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, 2020

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 200, 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 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, 2020, was approximately $95,918,409.

The number of shares of Registrant's Common Stock outstanding as of February 28, 2021 was 60,251,833.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or 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 recent and ongoing COVID-19 pandemic and associated shelter-in-place orders;
- our ability to develop and commercialize molecular testing products as well as innovate in the field of precision medicine;
- the size and growth potential of the markets for our products and product candidates, and our ability to serve those markets;
- the rate and degree of market acceptance and clinical utility of our products and product candidates, if approved;
- coverage and reimbursement for our products and product candidates;
- the performance of third parties in connection with the development of our products and product candidates, including third-party suppliers;
- regulatory developments in the United States and foreign countries;
- our ability to obtain and maintain regulatory approval or clearance of our products and product candidates on expected timelines;
- our ability to improve and enhance our current products and product candidates;
- our plans to research, develop, and commercialize new products and product candidates;
- the development, regulatory approval, efficacy, and commercialization of competing products;
- the outcome of pending investigations and legal proceedings;
- the loss or retirement of key scientific or management personnel;
- our ability to develop and maintain our corporate infrastructure, including maintaining effective internal control;
- our 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

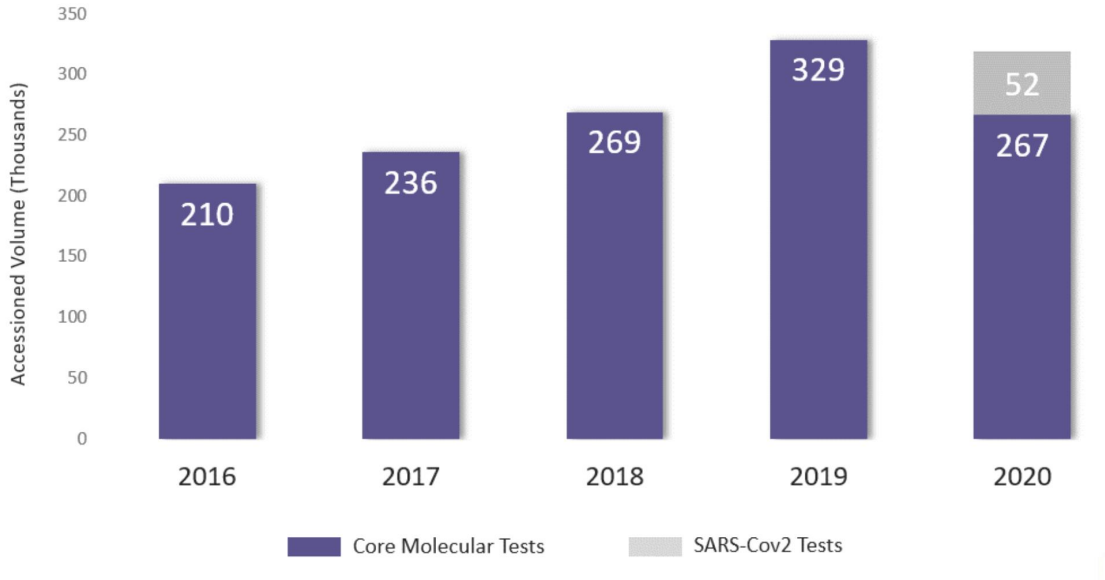
We are a biotechnology company with an established track record of success in developing and commercializing molecular testing products as well as innovating in the field of precision medicine. We believe that we are a market-leading provider of *in vitro* molecular tests designed to improve lives by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

Our internal core competencies, deep research and development pipeline and strategic acquisitions of novel technologies have fueled our innovation in women's health, supporting the development and launch of complementary molecular testing products that inform critical healthcare decision-making across a woman's lifetime.

