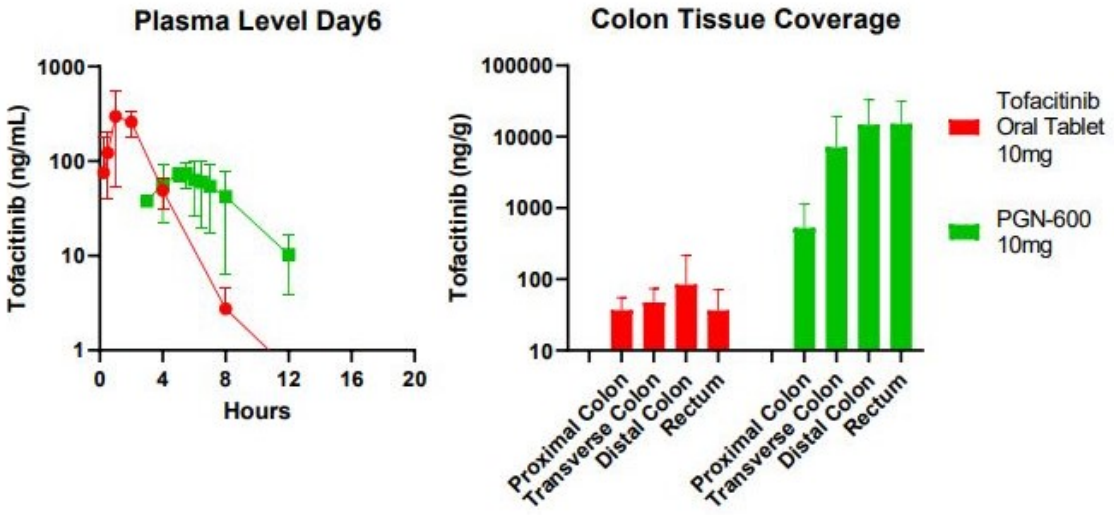
We have two lead programs, PGN-600 (tofacitinib) and PGN-001 (variant of adalimumab). Both tofacitinib and adalimumab have been approved for use in UC, but are dose limited by safety concerns at higher doses. Existing research, including research we have generated suggest that efficacy may be limited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

PGN-600: Liquid formulation of tofacitinib delivered with the DDS for the treatment of ulcerative colitis

Our most advanced targeted therapeutics candidate is PGN-600. Tofacitinib is approved for ulcerative colitis and dose limited based on safety concerns making it an ideal therapy for targeted delivery. We have generated data in animal models of colitis that tofacitinib delivered directly to the colon can lead to significantly higher colon tissue concentrations than equivalent standard oral doses.

We conducted a preclinical study of PGN-600 in a canine model comparing 7-day daily administration of 10 mg standard oral tablet formulation of tofacitinib to 10 mg of liquid formulation of tofacitinib delivered with the DDS (PGN-600). We evaluated mean concentration of tofacitinib in tissues at day 7 and systemic tofacitinib levels by AUC at day 1 and 6.

The PK data obtained with PGN-600 and tofacitinib oral tablet is illustrated in the graphs presented below.



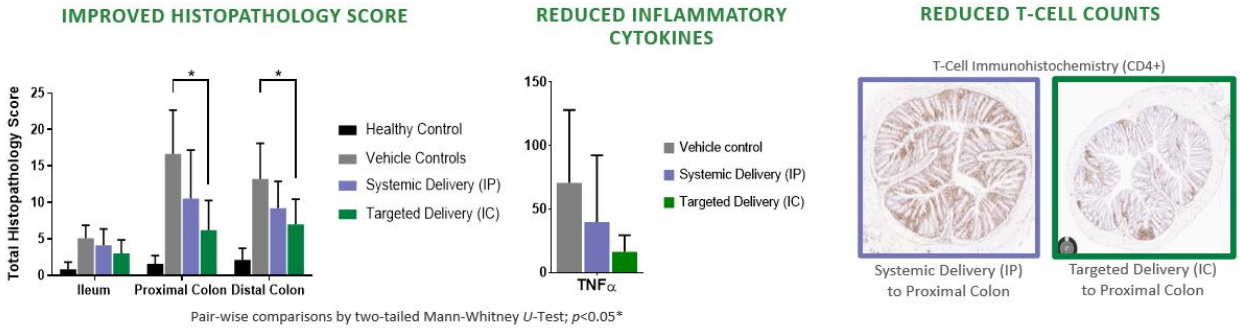
Results of the study demonstrated PGN-600 was well tolerated with a favorable safety profile and that when tofacitinib was delivered to the colon drug levels in blood were reduced as compared to oral tofacitinib tablets. In addition, tissue drug levels were at least 25 times higher along the length of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

We are continuing development of PGN-600 and, subject to regulatory approval we plan to initiate a Phase 1 clinical trial of PGN-600 in late 2022. We believe that if we demonstrate similar results clinically to what has been observed preclinically, and given the known efficacy of the currently approved doses of tofacitinib, PGN-600 has the potential to improve the management of UC patients.

PGN-001: Liquid formulation of Anti-TNF-alpha monoclonal antibody delivered with the DDS for the treatment of ulcerative colitis

Our second targeted therapeutics candidate is PGN-001. 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 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 3 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 PGN-001.

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

Systemic Therapeutics

Systemic Therapeutics Market

Over the past two decades, biologic drugs have become the standard of care for a variety of diseases, including rheumatoid arthritis, psoriasis, diabetes, Crohn's disease, UC, and a range of cancers. We estimate the total biologics market to be in excess of $250 billion (or over $100 billion for monoclonal antibodies alone). Generally, biologics are administered systemically via subcutaneous or intravenous injection because these substances cannot survive stomach acids and enzymes in the intestine, and are too large to be absorbed in the intestine. However, there is significant aversion to injections among patients with approximately 20% of adults affected by fear of needles and overall strong patient and physician preferences for the oral delivery of proteins as compared to subcutaneous injections. This aversion to painful injections affects compliance with therapy, which in turn impacts patient outcomes. For example, diabetes patients initiating treatment with an injectable GLP-1 agonist reported 71% higher discontinuation rate as compared to those starting oral therapy and 42% of patients failed to maintain treatment due to injection concerns. To reduce injections, many biologics have been developed for less frequent dosing such as weekly or monthly injections, however this means larger amounts of drug are in circulation which can lead to safety concerns. This also means that before the next dose, drug levels can drop lower than desired potentially impacting efficacy. An ideal dosing regimen would be a more frequent dosing schedule such as daily to maintain drug levels within a smaller window that is optimal for safety and efficacy.

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

Our Solution: Systemic Therapeutics

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

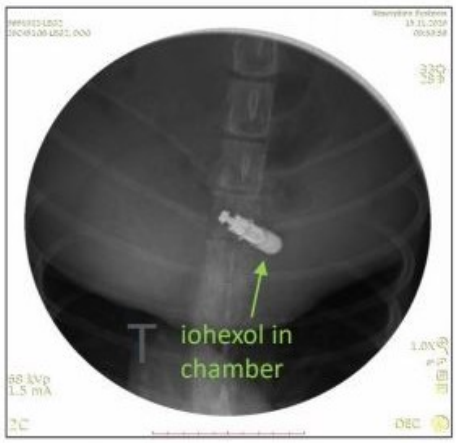
Oral Biotherapeutics Delivery System

Our Systemic Therapeutics pipeline leverages our OBDS capsule to orally deliver large molecules through a needle-free injection in the small intestine for systemic uptake. The OBDS capsule protects the drug from acids and proteolytic enzymes and upon reaching the small intestine, an enteric trigger degrades, activating the needle-free liquid jet formation and delivery. We initially developed an endoscopically or surgically placed, liquid jet device for optimization and early preclinical work. With the endoscopically or surgically placed device we assessed the potential bioavailability rates that may be achieved with our device in preclinical swine studies with drugs such as human insulin, dulaglutide, and adalimumab. In these studies, we have observed average bioavailability of approximately 19% (n=18), 29% (n=11), and 27% (n=11) respectively. We have since progressed to an autonomous, fully integrated preclinical device for further evaluation.

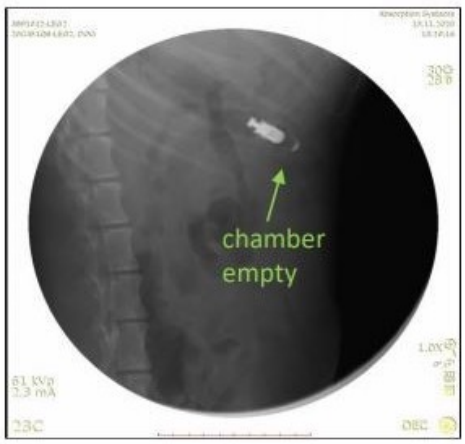
Oral Biotherapeutics Delivery System

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

We conducted a preclinical study with an autonomous OBDS device delivered orally to canines. The study was a single-dose study evaluating safety and tolerability of the device in addition to the ability of the device to activate and deliver payload when it reached the small intestine. We evaluated device function by loading the device with a contrast agent (iohexal) and sequentially imaged post administration as the device transited through the body. The images below are taken from the study and show the contrast agent inside the capsule in the stomach and after deployment in the small intestine.



Immediately after dosing in the stomach



After deployment in the small intestine

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

We are continuing to advance the OBDS through preclinical testing and we expect to enter into clinical studies to demonstrate OBDS function later this year.

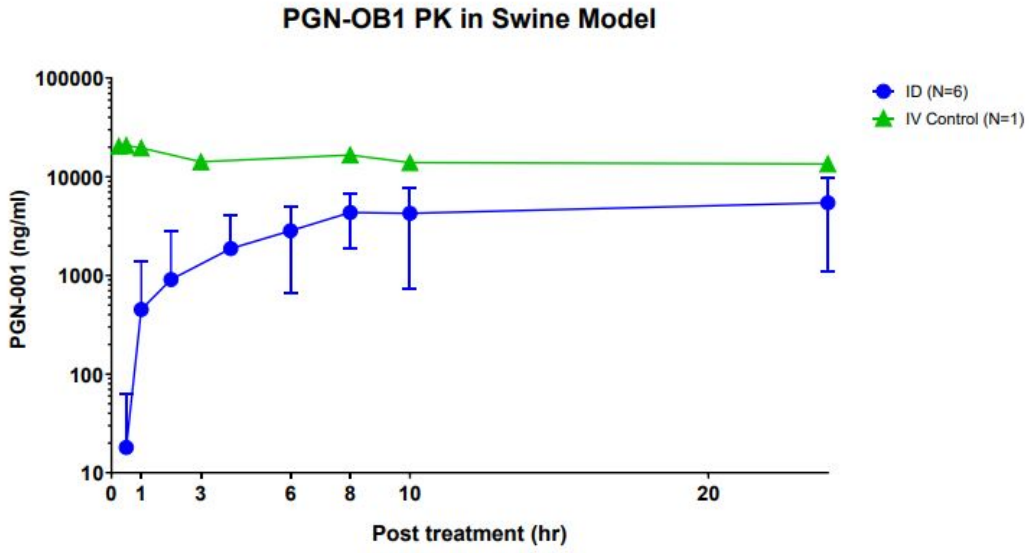
Lead Programs

We have two lead programs, PGN-OB1 (variant of adalimumab) and PGN-OB2 (GLP-1ra). Adalimumab is approved for a range of inflammatory disorders and generated approximately $20 billion in 2020 in annual sales, making it the best-selling drug globally. An oral variant of adalimumab presents a significant opportunity for the many patients that would like to avoid painful injections. GLP-1RAs are a leading class of therapeutics for type 2 diabetes and have a projected market of over $19 billion market by 2028. As a result of our use of known molecules, we believe that rapid proof of concept with preclinical and phase 1 pharmacokinetic results is possible.

PGN-OB1: liquid formulation of Anti-TNF-alpha monoclonal antibody delivered with the OBDS for the treatment of autoimmune conditions

Our most advanced systemic therapeutics candidate is PGN-OB1. Several anti-TNF-alpha antibodies have been approved to treat a range of autoimmune conditions. However, all require either intravenous or subcutaneous injection. An oral anti-TNF-alpha antibody may represent a significant market opportunity. PGN-OB1 is currently in preclinical stage development with an anti-TNF-alpha antibody formulation that we have developed and scaled to GMP grade material.

We have conducted a series of porcine preclinical studies demonstrating the ability of the OBDS to consistently trigger and release payload and achieve high bioavailability. The porcine model is preferred for bioavailability as the pig intestine anatomy more closely resembles human intestinal anatomy than canine and is therefore more appropriate, especially for our method of delivery. However, the porcine stomach anatomy requires endoscopic placement of the autonomous device. In porcine studies with endoscopic placement of the OBDS we have achieved up to 67% with an average of 23% bioavailability in animals where drug was detected in blood in our most recent study. The PK data obtained with PGN-OB1 is illustrated in the graph below.



We are currently advancing preclinical development of PGN-OB1 with additional preclinical studies planned in the second quarter of this year.

PGN-OB2: liquid formulation of a GLP-1 receptor agonist delivered with the OBDS for the treatment of Type 2 diabetes

We are also developing PGN-OB2 as we believe oral GLP-1RAs will be preferred by patients to injectables resulting in a significant market opportunity. In addition, we have the potential to leverage the abbreviated 505(b)(2) pathway for PGN-OB2, accelerating the path to market.

We are currently advancing preclinical development of PGN-OB2 with key preclinical studies planned in the second quarter of 2022.

Partnerships

Our strategy is to advance our own pipeline while partnering with third parties to also leverage their drug candidates and resources to help make the OBDS a leader in the oral delivery of biotherapeutics. We are currently engaged in three ongoing partnerships, two of which are with large pharmaceutical companies for the use of the OBDS with their molecules and one of which is with Ionis Pharmaceuticals for the delivery of antisense oligonucleotides with the OBDS.

Recoverable Sampling System

We are developing the RSS to analyze and characterize the GI tract. The RSS capsule is an investigational electromechanical capsule designed to autonomously collect and preserve intestinal fluids as it moves through the GI tract for *ex-vivo* analysis. The RSS utilizes the same localization technology as the DDS for accurate autonomous identification of location in the GI tract. The sample chamber of

the RSS capsule contains an absorbent sponge impregnated with preservative agents that can preserve a range of analytes including proteins, metabolites, and microbes. Once the capsule has been expelled, the subject would collect and ship the capsule to our or another designated laboratory for sample extraction and analysis.

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

We completed an initial small proof of concept clinical study in 2021 to demonstrate the functionality of the RSS at collecting and preserving a sample of the microbiome. With proof of concept demonstrated, we are focusing on further device design to enable larger scale manufacturing to support future clinical studies.

PIL Dx—Progenity Ingestible Laboratory Diagnostics

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

Our initial indication in development is measurement of the concentration of the bacteria in the small intestine to aid in the evaluation of SIBO. There are over 100 million patient visits in the United States each year for symptoms that may be due to SIBO. The capsule includes an integrated assay that is designed to measure with high sensitivity the change of a metabolically active substrate that correlates with the amount of live bacteria in the small intestine. We believe this technology, if successfully developed and approved or cleared, has the potential to become the standard of care for diagnosing SIBO. Currently the technology has undergone a series of tests of the various subsystems and evaluations. We have completed analysis of small intestinal fluid samples collected during endoscopy with aspiration on a benchtop version of our bacterial concentration assay at three clinical sites. Samples are measured for bacterial concentration with culture and plate count. As shown in the table below, the results show a concordance between the bacterial concentration assay and the reference standard of culture and plate count for identifying 10^5 colony forming units ("CFU"), per mL.

Table 3: Standalone Bacterial Concentration Assay Testing Results

Clinical Site	SIBO Assay vs TBC* (10^5 CFU per mL**)
1	36/39 (92%)
2	11/12 (92%)
3	15/15 (100%)
Total	62/66 (94%)

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

These results were presented at the 2020 American College of Gastroenterology Annual Scientific Meeting by a leading key opinion leader, Dr Satish Rao. The presentation was honored with the highest award by the college for the small bowel section.

Given the similarity in design with the RSS and synergies in development, we are also focusing on further device design of the PIL Dx to enable larger scale manufacturing.

Competition

The biotechnology and pharmaceutical industries are characterized by rapid technological advancement, intense competition, and a strong emphasis on intellectual property and proprietary products.

While we believe that our proprietary technologies, knowledge, experience, and scientific expertise provide us with competitive advantages, we face substantial competition from major pharmaceutical companies, biotechnology companies, academic institutions, government agencies, and public and private research institutions. For any products that we eventually commercialize, we will not only compete with existing technologies and therapies but also with those that may become available in the future.

Given our technology's potential utility across multiple applications, we expect to face intense competition from a diverse set of competitors. Many of our competitors, either alone or with strategic partners, have significantly greater financial, technical and human resources than we do. Competitors may also possess more experience developing, obtaining regulatory approval for, and marketing novel treatments and technologies in the areas we are pursuing. These factors could give our competitors an advantage in recruiting and retaining qualified personnel, developing similar or superior products, completing clinical development, securing strategic partnerships, and commercializing their products. We believe the key competitive factors that will affect the development and commercial success of our product candidates are efficacy, safety and tolerability profile, reliability, method of administration, convenience of dosing, price, reimbursement, patent protection and patents of our competitors.

Targeted Therapeutics Competition

The current IBD market is both established and mature, comprised of a range of therapeutic agents including branded and generic small molecules, biologics, 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 R&D efforts will likely result in the emergence of newer pharmaceuticals touting oral administration, more convenient dosing frequency, novel mechanisms of action, and improved safety profiles and drug availability. We believe that the majority of competition will come from those companies marketing or developing biologics and small molecule therapeutics, such as AbbVie, Eli Lilly, Galapagos, Gilead, J&J, Pfizer, Roche, Takeda, and UCB.

Systemic Therapeutics Competition

We expect to face competition from a number of technologies currently marketed or being developed to enhance or facilitate the oral administration of therapeutic agents. There is a wide range of competitive technologies and mechanisms that may challenge us, some of which are the subject of issued patents and pending patent applications, including issued patents and pending patent applications directed to ingestible devices for the oral administration of therapeutic agents.

The primary categories of oral biotherapeutic technologies currently available or being developed by our competitors include:

- Functional excipients designed to enhance the solubility and/or permeability of peptides and small molecules: Enteris Biopharma and Novo Nordisk;
- Enteric coating technologies designed to prevent gastric degradation of active pharmaceutical ingredients and facilitate GI delivery: Catalent, Cosmo Pharmaceuticals, Intract Pharma, Lonza, and Tillotts Pharma; and
- Ingestible devices designed for the targeted delivery of a therapeutic payload: Novo Nordisk, Lyndra Therapeutics, Rani Therapeutics and Amgen.

Recoverable Sampling System Competition

To our knowledge, there are no commercially available ingestible sampling devices competing with our technology. This is a nascent space, and we expect to see future competition from new entrants as companies develop potentially competitive technologies.

PIL Dx—Progenity Ingestible Laboratory Diagnostics Competition

We potentially face competition from a small number of currently marketed or in-development diagnostic devices and tests specifically targeting GI disorders, such as those from Medtronic and Commonwealth Diagnostics International. Additionally, we will face competition from new entrants as advances in diagnostics and engineering bring new technologies to market.

Intellectual Property

The proprietary nature of, and intellectual property protection for, our products and 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 350- 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 more than 70 distinct patent families comprising approximately 288 issued or 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 2041, in each case, subject to potential term extensions. Twenty-six 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 conditions;
- GI-specific drug formulations and dosing regimens;
- autonomous localization of an ingestible device in the GI tract using visible or infrared light;
- GI sampling mechanisms and compositions, including preservatives for GI analytes; and
- ingestible device assays, optics and analytics for detecting and quantifying GI analytes.

Molecular Testing Technology Patent Portfolio

Intellectual property rights relating to the molecular testing technology include a patent portfolio consisting of 17 distinct patent families comprising approximately 60 issued patents and pending applications. Of these patents and applications, the latest to expire issued U.S. patents are projected to expire in 2037 and the latest to expire U.S. patent applications, if issued, would expire in 2041, in each case, subject to potential term extensions. In general, we file our molecular testing patent applications in the United States, Europe, Canada, China, and sometimes Japan.

The patents and pending applications in this portfolio include claims that are directed to a range of molecular testing-related methods, systems and compositions, including but not limited to, the following:

- detecting chromosomal abnormalities including copy number variations;
- determining nucleosomal positioning patters of cell-free nucleic acids;
- isolating and analyzing rare cells; and
- diagnosing pregnancy-associated conditions like preeclampsia and preterm birth.

In addition to the patents and applications described above, our intellectual property rights relating to molecular testing and analyses include know-how relating to proprietary assays, databases, materials and software products. Examples include the following:

- discovery and diagnostic algorithms;
- well-characterized clinical samples; and
- variant classification, annotation, and reporting systems.

Government Regulation

Regulations Related to Clinical Laboratories

Prior to the Strategic Transformation and the shutdown of commercial operations in our laboratory in Ann Arbor, MI and the sale of our affiliated business Avero Diagnostics, both of which occurred in 2021, we operated clinical laboratories. During that time, we were required to comply with various regulations applicable to clinical laboratories and LDTs, as well as various healthcare fraud and abuse statutes that applied to our commercial operations, each which are described in detail in our prior SEC filings.

Regulations Related to Our Smart Capsules for Targeted and Systemic Delivery of Therapeutics

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 FD&C Act, the FDA has jurisdiction over medical devices, including in-vitro diagnostics devices ("IVDs") and other products we are currently developing. The FDA regulates, among other things, the research, design, development, preclinical and clinical testing, manufacturing, safety, effectiveness, packaging, labeling, storage, recordkeeping, pre-market clearance or approval, adverse event reporting, marketing, promotion, sales, distribution and import and export of medical devices. Unless an exemption applies, each new or significantly modified medical device we seek to commercially distribute in the United States will require either a premarket notification to the FDA requesting permission for commercial distribution under Section 510(k) of the FD&C Act, also referred to as a 510(k) clearance, or FDA approval of a PMA application. We are developing certain product candidates, such as ingestible diagnostic products, that are subject to the FDA's premarket review requirements applicable to medical devices.

Device Classification

Under the FD&C Act, medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurances with respect to safety and effectiveness.

Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be reasonably assured by adherence to General Controls, which require compliance with the applicable portions of the FDA's QSR, facility registration and product listing, reporting of adverse events and malfunctions, and appropriate, truthful and non-misleading labeling and promotional materials. Some Class I devices also require premarket clearance by the FDA through the 510(k) premarket notification process described below. Most Class I products are exempt from the premarket notification requirements.

Class II devices are those that are subject to the General Controls, as well as Special Controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These Special Controls can include performance standards, patient registries, FDA guidance documents, and post-market surveillance. Most Class II devices are subject to premarket review and clearance by the FDA. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification process.

Class III devices include devices deemed by the FDA to pose the greatest risk such as life-supporting or life-sustaining devices, or implantable devices, in addition to those deemed novel and not substantially equivalent following the 510(k) process. The safety and effectiveness of Class III devices cannot be reasonably assured solely by the General Controls and Special Controls described above. Therefore, these devices are subject to the PMA application process, which is generally more costly and time-consuming than the 510(k) process. Through the PMA application process, the applicant must submit data and information demonstrating reasonable assurance of the safety and effectiveness of the device for its intended use to the FDA's satisfaction.

510(k) Pathway

To obtain 510(k) clearance, we must submit a premarket notification under Section 510(k) of the FD&C Act demonstrating that the proposed device is "substantially equivalent" to a predicate device. A predicate device is a legally marketed device that is not subject to premarket approval, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was found substantially equivalent through the 510(k) process. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics

and not raise different questions of safety or effectiveness than the predicate device. Clinical data is sometimes required to support substantial equivalence. The FDA's 510(k) clearance pathway usually takes from three to 12 months from the date the notification is submitted, but it can take considerably longer, depending on the extent of FDA's requests for additional information and the amount of time a sponsor takes to fulfill them. After a 510(k) is submitted, the FDA determines whether to accept it for substantive review. If it lacks necessary information for substantive review, the FDA will refuse to accept the 510(k) submission. If it is accepted for filing, the FDA begins a substantive review. By statute, the FDA is required to complete its review of a 510(k) premarket notification within 90 days of receiving the 510(k) submission. As a practical matter, clearance often takes longer, and clearance is never assured.

Although many 510(k) premarket notifications are cleared without clinical data, the FDA may require further information, including clinical data, to make a determination regarding substantial equivalence, which may significantly prolong the review process. If the FDA agrees that the device is substantially equivalent to a predicate device, it will grant clearance to commercially market the device. If the FDA determines that the device is not "substantially equivalent" to a predicate device, or if the device is automatically classified into Class III, the device sponsor must then fulfill the much more rigorous premarketing requirements of the PMA approval process, or seek reclassification of the device through the *de novo* process.

After a device receives 510(k) clearance, any modification, including modification to or deviation from design, manufacturing processes, materials, packaging and sterilization that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, may require a new 510(k) clearance or, depending on the modification, could require a PMA application. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer's determination. If the FDA requires a new 510(k) clearance or approval of a PMA application for any modifications to a previously cleared product, the applicant may be required to cease marketing or recall the modified device until clearance or approval is received. In addition, in these circumstances, the FDA can impose significant regulatory fines or penalties for failure to submit the requisite 510(k) or PMA application(s).

Medical device types that the FDA has not previously classified as Class I, II, or III are automatically classified into Class III regardless of the level of risk they pose. The Food and Drug Administration Modernization Act of 1997 established a new route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the *de novo* classification procedure.

The *de novo* classification procedure allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA application. Prior to the enactment of the Food and Drug Administration Safety and Innovation Act of 2012, or FDASIA, a medical device could only be eligible for *de novo* classification if the manufacturer first submitted a 510(k) premarket notification and received a determination from the FDA that the device was not substantially equivalent. FDASIA streamlined the *de novo* classification pathway by permitting manufacturers to request *de novo* classification directly without first submitting a 510(k) premarket notification to the FDA and receiving a not substantially equivalent determination. Under FDASIA, the FDA is required to classify the device within 120 days following receipt of the *de novo* application, though in practice the process may take significantly longer. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for Special Controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. In addition, the FDA may reject the reclassification petition if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low to moderate risk or that General Controls would be inadequate to control the risks and Special Controls cannot be developed.

PMA Pathway

We must submit a PMA if a device cannot be cleared through the 510(k) clearance or *de novo* process. A PMA application must be supported by extensive data, including, but not limited to, technical information, preclinical data, clinical trial data, manufacturing data, and labeling, to demonstrate to the FDA's satisfaction the safety and efficacy of the device for its intended use.

Following receipt of a PMA application, the FDA conducts an administrative review to determine whether the application is sufficiently complete to permit a substantive review. If it is not, the agency will refuse to file the PMA. If it is, the FDA will accept the application for filing and begin the review. The FDA, by statute and by regulation, has 180 days to review a filed PMA application, although the review of an application more often occurs over a significantly longer period of time. During this review period, the FDA may request additional information or clarification of information already provided, and the FDA may issue a major deficiency letter to the applicant, requesting the applicant's response to deficiencies communicated by the FDA. The FDA considers a PMA or PMA supplement to have been voluntarily withdrawn if an applicant fails to respond to an FDA request for information (*e.g.*, major deficiency letter) within a total of 360 days. Before approving or denying a PMA, an FDA advisory panel may review the PMA at a public meeting and provide the FDA with the committee's recommendation on whether the FDA should approve the submission, approve it with specific conditions, or not approve it. The FDA is not bound by the recommendations of an advisory panel, but it

considers such recommendations carefully when making decisions. Prior to approval of a PMA, the FDA may conduct a bioresearch monitoring inspection of the clinical trial data and clinical trial sites, and a QSR inspection of the manufacturing facility and processes. The FDA can delay, limit, or deny approval of a PMA application for many reasons, including:

- the device may not be shown safe or effective to the FDA's satisfaction;
- the data from preclinical studies and/or clinical trials may be found unreliable or insufficient to support approval;
- the manufacturing process or facilities may not meet applicable requirements; and
- changes in FDA approval policies or adoption of new regulations may require additional data.

If the FDA evaluation of a PMA is favorable, the FDA will issue either an approval letter, or an approvable letter, the latter of which usually contains a number of conditions that must be met in order to secure final approval of the PMA. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA approval letter authorizing commercial marketing of the device, subject to the conditions of approval and the limitations established in the approval letter. If the FDA's evaluation of a PMA application or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. The FDA also may determine that additional tests or clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and data are submitted in an amendment to the PMA, or the PMA is withdrawn and resubmitted when the data are available. The PMA process can be expensive, uncertain, and lengthy and a number of devices for which the FDA approval has been sought by other companies have never been approved by the FDA for marketing.

New PMA applications or PMA supplements may be required for modifications to the manufacturing process, equipment or facility, quality control procedures, sterilization, packaging, expiration date, labeling, device specifications, components, materials or design of a device that has been approved through the PMA process. PMA supplements often require submission of the same type of information as an initial PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the approved PMA application and may or may not require as extensive technical or clinical data or the convening of an advisory panel, depending on the nature of the proposed change.

In approving a PMA application, as a condition of approval, the FDA may also require some form of postmarket studies or postmarket surveillance, whereby the applicant follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional or longer term safety and effectiveness data for the device. The FDA may require postmarket surveillance for certain devices approved under a PMA or cleared under a 510(k) notification, such as implants or life-supporting or life-sustaining devices used outside a device user facility, devices where the failure of which would be reasonably likely to have serious adverse health consequences, or devices expected to have significant use in pediatric populations. The FDA may also approve a PMA application with other post-approval conditions intended to ensure the safety and effectiveness of the device, such as, among other things, restrictions on labeling, promotion, sale, distribution, and use.

Clinical Trials

Clinical trials are almost always required to support a PMA and are sometimes required for a 510(k) premarket notification. In the United States, these trials often require submission of an application for an IDE if the investigation involves a significant risk device. Some types of studies deemed to present "non-significant risk" are deemed to have an approved IDE—without affirmative submission of an IDE application to the FDA—once certain requirements are addressed and IRB approval is obtained. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE must be approved in advance by the FDA for a specified number of patients, unless the product candidate is deemed a non-significant risk device and is eligible for more abbreviated IDE requirements. Clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and appropriate IRBs at the clinical trial sites. Submission of an IDE will not necessarily result in the ability to commence clinical trials, and although the FDA's approval of an IDE allows clinical testing to go forward for a specified number of subjects, it does not bind the FDA to accept the results of the trial as sufficient to prove the product's safety and efficacy, even if the trial meets its intended success criteria.

Future clinical trials involving our product candidates will most likely require that we obtain an IDE from the FDA prior to commencing clinical trials and that the trial be conducted under the oversight of IRBs at the clinical trial sites. All clinical trials must be conducted in accordance with the FDA's IDE regulations that govern investigational device labeling, prohibit promotion, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. Clinical trials must further comply with the FDA's GCP requirements for IRB approval and for informed consent and other human subject protections. Required records and reports are subject to inspection by the FDA. The results of clinical testing may be unfavorable, or, even if the intended safety and efficacy success criteria are achieved, may not be considered sufficient for the FDA to grant marketing approval or clearance of a product candidate.

Breakthrough Devices and Safer Technologies Programs

The Breakthrough Devices Program is a voluntary program intended to expedite the review, development, assessment and review of certain medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human diseases or conditions for which no approved or cleared treatment exists or that offer significant advantages over existing approved or cleared alternatives. For Breakthrough Devices, the FDA intends to provide interactive and timely communication with the sponsor during device development and throughout the review process. FDA also intends to assign staff to be available within a reasonable time to address questions by institutional review committees concerning the conditions and clinical testing expectations applicable to the investigational use of a Breakthrough Device. In addition, all submissions for devices designated as Breakthrough Devices will receive priority review, meaning that the review of the submission is placed at the top of the appropriate review queue and receives additional review resources, as needed.

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

Postmarket Requirements—U.S.

After the FDA permits a device to enter commercial distribution, numerous regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- the FDA's QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, production, control, supplier/contractor selection, complaint handling, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations, unique device identification requirements and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label uses;
- advertising and promotion requirements;
- Restrictions on sale, distribution or use of a device;
- PMA annual reporting requirements;
- PMA approval or clearance of a 510(k) for product modifications;
- medical device reporting, or MDR, regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur;
- medical device correction and removal reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FD&C Act that may present a risk to health;
- recall requirements, including a mandatory recall if there is a reasonable probability that the device would cause serious adverse health consequences or death;
- an order of repair, replacement or refund;
- device tracking requirements; and
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Additionally, once devices are commercialized, manufacturers are subject to unannounced inspections by the FDA to determine compliance with the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, device history file, and complaint files. Manufacturers are subject to periodic scheduled or unscheduled inspections by the FDA. A failure to maintain compliance with the QSR requirements could result in the shut-down of, or restrictions on, manufacturing operations and the recall or seizure of products. The discovery of previously unknown problems with products, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or approval or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market

or voluntary or mandatory device recalls. In addition, the FDA can issue warning letters or untitled letters, impose injunctions, suspend regulatory clearance or approvals, ban certain medical devices, detain or seize adulterated or misbranded medical devices, order repair, replacement or refund of these devices, and require notification of health professionals and others with regard to medical devices that present unreasonable risks of substantial harm to the public health. The FDA may also initiate action for criminal prosecution of such violations.

There are also certain requirements of state, local, and foreign governments that must be complied with in the manufacturing and marketing of our products once we have the appropriate marketing approvals. We 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. These regulations will be significantly modified in the next couple of years.

Drug and Biologics Regulation

Premarket Requirements—U.S.

Generally, a new drug may be marketed in the United States only if FDA has approved a NDA containing substantial evidence that the new drug is safe and effective for its intended use. A new biologic may generally only be marketed in the United States if FDA has approved a BLA containing substantial evidence that the biologic is safe, pure, and potent for its intended use. The results of preclinical studies and clinical trials, along with information regarding the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA/BLA, and FDA review and approval of the NDA/BLA is necessary prior to any commercial marketing or sale of a drug or biologic in the United States.