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

Since our inception, we have accessioned approximately 2.0 million tests in the United States. Beginning in March 2020, we began to observe declines in the volumes of both our molecular tests and the pathology tests conducted by Avero Diagnostics due to the impact of the COVID-19 pandemic and resulting work-from-home policies and other operational limitations mandated by federal, state and local governments. However, we believe our business is resilient and we observed positive signs of recovery in the second half of 2020. While we have implemented and continue to monitor our mitigation strategies to address these limitations, such as supporting patients and physicians virtually and offering COVID-19 PCR testing, there can be no assurance that the rate of decline in our testing volumes will not continue or accelerate in future periods. Our current assessment of the impact of the COVID-19 pandemic is that our NIPT test volumes have proved more resilient than our carrier screening test volumes; however, the comparative impact may continue to change over time.

Test Volume



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

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

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

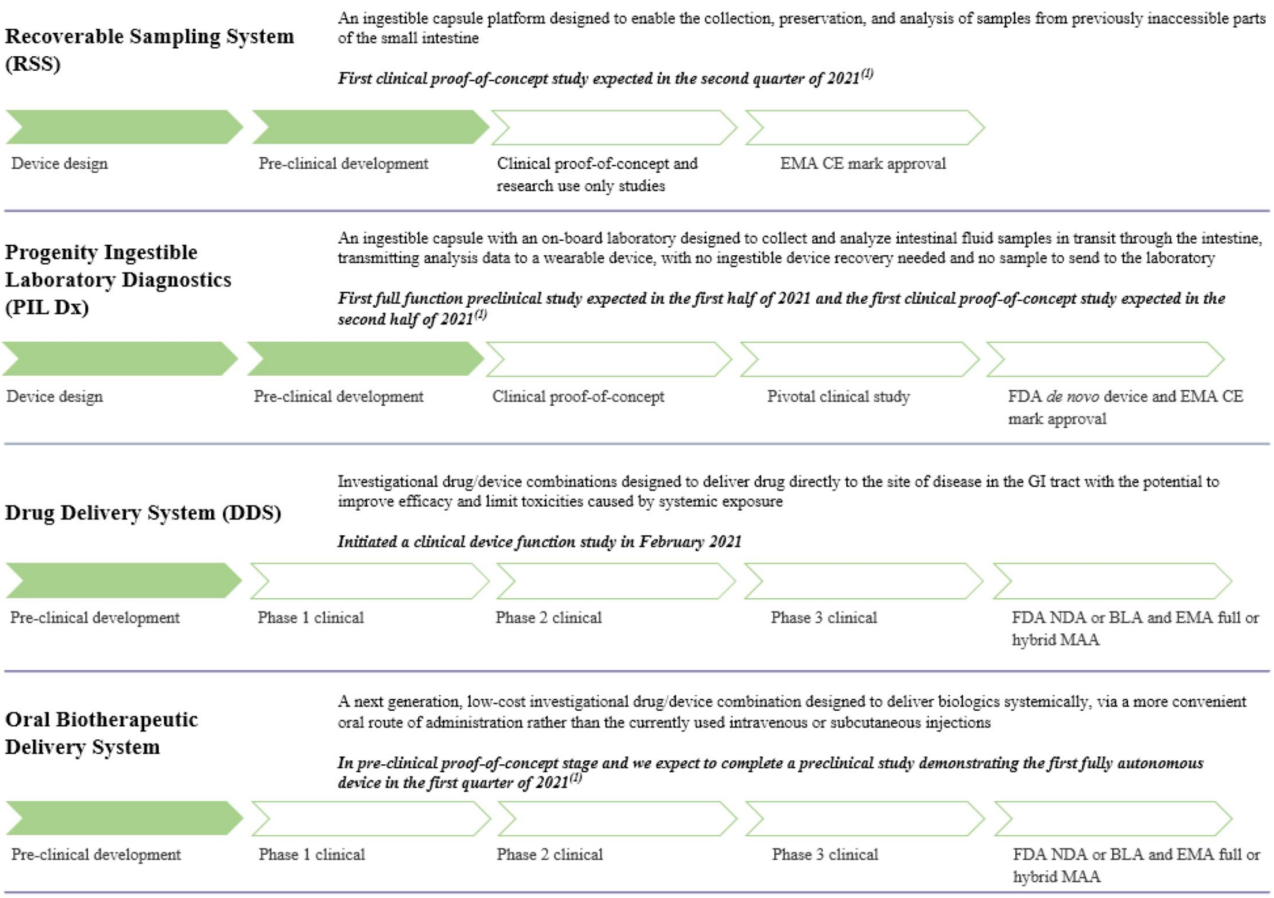
We believe our future success will be driven by continued capture of market share by our molecular testing business and new revenue streams resulting from our diversified product development pipeline, both within and beyond women's health. Our core expertise in complex assay development, bioinformatics,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

Product and Product Candidate Overview

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

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

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



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

Our Strengths

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

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

understand results and our customer support services provide convenient access to board-certified genetic counselors. We believe that these services collectively create substantial value and lead to customer loyalty.

- ***Breadth and depth of R&D capabilities driving breakthrough innovation***. We have built a first class research and development, or R&D, organization capable of harnessing and translating novel technologies into innovative platforms and product solutions as we strive to remain at the forefront of customer needs. Our technical expertise along the product development spectrum includes assay design, bioinformatics, and analytical and clinical validation and enables us to leverage existing knowledge to solve new challenges.
- ***Precision medicine platform targeting a large, underserved market***. We are developing an innovative and potentially scalable product platform that we believe will support the advancement of our precision medicine pipeline. This platform approach is based on an innovative capsule, which we believe could represent a paradigm shift from existing diagnostic and therapeutic approaches. We believe this platform has the potential to address significant unmet medical needs in the GI space, including the challenges in diagnosing, treating, and monitoring diseases without the repeated use of invasive procedures, such as upper GI endoscopies, colonoscopies, and biopsies.
- ***Comprehensive intellectual property portfolio***. We have retained worldwide rights to our internally-developed and acquired molecular testing and precision medicine technologies. We hold the rights to over 600 issued patents and pending patent applications that include claims that are directed to a range of molecular testing and precision medicine-related methods, systems, and compositions surrounding our suite of current and future products. In addition, we believe that our trade secrets and other know-how provide additional barriers to entry.
- ***Proven leadership with industry expertise***. Our senior management team and board of directors consist of veteran biotechnology and molecular testing professionals with deep industry experience. These individuals have extensive experience with numerous well-regarded biotechnology and diagnostic companies. Through their many years of experience, they have developed strong relationships with key thought leaders and medical societies.

Our Strategy

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

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

purposes. We believe our product candidates, if successfully developed and approved or cleared, could become the first precision medicine products to diagnose and treat at the site of the disease within the GI tract. Ultimately, we intend to pursue commercialization of such product candidates ourselves or via strategic partnership.

Our Molecular Tests

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

Our Current Test Portfolio

Innatal Prenatal Aneuploidy Screen

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

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

Table 1: Innatal Prenatal Screen Performance[(1)]

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

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

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

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

Market Opportunity

Numerous medical society guidelines have recognized that all pregnant women, regardless of age, should be offered screening, such as NIPT, for aneuploidy to better identify patients for whom more invasive procedures, such as amniocentesis, are recommended. We believe that guidelines will continue to develop in support of broader prenatal screening, and that provider and payor education will drive increased adoption of NIPT. In August 2020, ACOG issued new practice guidance recommending NIPT screening for all pregnant patients, not only those at higher risk. We believe this substantially increases the likelihood for payors and state Medicaids to expand coverage to the average risk population. We believe this represents a significant market opportunity to expand use of NIPT, and Innatal, in the future. We estimate that the total addressable market for NIPT is approximately $1.5 billion annually in the United States. We estimate that approximately 2 million NIPT were performed in the United States in 2018, of which an estimated 35% were

on high-risk patients (those with characteristics that increase their risk of an aneuploidy pregnancy, such as advanced age of >35 years, abnormal ultrasound, family history, or positive maternal serum screen result), and 65% were on average-risk (general population) patients. We also believe that efforts at expanding payor medical coverage policy to include all patients, regardless of *a priori* risk, would help further expand the covered market to include a larger portion of the approximately four million pregnancies that occur annually in the United States.