The process generally required by the FDA before a biologic or drug product candidate may be marketed in the United States involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's Good Laboratory Practice, or GLP, requirements, the Animal Welfare Act, and other laws and regulations, as applicable;
- submission to the FDA of an IND which must become effective before human clinical trials may begin and must be updated at least once annually;
- approval by an IRB, or ethics committee at each clinical site before the trial is initiated;
- performance of adequate and well-controlled clinical trials in accordance with the FDA's GCP requirements and other applicable regulations to establish the safety, purity and potency of the proposed biologic, and the safety and efficacy of the proposed drug for each indication;
- preparation of and submission to the FDA of a BLA or NDA after successful completion of all pivotal clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of an NDA or BLA to file the application for substantive review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product candidate is produced to assess cGMP and to assure that the facilities, methods and controls are adequate for manufacturing of the drug or biologic according to its specifications; and
- FDA review and approval of the BLA or NDA prior to any commercial marketing or sale of the biologic or drug product in the United States.

Preclinical Testing

Before testing any compound or biologic in human subjects in the United States, we must generate extensive preclinical data. Preclinical testing generally includes laboratory evaluation of product chemistry and formulation, as well as toxicological and pharmacological studies in several animal species to assess the quality and safety of the product candidate. Certain animal studies must be performed in compliance with the FDA's GLP regulations and the U.S. Department of Agriculture's Animal Welfare Act.

IND Submission

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

Clinical Trials

Clinical trials involve the administration of the drug to healthy human volunteers or to patients, under the supervision of a qualified investigator. The conduct of clinical trials is subject to extensive regulation, including compliance with the FDA's bioresearch monitoring regulations and GCP requirements, which establish standards for conducting, recording data from, and reporting the results of, clinical trials, and are intended to assure that the data and reported results are credible and accurate, and that the rights, safety, and well-being of study participants are protected. Clinical trials must be conducted under protocols that detail the study objectives, parameters for monitoring safety, and the efficacy criteria, if any, to be evaluated. Each protocol is reviewed by the FDA as part of the IND. In addition, each clinical trial must be reviewed and approved by, and conducted under the auspices of an IRB. Companies sponsoring the clinical trials, investigators, and IRBs also must comply with, as applicable, regulations and guidelines for obtaining informed consent from the study subjects, following the protocol and investigational plan, adequately monitoring the clinical trial, and timely reporting of adverse events. Foreign studies conducted under an IND must meet the same requirements that apply to studies being conducted in the United States. Data from a foreign study not conducted under an IND may be submitted in support of an NDA or BLA if the study was conducted in accordance with GCP requirements and the FDA is able to validate the data.

A study sponsor is required to publicly post certain details about clinical trials and clinical trial results on government or independent websites (such as http://clinicaltrials.gov). Human clinical trials typically are conducted in three or four sequential phases, although the phases may overlap with one another:

- Phase 1 clinical trials include the initial administration of the investigational drug or biologic to humans, typically to a small group of healthy human subjects, but occasionally to a group of patients with the targeted disease or disorder. Phase 1 clinical trials generally are intended to determine the metabolism and pharmacologic actions of the drug or biologic, the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness.
- Phase 2 clinical trials generally are controlled studies that involve a relatively small sample of the intended patient population, and are designed to develop data regarding the product candidate's effectiveness, to determine dose response and the optimal dose range, and to gather additional information relating to safety and potential adverse effects.
- Phase 3 clinical trials are conducted after preliminary evidence of effectiveness has been obtained, and are intended to gather the additional information about safety and effectiveness necessary to evaluate the drug's overall risk-benefit profile for a particular use, and to provide a basis for physician labeling. Generally, Phase 3 clinical development programs consist of expanded, large-scale studies of patients with the target disease or disorder to obtain statistical evidence of the efficacy and safety of the drug at the proposed dosing regimen, or the safety, purity, and potency of a biological product candidate.
- Phase 4 clinical trials may be conducted in some cases, including where the FDA conditions approval of an NDA or BLA for a product candidate on the sponsor's agreement to conduct additional clinical studies after approval. In other cases, a sponsor may voluntarily conduct additional clinical studies after approval to gain more information about the product candidate. Such post-approval studies are typically referred to as Phase 4 clinical trials.

A pivotal trial is a clinical study that is designed to generate substantial evidence of product candidate's safety and efficacy to meet regulatory agency requirements and serve as the basis for approval of the product candidate. Generally, pivotal trials are Phase 3 trials, but the FDA may accept results from Phase 2 trials if the trial design provides a well-controlled and reliable assessment of clinical benefit, particularly in situations where there is an unmet medical need and the results are sufficiently robust.

The sponsoring company, the FDA, or the IRB may suspend or terminate a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk. Further, success in early-stage clinical trials does not assure success in later-stage clinical trials. Data obtained from clinical activities are not always conclusive and may be subject to alternative

interpretations that could delay, limit, or prevent regulatory approval. Additionally, some clinical studies are overseen by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board or data monitoring committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial. We may also suspend or terminate a clinical study based on safety or efficacy concerns, evolving business objectives and/or competitive climate.

During the development of a new drug or biologic, sponsors may seek opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA or BLA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development. For example, sponsors typically use the meetings at the end of the Phase 2 trial to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trial that they believe will support approval of the new drug or biologic.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality, and purity of the final drug. In addition, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life. While the IND is active and before approval, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or *in vitro* testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

There are also requirements governing the reporting of ongoing clinical trials and completed trial results to public registries. Sponsors of certain clinical trials of FDA regulated products are required to register and disclose specified clinical trial information, which is publicly available at www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, trial sites and investigators and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to disclose certain results of their clinical trials after completion.

NDA/BLA Submission and Review

After completing clinical testing of an investigational drug or biologic, a sponsor must prepare and submit an NDA or BLA for review and approval by the FDA. The NDA is a comprehensive, multi-volume application that includes, among other things, the results of preclinical and clinical studies, information about the drug's composition, and plans for manufacturing, packaging, and labeling the drug. For certain product candidates, such as immunotherapeutic antibodies, this information is submitted in a BLA. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of a use of the product candidate, or from a number of alternative sources, including studies initiated by investigators. Under federal law, the submission of most NDAs and BLAs is subject to an application user fee, and the sponsor of an approved NDA or BLA is also subject to annual prescription drug program fees. These fees are typically increased annually. A waiver of user fees may be obtained under certain limited circumstances.

When an NDA or BLA is submitted, the FDA conducts a preliminary review to determine whether the application is sufficiently complete to be accepted for filing. If it is not, the FDA may refuse to file the application and request additional information, in which case the application must be resubmitted with the supplemental information, and review of the application is delayed.

FDA performance goals generally provide for action on a standard NDA or an original BLA submission within 10 months of the 60-day filing date, but that goal may be extended in certain circumstances. Moreover, the review process is often significantly extended by FDA requests for additional information or clarification. Before approving a BLA or NDA, the FDA typically will inspect the facility or facilities at which the product candidate is manufactured. The FDA will not approve the application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product candidate within required specifications. Additionally, before approving a BLA or NDA, the FDA will typically inspect one or more clinical sites or investigators to assure compliance with GCP requirements. If the FDA determines that the application, clinical data, manufacturing process, or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

As part of its review, the FDA may refer an NDA or BLA to an advisory committee for evaluation and a recommendation as to whether the application should be approved. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved

and under what conditions. Although the FDA is not bound by the recommendation of an advisory committee, the agency carefully considers such recommendations when making decisions. The FDA may also determine that a REMS is necessary to ensure that the benefits of a new product candidate outweigh its risks, and the product candidate can therefore be approved. A REMS may include various elements, ranging from medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools, depending on what the FDA considers necessary for the safe use of the drug.

After review of an NDA or BLA, the FDA may decide to not approve the application and issue a Complete Response letter outlining the deficiencies in the submission. The Complete Response letter also may request additional information, including additional preclinical or clinical data. Even if such additional information and data are submitted, the FDA may decide that the NDA or BLA still does not meet the standards for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than the sponsor. Obtaining regulatory approval often takes a number of years, involves the expenditure of substantial resources, and depends on a number of factors, including the severity of the disease in question, the availability of alternative treatments, and the risks and benefits demonstrated in clinical trials. Additionally, as a condition of approval, the FDA may impose restrictions that could affect the commercial success of a drug or require post-approval commitments, including the completion within a specified time period of additional Phase 4 clinical studies.

In addition, the Pediatric Research Equity Act ("PREA") requires a sponsor to conduct pediatric clinical trials for most drugs and biologics, including for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration. Under PREA, original NDAs, BLAs, and supplements thereto must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug or biologic is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin.

Post-approval modifications to the drug or biologic product candidate, such as changes in indications, labeling, or manufacturing processes or facilities, may require a sponsor to develop additional data or conduct additional preclinical or clinical trials, to be submitted in a new or supplemental NDA or BLA, which would require FDA approval.

Expedited Development and Review Programs

The FDA has established a number of programs intended to expedite the development and review of products intended to treat serious and life-threatening diseases or conditions. First, the FDA has a Fast Track program that is designed to expedite or facilitate the process for reviewing new drug products intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation applies to the product and the specific indication for which it is being studied. For a Fast Track-designated product, the FDA may consider for review sections of the NDA or BLA on a rolling basis before the complete application is submitted.

A product, including a product with a Fast Track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis, or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug designated for priority review in an effort to facilitate the review. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to ten months for review of original BLAs and new molecular entity NDAs under its standard review goals.

In addition, a product may be eligible for accelerated approval. Drug and biologic products intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality but that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform confirmatory clinical trials after approval. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Fast Track designation, priority review, and accelerated approval do not change the standards for approval but may expedite the development or approval process.

The FDA also designates certain products as “breakthrough therapies,” if the product is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the

product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. This designation includes all of the Fast Track program features, as well as more intensive FDA interaction and guidance. The Breakthrough Therapy Designation is a distinct status from both accelerated approval and priority review, which can also be granted to the same drug if relevant criteria are met. All requests for breakthrough therapy designation will be reviewed within 60 days of receipt, and the FDA will either grant or deny the request.

Fast track designation, priority review, accelerated approval, and breakthrough therapy designation do not change the standards for approval and may not result in fast or more efficient review.

Hatch-Waxman Act

The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, establishes two abbreviated approval pathways for pharmaceutical products that are in some way follow-on or bioequivalent versions of drugs approved through the NDA process.

Generic Drugs

A generic version of an approved drug is approved by means of an abbreviated new drug application, or ANDA. An ANDA is a comprehensive submission that contains, among other things, data, and information pertaining to the active pharmaceutical ingredient, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data and quality control procedures. Premarket applications for generic drugs are termed abbreviated because they generally do not include preclinical and clinical data to demonstrate safety and effectiveness. Instead, a generic applicant must demonstrate that its product performs in the same manner as, or is bioequivalent to, the innovator drug, also referred to as a reference listed drug, or RLD. In certain situations, an applicant may obtain ANDA approval of a generic product with a strength or dosage form that differs from a referenced innovator drug pursuant to the filing and approval of an ANDA Suitability Petition. The FDA will approve the generic product as suitable for an ANDA application if it finds that the generic product does not raise new questions of safety and effectiveness as compared to the innovator product. A product is not eligible for ANDA approval if the FDA determines that it is not bioequivalent to the referenced innovator drug, if it is intended for a different use, or if it is not subject to an approved Suitability Petition. However, such a product might be approved under an NDA, with supportive data from clinical trials.

505(b)(2) NDAs

Section 505(b)(2) of the FD&C Act provides an alternate regulatory pathway to obtain FDA approval for product candidates that represent modifications to formulations or uses of previously approved drug products. Specifically, Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely to some extent upon the FDA's findings of safety and effectiveness for an approved product that acts as the RLD and submit its own product-specific data—which may include data from preclinical studies or clinical trials conducted by or on behalf of the applicant—to address differences between the product candidate and the RLD. Unlike an ANDA, this does not excuse the sponsor from demonstrating the proposed product candidate's safety and effectiveness. Rather, the sponsor is permitted to rely to some degree on the FDA's finding that the RLD is safe and effective, and must submit its own product candidate-specific data of safety and effectiveness to an extent necessary because of the differences between the products. An NDA approved under Section 505(b)(2) may in turn serve as an RLD for subsequent applications from other sponsors.

RLD Patents

In seeking approval for a drug through an NDA, including a 505(b)(2) NDA, applicants are required to list with the FDA certain patents whose claims cover the applicant's product. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in the FDA publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the *Orange Book*. Any applicant who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a 505(b)(2) NDA referencing a drug listed in the Orange Book must certify to the FDA that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This last certification is known as a paragraph IV certification. A notice of the paragraph IV certification must be provided to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the ANDA or 505(b)(2) application refers. The applicant may also elect to submit a "section viii" statement certifying that its proposed label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the reference NDA holder and patent owners assert a patent challenge directed to one of the Orange Book listed patents within 45 days of the receipt of the paragraph IV certification notice, the FDA is prohibited from approving the application until the earlier of 30 months from the receipt of the paragraph IV certification expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the applicant. The ANDA or 505(b)(2) application

also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the branded reference drug has expired as described in further detail below.

Regulatory Exclusivities

The Hatch-Waxman Act provides periods of regulatory exclusivity for products that would serve as RLDs for an ANDA or 505(b)(2) application. For example, a pharmaceutical manufacturer may obtain five years of non-patent exclusivity upon NDA approval of a "new chemical entity," or NCE—which is a drug that contains an active moiety that has not been approved by the FDA in any other NDA. An "active moiety" is defined as the molecule or ion responsible for the drug substance's physiological or pharmacologic action. During this five year exclusivity period, the FDA may not accept for filing any ANDA seeking approval of a generic version of that drug or any 505(b)(2) application for a drug with the same active moiety. An ANDA or 505(b)(2) application may be submitted after four years, however, if the sponsor of the application makes a Paragraph IV certification.

A product that is not an NCE, including a product approved through a 505(b)(2) NDA, may qualify for a three-year period of exclusivity if the NDA contains new clinical data, derived from studies conducted by or for the sponsor (other than bioavailability or bioequivalence studies), that were essential for approval. In that instance, the exclusivity period does not preclude filing or review of the ANDA or 505(b)(2) application; rather, the FDA is precluded from granting final approval to the ANDA or 505(b)(2) application until three years after approval of the RLD. Additionally, the exclusivity applies only to the conditions of approval that required submission of the clinical data. For example, if an NDA is submitted for a product candidate that is not an NCE, but that seeks approval for a new indication, and clinical data were required to demonstrate the safety or effectiveness of the product candidate for that new application, the FDA could not approve an ANDA or 505(b)(2) application for another product candidate with that active moiety for that use.

The Biologics Price Competition and Innovation Act

The ACA includes a subtitle called the Biologics Price Competition and Innovation Act, which authorizes the FDA to license a biological product candidate that is biosimilar to or interchangeable with an FDA-licensed biologic through an abbreviated pathway. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being addressed by the FDA.

The BPCIA establishes criteria for determining that a product candidate is biosimilar to an already-licensed biologic, or reference product, and establishes a process by which a BLA for a biosimilar product candidate is submitted, reviewed, and licensed. The BPCIA provides periods of exclusivity that protect a reference product from biosimilars competition. Under the BPCIA, the FDA may not accept a biosimilar application for review until four years after the date of first licensure of the reference product, and the biosimilar may not be licensed until at least 12 years after the reference product's approval. During this twelve year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well controlled clinical trials to demonstrate the safety, purity, and potency of their product.

Additionally, the BPCIA establishes procedures by which the biosimilar applicant provides information about its application and product candidate to the reference product sponsor, and by which information about potentially relevant patents may be shared and litigation over patents may proceed in advance of approval. The timing of final FDA approval of a biosimilar for commercial distribution depends on a variety of factors, including whether the manufacturer of the reference product is entitled to one or more statutory exclusivity periods, during which time the FDA is prohibited from approving any product candidates that are biosimilar to the branded product. The BPCIA also provides a period of exclusivity for the first biosimilar determined by the FDA to be interchangeable with the reference product. To date, the FDA has not approved an interchangeable biosimilar product, and at this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, as these substitution practices are governed by state pharmacy law.

The contours of the BPCIA continue to be defined as the statute is implemented over a period of years. This likely will be accomplished by a variety of means, including decisions related to the statute by the relevant federal courts. The FDA has to date issued various guidance documents and other materials indicating the agency's thinking regarding a number of issues implicated by the BPCIA. Additionally, the FDA's approval of a number of biosimilar applications in recent years has helped define the agency's

approach to certain issues. However, the ultimate impact, implementation, and meaning of the BPCIA remains subject to significant uncertainty.

Post-Approval Regulation of Drug and Biologic Products

Once a drug or biologic is approved, it and its manufacturer will be subject to continuing regulation by the FDA. If ongoing regulatory requirements are not met or if safety problems occur after a product reaches the market, the FDA may at any time withdraw product approval or take actions that would limit or suspend marketing. Additionally, the FDA may require post-marketing studies or clinical trials if new safety information develops.

Other Requirements

In addition, if we hold approved NDAs or BLAs and/or manufacture or distribute drug or biological products, we must comply with other regulatory requirements, including registration and listing, submitting annual reports, reporting information about adverse drug experiences, and maintaining certain records. Similar, and in some cases additional, requirements exist in other countries, including the EU.

EU Requirements

We must obtain the requisite marketing authorizations from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of a product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application, or CTA, much like an IND, prior to the commencement of clinical trials. In the EU, for example, the conduct of clinical trials is currently governed by the EU Clinical Trials Directive 2001/20/EC, or Clinical Trials Directive, and will be replaced by the EU Clinical Trials Regulation (EU) No. 536/2014 ("CTR") once the latter comes into effect. The CTR introduces a complete overhaul of the existing regulation of clinical trials for medicinal products in the EU. It entered into force on January 31, 2022.

Under the current regime, which will expire after a transition period of one or three years, respectively, before a clinical trial can be initiated it must be approved in each EU Member State where there is a site at which the trial is to be conducted. The approval must be obtained from two separate entities: the National Competent Authority (“NCA”) and one or more Ethics Committees. Once the CTA is approved in accordance with a country’s requirements, clinical trial development may proceed.

The requirements and process governing the conduct of clinical trials, product licensing, pricing, and reimbursement vary from country to country. In all cases in EU Member States, for example, the clinical trials must be conducted in accordance with GCP requirements, applicable regulatory requirements, and ethical principles that have their origin in the Declaration of Helsinki. Other EU requirements include regulations concerning marketing authorizations, pricing and reimbursement, patient rights in cross-border healthcare, advertising, and promotion, interactions with physicians, bribery, and corruption.

For other countries outside of the EU, such as countries in Eastern Europe, Central and South America, or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing, and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP requirements, applicable regulatory requirements, and ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, warning letters or untitled letters, injunctions, civil, administrative, or criminal penalties, monetary fines or imprisonment, suspension or withdrawal of regulatory approvals, suspension of ongoing clinical studies, refusal to approve pending applications or supplements to applications filed by us, suspension or the imposition of restrictions on operations, product recalls, the refusal to permit the import or export of our products or the seizure or detention of products.

Combination Products

A combination product is the combination of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are combined or mixed and produced as a single entity; packaged together in a single package or as a unit; or a drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

To determine which of the FDA center or centers will review a combination product candidate submission, companies may submit a request for assignment to the FDA. Those requests may be handled formally or informally. In some cases, jurisdiction may be determined informally based on FDA experience with similar products. However, informal jurisdictional determinations are not binding on the FDA. Companies also may submit a formal Request for Designation to the FDA Office of Combination Products. The

Office of Combination Products will review the request and make its jurisdictional determination within 60 days of receiving a Request for Designation.

FDA will determine which center or centers within the FDA will review the product candidate and under what legal authority the product candidate will be reviewed. Depending on how the FDA views the product candidates that are developed, the FDA may have aspects of the product candidate reviewed by the FDA's Center for Biologics Evaluation and Research, Center for Devices and Radiological Health and Center for Drug Evaluation and Research, though one center will be designated as the center with primary jurisdiction, based on the product candidate's primary mode of action. The FDA determines the primary mode of action based on the single mode of action that provides the most important therapeutic action of the combination product candidate—the mode of action expected to make the greatest contribution to the overall intended therapeutic effects of the combination product candidate. The review of such combination product candidates is often complex and time consuming, as the FDA may select the combination product candidate to be reviewed and regulated by one or multiple of the FDA centers identified above, which could affect the path to regulatory clearance or approval. Furthermore, the FDA may also require submission of separate applications to multiple centers.

We are developing certain product candidates, that will be subject to regulation in the United States as combination products. We believe that the primary mode of action of these candidates is the drug or biologic component. We expect to seek approval for these candidates through submission of a BLA for biologic candidates and through submission of a NDA submitted under Section 505(b)(2) of the FD&C Act for small molecule candidates. Based on a pre-IND meeting, we do not expect that the FDA will require a separate marketing authorization for each constituent of these product candidates.

The post-market requirements that apply to the cleared or approved product will largely be aligned with the agency center determined to have primary jurisdiction over the product candidate and that provided marketing authorization, but manufacturers must also comply with certain post-market requirements with respect to the constituent parts of combination products. In April 2019, FDA published a final guidance document entitled Compliance Policy for Combination Product Postmarketing Safety Reporting, which is intended to assist manufacturers of combination products comply with reporting requirements applicable to such products. In December 2019, FDA issued draft guidance intended to clarify how sponsors of combination products can: establish the scientific relevance of information from another development program to support an application for FDA approval of a combination product. In December 2020, FDA issued final guidance on how sponsors of combination products can obtain feedback from FDA on scientific and regulatory questions pertaining to the combination product.

After issuing marketing authorizations, the FDA has discretion in determining post-approval compliance requirements for combination products and could thus require compliance with certain cGMP requirements as well as QSR requirements for device components of a combination product. Other post-market requirements analogous to those described above for medical devices and drugs/biologics will also apply, depending on the application type and center overseeing regulation of the combination product, including:

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

HIPAA and Other Data Privacy and Security Laws

We are subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. The regulations promulgated under HIPAA, as amended by HITECH, impose privacy, security and breach reporting obligations with respect to individually identifiable health information upon "covered entities" (health plans, healthcare clearinghouses and certain healthcare providers), and their respective "business associates," individuals or entities that create, receive, maintain, or transmit PHI, in connection with providing a service for or on behalf of a covered entity. Under HIPAA, covered entities must also enter into agreements with their business associates, which require the business associates to protect any PHI provided by the covered entity against improper use or disclosure. Additionally, HITECH mandates the reporting of certain breaches of health information to HHS, affected individuals, and if the breach is large enough, the media.

HITECH makes specific HIPAA privacy and security requirements directly applicable to business associates. We are both a covered entity and a business associate of our covered entity customers. Under the terms of the business associate agreements into which we have entered, we have certain obligations regarding the use and disclosure of any PHI that may be provided to us, and we could incur significant liability if we do not meet such obligations.

HHS promulgated various requirements under HIPAA with which we must comply. HHS rules define standards for electronic transactions, which establish standards for common healthcare transactions, such as claims information, plan eligibility, payment information, and the use of electronic signatures. We must also follow standards for the privacy of individually identifiable health information, which limit use and disclosure of most written and oral communications, including those in electronic form, regarding a patient's past, present or future physical or mental health or condition or disclosing healthcare provided to the individual or payment for that healthcare, if the individual may be identified from such information. In addition, HIPAA's security standards require us to ensure the confidentiality, integrity, and availability of all electronic PHI we create, receive, maintain, or transmit, to protect against reasonably anticipated threats or hazards to the security of such information and to protect such information from unauthorized use or disclosure.

There are significant civil and criminal fines and other penalties that may be imposed for violating HIPAA. A covered entity or business associate is also liable for civil money penalties for a violation that is based on an act or omission of any of its agents, which may include a downstream business associate, as determined according to the federal common law of agency. HITECH also increased the civil and criminal penalties applicable to covered entities and business associates and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions. To the extent that we submit electronic healthcare claims and payment transactions that do not comply with the electronic data transmission standards established under HIPAA and HITECH, payments to us may be delayed or denied.

Regardless of the applicability of HIPAA or other data privacy laws or regulations, failing to take what the FTC perceives to be appropriate steps to keep consumers' personal information secure may result in the FTC bringing a claim that a company has engaged in unfair or deceptive acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, or the FTCA, 15 U.S.C. § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. In addition, state consumer protection laws, which may or may not be modeled on the FTCA, may provide state-law causes of action for allegedly unfair or deceptive practices, among other things, including causes of action for alleged data privacy violations.

Moreover, various state and non-U.S. laws and regulations, such as the CCPA and the EU General Data Protection Regulation (Regulation (EU) 2016/679), or GDPR, may govern the privacy and security of health information in certain circumstances. Some of these laws and regulations are more stringent than HIPAA, and many differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation.

Especially in the EU, there has been increased attention to privacy and data protection issues with the potential to directly affect our business. The GDPR, which went into effect on May 25, 2018 and imposes penalties of up to 4% of annual worldwide turnover, and related implementing laws in individual EU Member States govern the collection and use of personal health data and other personal data in the EU. 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 within the EU and in the EEA, including health data from clinical trials and adverse event reporting. The GDPR also includes requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals prior to processing their personal data or personal health data, notification of data processing 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 implementing legislation.

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, 2021, we had 124 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

Reimbursement

Prior to the shutdown of commercial operations in our laboratory in Ann Arbor, MI and the sale of our affiliated business Avero Diagnostics, both of which occurred in 2021, we operated clinical laboratories. Laboratory tests are classified for reimbursement purposes under a coding system known as Current Procedure Terminology, or 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 AMA establishes a CPT code, CMS or its contractors may establish payment levels and coverage rules with respect to our molecular tests under Medicare and Medicaid. In addition, commercial third-party payors independently establish reimbursement rates and coverage rules for our molecular tests under their respective plans.

Prior to the shutdown of commercial operations in our laboratory in Ann Arbor, MI and the sale of our affiliated business Avero Diagnostics, 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 still receive small amounts of revenue in connection with the reimbursement for tests that were run prior to the closure of our Ann Arbor lab. We expect reimbursement for past tests to continue to decline and ultimately end in the near future. Subsequently, we expect that our primary sources of revenue will shift to potential grants and partnership revenues, though these amounts, if and when received, may be relatively small in magnitude.

Commercial Third-Party Payors

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

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

We have entered into settlement agreements with commercial third-party payors in order to settle claims related to past billing and coding practices that have been discontinued, including, without limitation: United HealthCare Services, Inc. and UnitedHealthcare Insurance Company, or United, and Aetna Health Management, Inc., or Aetna. In September 2019, we entered into a settlement agreement with United that governs past benefit claims and a corrective action plan which governs future benefit claims that we submit for reimbursement at an arm's length, out-of-network basis to United. As of December 31, 2021 the settlement with these commercial payors has been fully paid. Each of these settlement agreements provides for a release of past claims by the parties.

Payor Dispute

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

We have historically negotiated and settled similar claims with third-party payors. Although our practice in resolving disputes with other similar large commercial payors has generally led to agreed settlement amounts substantially less than the originally claimed amount, there can be no assurance that we will be successful in a similar settlement amount in any ongoing or future dispute. Historical settlement amounts and payment time periods may not be indicative of the final settlement terms with Anthem, if any. We dispute this claim of recoupment with Anthem in substantial part based on expired statutes of limitations and seek to offset any amounts owed by Anthem to us. It is not possible to predict the ultimate outcome of this matter and the timing for resolution.

Corporate Information

We were incorporated in Delaware in January 2012 under the name Ascendant MDx, Inc., and in August 2013 we changed our name to Progenity, 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 (855) 293-2639. Our website is www.progenity.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 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, or the Exchange Act. We make available on our website at www.progenity.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, (2) the last day of the year in which we have total annual gross revenue of at least $1.07 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," "Progenity" or the "company" refer to Progenity, Inc. and its subsidiaries.

Risk Factor Summary

- Beginning in the fourth quarter of 2020, we began to reallocate resources within our organization to align more closely with our business priorities. This included reducing the resources allocated to certain programs and refocusing our resources on other key areas of our business, such as our therapeutics pipeline. In addition, in June 2021, we announced a Strategic Transformation that involves certain cost realignment measures and in December 2021 we announced the sale of Avero Diagnostics. We may experience difficulties in managing these changes to our organization and if unsuccessful, our financial condition and operating results may be adversely affected.
- The ongoing COVID-19 pandemic could further materially affect our operations, as well as the business or operations of third parties with whom we conduct business. Our business could be adversely affected by the effects of other future health epidemics or pandemics in regions where we or third parties on which we rely have significant business operations.
- We have incurred losses in the past, and we may not be able to achieve or sustain profitability in the future.
- Operating our business will require a significant amount of cash, and our ability to generate sufficient cash depends on many factors, some of which are beyond our control. We expect to need to raise additional capital, and if we cannot raise additional capital when needed, we may have to curtail or cease operations.
- We 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 precision medicine platform 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 precision medicine products or product revenue. There can be no assurance that we will develop any precision medicine products that deliver diagnostic or therapeutic solutions, or, if developed, that such product candidates will be authorized for marketing by regulatory authorities, or will be commercially successful. This uncertainty makes it difficult to assess our future prospects and financial results.
- Our 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, commercialize, and manufacture some or all of our product candidates.
- If third-party payors do not adequately reimburse for our products under development, they might not be purchased or used, which may adversely affect our revenue and profitability.
- If we or our commercial partners act in a manner that violates healthcare laws or otherwise engage in misconduct, we could face substantial penalties and damage to our reputation, and our business operations and financial condition could be adversely affected.
- Third-party claims of intellectual property infringement could result in litigation or other proceedings, which would be costly and time-consuming, and could limit our ability to commercialize our products.

Risks Related to Our Business and Industry

Beginning in the fourth quarter of 2020, we began to reallocate resources within our organization to align more closely with our business priorities. This included reducing the resources allocated to certain programs and refocusing our resources on other key areas of our business, such as our therapeutics pipeline. In addition, in June 2021, we announced a Strategic Transformation that involves certain cost realignment measures and in December 2021 we announced the sale of Avero Diagnostics. We may experience difficulties in managing these changes to our organization and if unsuccessful, our financial condition and operating results may be adversely affected.

In November 2020, we approved a reduction in force that resulted in the termination of approximately 9.5% of our workforce. The reduction in force was a component of our broader efforts to materially reduce our research and development expenses by focusing on key milestones and to limit progression of other costs to track our top line performance.

In addition, on June 1, 2021, we announced a Strategic Transformation, which involves certain cost realignment measures including the discontinuation of the provision of commercial genetic laboratory-developed test services through our Ann Arbor, Michigan CLIA-certified laboratory and the termination of approximately 374 employees across the Company and our former affiliate, Mattison Pathology, LLP, a Texas limited liability partnership doing business as Avero Diagnostics, which represented approximately 56% of our workforce. In December 2021, we sold our interests in Avero Diagnostics via an asset sale.

As a result of the Strategic Transformation, our business is refocusing on our research and development pipeline, which we expect will materially reduce our operating expenditures, more effectively allocate capital and unlock the value of our differentiated research and development pipeline.

Over several years prior to November 2020, we significantly expanded the size of our organization. As a result of the Strategic Transformation, we have been reducing certain aspects of our organization, particularly personnel within our Laboratory Operations and support and sales and marketing teams. In addition, certain of our managerial, operational, research and development, financial, and other personnel have been or will be impacted by the Strategic Transformation. Whereas, the historical addition of employees imposed significant added responsibilities on members of management, our cost realignment measures pursuant to the Strategic Transformation may impose additional obligations on existing personnel, including increased responsibilities with respect to managing our internal development efforts effectively, while complying with our contractual obligations to contractors and other third parties, and executing on and improving our operational, financial, and management controls, reporting systems, and procedures.

Our future financial performance, our ability to successfully develop, market, and sell our products under development, and our ability to effectively implement the Strategic Transformation will each impact our needs in terms of personnel. Our management has and may continue to be required to devote a substantial amount of time to implementing the Strategic Transformation or pursuing additional strategic transactions, which may divert a disproportionate amount of attention away from day-to-day activities. Further, our future success depends on our ability to effectively implement the Strategic Transformation and the successful development and commercialization of our research and development pipeline. We cannot assure you that we will achieve the full magnitude of cost savings and reduced operating expenditures that we have disclosed that we expect the Strategic Transformation to achieve or that any of our businesses will achieve the revenues that we have disclosed that we expect them to achieve following the Strategic Transformation, as a result of unexpected costs, costs associated with the Strategic Transformation such as severance and contract terminations or otherwise. In addition, we cannot assure you that our efforts related to the Strategic Transformation will improve our financial condition due to necessarily decreased revenue, including as a result of the termination of testing services, or will increase stockholder value. Any inability to execute and evolve in accordance with the Strategic Transformation and our other business initiatives could adversely impact our financial condition and results of operations.

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

Our business and its operations, including but not limited to supply chain operations, research and development activities and capital raising activities, could be adversely affected by health epidemics in regions where we have business operations, including the ongoing COVID-19 pandemic, and such health epidemics could also cause significant disruption in the operations of third parties with whom we do business, including third parties upon whom we rely. While vaccines have shown a level of effectiveness against SARS CoV-2, some variants are more likely to infect even vaccinated individuals. Variants have and may in the future cause resurgences of COVID cases, and vaccination rates may be insufficient to achieve herd immunity in locations where we conduct business.

In response to public health directives and orders imposed as a result of the COVID-19 pandemic, we have implemented over the course of time various work-from-home policies and hybrid policies for most of our employees. The effects of the executive orders, the shelter-in-place orders, and our work-from-home policies have negatively impacted, and may further negatively impact, productivity, and our preclinical and clinical programs and timelines, and disrupt our business in other ways, the magnitude of which

will depend, in part, on future developments related to restrictions, variants, levels of vaccination and effectiveness of various vaccines, and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition. We continue to monitor relevant laws and regulations, and will continue to assess the situation over time and allow employees to return to the office, as needed, in accordance with our reopening plan, which is based on a phased approach that is appropriately tailored for each of our offices, with a focus on state and local orders, employee safety and optimal work environment.

Quarantines, shelter-in-place, executive, and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases, could impact personnel at third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials we use or require to conduct our business, including product development, which would disrupt our supply chain. In particular, some of our suppliers of certain materials used in our Laboratory Operations and research and development activities are located in areas that are or were subject to executive orders and shelter-in-place orders. While many of these materials may be obtained from more than one supplier, port closures and other restrictions resulting from the COVID-19 pandemic or future pandemics may disrupt our supply chain or limit our ability to obtain sufficient materials to operate our business. To date, we are aware of certain suppliers for our research and development activities who have experienced operational delays directly related to the COVID-19 pandemic.

The spread of COVID-19, which has caused a broad impact globally, has affected and may further materially affect us economically, including a continuing and significant reduction in laboratory testing volumes. A future recession or market correction resulting from the spread of COVID-19 and related government orders and restrictions could materially affect our business and the value of our common stock.

In addition, our preclinical and clinical trials have been and may continue to be affected by the COVID-19 pandemic. For example, while we originally intended to commence our pilot clinical study for PIL Dx in 2020, that timeline was delayed due to circumstances and uncertainties created by the COVID-19 pandemic. If COVID-19 experiences a resurgence in the United States and elsewhere, we may experience additional disruptions that could severely impact our business, preclinical studies and clinical trials, including:

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

The COVID-19 pandemic continues to evolve rapidly. Although vaccines are now available and are being distributed globally, we cannot predict the full scope, duration and severity of disruptions resulting from the COVID-19 pandemic. The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems, or the global economy as a whole.

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

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

Other than potential revenues from partnerships similar to those we have entered into in the recent past, we do not expect to generate significant revenues in the immediate future. We do not expect to generate sufficient revenue to cover our costs for the foreseeable future, including research and development expenses related to furthering our product pipeline. We may not generate significant revenue in the future until we are able to achieve commercialization of our product candidates or enter into licensing or collaboration agreements with respect to such product candidates.

Since we or any collaborators or licensees may not successfully develop additional product candidates, obtain required regulatory authorizations, manufacture products at an acceptable cost or with appropriate quality, or successfully market and sell such product candidates with desired margins, our expenses may continue to exceed any revenues we may receive. Our operating expenses also will increase as and if, among other things:

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

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

We expect to incur significant costs in connection with our operations, including but not limited to the research and development, marketing authorization, and/or commercialization of new medical devices, therapeutics, and other products. These development activities generally require a substantial investment before we can determine commercial viability, and the proceeds from our offerings to date will not be sufficient to fully fund these activities. In addition, as a result of the Strategic Transformation, our revenue has been significantly reduced. We will need to raise additional funds through public or private equity or debt financings, collaborations, licensing arrangements or sales of assets to continue to fund or expand our operations. Following the Strategic Transformation, we will 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, including for our precision medicine platform;
- the costs to fund our commercialization strategies for any product candidates for which we receive marketing authorization or otherwise launch and to prepare for potential product marketing authorizations, as required;
- the costs of any acquisitions of complementary businesses or technologies that we may pursue;
- potential licensing or partnering transactions, if any;
- our facilities expenses, which will vary depending on the time and terms of any facility lease or sublease we may enter into, and other operating expenses;
- the scope and extent of any future expansion of our sales and marketing efforts;

- potential and pending litigation, potential payor recoupments of reimbursement amounts, and other contingencies;
- the commercial success of our future products;
- the termination costs associated with our Strategic Transformation;
- any proceeds from strategic transactions; and
- our ability to collect our accounts receivable.

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

Additional capital, if needed, may not be available on satisfactory terms or at all. Furthermore, any additional capital raised through the sale of equity or equity-linked securities 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 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 the Avero Diagnostics business. We have explored the potential divestiture and/or out-license of other assets as well, including assets and intellectual property related to our Preecludia™ rule-out test for preeclampsia and single-molecule counting assay under development. 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 investment in these programs.

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 precision medicine competitors, see Part I, Item 1. "Business—Competition in Precision Medicine."

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

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

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

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

Effective execution of research and development activities and the timely introduction of new products and product candidates to the market are important elements of our business strategy. However, the development of new products and product candidates is complex, costly, and uncertain and requires us to, among other factors, accurately anticipate patients', clinicians', and payors' needs, and emerging technology trends. For more information on our current research and development efforts, see Part I, Item 1. "Business—Our Research and Development Activities."

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

- we will develop any products that meet our desired target product profile and address the relevant clinical need or commercial opportunity;

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

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

The research and development process in our industries generally requires a significant amount of time from the research and design stage through commercialization. The launch of such new products requires the completion of certain clinical development and/or assay validations in the 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 precision medicine platform 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 precision medicine products or product revenue. There can be no assurance that we will develop any precision medicine 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 precision medicine platform 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 DDS and RSS devices.

We seek to develop a suite of ingestible capsules for both diagnostic and therapeutic solutions. However, medical device and related diagnostic and therapeutic product development is a highly speculative undertaking and involves a substantial degree of uncertainty and we are in the early stages of our development programs. Our precision medicine platform has not yet demonstrated an ability to generate revenue or successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields such as ours for precision medicine. Consequently, the ability to accurately assess the future operating results or business prospects of our precision medicine platform is significantly more limited than if we had an operating history or approved commercial precision medicine products. Our success in developing commercial products that are based on our precision medicine platform will depend on a variety of factors, many of which are beyond our control, including, but not limited to:

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

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

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

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

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

The development of new product candidates, including development of the data necessary to obtain clearance or approval for such product candidates, is costly, time-consuming, and carries with it the risk of not yielding the desired results. The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of clinical trials do not necessarily predict success in future clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier development, and 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 Good Clinical Practice, or GCP, requirements, for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, safety, and welfare of trial participants are protected. Other countries' regulatory agencies also have requirements for clinical trials with which we must comply. We also are required to register certain ongoing clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, enforcement action, adverse publicity, and civil and criminal sanctions.

The initiation and completion of any clinical studies may be prevented, delayed, or halted for numerous reasons. We may experience delays in 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 investigational device exemption, or IDE, application to the FDA with respect to our medical device product candidates, which must become effective prior to commencing certain human clinical trials of medical devices, and the FDA may reject our IDE application and notify us that we may not begin clinical trials;
- regulators and other comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical trials;

- regulators and/or institutional review boards, or IRBs, or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site;
- we may not reach agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of subjects or patients required for clinical trials may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors, including those manufacturing products or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we or our investigators may have to suspend or terminate clinical trials for various reasons, including a finding that the subjects are being exposed to unacceptable health risks or based on a requirement or recommendation from regulators, IRBs or other parties due to safety signals or noncompliance with regulatory requirements;
- we may have to amend clinical trial protocols or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to submit to an IRB and/or regulatory authorities for re-examination;
- the cost of clinical trials may be greater than we anticipate;
- clinical sites may not adhere to the clinical protocol or may drop out of a clinical trial;
- we may be unable to recruit a sufficient number of clinical trial sites;
- regulators, IRBs, or other reviewing bodies may fail to approve or subsequently find fault with our manufacturing processes or facilities of third-party manufacturers with which we enter into agreement for clinical and commercial supplies, the supply of devices or other materials necessary to conduct clinical trials may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply;
- marketing authorization policies or regulations of the FDA or applicable foreign regulatory agencies may change in a manner rendering our clinical data insufficient for authorization; and
- our product candidates may have undesirable side effects or other unexpected characteristics.

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

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

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

Clinical trials must be also conducted in accordance with the laws and regulations of the FDA and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and IRBs at the medical institutions where the clinical trials are conducted. We rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance. We depend on our collaborators and on medical institutions and CROs to conduct our clinical trials in compliance

with the FDA's GCP requirements. To the extent our collaborators or the CROs fail to enroll participants for our clinical trials, fail to conduct the study to GCP requirements, or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays, or both. In addition, clinical trials that are conducted in countries outside the United States may subject us to further delays and expenses as a result of increased shipment costs, additional regulatory requirements and the engagement of non-U.S. CROs, as well as expose us to risks associated with clinical investigators who are unknown to the FDA, and different standards of diagnosis, screening and medical care.

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

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

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

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

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product, and our results of operations, liquidity and financial condition. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed significant by others with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the top-line data that we report differ from final results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain marketing authorization for, and commercialize, product candidates may be harmed, which could seriously harm our business.

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

As the healthcare reimbursement system in the United States evolves to place greater emphasis on comparative effectiveness and outcomes data, we cannot predict whether we will have sufficient data, or whether the data we have will be presented to the satisfaction of any payors seeking such data for determining coverage for our products under development, particularly in new areas such as in precision medicine diagnostic or therapeutic applications.

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

are inconsistent with certain results obtained from our previous studies, adoption of our products would suffer and our business would be harmed.

Peer-reviewed publications regarding our 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, 2021, we had approximately $126.4 million of convertible notes payable. Certain of our debt agreements contain various restrictive covenants.

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

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

- making it more difficult for us to satisfy our obligations under our existing debt instruments;
- increasing our vulnerability to general adverse economic and industry conditions;
- limiting our ability to obtain additional financing to fund our research, development, and commercialization activities, particularly when the availability of financing in the capital markets is limited;
- requiring a substantial portion of our cash flows from operations for the payment of principal and interest on our debt, reducing our ability to use our cash flows to fund working capital, research and development, and other general corporate requirements;
- limiting our flexibility to plan for, or react to, changes in our business and the industries in which we operate;
- further diluting our current stockholders as a result of issuing shares of our common stock upon conversion of our convertible notes; and
- placing us at a competitive disadvantage with competitors that are less leveraged than us or have better access to capital.

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

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

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

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

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

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

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

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

Certain states have also adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. In addition, California enacted the California Consumer Privacy Act, or CCPA, on June 28, 2018, which went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal data. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability, and many similar laws have been proposed at the federal level and proposed or enacted in other states. Any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, CROs, collaborators, or other third parties to

comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation, and adversely affect our business and results of operations.

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

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

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

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

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

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

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

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

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

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

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

We expect to depend on collaborators, partners, licensees, manufacturers, and other third parties to support our product candidate development efforts, 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. For example, following the discontinuation of genetic laboratory-developed test services in our Ann Arbor laboratory, we are unable to independently commercialize Preecludia™ as an LDT and will be required to partner with a third-party, or potentially to license-out or sell the technology and related assets. Prior to marketing Preecludia™ as an LDT, any future development partner would need to validate the test within their own lab, and such third party may not be successful in validating the test in their lab on a timely basis, or at all.

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

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

We rely on 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 of the items manufactured would heighten the risks that we face. Changes to, failure to renew or termination of our existing agreements or our inability to enter into new agreements with other suppliers could result in the loss of access to important components of our 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 precision medicine 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, diagnostic products, and pharmaceutical products. We have limited personnel with experience in, and we do not own facilities for, manufacturing any products. We depend upon our collaborators and other third parties, including sole source suppliers, to provide raw materials meeting FDA quality standards and related regulatory requirements, manufacture devices, diagnostic products, and drug substances, produce drug products and provide certain analytical services with respect to our products and product candidates. The FDA and other regulatory authorities require that many of our products be manufactured according to cGMP regulations and that proper procedures be implemented to assure the quality of our sourcing of raw materials and the manufacture of our products. Any failure by us, our collaborators, or our third-party manufacturers to comply with cGMP and/or scale-up manufacturing processes could lead to a delay in, or failure to obtain, marketing authorizations. In addition, such failure could be the basis for action by the FDA, including issuing a warning letter, initiating a product recall or seizure, fines, imposing operating restrictions, total or partial suspension of production or injunctions and/or withdrawing marketing authorizations for products previously granted to us. To the extent we rely on a third-party manufacturer, the risk of noncompliance with cGMPs may be greater and the ability to effect corrective actions for any such noncompliance may be compromised or delayed.

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

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

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

We rely and expect to continue to rely on third parties, such as engineering firms, CROs, clinical data management organizations, medical institutions, and clinical investigators, to conduct and manage certain aspects of the design, preclinical testing, and clinical trials for our products under development. Our reliance on these third parties for research and development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with GCP requirements, the general investigational plan, and the protocols established for such trials.

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

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

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

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

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

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

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

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

Our precision medicine product candidates under 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 precision medicine product candidates are prescribed only by trained professionals, the potential for misuse of our precision medicine product candidates, if authorized for marketing, still exists due to their complexity. Such misuse could result in adverse medical consequences for patients that could damage our reputation, subject us to costly product liability litigation, and otherwise have a material and adverse effect on our business, operating results, and financial condition.

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

We may develop product candidates regulated as biologics in the future in connection with our precision medicine platform. The successful development, manufacturing, and sale of biologics is a long, expensive, and uncertain process. There are unique risks and uncertainties with biologics. For example, access to and supply of necessary biological materials, such as cell lines, may be limited and governmental regulations restrict access to and regulate the transport and use of such materials. In addition, the testing, development, approval, manufacturing, distribution, and sale of biologics is subject to applicable provisions of the FD&C Act, PHSA, and regulations issued thereunder that are often more complex and extensive than the regulations applicable to other pharmaceutical products 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 Biologics Price Competition and Innovation Act, or BPCIA, created a framework for the approval of biosimilars in the United States that could allow competitors to reference data from any future biologic products for which we receive marketing approvals and otherwise increase the risk that any product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the original biologic was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full Biologics License Application, or BLA, for the competing product containing the sponsor's own 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 precision medicine platform that require FDA approval of a New Drug Application, or NDA, or a BLA before marketing or sale in the United States. In the NDA or BLA process, we, or our collaborative partners, must provide the FDA and similar foreign regulatory authorities with data from preclinical and clinical studies that demonstrate that our product candidates are safe and effective, or in the case of biologics, safe, pure, and potent, for a defined indication before they can be approved for commercial distribution. The FDA or foreign regulatory authorities may disagree with our clinical trial designs and our interpretation of data from preclinical studies and clinical trials. The processes by which regulatory approvals are obtained from the FDA and foreign regulatory authorities to market and sell a new product are complex, require a number of years, depend upon the type, complexity, and novelty of the product candidate, and involve the expenditure of substantial resources for research, development, and testing. The FDA and foreign regulatory authorities have substantial discretion in the drug approval process and may require us to conduct additional nonclinical and clinical testing or to perform post-marketing studies. Further, the implementation of new laws and regulations, and revisions to FDA clinical trial design guidance, may lead to increased uncertainty regarding the approvability of new drugs.

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

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

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

the approval may limit the indicated uses for which the drug may be marketed or impose significant restrictions or limitations on the use and/or distribution of such product.

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

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

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

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

The process of obtaining marketing authorizations, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if authorization is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. Changes in marketing authorization policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application we submit, or may decide that our data is insufficient for approval and require additional preclinical, clinical, or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent marketing authorization of a product candidate. Any marketing authorization we or our collaborators ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved medicine not commercially viable.

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

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

The use of our product candidates could be associated with side effects or adverse events, which can vary in severity (from minor reactions to death) and frequency (infrequent or prevalent). Side effects or adverse events associated with the use of our product candidates may be observed at any time, including in clinical trials or when a product is commercialized. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory authorization by the FDA or other comparable foreign authorities. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects such as toxicity or other safety issues and could require us or our collaboration partners to perform additional studies or halt development or sale of these product candidates or expose us to product liability lawsuits, which would harm our business and financial results. In such an event, we may be required by regulatory agencies to conduct additional animal or human studies regarding the safety and efficacy of our product candidates, which

we have not planned or anticipated or our studies could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny or withdraw approval of our product candidates for any or all targeted indications. There can be no assurance that we will resolve any issues related to any product-related adverse events to the satisfaction of the FDA or any other regulatory agency in a timely manner, if ever, which could harm our business, operating results, financial condition and prospects.

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

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

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

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

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

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

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

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, or TCJA, was passed into law. The TCJA has given rise to significant one-time and ongoing changes, including but not limited to a federal corporate tax rate decrease to 21% for tax years beginning after December 31, 2017, limitations on interest expense deductions, the immediate expensing of certain capital expenditures, the adoption of elements of a partially territorial tax system, new anti-base erosion provisions, a reduction to the maximum deduction allowed for net operating losses generated in tax years after December 31, 2017 and providing for indefinite carryforwards for losses generated in tax years after December 31, 2017. The legislation is unclear in many respects and could be subject to potential amendments and technical corrections, and will be subject to interpretations and implementing regulations by the Treasury and Internal Revenue Service, any of which could mitigate or increase certain adverse effects of the legislation. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation. Generally, future changes in applicable tax laws and regulations, or their interpretation and application, could have a material and adverse effect on our business, operating results, and financial condition.

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

As of December 31, 2021, we had net operating loss ("NOL") carryforwards of approximately $458.2 million for federal income tax purposes, and $221.7 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, or the Code, and corresponding provisions of state law, if a corporation undergoes an “ownership change,” which is generally defined as a greater than 50 percentage point change, by value, in its equity ownership by 5% stockholders over a rolling three-year period, the corporation’s ability to use its pre-change NOLs and other pre-change tax attributes to offset its post-change income may be limited. If we determine that an ownership change has occurred and our ability to use our historical NOLs is materially limited, it could harm our future operating results by effectively increasing our future tax obligations. In addition, under the TCJA, federal NOLs incurred in 2018 and in future years may be carried forward indefinitely but generally may not be carried back and the deductibility of such NOLs is limited to 80% of taxable income. On March 27, 2020, Congress enacted the Coronavirus Aid, Relief and Economic Security Act, known as the CARES Act, which provides some relief from the limitations on the utilization of NOLs and certain other tax attributes described above. During the three months ended March 31, 2020, we recorded a discrete tax benefit of $37.7 million related to the NOL carryback provisions available under the CARES Act for taxes paid in years 2013, 2014, 2015, and 2017, which we refer to as the CARES Act Tax Benefit. We agreed to pay 65% of any tax refund received in excess of $5.0 million in a single year, along with other civil settlements, damages awards, and tax refunds, to accelerate payments to the government in connection with our government settlement. During the year ended December 31, 2020, we received a tax refund of $37.7 million related to the NOL carryback provisions available under the CARES Act. For the year ended December 31, 2020, we had paid a total of $37.0 million to the government in connection with our government settlements. We did not receive any tax refunds during the year ended December 31, 2021,

Reimbursement Risks Related to Our Historical Testing Business

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

Our future success will depend on our or our potential partners' ability to obtain or maintain adequate reimbursement coverage from third-party payors. Third-party reimbursement for our testing historically represented a significant portion of our revenues, and we expect third-party payors such as third-party commercial payors and government healthcare programs to be a source of revenue in the future. It is to be determined whether and to what extent certain of our products under development will be covered or reimbursed. If we are unable to obtain or maintain coverage or adequate reimbursement from, or achieve in-network status with, third-party payors for our future tests or other products, our ability to generate revenues will be limited. For example, healthcare providers may be reluctant to order our tests or other products due to the potential of a substantial cost to the patient if coverage or reimbursement is unavailable or insufficient.

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 commercial operations in our laboratory in Ann Arbor, MI and the sale of our affiliated business Avero Diagnostics, both of which occurred in 2021, we operated clinical laboratories 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, and we expect these disputes and requests for recoupment to continue. Third-party payors may decide to deny payment or recoup payment for testing that they contend to have been not medically necessary, against their coverage determinations, or for which they have otherwise overpaid, and we may be required to refund reimbursements already received. We have entered into settlement agreements with 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 Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act of 2010, or collectively, the ACA, enacted in March 2010, requires providers and suppliers to report and return any overpayments received from government payors under the Medicare and Medicaid programs within 60 days of identification. Failure to identify and return such overpayments exposes the provider or supplier to liability under federal false claims laws and the OIG's healthcare enforcement authorities, and would be a potential violation of our obligations under our Corporate Integrity Agreement to report substantial overpayments to the 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, on November 16, 2020, we received a letter from Anthem informing us that Anthem is seeking recoupment for historical payments made by Anthem in an aggregate amount of approximately $27.4 million. The historical payments for which Anthem is seeking recoupment are claimed to relate primarily to discontinued legacy billing practices for our NIPT and microdeletion tests and secondarily to the implementation of the new CPT code for reimbursement for our Preparent expanded carrier screening tests. We can provide no assurance that we will not receive similar claims for recoupment from other third-party payors in the future. For more information on this claim, see Part I, Item 1. "Business—Reimbursement—Payor Dispute." Any of these outcomes, including recoupment or reimbursements, might also require us to restate our financials from a prior period, any of which could have a material and adverse effect on our business, operating results, and financial condition.

If the validity of an informed consent from a patient is challenged, we could be forced to refund amounts previously paid by third-party payors, or to exclude a patient's data from clinical trial results.

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

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, or EKRA, which, among other things, prohibits knowingly or willfully paying, offering to pay, soliciting or receiving any remuneration (including any kickback, bribe, or rebate), whether directly or indirectly, overtly or covertly, in cash or in kind, to induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory, or in exchange for an individual using the services of that recovery home, clinical treatment facility, or laboratory; violation of EKRA may result in 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;
- HIPAA, which, among other things, imposes criminal liability for executing or attempting to execute a scheme to defraud any healthcare benefit program, willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making false, fictitious or fraudulent statements relating to healthcare matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by HITECH, and their implementing regulations, which imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon entities subject to the law, such as health plans, healthcare clearinghouses and certain healthcare providers, known as covered entities, and their respective business associates, individuals or entities that perform services for them that involve individually identifiable health information; HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions;
- the federal transparency requirements under the Physician Payments Sunshine Act, created under the ACA, which requires, among other things, certain manufacturers of drugs, devices, biologics and medical supplies reimbursed under Medicare, Medicaid, or the Children's Health Insurance Program to annually report to CMS information related to payments and other transfers of value provided to physicians, certain other healthcare professionals beginning in 2022, and teaching hospitals and physician ownership and investment interests, including such ownership and investment interests held by a physician's immediate family members; we believe that we are currently exempt from these reporting requirements; we cannot assure you, however, that regulators, principally the federal government, will agree with our determination, and a determination that we have violated these laws and regulations, or a public announcement that we are being investigated for possible violations, could adversely affect our business;
- federal and state laws and regulations governing informed consent for genetic testing and the use of genetic material;
- state law equivalents of the above U.S. federal laws, such as the Stark Law, Anti-Kickback Statute and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers; and

- similar healthcare laws in the European Union and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

Furthermore, a development affecting our industry is the increased enforcement of the federal False Claims Act and, in particular, actions brought pursuant to the False Claims Act's "whistleblower" or "*qui tam*" provisions. The False Claims Act imposes liability for, among other things, knowingly presenting, or causing to be presented, a false or fraudulent claim for payment by a federal governmental payor program. The *qui tam* provisions of the False Claims Act allow a private individual to bring civil actions on behalf of the federal government for violations of the False Claims Act and permit such individuals to share in any amounts paid by the defendant to the government in fines or settlement.

When an entity is determined to have violated the False Claims Act, it is subject to mandatory damages of three times the actual damages sustained by the government, plus significant mandatory civil penalties for each false claim. In addition, various states have enacted false claim laws analogous to the federal False Claims Act, and in some cases apply more broadly because many of these state laws apply to claims made to private payors and not merely governmental payors.

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

For example, in April 2018, we received a civil investigative demand from an Assistant U.S. Attorney for the Southern District of New York, or SDNY, and a HIPAA subpoena issued by an Assistant U.S. Attorney for the Southern District of California, or SDCA. In May 2018, we received a subpoena from the State of New York Medicaid Fraud Control Unit. The civil and criminal investigations related to discontinued legacy billing practices for our NIPT and microdeletion tests and the provision of alleged kickbacks or inducements to physicians and patients and the civil investigations also involved inquiries about our laboratory licenses, our enrollment in state Medicaid programs, and the laboratories that performed testing for us.

On July 21, 2020, July 23, 2020, and October 1, 2020, we entered into agreements with certain governmental agencies and the 45 states participating in the settlement, or the 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 regarding our discontinued legacy billing practices for our non-invasive prenatal tests and microdeletion tests and the provision of alleged kickbacks or inducements to physicians and patients. Specifically, we entered into:

- a civil settlement agreement, effective July 23, 2020, with the DOJ through SDNY, and on behalf of the OIG and with the relator named therein, or the SDNY Civil Settlement Agreement;
- a civil settlement agreement, effective July 23, 2020, with the DOJ through SDCA, 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, or the SDCA Civil Settlement Agreement;
- a non-prosecution agreement, effective July 21, 2020, with SDCA, or the Non-Prosecution Agreement, in resolution of all criminal allegations (which agreement has since expired);
- a corporate integrity agreement, effective July 21, 2020, with the OIG, or the Corporate Integrity Agreement; and
- civil settlement agreements, effective October 1, 2020, with the State AGs.

The terms of these agreements require that we pay $49.0 million in the aggregate plus applicable interest. As of December 31, 2021, we have paid approximately $41.9 million towards this amount. We will pay the remaining portion of the settlement over an approximately two-year period, structured as follows: approximately $6.9 million in December 2022; and approximately $0.2 million in December 2023. For additional information regarding these agreements, please see Part I, Item 3. "Legal Proceedings—Federal Investigations."

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 planned medical device product candidates, and potentially some of our molecular testing products such as our planned preeclampsia test, are expected to be subject to regulation by the FDA, and numerous other federal and state governmental authorities. The process of obtaining regulatory approvals or clearances to market a medical device, particularly from the FDA and regulatory authorities outside the United States, can be costly and time-consuming, and approvals or clearances might not be granted for future products on a timely basis, if at all. To ensure ongoing customer safety, regulatory agencies such as the FDA may re-evaluate their

current approval or clearance processes and may impose additional requirements. In addition, the FDA and other regulatory authorities may impose increased or enhanced regulatory inspections for domestic or foreign facilities involved in the manufacture of medical devices.

We may develop new medical devices in connection with our precision medicine platform and new molecular test candidates that are regulated by the FDA as medical devices. Unless otherwise exempted, medical devices must receive one of the following marketing authorizations from the FDA before being marketed in the United States: "510(k) clearance," *de novo* classification, or PMA. The FDA determines whether a medical device will require 510(k) clearance, *de novo* classification, or the PMA process based on statutory criteria that include the risk associated with the device and whether the device is similar to an existing, legally marketed product. In the 510(k) clearance process, before a device may be marketed, the FDA must determine that a proposed device is "substantially equivalent" to a legally-marketed "predicate" device, which includes a device that has been previously cleared through the 510(k) process, a device that was legally marketed prior to May 28, 1976 (pre-amendments device), a device that was originally on the U.S. market pursuant to an approved PMA and later down-classified, or a 510(k)-exempt device. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data are sometimes required to support substantial equivalence. In the process of obtaining PMA approval, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, 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 precision medicine product candidates are subject to a complex set of regulations and rigorous enforcement, including by the FDA, DOJ, HHS, and numerous other federal, state, and non-U.S. governmental authorities. To varying degrees, each of these agencies requires us to comply with laws and regulations governing the development, testing, manufacturing, labeling, marketing, and distribution of our 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 precision medicine platform, our facilities and procedures and those of our suppliers will be subject to periodic inspections by the FDA to determine compliance with applicable regulations. The results of these inspections can include inspectional observations on FDA's Form-483, warning letters, or other forms of enforcement. If the FDA or a non-U.S. regulatory agency were to conclude that we are not in compliance with applicable laws or regulations, or that any of our product candidates, if

authorized for marketing, are ineffective or pose an unreasonable health risk, the FDA or such other non-U.S. regulatory agency could ban products, withdraw marketing authorizations for such products, detain or seize adulterated or misbranded products, order a recall, repair, replacement, or refund of such products, refuse to grant pending marketing applications, require certificates of non-U.S. governments for exports, and/or require us to notify health professionals and others that the products present unreasonable risks of substantial harm to the public health. The FDA and other non-U.S. regulatory agencies may also assess civil or criminal penalties against us, our officers, or employees and impose operating restrictions on a company-wide basis. The FDA may also recommend prosecution to the DOJ. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively marketing and selling our products and limit our ability to obtain future marketing authorizations, and could result in a substantial modification to our business practices and operations. Furthermore, we occasionally receive investigative demands, subpoenas, or other requests for information from state and federal governmental agencies, and we cannot predict the timing, outcome, or impact of any such investigations. See Part I, Item 3. "Legal Proceedings." Any adverse outcome in one or more of these investigations could include the commencement of civil and/or criminal proceedings, substantial fines, penalties, and/or administrative remedies, including exclusion from government reimbursement programs and/or amendments to our corporate integrity agreement with the OIG. In addition, resolution of any of these matters could involve the imposition of additional, costly compliance obligations. These potential consequences, as well as any adverse outcome from government investigations, could have a material and adverse effect on our business, operating results, and financial condition.

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

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

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

Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

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

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

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

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

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

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

We are developing certain precision medicine product candidates, including pharmaceutical products and medical devices, which if authorized for marketing by the FDA or other regulatory authorities, will be authorized for use in specific indications and patient populations. We expect to train our marketing personnel and direct sales force not to promote our product candidates for uses outside of the FDA-approved or -cleared indications for use, which are sometimes referred to as "off-label uses." We cannot, however, prevent a physician from using our products off-label, when in the physician's independent professional medical judgment he or she

deems it appropriate. There may be increased risk of injury to patients if physicians attempt to use our products off-label. Furthermore, the use of our products for indications other than those authorized for marketing by the FDA or any foreign regulatory body may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

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

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

Risks Related to Our Intellectual Property

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

Our success depends in part on our freedom-to-operate with respect to the patents or intellectual property rights of third parties. We operate in industries in which there have been substantial litigation and other proceedings regarding patents and other intellectual property rights. For example, we have identified a number of third-party patents that may be asserted against us with respect to certain of our future products, and have identified pending patent applications for which the ultimate claim scope and validity are uncertain. We believe that we do not infringe the relevant claims of these third-party patents and/or that the relevant claims of these patents are likely invalid or unenforceable. We may choose to challenge the validity of these patents, though the outcome of any challenge that we may initiate in the future is uncertain. We may also decide in the future to seek a license to those third-party patents, but we might not be able to do so on reasonable terms. Certain third parties, including our competitors or collaborators, have asserted and may in the future assert that we are employing their proprietary technology without authorization or that we are otherwise infringing their intellectual property rights. The risk of intellectual property proceedings may increase as the number of products and the level of competition in our industry segments grows. Defending against infringement claims is costly and may divert the attention of our management and technical personnel. If we are unsuccessful in defending against patent infringement claims, we could be required to stop developing or commercializing products, pay potentially substantial monetary damages, and/or obtain licenses from third parties, which we may be unable to do on acceptable terms, if at all, and which may require us to make substantial royalty payments. In addition, we could encounter delays in product introductions while we attempt to develop alternative non-infringing products. Any of these or other adverse outcomes could have a material and adverse effect on our business, operating results, and financial condition. See Part I, Item 3. "Legal Proceedings—Ravgen Lawsuit" for more information regarding a patent infringement suit filed by Ravgen, Inc. related to our laboratory developed test business, which is no longer in operation.

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

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

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

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

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

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

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

We may be required to file or defend infringement lawsuits and other contentious proceedings, such as *inter partes* reviews, reexaminations, oppositions, and declaratory judgement actions, to protect our interests, which can be expensive and time-consuming. We cannot assure you that we would prevail over an infringing third party, and we may become subject to counterclaims by such third parties. Our patents may be declared invalid or unenforceable, or narrowed in scope, as a result of such litigation or other proceedings. Some third-party infringers may have substantially greater resources than us and may be able to sustain the costs of complex infringement litigation more effectively than we can. Even if we have valid and enforceable patents, competitors may still choose to offer products that infringe our patents.

Further, preliminary injunctions that bar future infringement by the competitor are not often granted; therefore, remedies for infringement are not often immediately available. Even if we prevail in an infringement action, we cannot assure you that we would be fully or partially financially compensated for any harm to our business. We may be forced to enter into a license or other agreement with the third parties on terms less profitable or otherwise less commercially acceptable to us than those negotiated between a willing licensee and a willing licensor. Any inability to stop third-party infringement could result in the future in a loss in market share of our products under development, or lead to a delay, reduction, and/or inhibition of our development, manufacture, or sale of some of our

products. A product produced and sold by a third-party infringer may not meet our or other regulatory standards or may not be safe for use, which could cause irreparable harm to the reputation of our products, which in turn could result in substantial loss in our market share and profits.

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

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

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

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

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

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

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

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

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

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

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

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

Even if we are successful, litigation could result in substantial costs to us and could divert the time and attention of our management and other employees.

Risks Related to Ownership of Our Common Stock

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

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

- 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.

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.

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 and may currently be the target of a short squeeze, and stockholders may lose a significant portion or all of their investment if they purchase our shares at a rate that is significantly disconnected from our underlying value.

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

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

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

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

Provisions in the indenture governing our outstanding convertible notes could delay or prevent an otherwise beneficial takeover of us.

Certain provisions in our convertible notes and the indenture governing the convertible notes could make a third party attempt to acquire us more difficult or expensive. For example, if a takeover constitutes a "fundamental change" (which is defined in the indenture to include certain change-of-control events and the delisting of our common stock), then noteholders will have the right to require us to repurchase their convertible notes for cash. In addition, if a takeover constitutes a "make-whole fundamental change" (which is defined in the indenture to include, among other events, fundamental changes and certain additional business combination transactions), then we may be required to temporarily increase the conversion rate for the convertible notes. In either case, and in other cases, our obligations under the convertible notes and the indenture could increase the cost of acquiring us or otherwise discourage a third party from acquiring us or removing incumbent management, including in a transaction that holders of our common stock may view as favorable.