Preparent Carrier Test

Our Preparent Carrier Test, launched in 2015, screens for carrier status of hereditary diseases prior to or early in pregnancy. Carrier screening identifies couples at-risk of having a baby with a genetic disease and allows for informed medical management decisions. Our test offers a broad menu of genetic carrier screening tests with high detection rates for a variety of genetic diseases, including cystic fibrosis, spinal muscular atrophy, and fragile X syndrome. We designed the Preparent Carrier Test to assess a couple's risk of passing down any of 200+ serious heritable diseases. This test is designed to meet the guidelines of the American College of Obstetricians and Gynecologists, or ACOG, and the American College of Medical Genetics, or ACMG, using a combination of methods (DNA sequencing, HEXA enzyme analysis, and hemoglobin evaluation) to maximize sensitivity.

In 2017, we expanded the Preparent product portfolio with the launch of the Preparent Exon test in partnership with Baylor Genetics. The Preparent Exon test uses exon sequencing to provide the higher sensitivity desired for reproductive medicine applications. Exon sequencing evaluates all of the coding regions of each gene and can identify both known and novel changes within the genetic code. The Preparent Exon test combines full exon sequencing and select copy number variant, or CNV, analysis. CNV analysis identifies large extra or missing pieces of select genes in which this type of variation, otherwise missed by exon sequencing alone, is a common cause of disease. This test design includes analysis of up to 280+ genes for a more complete evaluation of carrier status, resulting in, on average, ≥95% clinical sensitivity in the general population. Our product portfolio includes four pre-curated panels of 3, 25, 150+, and 280+ genes, designed to fit the needs of different customer segments.

Market Opportunity

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

Riscover Hereditary Cancer Test

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

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

Market Opportunity

At present, we estimate there are over 82 million adults in the United States who are eligible for hereditary cancer screening in accordance with medical guidelines but that fewer than 5% of those adults have been screened. In addition, studies indicate that approximately 24% of women in OB/GYN practices meet NCCN guidelines for hereditary cancer screening, but that less than 15% of such eligible women are tested annually. We believe low penetration of this important market can be attributed to the challenges facing physicians in identifying eligible patients. For example, in a study of genetic testing for hereditary cancer published in the Journal of Clinical Oncology in 2017, the author estimated that more than 90% of unaffected, or asymptomatic, breast cancer susceptibility gene mutation carriers have yet to be identified.