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

Noteholders may require us to repurchase their convertible notes following a "fundamental change" (which is defined in the indenture governing the convertible notes to include certain change-of-control events and the delisting of our common stock) at a cash repurchase price generally equal to the principal amount of the convertible notes to be repurchased, plus accrued and unpaid interest, if any. In addition, noteholders that convert their convertible notes before December 1, 2022 will, in certain circumstances, be entitled to an additional cash payment representing the present value of any remaining interest payments on the convertible notes through December 1, 2022. 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 the listing standards of The Nasdaq Global Market, or Nasdaq. We may not have enough available cash or be able to obtain financing at the time we are required to repurchase the convertible notes or pay these cash amounts upon their conversion. In addition, applicable law, regulatory authorities and the agreements governing our other indebtedness may restrict our ability to repurchase the convertible notes or pay these cash amounts upon their conversion. Our failure to repurchase convertible notes when required or pay these cash amounts upon their conversion will constitute a default under the indenture governing the convertible notes. A default under the indenture or the fundamental change itself could also lead to a default under agreements governing our other indebtedness, which may result in that other indebtedness becoming immediately payable in full. We may not have sufficient funds to satisfy all amounts due under the other indebtedness and the convertible notes.

The accounting method for the convertible notes could adversely affect our reported financial results.

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

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

General Risk Factors

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

As of December 31, 2021, 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 by our existing stockholders could cause the price of our common stock to decline.

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

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 $1.07 billion or more during such fiscal year, and (b) the date on which we issue more than $1 billion in non-convertible debt in a three-year period.

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

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

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

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

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

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

Our eighth amended and restated certificate of incorporation and amended and restated bylaws 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 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 eighth amended and restated 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 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 or amended and restated bylaws, or (5) any other action asserting a claim that is governed by the internal affairs doctrine, shall be the Court of Chancery of the State of Delaware (or another state court or the federal court located within the State of Delaware if the Court of Chancery does not have or declines to accept jurisdiction), in all cases subject to the court's having jurisdiction over indispensable parties named as defendants. In addition, our eighth amended and restated certificate of incorporation 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 and amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, financial condition, and operating results. For example, under the Securities Act, federal courts have concurrent jurisdiction over all suits brought to enforce any duty or liability created by the Securities Act, and investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Any person or entity purchasing or otherwise acquiring any interest in our shares of capital stock shall be deemed to have notice of and consented to this exclusive forum provision, but will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

We currently lease approximately 25,800 square feet of office space in San Diego, California under several lease agreements that expire on June 30, 2023. Additionally, we lease approximately 10,500 square feet of office and laboratory space in San Diego, California under a lease agreement that expires in January 2027. We also own approximately 21,500 square feet of laboratory space in Ann Arbor, Michigan. We also lease approximately 26,500 square feet of office space in Ann Arbor, Michigan. Our lease expires in October 2023. We also lease approximately 4,000 square feet of property located in Irving, Texas, which is used for research and development. We believe our existing facilities will be sufficient for our needs for the foreseeable future.

Item 3. Legal Proceedings.

Refer to Note 11, "Commitments and Contingencies" to the audited financial statements included in this Annual Report on Form 10-K and our Annual Reports and Quarterly Reports on Form 10-Q for prior periods, for information on our historical and ongoing legal proceedings.

Colorado Recoupment

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

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

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

We disputed these claims of recoupment with the Department, filed an administrative complaint with the State of Colorado Office of Administrative Courts, and are also seeking to offset such claims by an amount of approximately $1.9 million previously paid to the Department in connection with the state settlement agreements referred to above. At this preliminary stage, we are unable to predict the ultimate outcome of this action, and therefore cannot estimate the reasonably possible loss or range of loss, if any, that may result from this action.

California Subpoena

On July 19, 2021, we received a subpoena from the California Attorney General's Office, Division of Public Rights, requesting documents and information related to our former genetic testing practices, including NIPT, particularly those with a nexus to California patients. The subpoena is captioned "In the Matter of the Investigation of: Prenatal Genetic Testing Companies." We continue to cooperate and provide information requested by the subpoena. At this preliminary stage, we are unable to predict the ultimate outcome of this action, and therefore cannot estimate the reasonably possible loss or range of loss, if any, that may result from this action.

OIG Inquiry

On October 16, 2019, we received an inquiry from the Texas Health & Human Services Commission Office of Inspector General, or the TX OIG, alleging that we did not hold the required CLIA Laboratory Certificate of Accreditation to perform, bill for, or be reimbursed by the Texas Medicaid Program for certain tests performed by us from January 1, 2015 through December 31, 2018. We submitted a written response to the inquiry on October 23, 2019. In October 2021, we received a letter from the TX OIG asking us to renew our engagement on the matter. We continue to cooperate with the TX OIG toward resolution of the matter. Although we believe that we hold and have held all required CLIA certificates and/or subcontract with third-party laboratories that hold and have held such certificates to perform all of the tests subject to the TX OIG inquiry, there can be no assurance that the TX OIG will agree with this position. The Company has recorded an accrual for the estimated probable loss for this matter as of December 31, 2021.

Ravgen Lawsuit

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

We believe the claims in Ravgen's complaint are without merit, and we are vigorously defending against them. On March 1, 2022, the court ordered a stay of the litigation pending resolution of patent validity challenges made against the two patents in inter partes review proceedings currently pending before the Patent Trial and Appeal Board of the United States Patent and Trademark Office.

IPO Litigation

On June 23, 2020, we closed our initial public offering of our common stock, or the 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, we moved to dismiss the first amended complaint. On September 1, 2021, the court granted our motion to dismiss, dismissing Lead Plaintiffs' claims without prejudice. On September 22, 2021, Lead Plaintiffs filed their second amended complaint. It alleges that our registration statement and related prospectus for the IPO contained false and misleading statements and omissions in violation of the Securities Act of 1933 by failing to disclose that (i) we had overbilled government payors for Preparent tests beginning in 2019 and ending in or before early 2020; (ii) there was a high probability that we had received, and would have to refund, a material amount of overpayments from government payors for Preparent tests; (iii) in February 2020 we ended a supposedly improper marketing practice on which the competitiveness of our business depended; and (iv) we were suffering from material negative trends with respect to testing volumes, average selling prices for our tests, and revenues. Lead Plaintiffs seek certification as a class, unspecified compensatory damages, interest, costs and expenses including attorneys' fees, and unspecified extraordinary, equitable, and/or injunctive relief. Together with the underwriters of the IPO, we moved to dismiss the second amended complaint on November 15, 2021. Lead Plaintiffs filed an opposition to the motion on January 14, 2022, and we filed our reply in support of the motion on February 22, 2022. We intend to continue to vigorously defend against these claims. Subject to a reservation of rights, we are advancing expenses subject to indemnification to the underwriters of the IPO.

On June 4, 2021, a purported shareholder filed a lawsuit in the U.S. District Court for the Southern District of California, 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. The complaint seeks the award of unspecified damages to the Company, equitable and injunctive remedies, and an order directing the Company to reform and improve its internal controls and board oversight. It also seeks the costs and disbursements associated with bringing suit, including attorneys', consultants', and experts' fees. The case is stayed pending the outcome of the motion to dismiss in the above-described securities lawsuit. We intend to vigorously defend against these claims.

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

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

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

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

Holders

As of March 15, 2022, there were approximately 50 stockholders of record of our common stock.

Dividends

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

Recent Sales of Unregistered Securities

None.

Item 6. Reserved

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

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

Overview

We are a biotechnology company innovating in the oral delivery of biotherapeutics. Our drug-device combinations could enable new treatment approaches in two main areas:

- Targeted 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
- Systemic delivery of biotherapeutics, designed to replace injection with needle-free, oral capsules.

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

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

Strategic Transformation and Factors Affecting Our Performance

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

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

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

We are engaged in research and development activities with respect to tests under development and precision medicine product candidates. Following the Strategic Transformation, we are devoting substantially all of our resources to developing and perfecting our intellectual property rights, conducting research and development activities (including undertaking preclinical and clinical studies of our precision medicine product candidates), conducting clinical trials of our most advanced precision medicine product candidates, organizing and staffing our company, business planning and raising capital. We do not have any precision medicine products approved for sale, and we have not generated any revenue from precision medicine product sales.

Our business involves significant investment in research and development activities for the development of new products. We intend to continue investing in our pipeline of new products and technologies. We expect our investment in research and development to increase as we pursue regulatory approval of our Targeted Therapeutics and Oral Biotherapeutics product candidates and expand our pipeline of diagnostics device product candidates. The achievement of key development milestones is a key factor in evaluating our performance.

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

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

We do not expect to generate significant product revenue unless and until we successfully complete development and obtain regulatory and marketing approval of, and begin to sell, one or more of our Targeted Therapeutics and Oral Biotherapeutics 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 precision medicine 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 precision medicine 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 precision medicine product candidates. In addition, we may not be profitable even if we commercialize any of our precision medicine product candidates.

Key Components of Our Results of Operations

We are providing the following summary of our revenues, research and development expenses and 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 precision medicine product candidates or other products under development 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 precision medicine 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 precision medicine product candidates or from license or collaboration agreements. We may never succeed in obtaining regulatory approval for any of our precision medicine product candidates.

Research and Development

Research and development expenses consist primarily of costs associated with developing new products, including our preeclampsia test and our precision medicine 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 Oral Biotherapeutics programs through preclinical studies and clinical trials. We also expect our investment in research and development to increase as we pursue regulatory approval of our product candidates and as we seek to expand our pipeline of product candidates.

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

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

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

Due to the impact of the COVID-19 pandemic and work-from-home policies and other operational limitations mandated by federal, state, and local governments as a result of the pandemic, certain of our research and development activities have been delayed and may be further delayed. For more information on risks related to COVID-19, see "Risk Factors—The ongoing COVID-19 pandemic could further materially affect our operations, as well as the business or operations of third parties with whom we conduct business. Our business could be adversely affected by the effects of other future health epidemics or pandemics in regions where we or third parties on which we rely have significant business operations."

Selling and Marketing

Selling and marketing expenses consist primarily of personnel costs, including salaries, commissions, bonuses, stock-based compensation expense, and benefits for our sales and marketing team. Selling and marketing expenses also include costs for communication, advertising, conferences, other marketing events, and allocated overhead costs. We expect selling and marketing expenses to decrease for the foreseeable future as a result of the closure of our Laboratory Operations in Ann Arbor and the sale of our Avero affiliate.

General and Administrative

General and administrative expenses consist primarily of personnel costs, including salaries, bonuses, stock-based compensation expense, and benefits, for our finance and accounting, legal, human resources, and other administrative teams. Additionally, these expenses include professional fees of audit, legal, and recruiting services. Following the listing of our common stock on Nasdaq, we incurred additional expenses as a result of operating as a public company, including costs to comply with the rules and regulations applicable to companies listed on a U.S. securities exchange and costs related to compliance and reporting obligations pursuant to the rules and regulations of the SEC. In addition, as a public company, we expect to continue to incur increased expenses in the areas of insurance, investor relations, and professional services. Furthermore, we will continue to incur expenses related to maintaining compliance with the stipulations of the government settlement and the legal costs associated with the California subpoena, the Colorado recoupment, the Ravgen lawsuit and IPO related litigation described in Part I, Item 3. “Legal Proceedings” in this Annual Report. Despite such expenses, we expect our overall general and administrative expenses to decrease for the foreseeable future as a result of the closure of our Laboratory Operations in Ann Arbor and the sale of our Avero affiliate.

Interest Income (Expense), Net

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

Loss on Warrant Liability

Loss on warrant liability consists of changes in the fair value of our liability-classified warrants to purchase common stock.

Other Income (Expense), Net

Other income (expense), net primarily consists of changes in the fair value of our embedded derivative liability related to the convertible notes, loss on extinguishment of our obligations outstanding under the Credit and Security Agreement, as amended, in the fourth quarter of 2020, loss on extinguishment of convertible note in the second quarter of 2020, inducement loss on our Convertible Notes, and changes in fair value of short-term investments.

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.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, was enacted. The CARES Act includes several significant provisions for corporations, including the usage of net operating losses, interest deductions and payroll benefits. Corporate taxpayers may carryback net operating losses, or NOLs, originating during 2018 through 2020 for up to five years. During the three months ended March 31, 2020, we recorded a discrete tax benefit of $37.7 million related to the NOL carryback provisions available under the CARES Act legislation for taxes paid in years 2013, 2014, 2015, and 2017. We agreed to pay 65% of any tax refund received in excess of $5.0 million in a single year, along with other civil settlements, damages awards, and tax refunds, to accelerate payments to the government in connection with our government settlement. During the year ended December 31, 2020, we received a tax refund of $37.7 million related to the NOL carryback provisions available under the CARES Act. As of December 31, 2020, we had paid a total of $37.0 million to the government in connection with our government settlements. See Part I, Item 3. “Legal Proceedings—Federal Investigations” in this Annual Report. There is no additional carryback for the year ended December 31, 2021.

Results of Operations.

Comparison of Years Ended December 31, 2021 and 2020

	Year Ended December 31,	
	2021	2020
	(in thousands)	
Statement of Operations Data:		
Revenues	$ 1,247	$ 162
Cost of sales	—	—
Gross profit	1,247	162
Operating expenses:		
Research and development	45,785	47,743
Selling and marketing	4,758	5,949
General and administrative	68,541	54,089
Total operating expenses	119,084	107,781
Loss from operations	(117,837)	(107,619)
Interest income (expense), net	(12,636)	(9,915)
Loss on warrant liability	(54,157)	—
Other income (expense), net	5,990	(25,084)
Loss before income taxes	(178,640)	(142,618)
Income tax benefit	(119)	(37,532)
Loss from continuing operations	(178,521)	(105,086)
Loss from discontinued operations	(68,891)	(87,442)
Net loss	$ (247,412)	$ (192,528)

Revenue

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

Cost of Sales

As a result of the classification of the Company's Laboratory Operations to discontinued operations, all cost of sales from Laboratory Operations has been classified as discontinued operations.

Research and Development Expenses

	Year Ended December 31,		Increase/	
	2021	2020	(Decrease)	% Change
	(in thousands)			
Research and development	$ 45,785	$ 47,743	$ (1,958)	(4.1)%

The decrease in research and development expenses was primarily attributable to a decrease in supplies costs and consulting costs, partially offset by an increase in salary and benefits.

Selling and Marketing Expenses

	Year Ended December 31,		Increase/	
	2021	2020	(Decrease)	% Change
	(in thousands)			
Selling and marketing	$ 4,758	$ 5,949	$ (1,191)	(20.0)%

The decrease in selling and marketing expenses was primarily attributable to a decrease in salary and benefits due to the Strategic Transformation, partially offset by an increase in consulting fees and advertising expense.

General and Administrative Expenses

	Year Ended December 31,		Increase/ (Decrease)	% Change
	2021	2020		
	(in thousands)			
General and administrative	$ 68,541	$ 54,089	$ 14,452	26.7%

The increase in general and administrative expenses was primarily attributable to an increase in consulting professional fees as part of the Strategic Transformation restructuring, legal fees related to general corporate and patent litigation matters, salary and benefits due to new equity awards and business insurance costs related to our director and officer insurance premiums.

Interest Income (Expense), Net

	Year Ended December 31,		Increase/ (Decrease)	% Change
	2021	2020		
	(in thousands)			
Interest income (expense), net	$ (12,636)	$ (9,915)	$ (2,721)	27.4%

The increase in interest expense, net was due to the extinguishment of the Term Loan and the issuance of the convertible notes in December 2020.

Loss on Warrant Liability

	Year Ended December 31,		Increase/ (Decrease)	% Change
	2021	2020		
	(in thousands)			
Loss on warrant liability	$ 54,157	$ —	$ 54,157	100.0%

The loss on warrant liability is attributable to issuances, exercises and remeasurement of liability classified warrants during the year ended December 31, 2021.

Other Income (Expense), Net

	Year Ended December 31,		Increase/ (Decrease)	% Change
	2021	2020		
	(in thousands)			
Other income (expense), net	$ 5,990	$ (25,084)	$ 31,074	*

* The change is more than 100%

The change in other income (expense), net was primarily due to a $32.3 million gain related to a decrease in the fair value of our embedded derivative liability related to the convertible notes during year ended 2021 and a loss on extinguishment of debt associated with the exchange of our obligations under the Credit and Security Agreement, as amended, for convertible notes issued to the same related party, and a loss on extinguishment of debt associated with the conversion of an unsecured promissory note into shares of common stock upon completion of the IPO in 2020 that did not reoccur in 2021.

Income Tax Benefit

	Year Ended December 31,		Increase/	
	2021	2020	(Decrease)	% Change
	(in thousands)			
Income tax benefit	$ 119	$ 37,532	$ (37,413)	(99.7)%

The tax benefit during the year ended December 31, 2020 was recorded primarily due to the NOL carryback provisions available under the CARES Act legislation enacted in March 2020. During the year ended December 31, 2018, we established a full valuation allowance on net deferred tax assets due to losses generated in 2018 and projected taxable losses anticipated in the future.

Discontinued Operations

	Year Ended December 31,		Increase/	
	2021	2020	(Decrease)	% Change
	(in thousands)			
Loss from discontinued operations	$ 68,891	$ 87,442	$ (18,551)	(21.2)%

In connection with the Strategic Transformation, we began reporting the results of our Laboratory Operations in discontinued operations. The decrease in loss was attributable to a decrease in revenues and cost of sales due to a decrease in volumes of Progenity tests during 2021, offset by the loss recognized from the sale of Avero. See Note 4 to our consolidated financial statements included 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 convertible notes.

As of December 31, 2021, we had $88.4 million of cash and cash equivalents and convertible notes, net outstanding of $126.4 million. Our accumulated deficit as of December 31, 2021, was $788.7 million. For the year ended December 31, 2021, we had a net loss of $247.4 million and cash used in operations of $167.5 million. Our primary requirements for liquidity have been to fund our working capital needs, capital expenditures, dividends, research and development, and general corporate needs.

While we have greatly reduced our cash burn following the Strategic Transformation and we are forecasting our spend to be less than our current cash and cash equivalents for the next 12 months, we have not yet built a track record for our lower spend profile. As a result, we have not completely eliminated the risks surrounding our ability to fund our operations for at least 12 months from the issuance date of the consolidated financial statements for the year ended December 31, 2021, without relying on additional funding. As a result, there is substantial doubt 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, 2021. We therefore intend 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 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 the ongoing COVID-19 pandemic.

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

On October 27, 2017, we entered into a credit and security agreement, (the "Credit Agreement") with a fund managed by Athyrium, as collateral agent and a lender. The Credit Agreement provided for a term loan of $75.0 million, the issuance of Series B Preferred Stock, and the issuance of a warrant to purchase Series B Preferred Stock, (the "Series B Preferred Stock Purchase Warrant"). The Credit Agreement was discharged in December 2020 in connection with the offering of convertible notes described below. The Credit Agreement contained customary covenants, including a requirement to maintain a minimum unrestricted cash balance at all times of at least $5.0 million. The term loan was secured by all our tangible and intangible property assets, with the exception of our intellectual property. The term loan accrued interest at a rate per annum equal to 9.5% and was due October 27, 2022.

During the year ended December 31, 2020, we recognized interest expense on the term loan of $7.5 million, respectively.

In connection with the IPO, on June 18, 2020, the Series B Preferred Stock Purchase Warrant became exercisable for 400,160 shares of common stock.

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

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

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

On May 8, 2020, we entered into a Note Purchase Agreement with Athyrium Opportunities 2020 LP, a fund managed by Athyrium, pursuant to which we issued and sold an unsecured convertible promissory note with an annual interest rate of 8.0% and in an aggregate principal amount of $15.0 million. The convertible note had a maturity date of May 8, 2022 and was convertible at the option of the holder into shares of our common stock at a per share conversion price of the lesser of $13.90 and eighty percent of the public price. In connection with the issuance and sale of the convertible note, we entered into (i) the Second Amendment to the Credit Agreement (the "Second Credit Agreement Amendment"), dated May 6, 2020, allowing for the creation or incurrence of certain indebtedness and the making of payments, in each case, in respect of the convertible note, among other matters, and (ii) the Second Amendment to Series B Preferred Stock Warrant, dated May 8, 2020, providing for the removal of certain restrictive exercise provisions in the Series B Preferred Stock Purchase Warrant. In June 2020, in connection with completion of our IPO, the Note was converted into 1,250,000 shares of common stock and all obligations under the convertible note were extinguished.

In December 2020, in connection with a private offering of the convertible notes pursuant to Rule 144A under the Securities Act, we issued a total of $168.5 million principal amount of our convertible notes (the "Convertible Notes"). The Convertible Notes were issued pursuant to, and are governed by, an indenture ("Indenture"), dated as of December 7, 2020, by and between the Company and The Bank of New York Mellon Trust Company, N.A., as trustee. The Convertible Notes are due on December 1, 2025, unless earlier repurchased, redeemed or converted, and accrue interest at a rate per annum equal to 7.25% payable semi-annually in arrears on June 1 and December 1 of each year, with the initial payment on June 1, 2021.

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

At any time, noteholders may convert their Convertible Notes at their option into shares of our common stock, together, if applicable, with cash in lieu of any fractional share, at the then-applicable conversion rate. The initial conversion rate is 278.0094 shares of common stock per $1,000 principal amount of Convertible Notes, which represents an initial conversion price of approximately $3.60 per share of common stock. Noteholders that convert their Notes before December 1, 2022 will, in certain circumstances, be entitled to an additional cash payment representing the present value of any remaining interest payments on the Convertible Notes through December 1, 2022. The conversion rate and conversion price are subject to customary adjustments upon

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

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

The Convertible Notes have customary provision relating to the occurrence of Events of Default (as defined in the Indenture), which include the following: (i) certain payment defaults on the Convertible Notes (which, in the case of a default in the payment of interest on the Convertible Notes, will be subject to a 30-day cure period); (ii) our failure to send certain notices under the Indenture within specified periods of time; (iii) our failure to comply with certain covenants in the Indenture relating to the Company's ability to consolidate with or merge with or into, or sell, lease or otherwise transfer, in one transaction or a series of transactions, all or substantially all of our assets and assets of our subsidiaries, taken as a whole, to another person; (iv) a default by us in our other obligations or agreements under the Indenture or the Convertible Notes if such default is not cured or waived within 60 days after notice is given in accordance with the Indenture; (v) certain defaults by us or any of our subsidiaries with respect to indebtedness for borrowed money of at least $7,500,000; (vi) the rendering of certain judgments against us or any of our subsidiaries for the payment of at least $7,500,000, where such judgments are not discharged or stayed within 60 days after the date on which the right to appeal has expired or on which all rights to appeal have been extinguished; and (vii) certain events of bankruptcy, insolvency and reorganization involving us or any of our significant subsidiaries. As of December 31, 2021, we were in compliance with all such covenants.

In October 2021, we entered into privately negotiated agreements with certain holders of Convertible Notes to exchange an aggregate of $20.2 million principal amount for 8,513,850 shares of our common stock. In addition, we issued an aggregate of 427,804 shares of common stock to certain investors in consideration for a waiver of certain contractual lock-up provisions to which we agreed to in connection with prior offerings of its securities.

In addition to the transaction discussed above, holders of Convertible Notes exchanged an aggregate of $15.6 million principal amount for 4,336,938 shares of our common stock during the year ended December 31, 2021.

PIPE Financings

In February 2021, we entered into a Securities Purchase Agreement for a private placement with certain institutional and accredited investors, pursuant to which the purchasers purchased an aggregate of 4,370,629 units representing (i) 4,370,629 shares of the Company's common stock, par value $0.001 per share, and (ii) warrants to purchase up to 4,370,629 shares of common stock. The purchase price for each unit was $5.72, for an aggregate purchase price of approximately $25.0 million. The transaction closed on February 25, 2021. The warrants are exercisable for cash at an exercise price of $6.86 per share, subject to adjustments as provided under the terms of the warrants. The warrants are immediately exercisable for cash and expire on the fifth anniversary of the date of issuance. If exercised for cash, the warrants would result in additional gross proceeds to us of approximately $30.0 million.

In June 2021, we entered into a Securities Purchase Agreement for a private placement with certain institutional and accredited investors, pursuant to which the purchasers have agreed to purchase an aggregate of 16,194,332 units representing (i) 16,194,332 shares of the Company's common stock, par value $0.001 per share (or pre-funded warrants in lieu thereof), and (ii) warrants to purchase up to 16,194,332 shares of common stock. The purchase price for each unit was $2.47, for an aggregate purchase price of approximately $40.0 million. The transaction closed on June 14, 2021. The warrants are immediately exercisable at an exercise price of $2.84 per share, subject to adjustments as provided under the terms of the warrants, and expire on the fifth anniversary of the date of issuance. The pre-funded warrants are exercisable at an exercise price of $0.001 per share and have no expiration date. If exercised for cash, the warrants would result in additional gross proceeds to us of approximately $46 million.

Registered Offerings

In August 2021, we issued and sold an aggregate of (i) 40,000,000 shares of common stock and (ii) warrants to purchase 40,000,000 shares of common stock in an underwritten public offering. Each share was sold together with one warrant to purchase one share of common stock at a combined public offering price of $1.00 per share of the common stock and the accompanying warrant. We received approximately $37.4 million in net proceeds, after deducting underwriting discounts and commissions and other offering expenses payable by the Company. The warrants have an exercise price of $1.00 per share, are exercisable at any time, and will expire

five years following the date of issuance. The agreement also allowed for the purchase of up to an additional 6,000,000 shares at the option of the underwriters, which was partially exercised for warrants to purchase an aggregate of 1,932,000 shares of common stock.

In October 2021, we entered into a securities purchase agreement with certain institutional and accredited investors relating to the offering and sale of 13,333,334 shares of common stock at a purchase price of $1.50 per share in a registered direct offering. We received approximately $18.7 million in net proceeds, after deducting placement agent fees and other offering expenses payable by the Company.

At-The-Market Sales Agreement and Offering

In November 2021, we entered into an At Market Issuance Sales Agreement ("Sale Agreement") with B. Riley Securities, Inc., BTIG, LLC, and H.C. Wainwright & Co. LLC ("Agents"), pursuant to which we may offer and sell shares of common stock having an aggregate offering price of up to $90,000,000, from time to time, in “at the market” offerings through the Agents. 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 Sale Agreement. During the three months ended December 31, 2021, we received net proceeds of $4.6 million, after deducting commissions and other offering expenses, from the sale of 1,763,754 shares under the Sale Agreement. We sold such shares at a weighted average purchase price of $2.84 per share.

Mortgages

In January 2014, we executed a mortgage with Comerica Bank for $1.8 million for the purpose of acquiring a facility located in Ann Arbor, Michigan, which was previously leased by us and is used primarily for laboratory testing and research purposes. The outstanding balance was $1.3 million as of December 31, 2020. The remaining mortgage was paid off in November 2021. We previously had a mortgage with American Bank of Commerce (originally executed in February 2008) outstanding on Avero Diagnostic’s property located in Lubbock, Texas, which was used primarily for laboratory testing. The outstanding balance was $1.7 million as of December 31, 2020, and is included in liabilities held for sale on the consolidated balance sheet. The mortgage was paid off in December 2021 prior to the sale of Avero.

Cash Flows

Our primary uses of cash are to fund our operations and research and development as we continue to grow our business. We expect to continue to incur operating losses in future periods as our operating expenses increase to support the growth of our business. We expect that our research and development expenses will continue to increase as we focus on developing innovative products, including our preeclampsia test and our precision medicine product candidates, through preclinical studies and clinical trials. We also expect our investment in research and development to increase as we pursue regulatory approval of our product candidates and as we seek to expand our pipeline of product candidates. We expect selling and marketing and general and administrative expenses to decrease as a result of the closure of our Laboratory Operations and the sale of our Avero affiliate. 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,	
	2021	2020
Cash used in operating activities	$ (167,486)	$ (165,744)
Cash used in investing activities	(1,242)	(4,944)
Cash provided by financing activities	165,049	229,722

Operating Activities

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

Net cash used in operating activities in the year ended December 31, 2020 was primarily attributable to a $192.5 million net loss, adjusted for an $87.4 million loss from discontinued operations and non-cash charges, primarily driven by $33.5 million of non-cash revenue reserve, $13.9 million change in the derivative liability fair value, $11.0 million loss on extinguishment of convertible notes and $8.2 million of stock-based compensation expense. The net cash outflow from changes in operating assets and liabilities was primarily attributable to a $61.8 million decrease in accrued expenses and other current liabilities and $3.0 million increase in prepaid expenses and other current assets, offset by $2.8 million increase in accounts payable. Additionally, net cash used in operating activities from discontinued operations contributed $72.8 million of outflows.

Investing Activities

Net cash used in investing activities during the year ended December 31, 2021 was attributable to $0.9 million in purchases of property and equipment and $0.4 million from discontinued operations. Net cash used in investing for the year ended December 31, 2020 was attributable to $3.9 million in purchases of property and equipment and $1.1 million from discontinued operations.

Financing Activities

Net cash provided by financing activities during the year ended December 31, 2021 was primarily attributable to $79.4 million in net proceeds from the issuance of common stock warrants, $46.8 million in net proceeds from the issuance of common stock, and $46.0 million in net proceeds from the exercise of common stock warrants, partially offset by $3.8 million in payments for insurance financing and $1.3 million in principal payments on mortgages payable. Net cash provided by financing activities during the year ended December 31, 2020 was primarily attributable to $116.4 million in net proceeds from the issuance of common stock, $99.7 million in net proceeds from issuance of convertible notes and $21.3 million in net proceeds from the issuance of Series B Preferred Stock, partially offset by $6.7 million in payments for insurance financing.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in conformity with GAAP. The preparation of financial statements in accordance with GAAP requires management to make estimates and assumptions about future events that affect the amounts of assets and liabilities reported, disclosures about contingent assets and liabilities, and reported amounts of revenue and expenses. These estimates and assumptions are based on management's best estimates and judgment. Management regularly evaluates its estimates and assumptions using historical experience and other factors; however, actual results could differ materially from these estimates and could have an adverse effect on our financial statements.

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

Assets Held for Sale and Discontinued Operations

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

Revenue Recognition

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

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

of consideration to which we expect to be entitled, or the transaction price, and considers the effects of variable consideration, which is discussed below.

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

Common Stock Warrant Liability

We account for the common stock warrants issued as part of the August 2021 financing 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 change in the fair value of the warrant liability is recorded to gain (loss) on warrant liability 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, 2021, the fair value of warrant liability of $18.7 million, was estimated using the Black-Scholes Model with the following inputs and assumptions:

	December 31, 2021
Risk-free interest rate	1.30%
Expected volatility	91.9%
Stock price	$ 2.09
Expected life (years)	4.6

Embedded Derivative Related to Convertible Notes

In December of 2020, we issued Convertible Notes due in December 2025 that have a conversion option which was required to be bifurcated upon issuance and then periodically remeasured to fair value separately as an embedded derivative. The conversion option includes additional interest payments payable to the noteholders if converted prior to December 1, 2022. We utilize a Monte Carlo simulation model to determine the fair value of the embedded features, which incorporates inputs including the common stock price, volatility of common stock, and time to maturity. The embedded feature will be remeasured to fair value at each balance sheet date with a resulting gain or loss related to the change in the fair value being recorded to other income (expense), net in the consolidated statements of operations. As of December 31, 2021, the fair value of the embedded derivative was zero, as presented in our consolidated balance sheet. Changes in our assumptions used to value the embedded derivative, such as our stock price and the estimated volatility of common stock, could result in material changes in the valuation in future periods.

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 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 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,	
	2021	**2020**
Risk-free interest rate	0.6% - 1.4%	0.4% - 1.7%
Expected volatility	52.9% - 77.0%	57.0% - 71.0%
Expected dividend yield	—	—
Expected life (years)	3.0 - 6.3	4.0 - 6.3

Goodwill and Intangible Assets

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

Intangible assets consist of identifiable intangible assets acquired through acquisitions. Identifiable intangible assets include payor relationships, trade names, and noncompete agreements. We amortize intangible assets using the straight-line method over their useful lives. We amortize noncompete covenants using the straight-line method over the terms of the related agreements. We review for impairment of intangible assets with estimable useful lives whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. No impairment existed as of December 31, 2021 or December 31, 2020. There are no intangible assets remaining as of December 31, 2021 as they were included as part of the sale of Avero.

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
Progenity, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Progenity, Inc. and subsidiaries (the Company) as of December 31, 2021 and 2020, 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, 2021 and 2020, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations and has an accumulated deficit that raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

We have served as the Company's auditor since 2011.

San Diego, California
March 28, 2022

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

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 88,397	$ 92,076
Accounts receivable, net	653	6,634
Prepaid expenses and other current assets	7,232	8,632
Current assets of disposal group held for sale	2,147	18,996
Total current assets	98,429	126,338
Property and equipment, net	4,012	8,106
Other assets	326	169
Goodwill	6,072	6,072
Long-term assets of disposal group held for sale	—	13,755
Total assets	$ 108,839	$ 154,440
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 8,709	$ 17,379
Accrued expenses and other current liabilities	34,157	54,437
Warrant liability	18,731	—
Current portion of mortgages payable	—	72
Current portion of capital lease obligations	12	266
Current liabilities of disposal group held for sale	—	516
Total current liabilities	61,609	72,670
Capital lease obligations, net of current portion	—	42
Mortgages payable, net of current portion	—	1,275
Convertible notes, net of unamortized discount of $6,333 and $9,614 as of December 31, 2021 and December 31, 2020, respectively	126,392	158,886
Embedded derivative liability	—	18,370
Other long-term liabilities	5,814	8,667
Long-term liabilities of disposal group held for sale	—	1,524
Total liabilities	$ 193,815	$ 261,434
Commitments and contingencies (Note 11)		
Stockholders' deficit:		
Common stock – $0.001 par value. 350,000,000 shares authorized as of December 31, 2021 and December 31, 2020, respectively; 185,736,890 and 59,287,331 shares issued as of December 31, 2021 and December 31, 2020, respectively; 181,872,676 and 55,772,303 shares outstanding as of December 31, 2021 and December 31, 2020, respectively	146	59
Additional paid-in capital	722,646	452,992
Accumulated deficit	(788,686)	(541,274)
Treasury stock – at cost; 3,864,214 shares of common stock as of December 31, 2021 and 3,515,028 shares of common stock as of December 31, 2020	(19,082)	(18,771)
Total stockholders' deficit	(84,976)	(106,994)
Total liabilities and stockholders' deficit	$ 108,839	$ 154,440

The accompanying notes are an integral part of these consolidated financial statements.

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

	Year Ended December 31,	
	2021	2020
Revenues	$ 1,247	$ 162
Cost of sales	—	—
Gross profit	1,247	162
Operating expenses:		
Research and development	45,785	47,743
Selling and marketing	4,758	5,949
General and administrative	68,541	54,089
Total operating expenses	119,084	107,781
Loss from operations	(117,837)	(107,619)
Interest income (expense), net	(12,636)	(9,915)
Loss on warrant liability	(54,157)	—
Other income (expense), net	5,990	(25,084)
Loss before income taxes	(178,640)	(142,618)
Income tax benefit	(119)	(37,532)
Loss from continuing operations	(178,521)	(105,086)
Loss from discontinued operations	(68,891)	(87,442)
Net loss	(247,412)	(192,528)
Dividend paid to preferred stockholders	—	(268)
Net loss attributable to common stockholders	$ (247,412)	$ (192,796)
Net loss per share from continuing operations, basic and diluted	$ (1.86)	$ (3.82)
Net loss per share from discontinued operations, basic and diluted	$ (0.72)	$ (3.18)
Net loss per share, basic and diluted	$ (2.57)	$ (7.00)
Net loss per share attributable to common stockholders, basic and diluted	$ (2.57)	$ (7.01)
Weighted average shares outstanding, basic and diluted	96,154,672	27,512,876

The accompanying notes are an integral part of these consolidated financial statements.

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

	Common Stock		Series A and A-1 Preferred Stock		Series B Preferred Stock		Additional Paid-In	Accumulated	Treasury Stock		Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Shares	Amount	Deficit
Balance at December 31, 2019	**8,451,415**	**$ 9**	**4,120,000**	**$ 4**	**101,867,405**	**$ 102**	**$ 283,260**	**$ (348,478)**	**(3,474,572)**	**$ (18,771)**	**$ (83,874)**
Exercise of common stock options	543,218	—	—	—	—	—	626	—	—	—	626
Initial public offering of common stock, net	6,666,667	7	—	—	—	—	88,658	—	—	—	88,665
Secondary public offering of common stock, net	8,792,047	9	—	—	—	—	26,929	—	—	—	26,938
Issuance of Series B Preferred Stock, net	—	—	—	—	10,478,240	10	23,995	—	—	—	24,005
Automatic conversion of preferred stock	33,443,562	33	(4,120,000)	(4)	(112,345,645)	(112)	83	—	—	—	—
Issuance of common stock upon conversion of debt	1,250,000	1	—	—	—	—	18,749	—	—	—	18,750
Issuance of stock purchase warrants	—	—	—	—	—	—	268	(268)	—	—	—
Issuance of common stock upon vesting of restricted stock units	140,422	—	—	—	—	—	(244)	—	(40,456)	—	(244)
Stock-based compensation expense	—	—	—	—	—	—	10,668	—	—	—	10,668
Net loss	—	—	—	—	—	—	—	(192,528)	—	—	(192,528)
Balance at December 31, 2020	**59,287,331**	**$ 59**	**—**	**$ —**	**—**	**$ —**	**$ 452,992**	**$ (541,274)**	**(3,515,028)**	**$ (18,771)**	**$ (106,994)**
Issuance of common stock, net	75,162,049	35	—	—	—	—	46,519	—	—	—	46,554
Exercise of common stock options	323,266	1	—	—	—	—	532	—	(102,720)	(311)	222
Issuance of common stock under employee stock purchase plan	316,746	1	—	—	—	—	711	—	—	—	712
Issuance of common stock upon vesting of restricted stock units	819,499	1	—	—	—	—	(722)	—	(246,466)	—	(721)
Exercise of common stock warrants	35,281,291	35	—	—	—	—	117,975	—	—	—	118,010
Issuance of common stock warrants	—	—	—	—	—	—	42,864	—	—	—	42,864
Issuance of common stock upon conversion of debt, net	13,278,592	13	—	—	—	—	44,593	—	—	—	44,606
Issuance of common stock upon conversion of interest, net	1,268,116	1	—	—	—	—	3,626	—	—	—	3,627
Stock-based compensation expense	—	—	—	—	—	—	13,556	—	—	—	13,556
Net loss	—	—	—	—	—	—	—	(247,412)	—	—	(247,412)
Balance at December 31, 2021	**185,736,890**	**$ 146**	**—**	**$ —**	**—**	**$ —**	**$ 722,646**	**$ (788,686)**	**(3,864,214)**	**$ (19,082)**	**$ (84,976)**

The accompanying notes are an integral part of these consolidated financial statements.

PROGENITY, INC.
Notes to Consolidated Financial Statements
PROGENITY, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,	
	2021	**2020**
Operating Activities:		
Net loss	$ (247,412)	$ (192,528)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss from discontinued operations	68,891	87,442
Non-cash revenue reserve	979	33,549
Depreciation and amortization	1,437	1,438
Stock-based compensation expense	11,962	8,244
Loss on extinguishment of convertible notes	946	10,952
Amortization of debt discount and non-cash interest	1,572	3,656
Inducement loss on convertible notes	11,265	—
Inventory write-down	—	143
Loss on disposal of property and equipment	99	67
Change in fair value of derivative liability	(18,365)	13,860
Change in fair value of warrant liability	54,157	—
Changes in operating assets and liabilities:		
Income tax receivable	—	635
Prepaid expenses and other current assets	1,399	(3,016)
Other assets	(158)	—
Accounts payables	(8,686)	2,826
Accrued expenses and other liabilities	(22,910)	(61,847)
Income tax payable	79	—
Other long-term liabilities	4,412	1,622
Net cash used in operating activities - continuing operations	(140,333)	(92,957)
Net cash used in operating activities - discontinued operations	(27,153)	(72,787)
Net cash used in operating activities	(167,486)	(165,744)
Investing Activities:		
Purchases of property and equipment	(855)	(3,871)
Net cash used in investing activities - continuing operations	(855)	(3,871)
Net cash used in investing activities - discontinued operations	(387)	(1,073)
Net cash used in investing activities	(1,242)	(4,944)
Financing Activities:		
Proceeds from issuance of common stock, net	46,776	116,435
Proceeds from issuance of common stock warrants	79,448	—
Proceeds from exercise of common stock warrants	46,000	—
Proceeds from issuance of Series B Preferred Stock and warrant, net	—	21,307
Proceeds from issuance of convertible notes, net	—	99,708
Payments for financing of insurance premiums	(3,750)	(6,745)
Principal payments on mortgages payable	(1,348)	(68)
Principal payments on capital lease obligations	(295)	(668)
Net cash provided by financing activities - continuing operations	166,831	229,969
Net cash used in financing activities - discontinued operations	(1,782)	(247)
Net cash provided by financing activities	165,049	229,722
Net (decrease) increase in cash and cash equivalents	(3,679)	59,034
Cash and cash equivalents at beginning of period	92,076	33,042
Cash and cash equivalents at end of period	$ 88,397	$ 92,076

The accompanying notes are an integral part of these consolidated financial statements.

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

	Year Ended December 31,	
	2021	**2020**
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 7,536	$ 3,927
Cash paid for income taxes	367	62
Supplemental schedule of non-cash investing and financing activities:		
Exchange of note payable for convertible notes	$ —	$ 75,000
Settlement of warrant liability	72,010	—
Issuance of common stock in settlement of accrued expenses	712	—
Conversion of convertible note	44,606	18,750
Issuance of common stock upon conversion of interest	3,627	—
Issuance of preferred stock in settlement of interest payable	—	2,698
Equity financing issuance costs incurred but not paid	200	205
Debt issuance costs incurred but not paid	—	239
Issuance of stock options in settlement of accrued bonuses	—	754
Purchases of property and equipment in accounts payable	16	1,204

Note 1. Organization and Description of Business

Progenity, Inc. (the “Company” or “Progenity”), a Delaware corporation, commenced operations in 2010 with its corporate office located in San Diego, California. Progenity’s historical operations included a licensed Clinical License Improvement Amendment and College of American Pathologists certified laboratory located in Michigan specializing in the molecular testing markets serving women’s health providers in the obstetric, gynecological, fertility, and maternal fetal medicine specialty areas in the United States.

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

In order to refocus efforts and resources on the Company's research and development pipeline, in June 2021, the Company announced a strategic transformation ("Strategic Transformation") that included the closure of the Progenity genetics lab in Ann Arbor, Michigan and indicated that the Company is seeking strategic alternatives for Avero, together referred to as the Laboratory Operations. In December 2021, the Company entered into an asset purchase agreement with Northwest Pathology to sell Avero. The Company has excluded from continuing operations for all periods presented in this report revenues and expenses associated with its Laboratory Operations, which are reported as discontinued operations. See Note 4 for additional information on the Laboratory Operations.

Liquidity

As of December 31, 2021, the Company had cash and cash equivalents of $88.4 million and an accumulated deficit of $788.7 million. For the year ended December 31, 2021, the Company reported a net loss of $247.4 million and cash used in operating activities of $167.5 million. The Company’s primary sources of capital have historically been the sale of common stock and warrants, private placements of preferred stock and incurrence of debt. As of December 31, 2021, the Company had $126.4 million of convertible senior notes ("Convertible Notes") outstanding (see Note 8). As a result of the Strategic Transformation announced, management believes that future operating expenses have been reduced. However, as the Strategic Transformation was announced in June of 2021 and the Company completed the sale of Avero in December of 2021, the Company has not completely eliminated the risks surrounding its ability to fund operations for at least 12 months from the issuance date of the consolidated financial statements for the year ended December 31, 2021, without relying on additional funding. As a result, there is substantial doubt 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, 2021.

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 critical 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 resulting from the ongoing COVID-19 pandemic. If the Company is unable to raise capital when needed or on attractive terms, it would be forced to delay, reduce, or eliminate its research and development programs or other operations. If any of these events occur, the Company’s ability to achieve its operational goals would be adversely affected.

Uncertainties Related to the COVID-19 Pandemic

The ongoing COVID-19 pandemic has negatively impacted the global economy, disrupted global supply chains and created significant volatility and disruption of financial markets. The Company has been materially and negatively affected by the COVID-19 pandemic; however, the extent of the impact of the COVID-19 pandemic on the Company’s operational and financial performance, including its ability to execute its business strategies and initiatives in the expected time frame, will depend on future developments, including the duration and continued spread of the pandemic which is uncertain and cannot be predicted. The Company could be further negatively affected by the widespread outbreak of an illness or any other communicable disease, or any other public health crisis that results in economic and trade disruptions, including the disruption of global supply chains. An extended period of global supply chain and economic disruption could materially affect the Company’s business, results of operations, access to sources of liquidity and financial condition.

The estimates used for, but not limited to, determining the amount to be collected for accounts receivable, fair value of long-lived assets, and fair value of goodwill could be impacted by the pandemic. While the full impact of the COVID-19 pandemic is unknown at this time, the Company has made appropriate estimates based on the facts and circumstances available as of the reporting date. These estimates may change as new events occur and additional information is obtained.

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 Progenity, Inc., its wholly owned subsidiaries, and an affiliated professional partnership with Avero with respect to which the Company currently has a specific management arrangement. The Company has determined that Avero is a variable interest entity and that the Company is the primary beneficiary resulting in the consolidation of Avero as required by the accounting guidance for consolidation (see Note 3). All significant intercompany balances and transactions have been eliminated in consolidation. Certain amounts in prior periods have been reclassified to reflect the impact of the discontinued operations treatment of the Company's Laboratory Operations in order to conform to the current period presentation.

As a result of the divestiture of the Laboratory Operations, the Company has retrospectively revised the consolidated statements of operations and the consolidated statement of cash flows for the year ended December 31, 2020 and the consolidated balance sheet as of December 31, 2020, to reflect the operations and cash flows of the Laboratory Operations as discontinued operations and the related assets and liabilities as held for sale.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant items subject to such estimates include the estimate of variable consideration in connection with the recognition of revenue, the valuation of stock options, the valuation of goodwill and intangible assets, the valuation of the derivative liability associated with the Convertible Notes, accrual for reimbursement claims and settlements, the valuation of warrant liabilities, the valuation of assets held for sale, assessing future tax exposure and the realization of deferred tax assets, and the useful lives and the recoverability of property and equipment. The Company bases these estimates on historical and anticipated results, trends, and various other assumptions that the Company believes are reasonable under the circumstances, including assumptions as to future events. These estimates form the basis for making judgments about the carrying values of assets and liabilities and recorded revenues and expenses that are not readily apparent from other sources. Actual results could differ from those estimates and assumptions.

Operating Segments

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker or decision-making group in making decisions on how to allocate resources and assess performance. The Company views its operations and manages its business as one operating segment. All revenues are attributable to U.S.-based operations and all assets are held in the United States.

Assets Held for Sale and Discontinued Operations

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

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

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

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 is primarily derived from providing molecular testing products, which are reimbursed through arrangements with third-party payors, laboratory distribution partners, and amounts from individual patients. Third-party payors include commercial payors, such as health insurance companies, health maintenance organizations and government health benefit programs, such as Medicare and Medicaid. The Company's contracts generally contain a single performance obligation, which is the delivery of the test results, and the Company satisfies its performance obligation at a point in time upon the delivery of the results, which then triggers the billing for the product. The amount of revenue recognized reflects the amount of consideration the Company expects to be entitled to the transaction price and considers the effects of variable consideration. Revenue is recognized when control of the promised product is transferred to customers, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those products.

The Company applies the following practical expedients and exemptions:

- Incremental costs incurred to obtain a contract are expensed as incurred because the related amortization period would be one year or less. The costs are included in selling and marketing expenses.
- No adjustments to amounts of promised consideration are made for the effects of a significant financing component because the Company expects, at contract inception, that the period between the transfer of a promised good or service and customer payment for that good or service will be one year or less.

Payor Concentration

The Company relies upon reimbursements from third-party government payors and private-payor insurance companies to collect accounts receivable. The Company's significant third-party payors and their related accounts receivable balances and revenues as a percentage of total accounts receivable balances and revenues are as follows:

	Percentage of Accounts Receivable	
	December 31, 2021	December 31, 2020
Blue Shield of Texas	4.0%	17.8%
Aetna	*	4.0%
United Healthcare	7.2%	6.6%
Government Health Benefits Programs	55.8%	26.2%
Anthem	*	3.5%

* Less than 1%

	Percentage of Revenue (1)	
	Year Ended December 31,	
	2021	2020
Blue Shield of Texas	10.7%	35.6%
Aetna	7.3%	11.0%
Cigna	5.7%	7.6%
United Healthcare	6.7%	6.7%
Government Health Benefits Programs	23.2%	3.7%

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

Accounts Receivable

Accounts receivable is recorded at the transaction price and considers the effects of variable consideration. The total consideration the Company expects to collect is an estimate and may be fixed or variable. Variable consideration includes reimbursement from third-party payors, laboratory distribution partners, and amounts from individual patients, and is adjusted for disallowed cases, discounts, and refunds using the expected value approach. The Company monitors these estimates at each reporting period based on actual cash collections in order to assess whether a revision to the estimate is required. Amounts included in accounts receivable consist of receivables generated from Progenity's genetics laboratory in Ann Arbor, Michigan. The Company plans to continue to collect these receivables and has not included these amounts as assets held for sale.

Cost of Sales

The components of the Company's cost of sales are materials and service costs, personnel costs, including stock-based compensation expense, equipment, and infrastructure expenses associated with processing blood and other samples, quality control analyses, shipping charges to transport samples and specimens from ordering physicians, clinics or individuals, third-party laboratory testing products, and allocated overhead including rent, information technology costs, equipment depreciation, and utilities. Costs associated with performing tests are recorded when the test is processed regardless of whether and when revenues are recognized with respect to such test. All costs of sales are associated with the Laboratory Operations and have been included in discontinued operations.

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.

Inventory

Inventory is stated at lower of cost (first-in, first-out method) or net realizable value. Inventory consists entirely of supplies, which are consumed when the Company is providing its test reports, and therefore the Company does not maintain any work in process or finished goods inventory. The Company reviews its inventory on a regular basis for excess and obsolete inventory based on an estimate for future consumption. Write-downs or losses of inventory are generally due to technological advances or new product introductions in the Company's laboratory testing products. The Company believes that the estimates used in calculating the inventory provision are reasonable and properly reflect the risk of excess and obsolete inventory. All inventory is related to the Laboratory Operations and has been included in assets held for sale. Inventory write-downs amounted to $5.9 million and $0.1 million in the years ended December 31, 2021 and 2020, respectively. Write-downs for the year ended December 31, 2021 are included in discontinued operations.

Property and Equipment, Net

Property and equipment are stated at cost. Assets acquired under capital leases are stated at the present value of future minimum lease payments. Depreciation is recognized on a straight-line basis over the estimated useful lives of the related assets as follows:

Property and Equipment	Estimated Useful Life (in years)
Computers and software	3
Laboratory equipment	5
Furniture, fixtures, and office equipment	8
Building	15

Assets acquired under capital leases and leasehold improvements are amortized on a straight-line basis over the shorter of the lease term or the useful life of the asset. Land is not depreciated.

Goodwill

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

If, after assessing qualitative factors, the Company determines it is not more likely than not that the fair value of a reporting unit is less than its carrying amount, then performing the two-step impairment test is unnecessary. If deemed necessary, a two-step test is used to identify the potential impairment and to measure the amount of goodwill impairment, if any. The first step is to compare the fair value of the reporting unit with its carrying amount, including goodwill. If the fair value of the reporting unit exceeds its carrying amount, goodwill is considered not impaired; otherwise, there is an indication that goodwill may be impaired and the amount of the loss, if any, is measured by performing step two. Under step two, the impairment loss, if any, is measured by comparing the implied fair value of the reporting unit goodwill with the carrying amount of goodwill. No impairment was recorded for the years ended December 31, 2021 and 2020.

Intangible Assets, Net

Intangible assets consist of identifiable intangible assets acquired through acquisitions. Identifiable intangible assets include payor relationships, trade names, and noncompete agreements. The Company amortizes payor relationships and trade names using the straight-line method over their useful lives. The Company amortizes noncompete covenants using the straight-line method over the terms of the related agreements. The Company reviews impairment for intangible assets with definite useful lives whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. Recoverability of these assets is measured by a comparison of the carrying amounts to the undiscounted future cash flows the assets are expected to generate. If such review indicates that the carrying amount of intangible assets is not recoverable, the carrying amount of such assets is reduced to fair value. No impairment was recorded for the years ended December 31, 2021 and 2020.

The amortization periods for the acquired intangible assets are:

Intangible Assets	Estimated Useful Life (in years)
Trade names	10
Payor relationships	10
Noncompete agreements	6

There are no intangible assets remaining as of December 31, 2021 as they were included as part of the sale of Avero.

Impairment of Long-Lived Assets

The Company accounts for the impairment of long-lived assets, such as property and equipment, by reviewing these assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If circumstances require a long-lived asset or asset group to be tested for possible impairment, the Company first compares undiscounted future cash flows expected to be generated by that asset or asset group to its carrying value. If the carrying value of the long-lived asset or asset group is not recoverable on an undiscounted-cash-flow basis, an impairment is recognized to the extent that the carrying value exceeds its fair value. No impairment was recorded as of December 31, 2021 and 2020.

Fair Value of Financial Instruments

The Company’s financial assets and liabilities are carried at fair value or at amounts that, because of their short-term nature, approximate current fair value, with the exception of its Convertible Notes, which are carried at amortized cost. The carrying value of the Company’s accounts receivable, accounts payable, and accrued expenses and other current liabilities are considered to be representative of their respective fair values because of their short-term nature (see Note 7). The carrying value of the Company’s mortgages payable approximates their estimated fair values because the instruments bear interest at rates, and have terms that are comparable to those available to the Company for similar loan instruments at December 31, 2020. There were no mortgages payable outstanding as of December 31, 2021.

Embedded Derivative Related to Convertible Notes

During 2020, the Company issued Convertible Notes with an embedded derivative that is required to be bifurcated from the host contract and remeasured to fair value at each balance sheet date. Any resulting gain or loss related to the change in the fair value of the embedded derivative is recorded to other income (expense), net 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.

Common Stock Warrant Liability

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 change in the fair value of the warrant liability is recorded to gain (loss) on warrant liability 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.

Repair and Maintenance

The Company incurs maintenance costs on its major equipment. Repair and maintenance costs are expensed as incurred.

Research and Development

Research and development expenses consist primarily of costs associated with performing research and development activities to develop new products. Research and development expenses also consist of personnel expenses, including salaries, bonuses, stock-based compensation expense, and benefits, and allocated overhead costs. Research and development expenses are expensed as incurred.

Selling and Marketing

Selling and marketing expenses consist primarily of costs for communication, advertising, conferences, and other marketing events. Selling and marketing expenses also consist of personnel expenses, including salaries, bonuses, stock-based compensation expense, benefits, and allocated overhead costs. Selling and marketing expenses are expensed as incurred. Advertising expense for the years ended December 31, 2021 and 2020 amounted to $0.6 million and $1.6 million, respectively.

General and Administrative

General and administrative expenses consist primarily of personnel costs, including salaries, bonuses, stock-based compensation expense, and benefits, for the Company's finance and accounting, legal, human resources, and other administrative teams. Additionally, these expenses include professional fees, including audit, legal, and recruiting services. General and administrative expenses are expensed as incurred.

Stock-Based Compensation

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

The fair value of stock options, ESPP awards and Performance Awards is estimated using the Black-Scholes option-pricing model and is affected by the Company's assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, the fair value of the common stock at the date of grant, the expected term of the awards, the expected

stock price volatility over the term of the awards, risk-free interest rate, and dividend rate. The Company's inputs and assumptions with respect to these variables are as follows:

Fair Value of Common Stock—Prior to the IPO, the Company's common stock was not publicly traded, therefore the Company estimated the fair value of its common stock. Following the 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 and diluted net loss per share attributable to common stockholders is presented in conformity with the two-class method required for participating securities. The Company considers all series of preferred stock to be participating securities as the holders of such stock are entitled to receive non-cumulative dividends on an as-converted basis in the event that a dividend is paid on common stock. Under the two-class method, the net loss attributable to common stockholders is not allocated to the preferred stock as the holders of preferred stock do not have a contractual obligation to share in the Company's losses. Under the two-class method, net income is attributed to common stockholders and participating securities based on their participation rights. Basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period. Net loss attributable to common stockholders is calculated by adjusting net loss with dividends to preferred stockholders, if any. As the Company has reported net losses for all periods presented, all potentially dilutive securities are antidilutive and, accordingly, basic net loss per share equals diluted net loss per share.

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, 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. 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 December 2019, FASB issued Accounting Standards Update ("ASU") No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, which simplified income tax accounting in various areas. The Company adopted this standard on January 1, 2021, which did not have a material impact on the consolidated financial statements.

Recent Accounting Pronouncements Not Yet Adopted

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which supersedes FASB ASC Topic 840, *Leases (Topic 840)*, and provides principles for the recognition, measurement, presentation and disclosure of leases for both lessees and lessors. The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method for finance leases or on a straight-line basis over the term of the lease for operating leases. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of classification. Leases with a term of 12 months or less will be accounted for similar to existing guidance for operating leases. In June 2020, the FASB issued ASU No. 2020-05, *Revenue from Contracts with Customers (Topic 606) and Leases (Topic 842): Effective Dates for Certain Entities,* which further defers the effective date for certain entities. As a result, the ASU is effective for EGCs for fiscal years beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022.

The Company adopted the provisions of this guidance on January 1, 2022, using the effective date method. As a result of adopting ASC 842, the Company recognized right-of-use assets and lease liabilities of $2.1 million and $2.2 million, respectively, on January 1, 2022. The difference between the right-of-use assets and lease liabilities is attributed to the elimination of deferred rent. There was no adjustment to the opening balance of accumulated deficit as a result of the adoption. The Company elected to use the package of practical expedients available in the new lease standard, allowing it not to reassess: (a) whether expired or existing contracts contain leases under the new definition of a lease; (b) lease classification for expired or existing leases; and (c) whether previously capitalized initial direct costs would qualify for capitalization under the new lease standard.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses*, which requires the measurement of expected credit losses for financial instruments carried at amortized cost, such as accounts receivable, held at the reporting date based on historical experience, current conditions and reasonable forecasts. The main objective of this standard is to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. In November 2018, the FASB issued ASU No. 2018-19, *Codification Improvements to Topic 326, Financing Instruments–Credit Losses*, which included an amendment of the effective date. The standard is effective for the Company for annual reporting periods beginning after December 15, 2022. The Company does not expect the adoption of this standard to have a significant impact on its consolidated financial statements.

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

In May 2021, the FASB issued ASU No. 2021-04*, Issuer's Accounting for Certain Modification or Exchanges of Freestanding Equity-Classified Written Call Options*, which provides a principles-based framework to determine whether an issuer should recognize the modification or exchange as an adjustment to equity or an expense. The amendments in the update are effective for the Company for fiscal years beginning January 1, 2022, including interim periods within those fiscal years with early adoption permitted. The Company does not expect the adoption of this standard to have a significant impact on its consolidated financial statements.

Note 3. Variable Interest Entity

In June 2015, the Company, through a wholly-owned subsidiary, entered into a series of agreements with Avero. The subsidiary entity entered into a purchase agreement to acquire certain assets from Mattison used in the operations of Avero. The purchase agreement was accounted for under the acquisition method in accordance with the provisions of ASC Topic 805, *Business Combinations*. The subsidiary entity also entered into a nominee agreement which provided it with the right, but not the obligation, to purchase, or to designate a person(s) to purchase, the stock of Avero at any time for a nominal amount.

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

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

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

In December 2018, Avero entered into a settlement agreement with Cigna. The Company provided financial support to Avero in the amount of $3.0 million during the year ended December 31, 2020 related to the Cigna settlement obligation, which was fully settled as of December 31, 2020. The Company did not provide any additional financial support to Avero during the years ended December 31, 2021 and 2020, other than the Cigna settlement obligation and agreed upon management services.

The following table presents the assets and liabilities of Avero that are included in the Company's consolidated balance sheets as of December 31, 2020 (in thousands). The assets and liabilities that were included in the sale of Avero in December 2021 are included in assets and liabilities held for sale (see Note 4). The assets and liabilities exclude intercompany balances that eliminate in consolidation:

	December 31, 2020
Assets of Avero that can only be used to settle obligations of Avero	
Cash and cash equivalents	$ 556
Accounts receivable, net	6,047
Inventory	3,382
Prepaid expenses and other current assets	1,254
Property and equipment, net	5,436
Other assets	30
Goodwill	147
Other intangible assets, net	3,843
Total assets of Avero that can only be used to settle obligations of Avero	$ 20,695
Liabilities of Avero	
Accounts payable	$ 4,722
Accrued expenses and other accrued liabilities	3,472
Current portion of capital lease obligations	46
Current portion of mortgage payable	199
Capital lease obligations, net of current portion	4
Mortgage payable, net of current portion	1,520
Other long-term liabilities	428
Total liabilities of Avero	$ 10,391

Note 4. Assets Held for Sale and Discontinued Operations

In June 2021, the Company announced its Strategic Transformation plan to reallocate resources to research and development to better position the business for future growth. The plan includes the closure of the Progenity genetics laboratory in Ann Arbor, Michigan and the divestiture of Avero. This plan represents a strategic business shift having a major effect on the Company's operations and financial results. The Company stopped providing genetic laboratory-developed test services in its Ann Arbor, Michigan laboratory and determined that the Laboratory Operations, including Avero, met the requirements of discontinued operations. The Company has classified the results of its Laboratory Operations as discontinued operations in its consolidated statements of operations and consolidated statements of cash flows for all periods presented. Additionally, the related assets and liabilities have been reported as assets and liabilities held for sale in the Company's consolidated balance sheet as of December 31, 2021 and December 31, 2020. The Company recognized a loss of $19.3 million for the year ended December 31, 2021 for contract terminations, severance, inventory and fixed asset write-downs in discontinued operations related to the Progenity genetics laboratory shutdown. In December 2021, the Company entered into an asset purchase agreement to sell certain assets and liabilities of Avero and recognized a loss of $6.0 million for the year ended December 31, 2021 and is included in discontinued operations. The loss on sale is calculated based on proceeds of $10.9 million less net assets of $15.1 million and transaction costs of $1.8 million.

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

	Year Ended December 31,	
	2021	2020
Revenues	$ 59,362	$ 74,151
Cost of sales	63,741	93,433
Gross loss	(4,379)	(19,282)
Operating expenses:		
Research and development	1,590	—
Selling and marketing	38,753	46,938
General and administrative	18,247	21,349
Total operating expenses	58,590	68,287
Other income (expense), net	(5,922)	127
Net loss from discontinued operations	$ (68,891)	$ (87,442)

The following table presents the carrying amounts of the classes of assets and liabilities held for sale related to the Laboratory Operations as of December 31, 2021 and December 31, 2020 (in thousands):

	December 31, 2021	December 31, 2020
Carrying amounts of assets of disposal group held for sale		
Current assets:		
Accounts receivable, net	$ —	$ 6,047
Inventory	—	12,220
Prepaid expenses and other current assets	—	729
Total current assets of disposal group held for sale (1)		18,996
Property and equipment, net	2,147	9,735
Other assets	—	30
Goodwill	—	147
Other intangible assets, net	—	3,843
Total assets of disposal group held for sale (1)	$ 2,147	$ 32,751
Carrying amounts of liabilities of disposal group held for sale		
Current liabilities:		
Accrued expenses and other current liabilities	—	272
Current portion of mortgages payable	—	198
Current portion of capital lease obligations	—	46
Total current liabilities of disposal group held for sale		516
Capital lease obligations, net of current portion	—	4
Mortgages payable, net of current portion	—	1,520
Total liabilities of disposal group held for sale	$ —	$ 2,040

(1) The assets of the remaining Progenity Laboratory Operations are classified as held for sale and are classified as current in the consolidated balance sheet at December 31, 2021, because they are expected to be sold within one year.

Note 5. Revenues

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

The Company applies the following five steps to recognize revenue: (1) identify the contract with the customer, (2) identify the performance obligations, (3) determine the transaction price, (4) allocate the transaction price to the performance obligations and (5) recognize revenues when the performance obligations are satisfied.

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

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

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

Revenues historically were derived from contracts with healthcare insurers, government payors, laboratory partners and patients in connection with sales of prenatal genetic, anatomic or molecular pathology tests. The Company entered into contracts with healthcare insurers related to tests provided to patients who had health insurance coverage. Insurance carriers are considered third-party payors on behalf of the patients, and the patients who receive genetic, anatomic or molecular pathology test products are considered the customers. Tests were billed to insurance carriers, patients, or a combination of insurance carriers and patients. The Company also sold tests to laboratory partners, which are considered customers.

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

The Company had established an accrual for refunds of payments previously made by healthcare insurers based on historical experience and executed settlement agreements with healthcare insurers. Any refunds are accounted for as reductions in revenues in the statement of operations as an element of variable consideration. In the United States, the American Medical Association ("AMA") generally assigns specific billing codes for laboratory tests under a coding system known as Current Procedure Terminology ("CPT"), which the Company and its ordering healthcare providers must use to bill and receive reimbursement for molecular tests. Effective January 1, 2019, the AMA issued a CPT code for genetic testing for severe inherited conditions that includes sequencing of at least 15 genes, which affects potential reimbursement for the Company's Preparent expanded carrier screening tests. As part of the Company's work to improve its compliance program, including its internal auditing and monitoring function, the Company commissioned a third-party review of its billing processes. In connection with that audit, the Company identified that it had not effectively transitioned to the implementation of the new CPT code in 2019, and as a result the Company received an overpayment of approximately $10.0 million from government payors during 2019 and early 2020. As of December 31, 2020, the Company settled all existing obligations to the relevant government programs as due.

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

The Company periodically updates its estimate of the variable consideration recognized for previously delivered performance obligations. These updates resulted in additional revenue of $6.6 million and a revenue reduction of $26.9 million for the years ended December 31, 2021 and 2020, respectively. These amounts included (i) adjustments for actual collections versus estimated variable consideration as of the beginning of the reporting period and (ii) cash collections and the related recognition of revenue in the current period for tests delivered in prior periods due to the release of the constraint on variable consideration, offset by (iii) reductions in revenue for the accrual for reimbursement claims and settlements described in Note 11.

Disaggregation of Revenues

The following tables show revenues disaggregated by payor type and revenue classification (in thousands):

	Year Ended December 31,	
	2021	2020
Commercial third-party payors	$ 42,100	$ 64,433
Government health benefit programs (1)	14,085	2,731
Patient/laboratory distribution partners	4,424	7,149
Total revenues	$ 60,609	$ 74,313

(1) The revenue amounts include accruals for reimbursement claims and settlements included in the estimates of variable consideration recorded during the years ended December 31, 2021 and 2020. Revenues recognized reflect the effects of variable consideration, and include adjustments for estimates of disallowed cases, discounts, and refunds. The variable consideration includes reductions in revenues for the accrual for reimbursement claims and settlements.