Resura Prenatal Test for Monogenic Disease

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

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

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

Services Supporting our Molecular Tests

Genetic Counseling Services

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

Electronic Medical Record Integration

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

Progenity Partnerships Program

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

Our Research and Development Activities

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

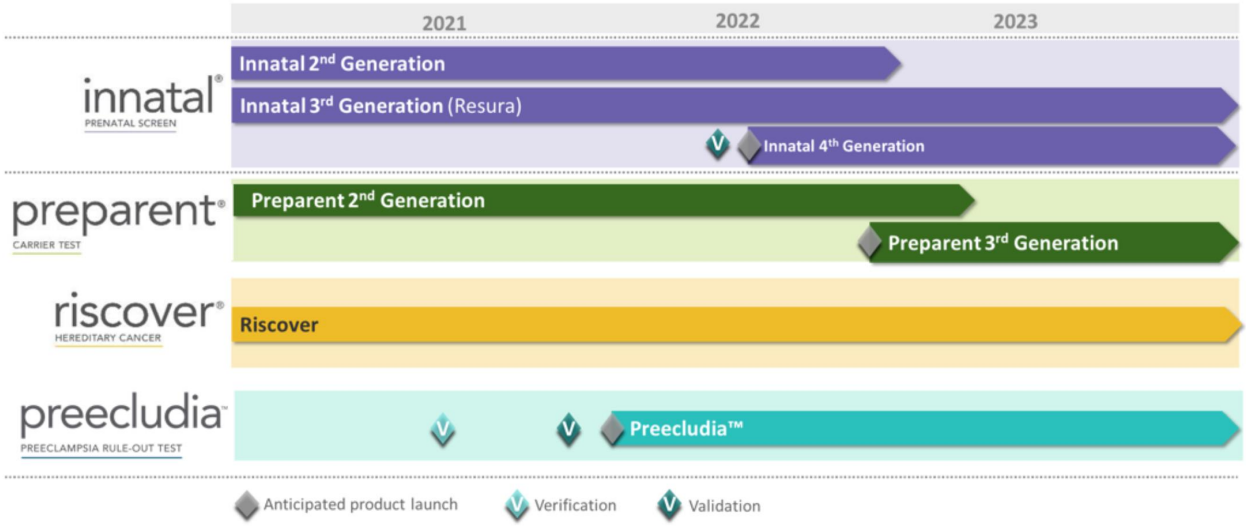
Molecular Tests

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

We have developed Preparent 3rd Generation based on our internally developed hybridization capture platform, which enables efficient and uniform sequencing of genomic regions ranging from a few hundred genes to the whole human exome by selecting, integrating, and optimizing the latest advances in library preparation, probe synthesis, and laboratory automation. The resulting data is interrogated for constitutional small nucleotide variants (1-100 bp) as well as larger copy number and structural variants. We have developed, verified, and validated the platform to support current carrier testing at a subsidiary laboratory and the platform is

optimized, scaled, verified and validated at our Ann Arbor CLIA lab with commercial launch contingent on laboratory software systems build and integration.

Our molecular tests and tests in development include:



Next Generation Innatal Prenatal Screen (Innatal 4th Generation)

We are developing a proprietary single molecule DNA counting assay platform utilizing advanced optics with custom chemistry and molecular biology that we believe will represent a substantial improvement to our existing Innatal platform as a first product application, with simplified and more cost-effective assay workflow resulting in the same high clinical quality and reliability but with a reduction in turnaround time and a substantial reduction in cost of goods sold for our NIPT. We have completed the feasibility assessment for this test and are in the process of completing the optimization process. We recently demonstrated this assay's potential to quantify fetal fraction and finalized the probe pool design. If successfully developed, we currently anticipate completing the validation of this product by the end of 2021. However, we cannot predict whether the COVID-19 pandemic or other factors will impact the timing of our validation study. For example, see "Risk Factors—The recent and ongoing COVID-19 pandemic could materially affect our operations, as well as the business or operations of third parties with whom we conduct business. Our business could be adversely affected by the effects of other future health epidemics or pandemics in regions where we or third parties on which we rely have significant business operations."

Preeclampsia Rule-Out Test, Preecludia™

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

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

including high affinity and specific antibodies, which we believe will deliver a differentiating platform focused on performance, sensitivity, and specificity.

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

The Preecludia test is being developed to serve as a potential triage and rule-out test to help providers differentiate between patients with symptoms who are at risk for preeclampsia. This proprietary test is a multi-analyte protein biomarker assay which is designed to be run from a simple blood draw. In the prospective, blinded PRO-129 clinical verification study, samples were collected and analyzed from over 400 pregnant women with substantial diversity, gathered from 24 U.S. clinical sites comprised of predominantly OB/GYN and Maternal Fetal Medicine practices. Subjects presented with possible signs and symptoms of preeclampsia, including new onset hypertension, but no clear diagnosis. Subject data were independently adjudicated by a third party, and subjects, for whom preeclampsia was not diagnosed at the time of enrollment, were followed longitudinally through delivery. In subjects sampled up to 37 weeks' gestational age, the Preecludia test showed an 88.0% sensitivity, 73.3% specificity, and NPV of 98.2% at a 10% prevalence to rule out a patient's risk of developing preeclampsia within the next 14 days from the date of specimen collection. These data were generally consistent with previous results observed in the test's feasibility and optimization studies.