	Year Ended December 31,	
Classification	2021	2020
Revenue from continuing operations	$ 1,247	$ 162
Revenue from discontinued operations	59,362	74,151
Total revenues	$ 60,609	$ 74,313

Note 6. Balance Sheet Components

Prepaid Expenses and Other Current Assets

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

	December 31, 2021	December 31, 2020
Prepaid expenses	$ 6,123	$ 8,521
Other current assets	1,109	111
Total	$ 7,232	$ 8,632

Property and Equipment, Net

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

	December 31, 2021	December 31, 2020
Computers and software	$ 5,004	$ 6,150
Building and leasehold improvements	437	437
Laboratory equipment	2,688	3,044
Furniture, fixtures, and office equipment	1,142	1,143
Construction in progress	16	2,774
Land	346	346
Total property and equipment	9,633	13,894
Less accumulated depreciation and amortization	(5,621)	(5,788)
Property and equipment, net	$ 4,012	$ 8,106

Depreciation expense included in continuing operations was $1.4 million and $1.4 million for the years ended December 31, 2021 and 2020, respectively.

Goodwill

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

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

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

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

Intangible Assets, Net

All intangible assets have been classified as assets held for sale (see Note 4) as of December 31, 2020 and were included as part of the sale of Avero in December 2021. Amortization expense of intangible assets was $0.5 million and $0.9 million for the years ended December 31, 2021 and 2020, respectively, and is included in discontinued operations.

Accrued Expenses and Other Current Liabilities

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

	December 31, 2021	December 31, 2020
Accrual for reimbursement claims and settlements, current (1)	$ 18,127	$ 30,487
Commissions and bonuses	3,883	4,619
Vacation and payroll benefits	6,894	8,896
Accrued professional services	652	3,385
Accrued interest	802	855
Insurance financing	489	2,070
Contract liabilities	301	378
Other (2)	3,009	3,747
Total	$ 34,157	$ 54,437

(1) All of the Company's revenues related to Progenity's Laboratory Operations have been discontinued, amounts related to the revenue reserve generated from the Progenity Laboratory Operations are not included in liabilities held for sale.
(2) Included in this amount are contracts that Progenity will be responsible for that cannot be terminated, as there is no future benefit to the Company, they have been expensed in discontinued operations, but are not included in liabilities held for sale.

Other Long-term Liabilities

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

	December 31, 2021	December 31, 2020
Accrual for reimbursement claims and settlements, net of current portion (1)	$ 192	$ 7,053
Other (2)	5,622	1,614
Total	$ 5,814	$ 8,667

(1) All of the Company's revenues related to Progenity's Laboratory Operations have been discontinued, amounts related to the revenue reserve generated from the Progenity Laboratory Operations are not included in liabilities held for sale.
(2) Included in this amount are contracts that Progenity will be responsible for that cannot be terminated, as there is no future benefit to the Company, they have been expensed in discontinued operations, but are not included in liabilities held for sale.

Note 7. Fair Value Measurements

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

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

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

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

There were no significant transfers between these fair value measurement classifications during the years ended December 31, 2021 and 2020.

Fair Value of Financial Instruments

The Company’s Level 3 liabilities consist of the embedded derivative liability associated with the Company’s Convertible Notes (see Note 8) and the warrant liability resulting from the August 2021 issuance of warrants (see Note 12). The Convertible Notes conversion feature was bifurcated and recorded as an embedded derivative liability with a corresponding discount at the date of issuance that is netted against the principal amount of the Convertible Notes. The Company utilizes a Monte Carlo simulation method to determine the fair value of the conversion feature, which utilizes inputs including the common stock price, volatility of common stock, the risk-free interest rate and the probability of conversion to common shares at the conversion rate in the event of a major transaction (e.g. a change in control). Due to the use of significant unobservable inputs, the overall fair value measurement of the conversion feature is classified as Level 3.

The Company uses the Black-Scholes Model to value the Level 3 warrant liability at inception and on subsequent valuation dates. This model incorporates transaction details such as the Company’s stock price, contractual terms, maturity, risk free rates, and volatility. The significant unobservable input for the Level 3 warrant liability 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, 2021, the fair value of warrant liability was estimated using the Black-Scholes Model with the following inputs and assumptions:

	December 31, 2021
Risk-free interest rate	1.30%
Expected volatility	91.9%
Stock price	$ 2.09
Expected life (years)	4.6

The following table presents information about the Company's assets and liabilities that are measured at fair value on a recurring basis and indicates the fair value hierarchy of the valuation techniques utilized to determine such fair value (in thousands):

	Level 1	Level 2	Level 3
December 31, 2021			
Money market funds (1)	$ 85,866	$ —	$ —
Warrant Liability	$ —	$ —	$ 18,731
December 31, 2020			
Money market funds (1)	$ 90,254	$ —	$ —
Embedded derivative liability (2)	$ —	$ —	$ 18,370

(1) Included in cash and cash equivalents in the accompanying consolidated balance sheets.
(2) The fair value of the embedded derivative liability was zero as of December 31, 2021.

The carrying value of the Company's Convertible Notes does not approximate its fair value because the carrying value of the Convertible Notes reflects the balance of unamortized discount related to the derivative liability associated with the value of the conversion feature assessed at inception. The carrying value of the Company's Convertible Notes, net of discount, was $126.4 million and $158.9 million at December 31, 2021 and 2020, respectively. Based on unadjusted quoted prices in active market obtained from third-party pricing services, the Company determined the fair value of the Convertible Notes was $86.6 million and $250.2 million as of December 31, 2021 and 2020, respectively.

Note 8. Convertible Notes

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

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

At any time, noteholders may convert their Convertible Notes at their option into shares of 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 278.0094 shares of common stock per $1,000 principal amount of Convertible Notes, which represents an initial conversion price of approximately $3.60 per share of common stock. Noteholders that convert their Convertible Notes before December 1, 2022 will, in certain circumstances, be entitled to an additional cash payment representing the present value of any remaining interest payments on the Convertible Notes through December 1, 2022. The conversion rate and conversion price are subject to customary adjustments upon the occurrence of certain dilutive events. In addition, if certain corporate events that constitute a "Make-Whole Fundamental Change" (as defined in the Indenture) occur, then the conversion rate will, in certain circumstances, be increased for a specified period of time.

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

The Convertible Notes have customary provisions relating to the occurrence of "Events of Default" (as defined in the Indenture), which include the following: (i) certain payment defaults on the Convertible Notes (which, in the case of a default in the

payment of interest on the Convertible Notes, will be subject to a 30-day cure period); (ii) the Company's failure to send certain notices under the Indenture within specified periods of time; (iii) the Company's failure to comply with certain covenants in the Indenture relating to the Company's ability to consolidate with or merge with or into, or sell, lease or otherwise transfer, in one transaction or a series of transactions, all or substantially all of the assets of the Company and its subsidiaries, taken as a whole, to another person; (iv) a default by the Company in its other obligations or agreements under the Indenture or the Convertible Notes if such default is not cured or waived within 60 days after notice is given in accordance with the Indenture; (v) certain defaults by the Company or any of its subsidiaries with respect to indebtedness for borrowed money of at least $7.5 million; (vi) the rendering of certain judgments against the Company or any of its subsidiaries for the payment of at least $7.5 million, where such judgments are not discharged or stayed within 60 days after the date on which the right to appeal has expired or on which all rights to appeal have been extinguished; and (vii) certain events of bankruptcy, insolvency and reorganization involving the Company or any of the Company's significant subsidiaries. As of December 31, 2021 and December 31, 2020, the Company was in compliance with all such covenants.

The Convertible Notes have a conversion option which was required to be bifurcated upon issuance and then periodically remeasured to fair value separately as an embedded derivative. The conversion option includes additional interest payments payable to the noteholders if converted prior to December 1, 2022 (the "Early Voluntary Conversion Option"). The conversion feature was bifurcated as recorded separately as an embedded derivative as (1) the conversion feature is not clearly and closely related to the debt instrument and is not considered to be indexed to the Company's equity, (2) the conversion feature standing alone meets the definition of a derivative, and (3) the Convertible Notes are not remeasured at fair value each reporting period with changes in fair value recorded in the consolidated statement of operations.

The initial embedded derivative liability of $4.6 million on the issuance date was recorded as a noncurrent liability in the consolidated balance sheet and is remeasured to fair value at each balance sheet date with a resulting gain or loss related to the change in the fair value being charged to other income (expense), net in the consolidated statement of operations. As of December 31, 2020, the fair value of the derivative liability was $18.4 million. As a result of the derivative liability and issuance costs of $9.7 million, a corresponding debt discount was recorded on the issuance date, which was netted against the principal amount of the Convertible Notes. As of December 31, 2020, the unamortized debt discount was $9.6 million. The Company amortizes the debt discount using the effective interest method over the term of the Convertible Notes, at a resulting effective interest rate of approximately 8.7%. For the year ended December 31, 2020, the amortization of the Convertible Notes debt discount was $0.1 million, and was included in interest income (expense), net in the consolidated statements of operations.

As of December 31, 2021 the fair value of the derivative liability was zero. The change in the fair value of the derivative liability of $18.4 million is included in other income (expense), net in the consolidated statement of operations for the year ended December 31, 2021. As of December 31, 2021 the unamortized debt discount was $6.3 million. For the year ended December 31, 2021 the amortization of the Convertible Notes debt discount was $1.6 million and is included in interest income (expense), net in the consolidated statements of operations.

In October 2021, holders of Convertible Notes exchanged an aggregate of $20.2 million principal amount for 8,513,850 shares of the Company's common stock. As the Convertible Notes were exchanged for an amount over the fair value of shares issuable under the original conversion terms, the Company recorded an inducement loss of $9.8 million, included in other income (expense) in the consolidated statements of operations. In addition, the Company issued an aggregate of 427,804 shares of common stock to certain investors in consideration for a waiver of certain contractual lock-up provisions to which the Company agreed to in connection with prior offerings of its securities. The Company recorded an inducement loss of $1.4 million in other income (expense), net, in the consolidated statements of operations, related to these shares.

In addition to the transaction discussed above, holders of Convertible Notes exchanged an aggregate of $15.6 million principal amount for 4,336,938 shares of the Company's common stock during the year ended December 31, 2021. The Convertible Notes were converted under the Early Voluntary Conversion Option and the Company recognized a $0.9 million extinguishment loss, which is included in other income (expense), net in the consolidated statements of operations.

Note 9. Related Party Transactions

On October 27, 2017, the Company entered into a Credit and Security Agreement and a Series B Convertible Preferred Stock Purchase Agreement with a private equity firm ("2017 Transaction"). The 2017 Transaction provided for the 2017 Term Loan, the issuance of Series B Preferred Stock ("Series B Preferred Stock"), and the issuance of a warrant to purchase Series B Preferred Stock ("Series B Preferred Stock Purchase Warrant"). The 2017 Term Loan accrued interest at a rate per annum equal to 9.5% and was due October 27, 2022.

The 2017 Term Loan contained customary covenants, including a requirement to maintain a minimum unrestricted cash balance at all times of at least $5.0 million and was secured by all tangible and intangible property and assets of the Company, with the exception of its intellectual property.

The total proceeds of $124.2 million from the 2017 Transaction were allocated to the 2017 Term Loan, Series B Preferred Stock, and the Series B Preferred Stock Purchase Warrant based on the relative fair value of the term loan, equity, and warrant issued. As a result, the Company allocated proceeds of $65.7 million to the 2017 Term Loan. As the proceeds allocated to the 2017 Term Loan are lower than the stated loan amount of $75.0 million, the resulting $9.3 million discount was amortized as interest expense using the effective interest method over the term of the loan.

During the year ended December 31, 2020, the Company recognized interest expense of $7.5 million, inclusive of $2.1 million of discount amortization, respectively. The Term Loan was discharged in December 2020 in connection with the offering of Convertible Notes.

In connection with the Company's initial public offering ("IPO"), on June 18, 2020, the Series B Preferred Stock Purchase Warrant became exercisable for 400,160 shares of common stock.

On March 31, 2020, the Company entered into the First Amendment to the Credit Agreement ("Credit Agreement Amendment"), with the collateral agent and lender party thereto, providing for the payment of interest due and payable as of March 31, 2020 in shares of Series B Preferred Stock, and further providing for the payment of interest due and payable as of June 30, 2020 in shares of the Series B Preferred Stock in the event the IPO has not been consummated by such date. Pursuant to the Credit Agreement Amendment, the Company concurrently entered into a Series B Preferred Stock Subscription Agreement (the "Subscription Agreement"), with the lender, which provided for the issuance of 967,130 shares of Series B Preferred Stock at a subscription price of $2.25 per share, as payment for interest due and payable as of March 31, 2020 and all applicable fees as set forth in the Credit Agreement Amendment.

On May 8, 2020, the Company entered into an unsecured convertible promissory note ("Note") with the same private equity firm pursuant to a note purchase agreement, in an aggregate principal amount of $15.0 million, with an annual interest rate of 8.0% and a maturity date of May 8, 2022. The Note was convertible into (i) common stock upon an initial public offering at the lesser of the conversion price then in effect and a conversion price equal to 80% of the public offering price (or, if not a "qualified IPO" as defined in the Company's certificate of incorporation, at the election of a majority of the holders), (ii) on the maturity date or at the election of a majority of the holders, Series B preferred stock at an initial conversion price of $13.90 per share subject to certain adjustments, or (iii) at the election of a majority of the holders, shares of another class of equity securities issued by the Company in a future financing at 80% of the price per share of such class of equity securities issued in such offering. Interest under the Note was not generally payable except that if the Note is not converted pursuant to its terms on or prior to the maturity date and there are not sufficient authorized and unissued shares of Series B preferred stock for issuance upon the conversion of the Note on the maturity date, then the Company is required to pay all outstanding principal and any accrued and unpaid interest under the Note in cash. If the holders of the Note have not elected to convert the Note prior to, or in connection with, any sale transaction or a liquidation, dissolution or winding up of the Company, either voluntary or involuntary, then, upon any such sale transaction or liquidation, dissolution or winding up of the Company, the Company would have been required to pay in cash the outstanding principal balance of the Note, together with accrued and unpaid interest thereon, plus a make whole premium of 50% of the aggregate principal amount (less accrued and unpaid interest). The Company evaluated the economic features embedded in the Note and identified features that were required to be bifurcated and accounted for separately as a derivative. Accordingly, a derivative liability of $3.6 million was recorded on the issuance date of the Note and $3.8 million was subsequently reclassified to equity representing the fair value of the derivative liability on the date of extinguishment. The change in the fair value of the derivative liability of $0.2 million is included in other income (expense), net in the accompanying consolidated statements of operations. In June 2020, in connection with completion of the IPO, the Note was converted into 1,250,000 shares of common stock and all obligations under the Note were extinguished. Upon the conversion, the Company recorded a $3.6 million loss on extinguishment of the debt, which represented the difference between the carrying value of the Note and the derivative liability and the fair value of the shares of common stock issued to the Note holder of $3.4 million combined with amortization of the related debt discount of $0.2 million. The loss on extinguishment of debt was included in other income (expense), net in the accompanying consolidated statement of operations for the year ended December 31, 2020. The same private equity firm participated in the IPO and acquired 3,333,333 shares at a price of $15.00 per share, which was at par with the price to other investors.

In December 2020, the private equity firm discharged any and all amounts owed and any obligations outstanding under the 2017 Term Loan in exchange for $78.5 million principal amount of Convertible Notes issued by the Company. The exchange was accounted for as an extinguishment of the 2017 Term Loan and resulted in $7.6 million of loss on extinguishment, which was included in other income (expense), net in the accompanying consolidated statement of operations for the year ended December 31, 2020. This private equity firm also acquired an additional $25.0 million principal amount of Convertible Notes for cash in this private offering,

which resulted in $103.5 million aggregate principal amount of the Convertible Notes acquired by this private equity firm (see Note 8). During the year ended December 31, 2021 the private equity firm entered into an agreement with the Company to waive its interest due of $3.6 million through June 1, 2021 and received 1,268,116 shares of common stock. For the years ended December 31, 2021 and 2020, the accrued interest expense related to the Convertible Notes held by this private equity firm was $0.6 million and $0.5 million, respectively.

In December 2020, the same private equity firm participated in an underwritten public offering and acquired 4,128,440 shares as a price of $3.27 per share resulting in the proceeds to the Company of $13.2 million before expenses. In June 2021, this private equity firm participated in a private placement and acquired 8,097,166 units, representing 8,097,166 shares of common stock and warrants to purchase up to 8,097,166 shares of common stock at a price of $2.47 per unit (see Note 12).

Note 10. Mortgages Payable

In January 2014, the Company executed a mortgage with Comerica Bank for $1.8 million for the purpose of acquiring property located in Ann Arbor, Michigan, which is used for laboratory testing and research purposes. The mortgage matured in 2024 and required monthly principal and interest payments at a fixed interest rate of 2.94% plus a floating rate at LIBOR. As of December 31, 2020, the outstanding balance of this mortgage was $1.3 million. The Company paid off the remaining mortgage in November 2021. The Company also had a mortgage with American Bank of Commerce (originally executed in February 2008) outstanding on Avero's property located in Lubbock, Texas, that matured in 2029 and required monthly principal and interest payments at an interest rate of 3.25%. As of December 31, 2020, the outstanding balance of this mortgage was $1.7 million and is included in liabilities held for sale. The remaining mortgage was paid off in December 2021 prior to the sale of Avero.

Note 11. Commitments and Contingencies

Operating Leases

The Company has entered into various noncancelable operating lease agreements, primarily for office space, laboratory space, and vehicles, which expire over the next one to five years. Minimum rent payments under operating leases are recognized on a straight-line basis over the term of the lease. Rent expense included in continuing operations for operating leases was $5.1 million and $5.9 million, for the years ended December 31, 2021 and 2020, respectively.

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

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

Contingencies

The Company, in the ordinary course of its business, can be involved in lawsuits, threats of litigation, and audit and investigative demands from third parties. While management is unable to predict the exact outcome of such matters, it is management's current belief, that any potential liabilities of Avero or Progenity 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 complies in all material respects with the statutes, regulations, and other requirements applicable to its 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 (“SDNY”) and a Health Insurance Portability and Accountability Act subpoena issued by an AUSA for the Southern District of California (“SDCA”) around legacy commercial practices. In May 2018, the Company received a subpoena from the State of New York Medicaid Fraud Control Unit.

On July 21, 2020, July 23, 2020, and October 1, 2020, the Company entered into agreements ("the Agreements") with certain governmental agencies and the 45 states participating in the settlement (“State AGs”) to resolve, with respect to such agencies and State AGs, all of such agencies’ and State AGs’ outstanding civil, and, where applicable, federal criminal investigations described above. The Company paid approximately $5.0 million and $36.9 million as required by the Agreements during the years ended December 31, 2021 and 2020, respectively. 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.

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. During the year ended December 31, 2020, the Company received a tax refund of approximately $37.7 million related to the NOL carryback provisions available under the Coronavirus Aid, Relief and Economic Security Act (“CARES Act”) and made accelerated payments of approximately $7.5 million under the Agreements. The Company did not receive any tax refunds during the year ended December 31, 2021.

Non-Prosecution Agreement

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

Corporate Integrity Agreement

In connection with the resolution of the investigated matters, and in exchange for the OIG’s 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, effective March 16, 2022 the OIG agreed to suspend the Company’s obligations under the Corporate Integrity Agreement except for the Company’s obligation to continue its engagement of an independent review organization to conduct billing claims reviews and reporting of those reviews to OIG with respect to ongoing reimbursement payments being received from federal healthcare programs for historical laboratory services performed by the Company prior to the Company’s cessation of services in the summer of 2021. The Company’s failure to comply with its remaining obligations under the Corporate Integrity Agreement could result in monetary penalties and/or the Company being excluded from participating in federal healthcare programs.

Settlement Accruals

As of December 31, 2020, the Company had accrued an aggregate of $12.1 million associated with a potential settlement with the DOJ and the participating State Attorney Generals within accrued expenses and other current liabilities and as a reduction of revenue as reflected on the consolidated balance sheets as of December 31, 2020 and consolidated statement of operations for the year ended December 31, 2020. As of December 31, 2021, the Company’s accrual consists of $6.9 million in accrued expenses and other current liabilities and $0.2 million in other long-term liabilities.

Colorado Recoupment

On July 21, 2021, the Company received a letter from the Colorado Department of Health Care Policy and Financing, or 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 related to the Company's Preparent expanded carrier screening tests primarily on the basis that such tests were not medically necessary.

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

The Company has disputed these claims of recoupment with the Department, filed an administrative complaint with the State of Colorado Office of Administrative Courts, and also seeks to offset such claims by an amount of approximately $1.9 million previously paid to the Department in connection with the state settlement agreements referred to above. At this preliminary stage, the Company is unable to predict the ultimate outcome of this action, and therefore cannot estimate the reasonably possible loss or range of loss, if any, that may result from this action.

California Subpoena

On July 19, 2021, the Company received a subpoena from the California Attorney General's Office, Division of Public Rights, requesting documents and information related to Progenity's former genetic testing practices, including NIPT, particularly those with a nexus to California patients. The subpoena is captioned "In the Matter of the Investigation of: Prenatal Genetic Testing Companies." The Company continues to cooperate and provide information requested by the subpoena. At this preliminary stage, the Company is unable to predict the ultimate outcome of this action, and therefore cannot estimate the reasonably possible loss or range of loss, if any, that may result from any unfavorable outcome related to this action.

Payor Settlement Agreements

In December 2018, the Company and Cigna entered into a settlement agreement whereby Avero agreed to pay an aggregate amount of $12.0 million. As of December 31, 2020 the settlement has been fully paid.

In November 2019, the Company and Aetna entered into a settlement agreement for $15.0 million. As of December 31, 2021 the settlement has been fully paid.

On September 30, 2019, the Company entered into a settlement agreement with United HealthCare Services, Inc. and UnitedHealthcare Insurance Company in which the Company agreed to pay an aggregate amount of $30.0 million. As of December 31, 2021 the settlement has been fully paid.

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. If a third-party payor successfully challenges that a payment to the Company for prior testing was in breach of contract or otherwise contrary to policy or law, they may recoup such payment. The Company may also decide to negotiate and settle with a third-party payor in order to resolve an allegation of overpayment. In the ordinary course of business, the Company addresses and evaluates a number of such claims from payors. In the past, the Company has negotiated and settled these types of claims with third-party payors. The Company may be required to resolve further disputes in the future. While management is unable to predict the exact outcome of any such claims, it is management's current belief that any potential liabilities resulting from these contingencies, individually or in the aggregate, could have a material impact on the Company's financial position and results of operations.

In connection with the third-party review of the Company's coding and billing processes described in Note 5, which identified that the Company had not effectively transitioned to the implementation of the new CPT code for reimbursement for the Company's Preparent expanded carrier screening tests during 2019 and early 2020, the Company reviewed its reimbursement from commercial payors for these tests over the same time period. The Company may need to engage with payors in order to determine if any amounts could be subject to recovery or recoupment, as it is customarily done with commercial payors. Any amounts subject to recovery or recoupment will depend on the interpretation of widely variable payor medical and billing policies. The Company will not know if any overpayments exist until it completes this engagement with individual commercial payors. If negotiations with payors result in claims or conclusions that overpayments have been made, this could have a material impact on the Company's financial results and position.

The Company is unable to predict the outcome of this matter and is unable to make a meaningful estimate of the amount or range of loss, if any, that could result from any unfavorable outcome related to this matter.

Payor Dispute

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

As noted above, the Company has historically negotiated and settled similar claims with third-party payors. Although the Company's practice in resolving disputes with other similar large commercial payors has generally led to agreed settlement amounts substantially less than the originally claimed amount, there can be no assurance that the Company will be successful in a similar settlement amount in any ongoing or future dispute. Historical settlement amounts and payment time periods may not be indicative of the final settlement terms with Anthem, if any. Management disputes this claim of recoupment with Anthem in substantial part based on expired statutes of limitations and seeks to offset any amounts owed by Anthem to the Company. The Company has an accrual for the estimated probable loss for this matter as of December 31, 2021.

OIG Inquiry

On October 16, 2019, the Company received an inquiry from the Texas Health & Human Services Commission Office of Inspector General ("TX OIG") alleging that the Company did not hold the required CLIA Laboratory Certificate of Accreditation to perform, bill for, or be reimbursed by the Texas Medicaid Program for certain tests performed by us from January 1, 2015 through December 31, 2018. The Company submitted a written response to the inquiry on October 23, 2019. In October 2021, the Company received a letter from the TX OIG asking the Company to renew its engagement on the matter. The Company continues to cooperate with TX OIG toward resolution of the matter. Although management believes that the Company holds and have held all required CLIA certificates and/or subcontract with third-party laboratories that hold and have held such certificates to perform all of the tests subject to the TX OIG inquiry, there can be no assurance that the TX OIG will agree with this position. The Company has recorded an accrual of $0.4 million for the estimated probable loss for this matter as of December 31, 2021.

Natera Settlement

On June 17, 2020, Natera, Inc. filed suit in the Western District of Texas (W.D. Texas Civil Action No. 6:20-cv-532) asserting the Company's infringement of six Natera patents based on a portion of the Company's NIPT product offering. In August 2021, the Company and Natera entered into a settlement agreement and thereafter the matter (and all related matters) were ordered dismissed by the courts in August 2021. The settlement agreement does not require a cash payment by the Company.

Ravgen Lawsuit

On December 22, 2020, Ravgen, Inc. ("Ravgen") filed suit in the District of Delaware (D. Del. Civil Action No. 1:20-cv-1734) asserting the Company's infringement of two Ravgen patents based on the Company's former NIPT testing business. The complaint seeks monetary damages and injunctive relief. The Company responded to the complaint on March 23, 2021. Management believes the claims in Ravgen's complaint are without merit, and the Company is vigorously defending against them. On March 1, 2022 the court ordered a stay of the litigation pending resolution of patent validity challenges made against the two patents in inter partes review proceedings currently pending before the Patent Trial and Appeal Board of the United States Patent and Trademark Office.

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. It 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 of 1933 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. Together with the underwriters of the IPO, the Company moved to dismiss the second amended complaint on November 15, 2021. Lead Plaintiffs filed an opposition to the motion on January 14, 2022, and the Company filed a reply in support of the motion on February 22, 2022. The Company intends to continue to vigorously defend against these claims. Subject to a reservation of rights, the Company is advancing expenses subject to indemnification to the underwriters of the IPO.

On June 4, 2021, a purported shareholder filed a lawsuit in the U.S. District Court for the Southern District of California, 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. The complaint seeks the award of unspecified damages to the Company, equitable and injunctive remedies, and an order directing the Company to reform and improve its internal controls and board oversight. It also seeks the costs and disbursements associated with bringing suit, including attorneys', consultants', and experts' fees. The case is stayed pending the outcome of the motion to dismiss in the above-described securities lawsuit. The Company intends to vigorously defend against these claims.

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

Given the uncertainty of litigation, the preliminary stages of the Ravgen and IPO litigations, 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 12. Stockholders' Equity

Common 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 is authorized to issue 350,000,000 shares of common stock and 10,000,000 shares of undesignated preferred stock. Each holder of common stock is entitled to one vote per share of common stock held.

On June 18, 2020, the Company completed its IPO. In the IPO, the Company issued and sold 6,666,667 shares of its common stock, at a price to the public of $15.00 per share. The Company received approximately $88.7 million in net proceeds, after deducting $7.0 million in underwriting discounts and commissions and $4.3 million in other offering expenses payable by the Company. Other offering costs consisted primarily of legal and accounting fees, which were direct and incremental fees related to the IPO.

In December 2020, the Company issued and sold 8,792,047 shares of its common stock in an underwritten public offering, at a price of $3.27 per share. The Company received approximately $26.9 million in net proceeds, after deducting underwriting discounts and commissions and other offering expenses payable by the Company.

In February 2021, the Company entered into a Securities Purchase Agreement for a private placement with certain institutional and accredited investors ("February Purchasers"). Pursuant to the Securities Purchase Agreement, the February Purchasers purchased an aggregate of 4,370,629 units ("February Units"), representing (i) 4,370,629 shares of the Company's common stock and (ii) warrants to purchase up to 4,370,629 shares of common stock. The purchase price for each February Unit was $5.72, for an aggregate purchase price of approximately $25.0 million. The warrants are exercisable for cash at an exercise price of $6.86 per share, subject to adjustments as provided under the terms of the warrants. The warrants are exercisable at any time for cash and expire on the fifth anniversary of the date of issuance. If exercised for cash, the warrants would result in additional gross proceeds to the Company of approximately $30.0 million.

Pursuant to ASC 815-40, Derivatives and Hedging – Contracts in Entity's Own Equity ("ASC 815"), the Company deemed the warrants to be liability classified and allocated the proceeds from issuance between the warrants and common stock using the with-and-without method. $12.8 million of the proceeds, equal to the fair value of the warrants determined using the Black-Scholes Model, were allocated to the warrant liability, and the remaining proceeds of $12.2 million were allocated to the common stock. The

Company incurred a total of $1.4 million in issuance costs, which were allocated between the warrants and common stock on a relative fair value basis, $0.5 million and $0.9 million, respectively. The warrant liability was remeasured at $10.2 million as of March 31, 2021 and the Company recognized a gain on warrant liability in the amount of $2.6 million associated with this transaction during the three months ended March 31, 2021. On April 1, 2021, the registration statement to register the shares of common stock underlying the warrants was declared effective by the SEC. As a result, the warrants met the conditions to be classified in equity and the related warrant liability was reclassified from liability to equity on April 1, 2021.

In June 2021, the Company entered into a Securities Purchase Agreement for a private placement with certain institutional and accredited investors (“June Purchasers”). Pursuant to the Securities Purchase Agreement, the June Purchasers purchased an aggregate of 16,194,332 units (“June Units”), representing (i) 15,694,332 shares of the Company’s common stock (ii) warrants to purchase up to 16,194,332 shares of common stock and (iii) pre-funded warrants to purchase up to 500,000 shares of common stock. The purchase price for each June Unit was $2.47, for an aggregate purchase price of approximately $40.0 million. The warrants are exercisable for cash at an exercise price of $2.84 per share, subject to adjustments as provided under the terms of the warrants. The warrants are exercisable at any time and expire on the fifth anniversary of the date of issuance. If exercised for cash, the warrants would result in additional gross proceeds to the Company of approximately $46.0 million. The pre-funded warrants are exercisable at an exercise price of $0.001 per share and have no expiration date. In July 2021, the Company issued 500,000 shares of common stock as a result of the exercise of the outstanding pre-funded warrants at an exercise price of $0.001 per share. During the year ended December 31, 2021, the Company issued 6,097,166 shares of common stock as a result of the exercise of outstanding warrants at an exercise price of $2.84 per share for proceeds of $17.3 million.

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

In August 2021, in order to raise capital to fund the Company's planned expenditures and meet its obligations, the Company issued and sold an aggregate of (i) 40,000,000 shares of common stock and (ii) warrants to purchase 40,000,000 shares of common stock in an underwritten public offering. Each share was sold together with one warrant to purchase one share of common stock at a combined public offering price of $1.00 per share of the common stock and the accompanying warrant. The warrants have an exercise price of $1.00 per share, are exercisable at any time, and will expire five years following the date of issuance. In addition, the Company granted the underwriter a 30-day option to purchase up to 6,000,000 shares of common stock ("Overallotment Stock Option") and/or warrants to purchase 6,000,000 shares of common stock (“Overallotment Warrant Option”) at a price of $0.99 per share of common stock and/or $0.01 per warrant. The warrants and Overallotment Warrant Options were issued in the money based on the public offering terms. The Company received approximately $37.4 million in net proceeds, after deducting underwriting discounts and commissions and other offering expenses payable by the Company.

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

The Overallotment Warrant Option was partially exercised in August for warrants to purchase an aggregate of 1,932,000 shares of common stock and the Company recognized a gain on the warrant liability in the amount of $3.4 million in the consolidated statements of operations. The remaining Overallotment Warrant Option expired in September 2021 and the Company recognized a gain of $1.9 million in the consolidated statements of operations. The Warrant Liability was remeasured at $18.7 million as of December 31, 2021 and the Company recognized a loss on warrant liability in the amount of $6.7 million in the consolidated statements of operations during the year ended December 31, 2021.

During the year ended December 31, 2021, the Company issued 28,684,125 shares of common stock as a result of the exercise of outstanding warrants at an exercise price of $1.00 per share for proceeds of $28.7 million. The Warrant Liability was remeasured upon exercise of the warrants throughout the period, resulting in a loss on warrant liability in the amount of $41.6 million in the consolidated statements of operations during the year ended December 31, 2021.

In October 2021, the Company entered into a securities purchase agreement with certain institutional and accredited investors for the purchase and sale of 13,333,334 shares of the Company's common stock, at a purchase price of $1.50 per share in a registered direct offering. The Company received approximately $18.7 million in net proceeds, after deducting placement agent fees and other offering expenses payable by the Company.

In November 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 $90,000,000, from time to time, in “at the market” offerings through the Agents. Sales of the shares of common stock, if any, will be made at prevailing market prices at the time of sale, or as otherwise agreed with the Agents. The Agents will receive a commission from the Company of up to 3.0% of the gross proceeds of any shares of common stock sold under the ATM Sale Agreement. During the three months ended December 31, 2021, we received net proceeds of $4.6 million, after deducting commissions and other offering expenses, from the sale of 1,763,754 shares under the ATM Sale Agreement. The Company sold such shares at a weighted average purchase price of $2.84 per share.

Convertible Preferred Stock

As of December 31, 2019, the Company had outstanding Series A Preferred Stock and Series B Preferred Stock.

In February 2020, the Company issued and sold an aggregate of 5,066,666 shares of Series B Preferred Stock at a purchase price of $2.25 per share to existing investors in exchange for aggregate consideration of approximately $11.4 million.

On March 31, 2020, in connection with the Credit Agreement Amendment, which provided for the payment of interest due and payable as of March 31, 2020 and June 30, 2020 (only in the event the IPO had not been consummated by such date) in shares of Series B Preferred Stock, the Company issued an aggregate of 967,130 shares of Series B Preferred Stock at a subscription price of $2.25 per share to existing investors as payment for interest due and payable as of March 31, 2020 and all applicable fees.

On April 3, 2020, the Company issued and sold an aggregate of 4,444,444 shares of its Series B Preferred Stock at a purchase price of $2.25 per share to existing investors in exchange for aggregate consideration of approximately $10.0 million in cash.

The fair value of the preferred stock was estimated using a hybrid between a probability-weighted expected return method (“PWERM”) and option pricing model (“OPM”), estimating the probability weighted value across multiple scenarios, while using an OPM to estimate the allocation of value within one or more of these scenarios. Under a PWERM, the value of the Company’s various classes of stock was estimated based upon an analysis of future values for the Company assuming various future outcomes, including two IPO scenarios and one scenario contemplating the continued operation of the Company as a privately held enterprise. Guideline public company multiples were used to value the Company under its various scenarios. Share value for each class of stock was based upon the probability-weighted present value of expected future share values, considering each of these possible future outcomes, as well as the rights of each share class.

The significant unobservable inputs into the valuation model used to estimate the fair value of the preferred stock include the timing of potential events (primarily the IPO) and their probability of occurring, the selection of guideline public company multiples, a discount for the lack of marketability of the common stock, and the discount rate used to calculate the present value of the estimated equity value allocated to each share class.

In connection with the IPO, on June 18, 2020, all outstanding Series A Preferred Stock and Series B Preferred Stock converted into 33,443,562 shares of common stock, including the issuance of 2,045,522 shares of common stock pursuant to an adjustment in the conversion rate of all of the shares of Series B Preferred Stock outstanding immediately prior to the IPO. Upon conversion of the convertible preferred stock, the Company reclassified their carrying value to common stock and additional paid-in capital.

Common Stock Reserved for Future Issuance

The Company reserved shares of common stock, on an as-if-converted basis, for future issuance as follows:

	December 31, 2021	December 31, 2020
Outstanding stock options to purchase common stock	8,640,951	4,268,945
Restricted stock units outstanding	3,879,110	1,468,765
Available for future issuance under equity incentive plans	13,649,346	2,938,616
Common stock warrants	26,183,830	400,160
Common stock issuable upon conversion of convertible notes	40,588,672	51,529,036
Total	92,941,909	60,605,522

Note 13. 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 the 2015 Consultant Stock Plan ("2015 Plan") and is administered with either stock options or restricted stock units. The Board of Directors administers the plans. Upon adoption of the 2018 Plan, no new stock options or awards are issuable under the 2012 Plan, as amended, or the 2015 Plan. The 2018 Plan also provides for other types of equity to issue awards, which at this time the Company does not plan to utilize. The 2018 Plan was amended in March 2019 with 1,100,000 shares available for future grant.

In December 2019, the Company adopted the Second Amended and Restated 2018 Equity Incentive Plan, which increased the number of shares available for future grant to 2,700,000 shares. On March 4, 2020, the Board of Directors adopted the Third Amended and Restated 2018 Equity Incentive Plan ("2018 Third Amended Plan"), which increased the number of shares available for future grant to a total of 7,615,733 shares and was approved by stockholders on March 5, 2020.

The 2018 Third Amended Plan provides for automatic annual increase in the number of shares of common stock reserved for issuance, which resulted in an additional 4,537,676 shares reserved for future issuance effective January 1, 2021. On May 5, 2021, holders of a majority of the outstanding common stock executed a written consent approving the Fourth Amended and Restated 2018 Equity Incentive Plan ("2018 Fourth Amended Plan") and an increase of 7,700,000 shares authorized for issuance, resulting in a total of 19,853,409 shares authorized for issuance under the 2018 Fourth Amended Plan.

On November 3, 2021, the Board of Directors approved and adopted the Company's 2021 Inducement Plan ("2021 Inducement Plan") to provide for the reservation of 6,500,000 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, 2021, 13,649,346 shares were available for grant under the 2018 Fourth Amended Plan and the 2021 Inducement Plan.

Stock Options

The following table summarizes stock option activity, which includes Performance Awards, under the 2012 Plan, the 2015 Plan, the 2018 Fourth Amended Plan and the 2021 Inducement Plan during the year ended December 31, 2021:

	Stock Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Balance at December 31, 2020	4,268,945	$ 8.14		
Options granted	11,175,962	$ 3.52		
Options exercised	(323,266)	$ 2.04		
Options forfeited/cancelled	(6,480,690)	$ 5.01		
Balance at December 31, 2021	8,640,951	$ 4.74	8.17	$ 235
Vested and expected to vest at December 31, 2021	8,640,951	$ 4.74	8.17	$ 235
Vested and exercisable at December 31, 2021	2,155,157	$ 7.35	4.63	$ 72

The aggregate intrinsic value in the above table is calculated as the difference between the closing price of our common stock at December 31, 2021 of $2.09 per share and the exercise price of stock options that had strike prices below the closing price. The intrinsic value of all stock options exercised during the year ended December 31, 2021 was $0.8 million.

In January 2020 the Board of Directors approved the modification of the exercise price of certain outstanding stock options under the existing incentive plans. As a result of this modification, an additional stock-based compensation expense of $0.9 million is being recognized over the remaining vesting period for the outstanding stock options.

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, 2021 and 2020:

	Year ended December 31,	
	2021	2020
Risk-free interest rate	0.6% - 1.4%	0.4% - 1.7%
Expected volatility	52.9% - 77.0%	57.0% - 71.0%
Expected dividend yield	—	—
Expected life (years)	3.0 - 6.3	4.0 - 6.3

The weighted-average grant date fair value of options granted during the years ended December 31, 2021 and 2020 was $2.11 per option and $5.15 per option, respectively.

Restricted Stock Units

The following table summarizes RSU activity for the year ended December 31, 2021:

	Number of Shares	Weighted-Average Grant Date Fair Value
Balance at December 31, 2020	1,468,765	$ 8.73
Granted	5,810,122	$ 3.33
Vested	(819,499)	$ 6.69
Forfeited/cancelled	(2,580,278)	$ 4.63
Balance at December 31, 2021	3,879,110	$ 3.80

2020 Employee Stock Purchase Plan

In June 2020, the Company's board of directors adopted the ESPP with 510,000 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, which resulted in an additional 557,723 shares reserved for future issuance effective January 1, 2021. As of December 31, 2021 there were 750,977 total shares of common stock reserved for future issuance.

The Company commenced a series of offerings under the ESPP on December 1, 2020. The initial offering began December 1, 2020, ends on November 30, 2022 (unless terminated earlier, as described below) and consists of four purchase periods. The purchase periods end on the last trading day of May and November of each year. Eligible employees who enroll in the initial offering or any subsequent offering will be able to purchase shares of the Company's common stock at a discount through payroll deductions, subject to certain limitations. The purchase price of the shares of common stock will be the lesser of (i) 85% of the fair market value of such shares on the offering date and (ii) 85% of the fair market value of such shares on the purchase date. Following the commencement of the initial offering, a new 24-month offering with four six-month purchase periods will automatically begin approximately every six months thereafter over the term of the ESPP. Offerings will be concurrent, but in the event the fair market value of a share of common stock on the first day of any purchase period during an offering (the "New Offering") is less than or equal to the fair market value of a share of common stock on the offering date for an ongoing offering (the "Ongoing Offering"), then the Ongoing Offering terminates immediately following the purchase of shares on the purchase date immediately preceding the New Offering and the participants in the terminated Ongoing Offering are automatically enrolled in the New Offering. Notwithstanding the above, the Company's board of

directors (or an authorized committee thereof) may modify the terms of or suspend any future offerings prior to their commencement. The Company issues new shares for purchases of stock made pursuant to the ESPP.

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,	
	2021	2020
Cost of sales	$ —	$ —
Research and development	3,584	2,804
Selling and marketing	224	215
General and administrative	8,154	5,225
Discontinued operations	1,594	2,424
Total stock-based compensation expense	$ 13,556	$ 10,668

At December 31, 2021 there was $13.6 million of compensation cost related to unvested stock options expected to be recognized over a remaining weighted average vesting period of 2.94 years and $12.6 million of compensation cost related to unvested RSUs expected to be recognized over a remaining weighted average vesting period of 3.27 years.

Note 14. Income Taxes

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

	Year Ended December 31,	
	2021	2020
Current provision:		
Federal	$ —	$ (37,697)
State	—	82
	—	(37,615)
Deferred expense:		
Federal	(119)	22
State	—	61
	(119)	83
Net income tax provision	$ (119)	$ (37,532)

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

	Year Ended December 31,	
	2021	2020
Income tax benefit at U.S. federal statutory rate	$ (37,514)	$ (29,950)
NOL carryback and other true ups	—	(15,517)
Government litigation settlements	—	4,611
Federal research and development credit	2,978	(2,978)
Convertible debt and warrant liability	12,225	740
Stock-based compensation	1,700	84
Change in valuation allowance	18,211	5,418
Other	2,281	60
Total income tax benefit	$ (119)	$ (37,532)

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, 2021 and 2020 are presented below (in thousands):

	December 31, 2021	December 31, 2020
Deferred tax assets:		
Net operating losses and carryforwards	$ 124,230	$ 87,329
Reserves	3,454	7,211
Intangible assets	1,571	3,878
Accrued expenses	1,447	1,816
Stock-based compensation	2,603	2,289
Convertible debt	—	3,290
Other, net	112	—
Total deferred tax assets	133,417	105,813
Deferred tax liabilities:		
Fixed assets	(864)	(1,698)
Prepaid expenses	(1,123)	(1,146)
Goodwill	—	(402)
Adoption of ASC 606	(1,341)	(2,824)
Convertible debt	(677)	
Other, net	(33)	—
Total deferred tax liabilities	(4,038)	(6,070)
Net deferred tax assets	129,379	99,743
Less: valuation allowance	(129,379)	(99,862)
Net deferred tax assets (liabilities)	$ —	$ (119)

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, 2021 was an increase of $29.5 million.

At December 31, 2021, the Company had federal and state income tax net operating loss (“NOL”) carryforwards of approximately $458.2 million and $221.7 million, respectively. The U.S. federal net operating losses will be carried forward indefinitely and state net operating losses will begin to expire in various years, depending on the applicable jurisdiction. Federal net operating loss carryforwards generated post TCJA may be carried forward indefinitely, subject to the 80% taxable income limitation on the utilization of the carryforwards. In addition, the Company had federal and state research and expenditure credit carryforwards of approximately $8.7 million and $1.4 million, respectively, as of December 31, 2021. The federal research and expenditure credit will begin to expire after 2033 if unused and the state research and expenditure credit may be carried forward indefinitely.

Pursuant to Section 382 and Section 383 of the Internal Revenue Code, annual use of the Company’s net operating loss carryforwards and tax credit carryforwards may be limited as a result of cumulative changes of ownership resulting in a change of control of the Company. The Company performed a formal study through the date of the IPO and determined future utilization of tax attribute carryforwards are not limited per Section 382 of the Internal Revenue Code. The Company has not updated their 382 study since the IPO offering 2020. Any future changes may limit future utilization of tax attribute carryforwards. Due to the existence of the valuation allowance, limitations created by future ownership changes, if any, will not impact the Company's effective tax rate.

In accordance with ASC 740-10, *Income Taxes—Overall,* the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more likely than not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. The Company has no uncertain tax positions at December 31, 2021.

The Company is subject to taxation in the United States, various US 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, 2021, there were no interest and penalties related to uncertain tax positions.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") was enacted. The CARES Act includes several significant provisions for corporations, including those pertaining to net operating loss carryforwards, interest deductions and payroll tax benefits. Corporate taxpayers may carryback NOLs originating during 2018 through 2020 for up to five years. During the first quarter of 2020, the Company recorded a discrete tax benefit of $37.7 million related to the NOL carryback provisions available under the CARES Act legislation corresponding to anticipated tax refunds applicable to taxable years 2013, 2014, 2015, and 2017. If any tax refund is received that is more than $5.0 million in a single year, along with other civil settlements, damages awards, and tax refunds, the Company has agreed to pay 65% of all such amounts received to accelerate payments to the government in connection with our government settlement (see Note 11). During the year ended December 31, 2020, we received a full tax refund related to the NOL carryback provisions available under the CARES Act. There is no additional carryback for the year ended December 31, 2021.

Note 15. Net Loss Per Share

Net loss per share is computed by dividing net loss attributable to common stockholders for the period by the weighted average number of common shares outstanding during the period. Diluted loss per share reflects the additional dilution from potential issuances of common stock, such as stock issuable pursuant to the exercise of stock options, as well as from the possible conversion of the Company's preferred stock and exercise of the outstanding warrant. The treasury stock and if-converted methods are used to calculate the potential dilutive effect of these common stock equivalents. However, potentially dilutive shares are excluded from the computation of diluted loss per share when their effect is antidilutive. Due to the Company reporting a net loss attributable to common stockholders for all periods presented, all potentially dilutive securities were antidilutive and have been excluded from the computation of diluted loss per share.

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

	Year Ended December 31,	
	2021	2020
Stock options to purchase common stock	8,640,951	4,268,945
Restricted stock units	3,879,110	1,468,765
Common stock warrant	26,183,830	400,160
Common stock issuable upon conversion of Convertible Notes	40,588,672	51,529,036
Total	79,292,563	57,666,906

Note 16. 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 $2.4 million and $2.9 million for the years ended December 31, 2021 and 2020, respectively.

Note 17. Quarterly Financial Data (Unaudited)

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

	Three Months Ended			
2021	**December 31,**	**September 30,**	**June 30,**	**March 31,**
Revenues	$ 435	$ 182	$ 463	$ 167
Loss from continuing operations	(82,787)	(36,874)	(41,400)	(17,460)
Loss from discontinued operations	(10,087)	(6,870)	(37,131)	(14,803)
Net loss	(92,874)	(43,744)	(78,531)	(32,263)
Net loss attributable to common stockholders	(92,874)	(43,744)	(78,531)	(32,263)
Net loss per share, basic and diluted	(0.56)	(0.46)	(1.23)	(0.56)
2020				
Revenues	$ 106	$ 56	$ —	$ —
Loss from continuing operations	(52,526)	(33,142)	(32,627)	13,209
Loss from discontinued operations	(23,002)	(13,923)	(20,156)	(30,361)
Net loss	(75,528)	(47,065)	(52,783)	(17,152)
Net loss attributable to common stockholders	(75,528)	(47,065)	(53,051)	(17,152)
Net loss per share, basic and diluted	(1.53)	(1.01)	(6.11)	(3.43)

Note 18. Subsequent Events

From January 1, 2022 through February 9, 2022, the Company received net proceeds of $3.6 million, after deducting commissions and other offering expenses, from the sale of 2,130,327 shares under the ATM Sale Agreement. The Company sold such shares at a weighted average purchase price of $1.76 per share.

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, 2021, 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, 2021 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

As disclosed elsewhere in this Annual Report on Form 10-K, we announced our Strategic Transformation in June 2021 and shut down Progenity laboratory operations by June 30, 2021 and completed the sale of Avero in December 2021. As a result, certain previously existing internal controls over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) are no longer applicable to the Company as of December 31, 2021.

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, 2021, 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, 2021.

Attestation Report of Registered Public Accounting Firm

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

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information required by this item will be contained in our definitive proxy statement to be filed with the SEC on Schedule 14A within 120 days after December 31, 2021, and is incorporated herein by reference, including under the heading "Directors, Executive Officers, and Corporate Governance."

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

Item 11. Executive Compensation.

Information required by this item will be contained in our definitive proxy statement to be filed with the SEC on Schedule 14A within 120 days after December 31, 2021, and is incorporated herein by reference, including under the headings "Executive Compensation" and "Directors, Executive Officers and Corporate Governance."

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

Information required by this item will be contained in our definitive proxy statement to be filed with the SEC on Schedule 14A within 120 days after December 31, 2021, and is incorporated herein by reference, including under the headings "Security Ownership of Certain Beneficial Owners and Management" and "Executive Compensation-Securities Authorized for Issuance Under Equity Compensation Plans."

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

Information required by this item will be contained in our definitive proxy statement to be filed with the SEC on Schedule 14A within 120 days after December 31, 2021, and is incorporated herein by reference, including under the headings "Directors, Executive Officers and Corporate Governance" and "Certain Relationships and Related Party Transactions."

Item 14. Principal Accountant Fees and Services.

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

Information required by this item will be contained in our definitive proxy statement to be filed with the SEC on Schedule 14A within 120 days after December 31, 2021, and is incorporated herein by reference, including under heading "Proposal 2: Ratification of Selection of Independent Registered Public Accounting Firm."

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) 1. FINANCIAL STATEMENTS

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

2. FINANCIAL STATEMENT SCHEDULES

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

3. EXHIBITS

EXHIBIT NO.	DESCRIPTION
3.1	Eighth Amended and Restated Certificate of Incorporation of the registrant (filed with the SEC as Exhibit 3.1 to the registrant's Form 8-K filed on June 26, 2020).
3.2	Amended and Restated Bylaws of the registrant (filed with the SEC as Exhibit 3.2 to the registrant's Form 8-K filed on June 26, 2020).
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	Series B Preferred Stock Purchase Warrant (filed with the SEC as Exhibit 4.2 to the registrant's Form S-1 filed on May 27, 2020).
4.3	First Amendment to Series B Preferred Stock Purchase Warrant (filed with the SEC as Exhibit 4.3 to the registrant's Form S-1 filed on May 27, 2020).
4.4	Second Amendment to Series B Preferred Stock Purchase Warrant (filed with the SEC as Exhibit 4.4 to the registrant's Form S-1 filed on May 27, 2020).
4.5	Fourth Amended and Restated Investors' Rights Agreement, dated as of August 27, 2019, by and among Progenity, Inc. and certain of its stockholders (filed with the SEC as Exhibit 4.5 to the registrant's Form S-1 filed on May 27, 2020).
4.6	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).
4.7	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).
4.8	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).
4.9	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).
4.10	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 registrant's Form 8-K filed on February 25, 2021).
4.12	Description of Securities (filed with the SEC as Exhibit 4.11 to the registrant's Form 10-K filed on March 18, 2021).
4.13	Form of Warrant (filed with the SEC as Exhibit 4.1 to registrant's Form 8-K filed on June 14, 2021).
4.14	Form of Warrant (filed with the SEC as Exhibit 4.1 to registrant's Form 8-K filed on August 23, 2021).
4.15	Form of Pre-Funded Warrant (filed with the SEC as Exhibit 4.2 to registrant's Form 8-K filed on June 14, 2021).
10.1	Form of Indemnification Agreement for directors and executive officers (filed with the SEC as Exhibit 10.1 to the registrant's Form S-1/A filed on June 4, 2020).
10.2+	2011 Incentive Stock Plan (filed with the SEC as Exhibit 10.2 to the registrant's Form S-1 filed on May 27, 2020).
10.3+	Second Amended and Restated 2012 Stock Plan (filed with the SEC as Exhibit 10.3 to the registrant's Form S-1 filed on May 27, 2020).
10.4+	2015 Consultant Stock Plan (filed with the SEC as Exhibit 10.4 to the registrant's Form S-1 filed on May 27, 2020).

10.5+	Third Amended and Restated Progenity, Inc. 2018 Equity Incentive Plan (filed with the SEC as Exhibit 10.5 to the registrant's Form S-1/A filed on June 15, 2020).
10.6+	Fourth Amended and Restated Progenity, Inc. 2018 Equity Incentive Plan dated May 5, 2021 (filed with the SEC as Exhibit 10.2 to the registrant's Form 10-Q filed on August 12, 2021).
10.7+*	2020 Employee Stock Purchase Plan
10.8+	Progenity, Inc. 2021 Inducement Plan (filed with the SEC as Exhibit 10.3 to the registrant's Form 8-K filed on November 9, 2021).
10.9+*	Form of 2021 Inducement Plan Stock Option Grant Notice.
10.10+*	Form of Inducement Plan Stock Option Award Agreement.
10.11+*	Form of Inducement Plan RSU Grant Notice.
10.12+*	Form of 2021 Inducement Plan RSU Award Agreement.
10.13+	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).
10.14+	Offer Letter by and between Progenity, Inc. and Sami Shihabi, dated as of December 13, 2017 (filed with the SEC as Exhibit 10.8 to the registrant's Form S-1 filed on May 27, 2020).
10.15+	Offer Letter by and between Progenity, Inc. and Matt Cooper, dated as of March 20, 2015 (filed with the SEC as Exhibit 10.9 to the registrant's Form S-1 filed on May 27, 2020).
10.16+	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).
10.17+	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)
10.18+	Severance Plan (filed with the SEC as Exhibit 10.14 to the registrant's Form S-1/A filed on June 4, 2020).
10.19#	Supply & Service Agreement by and between Progenity, Inc. and Illumina, Inc. dated as of November 26, 2014, as amended (filed with the SEC as Exhibit 10.15 to the registrant's Form S-1 filed on May 27, 2020).
10.20#	Settlement Agreement by and between Progenity, Inc. and Aetna Health Management, Inc., dated as of November 11, 2019 (filed with the SEC as Exhibit 10.16 to the registrant's Form S-1 filed on May 27, 2020).
10.21#	Settlement and General Release Agreement by and among Progenity, Inc., Connecticut General Life Insurance Company and Cigna Health and Life Insurance Company, dated as of December 5, 2018 (filed with the SEC as Exhibit 10.19 to the registrant's Form S-1 filed on May 27, 2020).
10.22#	Amendment to Settlement Agreement by and between Progenity, Inc. and Aetna Health Management, Inc., dated as of April 29, 2020 (filed with the SEC as Exhibit 10.17 to the registrant's Form S-1 filed on May 27, 2020).
10.23#	Settlement and General Release Agreement by and among Mattison Pathology, LLP d/b/a Avero Diagnostics, Connecticut General Life Insurance Company and Cigna Health and Life Insurance Company, dated as of December 5, 2018 (filed with the SEC as Exhibit 10.20 to the registrant's Form S-1 filed on May 27, 2020).
10.24#	Confidential Settlement Agreement and Mutual Release by and among Progenity, Inc., United HealthCare Services, Inc. and UnitedHealthcare Insurance Company, dated as of September 30, 2019 (filed with the SEC as Exhibit 10.18 to the registrant's Form S-1 filed on May 27, 2020).
10.25	Nominee Agreement, by and among Avero Laboratory Holdings, LLC, a Delaware limited liability company, Mattison Pathology, LLP d/b/a Avero Diagnostics, a Texas limited liability partnership, Thomas R. Mattison, M.D., P.A., Michael T. Mattison, M.D., P.A., Tanner L. Mattison, M.D., P.A., Thomas R. Mattison, M.D., Michael T. Mattison, M.D., and Tanner L. Mattison, M.D., dated as of June 8, 2015 (filed with the SEC as Exhibit 10.25 to the registrant's Form S-1/A filed on June 18, 2020).
10.26	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).
10.27	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).

10.28	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).
10.29	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).
10.30	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).
10.31	Amendment to Settlement Agreement by and between Progenity, Inc. and UnitedHealth Group, dated as of November 19, 2020 (filed with the SEC as Exhibit 10.31 to the registrant's Form S-1 filed on November 30, 2020).
10.32	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).
10.33	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).
10.34	Separation Agreement and General Release, dated September 1, 2021, by and between the registrant and Harry Stylli, Ph.D. (filed with the SEC as Exhibit 10.1 to the registrant's Form 8-K filed on September 1, 2021).
10.35	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).
21.1*	List of subsidiaries.
23.1*	Consent of Independent Registered Public Accounting Firm.
31.1*	Certification of principal executive officer pursuant to Rule 13a-14(A) promulgated under the Securities Exchange Act of 1934.
31.2*	Certification of principal financial officer pursuant to Rule 13a-14(A) promulgated under the Securities Exchange Act of 1934.
32.1†	Certification of principal executive officer and principal financial officer pursuant to 18 U.S.C. Section 1350 and Rule 13a-14(B) promulgated under the Securities Exchange Act of 1934.
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.
\+ Indicates management contract or compensatory plan.
\# Certain confidential portions of this exhibit were omitted by means of marking such portions with asterisks because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.
† Furnished herewith and not deemed to be "filed" for purposes of Section 18 of the Exchange Act, and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act.

Item 16. Form 10-K Summary

None.

SIGNATURES

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

Progenity, Inc.

Date: March 28, 2022

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 Progenity, Inc. to comply with the provisions of the Securities Exchange Act of 1934 and all the requirements of the SEC, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitute, or substitutes, may lawfully do or cause to be done by virtue hereof.

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

Name	Title	Date
/s/ Aditya P. Mohanty **Aditya P. Mohanty**	Chief Executive Officer (principal executive officer)	March 28, 2022
/s/ Eric d'Esparbes **Eric d'Esparbes**	Chief Financial Officer (principal financial and accounting officer)	March 28, 2022
/s/ Jeffrey Alter **Jeffrey Alter**	Director	March 28, 2022
/s/ Jeffrey Ferrell **Jeffrey Ferrell**	Director	March 28, 2022
/s/ Jill Howe **Jill Howe**	Director	March 28, 2022
/s/ Dr. Brian L. Kotzin **Dr. Brian L. Kotzin**	Director	March 28, 2022
/s/ Lynne Powell **Lynne Powell**	Director	March 28, 2022
/s/ Surbhi Sarna **Surbhi Sarna**	Director	March 28, 2022

PROGENITY, INC.

2020 EMPLOYEE STOCK PURCHASE PLAN

Section 1. PURPOSE

The purpose of this Employee Stock Purchase Plan (the "Plan") is to provide an opportunity for Employees of Progenity, Inc., a Delaware corporation ("Sponsor") and its Participating Subsidiaries (collectively Sponsor and its Participating Subsidiaries shall be referred to as the "Company"), to purchase Common Stock of Sponsor and thereby to have an additional incentive to contribute to the prosperity of the Company. It is the intention of the Company that the Plan (excluding any sub-plans thereof except as expressly provided in the terms of such sub-plan) qualify as an "Employee Stock Purchase Plan" under Section 423 of the U.S. Internal Revenue Code of 1986, as amended (the "Code"), and the Plan shall be administered in accordance with this intent. In addition, the Plan authorizes the grant of options pursuant to sub-plans or special rules adopted by the Committee designed to achieve desired tax or other objectives in particular locations outside of the United States or to achieve other business objectives in the determination of the Committee, which sub-plans shall not be required to comply with the requirements of Section 423 of the Code or all of the specific provisions of the Plan, including but not limited to terms relating to eligibility, Offering Periods or Purchase Price.

Section 2. DEFINITIONS

(a) "Applicable Law" shall mean the legal requirements relating to the administration of an employee stock purchase plan under applicable U.S. state corporate laws, U.S. federal and applicable state securities laws, the Code, any stock exchange rules or regulations and the applicable laws of any other country or jurisdiction, as such laws, rules, regulations and requirements shall be in place from time to time.

(b) "Board" shall mean the Board of Directors of Sponsor.

(c) "Code" shall mean the Internal Revenue Code of 1986, as such is amended from time to time, and any reference to a section of the Code shall include any successor provision of the Code.

(d) "Commencement Date" shall mean, with respect to a given Offering Period, the first Trading Day during such Offering Period.

(e) "Committee" shall mean the Compensation Committee of the Board or the officer, officers or committee appointed by the Compensation Committee in accordance with Section 15 of the Plan (to the extent of the duties and responsibilities delegated by the Compensation Committee of the Board).

(f) "Common Stock" shall mean the common stock of Sponsor, par value $0.001 per share, or any securities into which such Common Stock may be converted.

(g) "Compensation" shall mean the total cash compensation paid by the Company to an Employee with respect to an Offering Period, including salary, commissions, overtime, shift differentials and all or any portion of any item of compensation considered by the Company to be part of the Employee's regular earnings, but excluding items not considered by the Company to be part of the Employee's regular earnings. Items excluded from the definition of "Compensation" include but are not limited to such items as relocation bonuses, MBO bonuses and similar incentive bonuses, expense reimbursements, certain bonuses paid in connection with mergers and acquisitions, author incentives, recruitment and referral bonuses, foreign service premiums, differentials and allowances, imputed income pursuant to Section 79 of the Code, income realized as a result of participation in any stock option, restricted stock, restricted stock unit, stock purchase or similar equity plan maintained by Sponsor or a Participating Subsidiary, tuition and other reimbursements, taxable fringe benefits and severance benefits. The Committee shall have the authority to determine and approve all forms of pay to be included in the definition of Compensation and may change the definition on a prospective basis.

(h) "Effective Date" shall mean the date of the underwriting agreement between the Company and the underwriters(s) managing the initial public offering of the Common Stock, pursuant to which the Common Stock is priced for the initial public offering of the Company's securities pursuant to a registration statement filed and declared effective pursuant to the Securities Act.

(i) "Employee" shall mean an individual classified as an employee (within the meaning of Code Section 3401(c) and the regulations thereunder) by Sponsor or a Participating Subsidiary on Sponsor's or such Participating Subsidiary's payroll records during the relevant participation period. Notwithstanding the foregoing, no employee of Sponsor or a Participating Subsidiary shall be included within the definition of "Employee" if such person's customary employment is for less than twenty (20) hours per week or

for less than five (5) months per year. Individuals classified as independent contractors, consultants, advisers, or members of the Board are not considered "Employees."

(j) "Enrollment Period" shall mean, with respect to a given Offering Period, that period established by the Committee prior to the commencement of such Offering Period during which Employees may elect to participate in order to purchase Common Stock at the end of that Offering Period in accordance with the terms of this Plan.

(k) "Exchange Act" shall mean the U.S. Securities Exchange Act of 1934, as amended from time to time, and any reference to a section of the Exchange Act shall include any successor provision of the Exchange Act.

(l) "Market Value" on a given date of determination (e.g., a Commencement Date or Purchase Date, as appropriate) means, as of any date, the value of the Common Stock determined as follows:

(i) If the Common Stock is listed on any established stock exchange or traded on any established market, the Market Value of a share of Common Stock as of any date of determination will be, unless otherwise determined by the Board or Committee, the closing sales price for such stock as quoted on such exchange or market (or the exchange or market with the greatest volume of trading in the Common Stock) on the date of determination, as reported in a source the Board or Committee deems reliable.

(ii) Unless otherwise provided by the Board or Committee, if there is no closing sales price for the Common Stock on the date of determination, then the Market Value will be the closing selling price on the last preceding date for which such quotation exists.

(iii) In the absence of such markets for the Common Stock, the Market Value will be determined by the Board or Committee in good faith.

(m) "Offering Period" shall mean a period of no more than twenty-seven (27) months. The Plan shall be implemented by a series of Offering Periods with terms established by the Committee in accordance with the Plan. Once established, the duration and timing of Offering Periods may be changed or modified by the Committee as permitted by the Plan. If the Committee does not establish different rules with respect to an Offering Period, then the duration of an Offering Period shall be twenty-four (24) months and each Offering Period shall consist of four (4) consecutive purchase periods each having a duration of six (6) months (individually, a "Purchase Period"), commencing on the first Trading Day following one Purchase Date and ending with the next Purchase Date, except that the first Purchase Period of any Offering Period will commence on the Commencement Date and end with the next Purchase Date. If the Committee does not establish different rules with respect to the frequency of Offering Periods, a new Offering Period shall commence every six (6) months following the Commencement Date of the previous Offering Period.

(n) "Offering Price" shall mean the Market Value of a share of Common Stock on the Commencement Date for a given Offering Period.

(o) "Participant" shall mean a participant in the Plan as described in Section 5 of the Plan.

(p) "Participating Subsidiary" shall mean a Subsidiary that has been designated by the Committee in its sole discretion as eligible to participate in the Plan with respect to its Employees.

(q) "Plan" shall mean this 2020 Employee Stock Purchase Plan, including any sub-plans or appendices hereto.

(r) "Purchase Date" shall mean, for any Purchase Period, the last Trading Day of such Purchase Period.

(s) "Purchase Period" shall have the meaning set out in Section 2(m).

(t) "Purchase Price" shall have the meaning set out in Section 8(b).

(u) "Securities Act" shall mean the U.S. Securities Act of 1933, as amended, as amended from time to time, and any reference to a section of the Securities Act shall include any successor provision of the Securities Act.

(v) "Stockholder" shall mean a record holder of shares entitled to vote such shares of Common Stock under Sponsor's by-laws.

(w) "Subsidiary" shall mean any entity treated as a corporation (other than Sponsor) in an unbroken chain of corporations beginning with Sponsor, within the meaning of Code Section 424(f), whether or not such corporation now exists or is hereafter organized or acquired by Sponsor or a Subsidiary.

(x) "Trading Day" shall mean a day on which U.S. national stock exchanges are open for trading and the Common Stock is being actively traded on one or more of such markets.

Section 3. ELIGIBILITY

(a) Any Employee employed by Sponsor or by any Participating Subsidiary at the beginning of an Enrollment Period for a given Offering Period shall be eligible to participate in the Plan with respect to such Offering Period and future Offering Periods, provided that the Committee may establish administrative rules requiring that employment commence some minimum period (not to exceed 90 days) prior to an Enrollment Period and/or that customary employment exceed a specified number of hours or period during a calendar year (not to exceed 20 hours per week or 5 months in a calendar year) to be eligible to participate with respect to the associated Offering Period and provided further that an Employee may only participate in one Offering Period at a time. The Committee may also determine that a designated group of highly compensated Employees is ineligible to participate in the Plan so long as the excluded category fits within the definition of "highly compensated employee" in Code Section 414(q). If the Committee does not establish different rules with respect to an Offering Period, the minimum period of employment that must be completed prior to the beginning of an Enrollment Period shall be five (5) working days. No Employee who becomes eligible to participate in the Plan may become a participant in an Offering Period following the Commencement Date of such Offering Period or after the commencement of any minimum period of employment established pursuant to the preceding sentence with respect to such Offering Period.