The final planned step in the development program is completion of the clinical validation study. We have already collected over 3,000 samples from more than 1,700 patients across 21 U.S. clinical sites enrolled in the PRO-104 validation study, and initiated this study in the first quarter of 2021. The study is expected to conclude in mid-2021.

If successfully developed, we anticipate a targeted commercial launch of this product in the second half of 2021. However, we cannot predict whether the COVID-19 pandemic or other factors will impact the timing of our commercial launch. For example, see "Risk Factors—The recent and ongoing COVID-19 pandemic could materially affect our operations, as well as the business or operations of third parties with whom we conduct business. Our business could be adversely affected by the effects of other future health epidemics or pandemics in regions where we or third parties on which we rely have significant business operations." We may also explore various alternatives for future iterations of the test, including different target gestational ages.

We believe Preecludia, if successfully developed, will have the potential to impact the cadence and amount of patient visits and timing of indicated delivery, potentially saving the healthcare system money while also improving patient care for both mother and baby. We have discovered a novel biomarker for our preeclampsia test that we believe improves performance over prior tests. By designing the test to have high sensitivity and NPV rates, we expect the test, if and when offered, to be well suited to complement existing tools already part of the current standard of care, giving clinicians an additional strong, objective tool with which to better manage hypertensive disorders during pregnancy.

Market Opportunity

According to the Preeclampsia Foundation, preeclampsia occurs in 5% to 8% of pregnancies in the United States and is one of the leading causes of premature birth and maternal and neonatal morbidity and mortality. Based on our estimates, annually, over 700,000 pregnant women in the United States experience signs and symptoms that could be attributed to preeclampsia. In addition, due to poor screening tools, we estimate that the number of pregnant women monitored for preeclampsia is four times greater than the number affected. An estimated 18% of maternal deaths in the United States are directly associated with preeclampsia or eclampsia. The rate of preeclampsia in the United States has increased by about 25% in the last two decades, consistent with increases in preeclampsia risk factors such as obesity, maternal age, and diabetes in the population. The only consensus treatment is early delivery of the infant, regardless of gestational age. We estimate that the incremental healthcare cost burden associated with managing preeclamptic pregnancies exceeds $9 billion. We believe the total addressable market of our preeclampsia test is approximately $3 billion per year in the United States alone.

Other Opportunities

In response to the COVID-19 pandemic, the Avero Diagnostics laboratory is providing molecular testing for diagnosing COVID-19. The test is run on the Hologic Panther platform using the transcription-mediated amplification version of Hologic's SARS-CoV-2 assay, which received emergency use authorization from the FDA. In September 2020, Avero Diagnostics secured a substantial increase in its COVID-19 PCR testing capacity and supply chain access through a new relationship with ThermoFisher. Avero Diagnostics began a gradual expansion of its commercial testing offering nationally in mid-November 2020. Future demand for COVID-19 testing is becoming increasing difficult to predict due to various factors, including but not limited to, the availability of

vaccinations, the number of individuals who choose to be vaccinated, the effectiveness of the various vaccinations against variants, the rate of new cases, and evolving government directives, laws, regulations and rules related to COVID-19 testing. In the long term, we expect that the COVID-19 pandemic will eventually dissipate and, as a result, the significance of COVID-19 testing to our business and financial results will decrease.

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

Precision Medicine for GI-Related Disorders

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

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

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

Recoverable Sampling System

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

We believe the potential for this capsule is significant. For example, we believe it could help companies developing locally-active GI drugs to assess signals of early efficacy by measuring pharmacodynamic and associated downstream biomarkers at the site of action.

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

We expect to initiate the first clinical proof-of-concept trial evaluating this technology in the second quarter of 2021. In preparation for our clinical trials, we have initiated manufacturing activities for clinical supply of the RSS capsule. Assuming successful results, we would expect to seek CE marking for this device in Europe and that, if CE marking is obtained, initial applications for this device would be in internal programs, partnerships, research use and academic programs.