(b) No Employee may participate in the Plan if immediately after an option is granted the Employee owns or is considered to own (within the meaning of Code Section 424(d)) shares of Common Stock, including Common Stock which the Employee may purchase by conversion of convertible securities or under outstanding options granted by Sponsor or its Subsidiaries, possessing five percent (5%) or more of the total combined voting power or value of all classes of stock of Sponsor or of any of its Subsidiaries. All Employees who participate in the Plan shall have the same rights and privileges under the Plan, except for differences that may be mandated by local law and that are consistent with Code Section 423(b)(5); provided that individuals participating in a sub-plan adopted pursuant to Section 16 hereof which is not designed to qualify under Code Section 423 need not have the same rights and privileges as Employees participating in the Code Section 423 Plan. No Employee may participate in more than one Offering Period at a time.

Section 4. OFFERING PERIODS

The Plan shall be implemented by a series of Offering Periods, which shall possess terms specified by the Committee in accordance with the terms of the Plan. Offering Periods shall continue until the Plan is terminated pursuant to Section 14 hereof. Once established, the Committee shall have the authority to change the frequency and/or duration of Offering Periods (including the Commencement Dates thereof) with respect to future Offering Periods if such change is announced prior to the scheduled occurrence of the Enrollment Period for the first Offering Period to be affected thereafter. If the Committee does not establish different rules with respect to an Offering Period, then the duration of an Offering Period shall be twenty-four (24) months and each Offering Period shall consist of four (4) Purchase Periods commencing on the first Trading Day following one Purchase Date and ending with the next Purchase Date, except that the first Purchase Period of any Offering Period will commence on the Commencement Date and end with the next Purchase Date. If the Committee does not establish different rules with respect to the frequency of Offering Periods, a new Offering Period shall commence every six (6) months following the Commencement Date of the previous Offering Period.

Section 5. PARTICIPATION

(a) An Employee who is eligible to participate in the Plan in accordance with its terms at the beginning of an Enrollment Period for an Offering Period and elects to participate in such Offering Period shall automatically receive an option in accordance with Section 8(a). Such an Employee shall become a Participant by completing and submitting, on or before the date prescribed by the Committee with respect to a given Offering Period, a completed payroll deduction authorization and Plan enrollment form provided by Sponsor or its Participating Subsidiaries or by following an electronic or other enrollment process as prescribed by the Committee. An eligible Employee may authorize payroll deductions at the rate of any whole percentage of the Employee's Compensation, not to be less than one percent (1.0%) and not to exceed fifteen percent (15.0%) (or such other percentages as the Committee may establish from time to time before an Enrollment Period for a future Offering Period) of such Employee's Compensation on each payday during the Offering Period. All payroll deductions will be held in a general corporate account or a trust account. No interest shall be paid or credited to the Participant with respect to such payroll deductions. Sponsor shall maintain or cause to be maintained a separate bookkeeping account for each Participant under the Plan and the amount of each Participant's payroll deductions shall be credited to such account. A Participant may not make any additional payments into such account, unless payroll deductions are prohibited under

Applicable Law, in which case the provisions of Section 5(b) of the Plan shall apply. A Participant will automatically participate in each Offering Period commencing immediately following the last day of the prior Offering Period unless he or she withdraws or is deemed to withdraw from this Plan or terminates further participation in the Offering Period. A Participant is not required to file any additional agreement in order to continue participation in this Plan following the end of an Offering Period in which the Participant is then participating.

(b) Notwithstanding any other provisions of the Plan to the contrary, in locations where local law prohibits payroll deductions, an eligible Employee may elect to participate through contributions to his or her account under the Plan in a form acceptable to the Committee. In such event, any such Employees shall be deemed to be participating in a sub-plan, unless the Committee otherwise expressly provides that such Employees shall be treated as participating in the Plan.

(c) Under procedures and at times established by the Committee, a Participant may withdraw from the Plan during an Offering Period, by completing and filing a new payroll deduction authorization and Plan enrollment form with the Company or by following electronic or other procedures prescribed by the Committee. If a Participant withdraws from the Plan during an Offering Period, his or her accumulated payroll deductions will be refunded to the Participant without interest, his or her right to participate in the current Offering Period will be automatically terminated and no further payroll deductions for the purchase of Common Stock will be made during the Offering Period. Any Participant who wishes to withdraw from the Plan during an Offering Period, must complete the withdrawal procedures prescribed by the Committee, subject to any rules established by the Committee, or changes to such rules, pertaining to the timing of withdrawals, limiting the frequency with which Participants may withdraw and re-enroll in the Plan, or imposing a waiting period on Participants wishing to re-enroll following withdrawal.

(d) Notwithstanding the preceding provisions of this Section 5, if the Market Value on the day of commencement of a Purchase Period is less than the Offering Price for such Offering Period, each Participant who purchased shares of Common Stock in the preceding Purchase Period of such Offering Period shall automatically be withdrawn from that original Offering Period and re-enrolled in the next twenty four-month Offering Period.

(e) A Participant may not increase his or her rate of contribution through payroll deductions or otherwise during a given Offering Period. A Participant may decrease his or her rate of contribution through payroll deductions during a given Offering Period during such times specified by the Committee by filing a new payroll deduction authorization and Plan enrollment form or by following electronic or other procedures prescribed by the Committee. If a Participant has not followed such procedures to change the rate of contribution, the rate of contribution shall continue at the originally elected rate throughout the Offering Period and future Offering Periods. Notwithstanding the foregoing, to the extent necessary to comply with Section 423(b)(8) of the Code for a given calendar year, the Committee may reduce a Participant's payroll deductions to zero percent (0%) at any time during an Offering Period scheduled to end during such calendar year. Payroll deductions shall re-commence at the rate provided in such Participant's enrollment form at the beginning of the first Offering Period which is scheduled to end in the following calendar year, unless terminated by the Participant as provided in Section 5(c).

Section 6. TERMINATION OF EMPLOYMENT

In the event any Participant terminates employment with Sponsor and its Participating Subsidiaries for any reason (including death) prior to the expiration of an Offering Period, the Participant's participation in the Plan shall terminate and all amounts credited to the Participant's account shall be paid to the Participant or, in the case of death, to the Participant's heirs or estate, without interest. Whether a termination of employment has occurred shall be determined by the Committee. The Committee may provide that if a Participant's termination of employment occurs within a certain period of time as specified by the Committee (not to exceed 30 days) prior to a Purchase Date during an Offering Period then in progress, his or her option for the purchase of shares of Common Stock will be exercised on such Purchase Date in accordance with Section 9 as if such Participant were still employed by the Company. If the Committee does not establish different rules with respect to an Offering Period, then a Participant must be employed on a Purchase Date in order for his or her option to be exercised on such Purchase Date. The Committee may also establish rules regarding when leaves of absence or changes of employment status will be considered to be a termination of employment, including rules regarding transfer of employment among Participating Subsidiaries, Subsidiaries and Sponsor, and the Committee may establish termination-of-employment procedures for the Plan that are independent of similar rules established under other benefit plans of Sponsor and its Subsidiaries; provided that such procedures are not in conflict with the requirements of Section 423 of the Code.

Section 7. STOCK

(a) Subject to adjustment as set forth in Section 11 and the "evergreen" provision in this Section 7, the aggregate number of shares of Common Stock which may be issued pursuant to the Plan shall not exceed Five Hundred Ten Thousand (510,000) shares (the "Share Reserve"). The Share Reserve will automatically increase on January 1st of each calendar year, for ten years, commencing on January 1 of the calendar year following the Effective Date, in an amount equal to the lesser of (i) one percent (1%) of the total number of shares of Common Stock outstanding on December 31st of the preceding calendar year or (ii) Six Hundred Thousand

(600,000) shares (subject to adjustment as set forth in Section 11). The Board may act prior to January 1st of a given year to provide that there will be no January 1st increase of the Share Reserve for such year or that the increase in the Share Reserve for such year will be a smaller number of shares of Common Stock than would otherwise occur pursuant to the preceding sentence.

(b) Notwithstanding the above, subject to adjustment as set forth in Section 11, the maximum number of shares of Common Stock that may be issued to any Employee in a given Offering Period shall be that number of shares of Common Stock that could be purchased on the Commencement Date of such Offering Period with Fifty-Thousand Dollars (USD$50,000), taking into consideration any discount from the Offering Period pursuant to Section 8(b). The Committee may change this limitation at any time on a prospective basis to apply to future Offering Periods. If, on a given Purchase Date, the number of shares with respect to which options are to be exercised exceeds either maximum, the Committee shall make, as applicable, such adjustment or pro rata allocation of the shares remaining available for purchase in as uniform a manner as shall be practicable and as it shall determine to be equitable.

Section 8. OFFERING

(a) On the Commencement Date relating to each Offering Period, each eligible Employee, whether or not such Employee has elected to participate as provided in Section 5(a), shall be granted an option to purchase that number of whole shares of Common Stock (as adjusted as set forth in Section 11) not to exceed that number of shares of Common Stock determined in accordance with the last paragraph of Section 7 above (or such lower number of shares as determined by the Committee), which may be purchased with the payroll deductions accumulated on behalf of such Employee during each Offering Period at the purchase price specified in Section 8(b) below, subject to the additional limitation that no Employee participating in the Plan shall be granted an option to purchase Common Stock under the Plan if such option would permit his or her rights to purchase stock under all employee stock purchase plans (described in Section 423 of the Code) of Sponsor and its Subsidiaries to accrue at a rate which exceeds Twenty-Five Thousand Dollars (USD$25,000) of the Market Value of such Common Stock (determined at the time such option is granted) for each calendar year in which such option is outstanding at any time. For purposes of the Plan, an option is "granted" on a Participant's Commencement Date. An option will expire upon the earliest to occur of (i) the termination of a Participant's participation in the Plan or such Offering Period, (ii) the beginning of a subsequent Offering Period in which such Participant is participating, or (iii) the termination of the Offering Period. For avoidance of doubt, if an option is granted to an Employee who is not a Participant in such Offering Period, that option shall expire upon the Commencement Date with any right or ability of such Employee to exercise the option. This Section 8(a) shall be interpreted so as to comply with Code Section 423(b)(8).

(b) The Purchase Price under each option shall be with respect to each Purchase Period in an Offering Period the lower of (i) a percentage (not less than eighty-five percent (85%)) ("Designated Percentage") of the Offering Price, or (ii) the Designated Percentage of the Market Value of a share of Common Stock on the Purchase Date on which the Common Stock is purchased; provided that the Purchase Price may be adjusted by the Committee pursuant to Sections 11 or 12 in accordance with Section 424(a) of the Code. For a given Offering Period, the Designated Percentage shall be established no later than the beginning of the Enrollment Period for such Offering Period. The Committee may change the Designated Percentage with respect to any future Offering Period, but not to below eighty-five percent (85%), and the Committee may determine with respect to any prospective Offering Period that the Purchase Price shall be the Designated Percentage of the Market Value of a share of the Common Stock solely on each Purchase Date. If the Committee does not establish the Designated Percentage prior to the beginning of the Enrollment Period for a given Offering Period, the Designated Percentage for such Offering Period shall be eighty-five percent (85%).

Section 9. PURCHASE OF STOCK

Unless a Participant withdraws from the Plan as provided in Section 5(c), terminates employment prior to the end of an Offering Period as provided in Section 6, or except as provided in Sections 7, 12 or 14(b), upon each Purchase Date in the Offering Period, a Participant's option shall be exercised automatically for the purchase of that number of whole shares of Common Stock which the accumulated payroll deductions credited to the Participant's account at that time shall purchase at the applicable price specified in Section 8(b) in accordance with the terms of the Plan, including Section 7. If a Participant's contributions are collected in a currency other than U.S. Dollars, then unless otherwise provided by the Committee with respect to an Offering Period, such contributions shall be converted into U.S. Dollars using an exchange rate prevailing on the Purchase Date as selected in the reasonable determination of the Sponsor. Notwithstanding the foregoing, Sponsor or its Participating Subsidiary may make such provisions and take such action as it deems necessary or appropriate for the withholding of taxes and/or social insurance and/or other amounts which Sponsor or its Participating Subsidiary determines is required by Applicable Law. Each Participant, however, shall be responsible for payment of all individual tax liabilities arising under the Plan. The shares of Common Stock purchased upon exercise of an option hereunder shall be considered for tax purposes to be sold to the Participant on the Purchase Date. A Participant's option to purchase shares of Common Stock hereunder is exercisable only by him or her.

Section 10. PAYMENT AND DELIVERY

Within an administratively reasonable period of time after the exercise of an option, Sponsor shall deliver or cause to have delivered to the Participant a record of the Common Stock purchased and the balance of any amount of payroll deductions credited to the Participant's account not used for the purchase of Common Stock, except as specified below. The Committee may permit or require that shares be deposited directly with a broker designated by the Committee or to a designated agent of the Company, and the Committee may utilize electronic or automated methods of share transfer. The Committee may require that shares be retained with such broker or agent for a designated period of time and/or may establish other procedures to permit tracking of disqualifying dispositions of such shares. Sponsor or its Participating Subsidiary shall retain the amount of payroll deductions used to purchase Common Stock as full payment for the Common Stock and the Common Stock shall then be fully paid and non-assessable. No Participant shall have any voting, dividend, or other Stockholder rights with respect to shares subject to any option granted under the Plan until the shares subject to the option have been purchased and delivered to the Participant as provided in this Section 10. Following the last Purchase Date in an Offering Period, the Committee may in its discretion direct Sponsor to retain in a Participant's account for a subsequent Offering Period any payroll deductions which are not sufficient to purchase a whole share of Common Stock or return such amount to the Participant. Any other amounts left over in a Participant's account after the final Purchase Date in each Offering Period shall be returned to the Participant. If the Committee does not establish different rules with respect to an Offering Period, then all amounts left over in a Participant's account after the final Purchase Date of such Offering Period shall be returned to the Participant.

Section 11. RECAPITALIZATION

Subject to any required action by the Stockholders of Sponsor, if there is any change in the outstanding shares of Common Stock or other securities of Sponsor because of a merger, consolidation, spin-off, reorganization, recapitalization, dividend in property other than cash, extraordinary dividend whether in cash and/or other property, stock split, reverse stock split, stock dividend, liquidating dividend, combination or reclassification of the Common Stock or other securities (including any such change in the number of shares of Common Stock or other securities effected in connection with a change in domicile of Sponsor), or any other increase or decrease in the number of shares of Common Stock or other securities effected without receipt of consideration by Sponsor, provided that conversion of any convertible securities of Sponsor shall not be deemed to have been "effected without receipt of consideration," the type and number of securities covered by each option under the Plan which has not yet been exercised, the type and number of securities which have been authorized and remain available for issuance under the Plan, the maximum number of shares that may be added to the Plan in accordance with Section 7(a)(ii), as well as the maximum number of securities which may be purchased by a Participant in an Offering Period, and the price per share covered by each option under the Plan which has not yet been exercised, shall be appropriately and proportionally adjusted by the Board, and the Board shall take any further actions which, in the exercise of its discretion, may be necessary or appropriate under the circumstances. The Board's determinations under this Section 11 shall be conclusive and binding on all parties.

Section 12. MERGER, LIQUIDATION, OTHER CORPORATE TRANSACTIONS

(a) In the event of the proposed liquidation or dissolution of Sponsor, each Offering Period will terminate immediately prior to the consummation of such proposed transaction, unless otherwise provided by the Board in its sole discretion, and all outstanding options shall automatically terminate and the amounts of all payroll deductions will be refunded without interest to the Participants.

(b) In the event of a proposed sale of all or substantially all of the assets of Sponsor, or the merger or consolidation or similar combination of Sponsor with or into another entity, then in the sole discretion of the Board, (1) each option shall be assumed or an equivalent option shall be substituted by the successor corporation or parent or subsidiary of such successor entity, (2) on a date established by the Board on or before the date of consummation of such merger, consolidation, combination or sale, such date shall be treated as the final Purchase Date of each Offering Period, and all outstanding options shall be exercised on such date, (3) all outstanding options shall terminate and the accumulated payroll deductions will be refunded without interest to the Participants, or (4) outstanding options shall continue unchanged.

Section 13. TRANSFERABILITY

Neither payroll deductions credited to a Participant's bookkeeping account nor any rights to exercise an option or to receive shares of Common Stock under the Plan may be voluntarily or involuntarily assigned, transferred, pledged, or otherwise disposed of in any way, and any attempted assignment, transfer, pledge, or other disposition shall be null and void and without effect. If a Participant in any manner attempts to transfer, assign or otherwise encumber his or her rights or interests under the Plan, other than as permitted by the Code, such act shall be treated as an election by the Participant to discontinue participation in the Plan pursuant to Section 5(c).

Section 14. AMENDMENT OR TERMINATION OF THE PLAN

(a) The Plan shall continue from the Effective Date until the time that the Plan is terminated in accordance with Section 14(b).

(b) The Board or the Committee may, in its sole discretion, insofar as permitted by law, terminate or suspend the Plan, or revise or amend it in any respect whatsoever, except that, without approval of the Stockholders, no such revision or amendment shall increase the number of shares subject to the Plan, other than an adjustment under Section 11 of the Plan, or make other changes for which Stockholder approval is required under Applicable Law. Upon a termination or suspension of the Plan, the Board may in its discretion (i) return without interest, the payroll deductions credited to Participants' accounts to such Participants or (ii) set an earlier final Purchase Date with respect to each Offering Period then in progress.

Section 15. ADMINISTRATION

(a) The Board has appointed the Compensation Committee of the Board to administer the Plan (the "Committee"), who will serve for such period of time as the Board may specify and whom the Board may remove at any time. The Committee will have the authority and responsibility for the day-to-day administration of the Plan, the authority and responsibility specifically provided in this Plan and any additional duty, responsibility and authority delegated to the Committee by the Board, which may include any of the functions assigned to the Board in this Plan. The Committee may delegate to a sub-committee and/or to officers or employees of Sponsor the day-to-day administration of the Plan. The Committee shall have full power and authority to adopt, amend and rescind any rules and regulations which it deems desirable and appropriate for the proper administration of the Plan, to construe and interpret the provisions and supervise the administration of the Plan, to make factual determinations relevant to Plan entitlements and to take all action in connection with administration of the Plan as it deems necessary or advisable, consistent with the delegation from the Board. Decisions of the Committee shall be final and binding upon all Participants. Any decision reduced to writing and signed by a majority of the members of the Committee shall be fully effective as if it had been made at a meeting of the Committee duly held. The Company shall pay all expenses incurred in the administration of the Plan.

(b) In addition to such other rights of indemnification as they may have as members of the Board or officers or employees of the Company, members of the Board and of the Committee and their delegates shall be indemnified by the Company against all reasonable expenses, including attorneys' fees, actually and necessarily incurred in connection with the defense of any action, suit or proceeding, or in connection with any appeal therein, to which they or any of them may be a party by reason of any action taken or failure to act under or in connection with the Plan, or any right granted under the Plan, and against all amounts paid by them in settlement thereof (provided such settlement is approved by independent legal counsel selected by the Sponsor) or paid by them in satisfaction of a judgment in any such action, suit or proceeding, except in relation to matters as to which it shall be adjudged in such action, suit or proceeding that such person is liable for gross negligence, bad faith or intentional misconduct in duties; provided, however, that within sixty (60) days after the institution of such action, suit or proceeding, such person shall offer to the Company, in writing, the opportunity at its own expense to handle and defend the same.

Section 16. COMMITTEE RULES FOR JURISDICTIONS OTHER THAN THE UNITED STATES

The Committee may adopt rules or procedures relating to the operation and administration of the Plan to accommodate the specific requirements of the laws and procedures of jurisdictions outside of the United States. Without limiting the generality of the foregoing, the Committee is specifically authorized to adopt rules and procedures regarding handling of payroll deductions or other contributions by Participants, payment of interest, conversion of local currency, data privacy security, payroll tax, withholding procedures and handling of stock certificates which vary with local requirements; however, if such varying provisions are not in accordance with the provisions of Section 423(b) of the Code, including but not limited to the requirement of Section 423(b)(5) of the Code that all options granted under the Plan shall have the same rights and privileges unless otherwise provided under the Code and the regulations promulgated thereunder, then the individuals affected by such varying provisions shall be deemed to be participating under a sub-plan and not in the Plan. The Committee may also adopt sub-plans applicable to particular Subsidiaries or locations, which sub-plans may be designed to be outside the scope of Code Section 423 and shall be deemed to be outside the scope of Code Section 423 unless the terms of the sub-plan provide to the contrary. The rules of such sub-plans may take precedence over other provisions of this Plan, with the exception of Section 7, but unless otherwise superseded by the terms of such sub-plan, the provisions of this Plan shall govern the operation of such sub-plan. The Committee shall not be required to obtain the approval of the Stockholders prior to the adoption, amendment or termination of any sub-plan unless required by the laws of the jurisdiction in which Employees participating in the sub-plan are located.

Section 17. SECURITIES LAWS REQUIREMENTS

(a) No option granted under the Plan may be exercised to any extent unless the shares to be issued upon such exercise under the Plan are covered by an effective registration statement pursuant to the Securities Act and the Plan is in material compliance with all applicable provisions of any applicable national, regional, state, local or other jurisdiction, including, without limitation, the Securities Act, the Exchange Act, the rules and regulations promulgated thereunder, applicable state and foreign securities laws and the requirements of any stock exchange upon which the Shares may then be listed, subject to the approval of counsel for the Company with respect to such compliance. If on a Purchase Date in any Offering Period hereunder, the Plan is not so registered or in such compliance, options granted under the Plan which are not in material compliance shall not be exercised on such Purchase Date, and

the Purchase Date shall be delayed until the Plan is subject to such an effective registration statement and such compliance, except that each Purchase Date shall not be delayed more than twelve (12) months and the final Purchase Date shall in no event be more than twenty-seven (27) months from the Commencement Date relating to such Offering Period. If, on the Purchase Date of any offering hereunder, as delayed to the maximum extent permissible, the Plan is not registered and in such compliance, options granted under the Plan which are not in material compliance shall not be exercised and all payroll deductions accumulated during the Offering Period (reduced to the extent, if any, that such deductions have been used to acquire shares of Common Stock) shall be returned to the Participants, without interest. The provisions of this Section 17 shall comply with the requirements of Section 423(b)(5) of the Code to the extent applicable.

(b) As a condition to the exercise of an option, Sponsor may require the person exercising such option to represent and warrant at the time of any such exercise that the Shares are being purchased only for investment and without any present intention to sell or distribute such Shares if, in the opinion of counsel for Sponsor, such a representation is required by any of the aforementioned applicable provisions of law.

Section 18. GOVERNMENTAL REGULATIONS

This Plan and Sponsor's obligation to sell and deliver shares of its stock under the Plan shall be subject to the approval of any governmental authority required in connection with the Plan or the authorization, issuance, sale, or delivery of stock hereunder.

Section 19. NO ENLARGEMENT OF EMPLOYEE RIGHTS

Nothing contained in this Plan shall be deemed to give any Employee or other individual the right to be retained in the employ or service of Sponsor or any Participating Subsidiary or to interfere with the right of Sponsor or Participating Subsidiary to discharge any Employee or other individual at any time, for any reason or no reason, with or without notice.

Section 20. GOVERNING LAW

This Plan shall be governed by applicable laws of the State of Delaware without regard for the conflicts of laws provisions thereof, and other applicable law.

Section 21. EFFECTIVE DATE

This Plan shall be effective on the Effective Date, subject to approval of the Stockholders of Sponsor within twelve (12) months before or after its date of adoption by the Board.

Section 22. REPORTS

Individual accounts shall be maintained for each Participant in the Plan. Statements of account shall be made available to Participants at least annually, which statements shall set forth the amounts of payroll deductions, the Purchase Price, the number of shares of Common Stock purchased and the remaining cash balance, if any.

Section 23. DESIGNATION OF BENEFICIARY FOR OWNED SHARES

With respect to shares of Common Stock purchased by the Participant pursuant to the Plan and held in an account maintained by Sponsor or its assignee on the Participant's behalf, the Participant may be permitted to file a written designation of beneficiary, who is to receive any shares and cash, if any, from the Participant's account under the Plan in the event of such Participant's death subsequent to the end of a Purchase Period but prior to delivery to him or her of such shares and cash. In addition, a Participant may file a written designation of a beneficiary who is to receive any cash from the Participant's account under the Plan in the event of such Participant's death prior to any Purchase Date(s) of an Offering Period. If a Participant is married and the designated beneficiary is not the spouse, spousal consent shall be required for such designation to be effective to the extent required by local law. The Participant (and if required under the preceding sentence, his or her spouse) may change such designation of beneficiary at any time by written notice. Subject to local legal requirements, in the event of a Participant's death, Sponsor or its assignee shall deliver any shares of Common Stock and/or cash to the designated beneficiary. Subject to local law, in the event of the death of a Participant and in the absence of a beneficiary validly designated who is living at the time of such Participant's death, Sponsor shall deliver such shares of Common Stock and/or cash to the executor or administrator of the estate of the Participant, or if no such executor or administrator has been appointed (to the knowledge of Sponsor), Sponsor in its sole discretion, may deliver (or cause its assignee to deliver) such shares of Common Stock and/or cash to the spouse, or to any one or more dependents or relatives of the Participant, or if no spouse, dependent or relative is known to Sponsor, then to such other person as Sponsor may determine. The provisions of this Section 23 shall in no event require Sponsor to violate local law, and Sponsor shall be entitled to take whatever action it reasonably concludes is desirable or appropriate in order to transfer the assets allocated to a deceased Participant's account in compliance with local law.

Section 24. ADDITIONAL RESTRICTIONS OF RULE 16b-3.

The terms and conditions of options granted hereunder to, and the purchase of shares of Common Stock by, persons subject to Section 16 of the Exchange Act shall comply with the applicable provisions of Rule 16b-3. This Plan shall be deemed to contain, and such options shall contain, and the shares of Common Stock issued upon exercise thereof shall be subject to, such additional conditions and restrictions, if any, as may be required by Rule 16b-3 to qualify for the maximum exemption from Section 16 of the Exchange Act with respect to Plan transactions.

Section 25. NOTICES

All notices or other communications by a Participant to Sponsor or the Committee under or in connection with the Plan shall be deemed to have been duly given when received in the form specified by Sponsor or the Committee at the location, or by the person, designated by Sponsor for the receipt thereof.

Exhibit 10.9

PROGENITY, INC.

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

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

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

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

If you have any questions, please contact the Company by e-mail at stockadministration@progenity.com.

Exhibit 10.10

STOCK OPTION AGREEMENT

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

1. **DEFINITIONS AND CONSTRUCTION.**

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

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

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

3. **EXERCISE OF THE OPTION.**

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

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

the Company of such electronic notice by the designated broker and the aggregate Exercise Price.

3.3 **Payment of Exercise Price. Forms of Consideration Authorized.** Except as otherwise provided below, payment of the aggregate Exercise Price for the number of shares of Common Stock for which the Option is being exercised shall be made (i) by cash, check, bank draft or money order payable to the Company, (ii) if established by the Company and permitted by the Company with respect to the Option, pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board or a successor regulation, or a similar rule in a foreign jurisdiction of domicile of the Participant, that, prior to or contemporaneously with the issuance of shares of Common Stock subject to the Option, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the aggregate Exercise Price to the Company from the proceeds of sale of such stock, (iii) if permitted by the Company, by delivery to the Company (either by actual delivery or attestation) of shares of Common Stock, (iv) if permitted by the Company, by a "net exercise" arrangement pursuant to which the Company will reduce the number of shares of Common Stock issuable upon exercise by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price; provided, however, that the Company will accept cash or other payment from the Participant to the extent of any remaining balance of the aggregate exercise price not satisfied by such reduction in the number of whole shares to be issued, (v) in any other form of legal consideration that the Board determines is a benefit to the Company, or (vi) by any combination of the foregoing that is permitted with respect to the Option.

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

3.5 **Beneficial Ownership of Shares; Certificate Registration.** The Participant hereby authorizes the Company, in its sole discretion, to deposit for the benefit of the Participant with any broker selected by the Company, or with the concurrence of the Company, any broker with which the Participant has an account relationship of which the Company has notice any or all shares of Common Stock acquired by the Participant pursuant to the exercise of the Option.

Except as provided by the preceding sentence, a certificate for the shares as to which the Option is exercised shall be registered in the name of the Participant, or, if applicable, in the names of the heirs of the Participant (or for any uncertificated shares, such entry shall be made in book- entry form).

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

4. **TERMINATION OF THE OPTION.**

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

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

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

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

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

(c) **Termination for Cause.** Notwithstanding any other provision of this Option Agreement, if the Participant's Continuous Service is terminated for Cause, the Option will terminate upon the date on which the event giving rise to the termination for Cause first occurred, and the Participant will be prohibited from exercising the Option from and after the date on which the event giving rise to the termination for Cause first occurred (or, if required by law, the date of termination of Continuous Service). If Participant's Continuous Service is suspended pending an investigation of the existence of Cause, all of the Participant's rights under the Option will also be suspended during the investigation period.

(d) **Other Termination of Service.** If the Participant's Continuous

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

5.2 **Extension if Exercise Prevented by Law.** Notwithstanding the foregoing other than termination of Continuous Service for Cause, if the exercise of the Option within the applicable time periods set forth in Section 5.1 is prevented solely because the issuance of shares of Common Stock would violate any provision of applicable securities law, the Option shall remain exercisable until the earlier of (a) the expiration of a total period of three (3) months (that need not be consecutive) after the termination of the Participant's Continuous Service during which the exercise of the Option would not be in violation of such provisions, and (b) the Option Expiration Date. If the sale of any Common Stock received upon exercise of the Option following the termination of the Participant's Continuous Service (other than for Cause) would violate the Company's Insider Trading Policy (the "***Insider Trading Policy***"), and the Company does not waive the potential violation of the policy or otherwise permit the sale, or allow the Participant to surrender shares of Common Stock to the Company in satisfaction of any exercise price and/or any withholding obligations, then the Option will terminate on the earlier of (i) the expiration of a period of months (that need not be consecutive) equal to the applicable post-termination exercise period after the termination of the Participant's Continuous Service during which the sale of the Common Stock received upon exercise of the Option would not be in violation of the Insider Trading Policy or (ii) the Option Expiration Date.

6. **LEGENDS.**

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

7. **MISCELLANEOUS PROVISIONS.**

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

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

7.3 **Delivery of Documents and Notices.** Any document relating to participation in the Plan, or any notice required or permitted hereunder shall be given in writing and shall be

deemed effectively given upon personal delivery or electronic delivery at the e-mail address, if any, provided by the Company or the Participant to the other party, or, upon deposit in the U.S. Post Office or foreign postal service, by registered or certified mail, or with a nationally recognized overnight courier service with postage and fees prepaid, addressed to the other party at the address of such party set forth in the Grant Notice or at such other address as such party may designate in writing from time to time to the other party. If the Participant does not affirmatively designate a different e-mail address and/or physical address, the Company may use the Participant's Company e-mail address and may rely upon the use of the most recent address for the Participant in the Company's books and records.

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

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

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

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

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

Exhibit 10.11

PROGENITY, INC.

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

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

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

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

If you have any questions, please contact the Company by email at stockadministration@progenity.com.

1 : The number of shares subject to the RSU award is calculated by dividing the aggregate dollar value of the award by the 30-day trailing average of the company's closing stock price, up to and including the date of grant.

RESTRICTED STOCK UNIT AGREEMENT

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

1. **DEFINITIONS AND CONSTRUCTION.**

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

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

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

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

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

3.2 **Change in Control.** Upon a Change in Control that occurs while any portion of the RSU Award remains unvested, the RSU Award shall be assumed or an equivalent award substituted by the successor corporation (or a parent thereof) (the "***Acquiror***") and such award shall continue to be subject to the same vesting terms provided under the Grant Notice and this Agreement;

provided, that the Participant shall be eligible to receive 100% of the shares of Common Stock then subject to the RSU Award if the Acquiror does not either assume the RSU Award or substitute an equivalent award for the RSU Award and the Board does not take other action provided for under Section 9(c) of the Plan.

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

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

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

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

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

(b) In the event that the holders of shares of Common Stock receive as a

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

4. **EFFECT OF TERMINATION OF CONTINUOUS SERVICE.**

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

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

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

5. **PROHIBITION ON TRANSFER**

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

6. **LEGENDS AND PARTICIPANT REPRESENTATIONS.**

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

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

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

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

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

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

7. MISCELLANEOUS PROVISIONS.

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

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

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

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

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

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

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

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

Exhibit 21.1

Subsidiaries of Progenity, Inc.

SPX3, Inc., a Delaware corporation

Molecular Diagnostic Health Sciences, LLC, a Delaware limited liability company

Progenity Holding Company, Inc., a Delaware corporation

Avero Laboratory Holdings LLC, a Delaware limited liability company

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

Progenity Pty Ltd, an Australian company

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the registration statement (No. 333-246343) on Form S-8, in the registration statement (No. 333-258301) on Form S-3, and in the registration statements (Nos. 333-254471 and 333-257187) on Form S-1 of our report dated March 28, 2022, with respect to the consolidated financial statements of Progenity, Inc. Our report contains an explanatory paragraph that states that the Company has suffered recurring losses from operations and has an accumulated deficit that raises substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of that uncertainty.

/s/ KPMG LLP

San Diego, California
March 28, 2022

Exhibit 31.1

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

I, Aditya P. Mohanty, certify that:

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

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

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

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

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 28, 2022

By: /s/ Aditya P. Mohanty
Aditya P. Mohanty, Chief Executive Officer
(principal executive officer)

Exhibit 31.2

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

I, Eric d'Esparbes, certify that:

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

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

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

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

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 28, 2022

By: /s/ Eric d'Esparbes

Eric d'Esparbes, Executive Vice President and Chief Financial Officer
(principal financial and accounting officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Progenity, Inc. (the "Company") for the year ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 28, 2022

By: /s/ Aditya P. Mohanty
Aditya P. Mohanty, Chief Executive Officer
(principal executive officer)

By: /s/ Eric d'Esparbes
Eric d'Esparbes, Executive Vice President and Chief Financial Officer
(principal financial and accounting officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. §1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Note: A signed original of this written statement required by §906 has been provided to Progenity, Inc. and will be retained by Progenity, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.