PIL Dx—Progenity Ingestible Laboratory Diagnostics

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

Our most advanced investigational PIL Dx capsule is the Smart Capsule Bacterial Detection System, or SCBDS. The SCBDS capsule includes an integrated assay which is designed to measure with high sensitivity the change of a metabolically active substrate that correlates with the amount of live bacteria in the small intestine. We believe this technology, if successfully developed and approved or cleared, has the potential to become the standard of care for diagnosing SIBO. Currently the SCBDS capsule has undergone a series of validation and verification tests of the various subsystems and evaluations of the localization algorithm. In these studies, the localization of the capsule was confirmed either by CT scan or scintigraphy. In addition, in an ongoing study, clinical samples acquired via aspiration and endoscopy are being evaluated with the SIBO assay on a standalone basis. Beyond SIBO, we believe the PIL Dx capsule, if it can be designed to measure other analytes, will have broad potential applications, such as for early tumor detection and disease characterization and subtyping, and disease activity monitoring for conditions such as IBD. We have begun testing small intestinal fluid samples collected during endoscopy with aspiration on a benchtop version of our bacterial concentration assay at three clinical sites. Samples are measured for bacterial concentration with culture and plate count. As shown in Table 3 below, the interim test results as of October 13, 2020 show a concordance between the bacterial concentration assay and the reference standard of culture and plate count for identifying 10^5 colony forming units, or CFU, per mL.

Table 3: Standalone Bacterial Concentration Assay Testing Results

Clinical Site	SIBO Assay vs TBC* (10^5 CFU per mL**)
1	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.

In the first half of 2021, we expect to initiate our first full function preclinical study and in the second half of 2021, we expect to initiate the first clinical proof-of-concept trial evaluating this technology. In preparation for our clinical trials, we have initiated manufacturing activities and are improving our manufacturing yield for clinical supply of the PIL Dx capsule. Assuming successful results, we expect to initiate a pivotal clinical study to support CE mark certification for this device in Europe and submission of an application seeking *de novo* classification in the United States. We expect to commercialize the PIL Dx capsule, if approved, through

a combination of our current OB/GYN sales force, a new gastroenterology sales force, and/or partnership opportunities in the primary care market.

Market Opportunity

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

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

Targeted Therapeutics

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

Drug Delivery System

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

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

Our current internal pipeline includes PGN-001, an oral version of adalimumab (a drug with approximately $19 billion in annual sales and for which we have produced a GMP batch). As a result of our use of known molecules, we believe that rapid proof of concept and value inflexion with preclinical and phase 1 pharmacokinetic results is possible.

Our lead DDS programs are in preclinical proof-of-concept stage and we recently announced successful completion of an *in vivo* preclinical device function study and initiation of clinical device function study in February 2021. Assuming successful results, we

expect to initiate Phase 1 clinical studies followed by Phase 2 studies and subsequent Phase 3 studies to support MAA filings in Europe and NDA or BLA submissions in the United States. We believe certain programs may be eligible for the 505(b)(2) pathway in the United States and/or the hybrid MAA pathway in Europe.

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

Oral Biotherapeutic Delivery System

Over the past two decades, biologic drugs have become the standard of care for a variety of diseases including rheumatoid arthritis, psoriasis, diabetes, Crohn's disease, ulcerative colitis, and a range of cancers. Generally, these biologics are administered systemically via subcutaneous or intravenous injection. We are developing drug/device combinations designed to deliver biologics systemically, via a more convenient oral route of administration. Our unique approach to oral delivery of biologic drugs is through use of an ingestible capsule designed to spray a liquid drug substance past the mucosal surface into the submucosal tissues of the small intestine where it can be absorbed systemically. This ingestible capsule technology is designed to protect the drug from acids and proteolytic enzymes of the gut until it reaches the site of delivery through means other than our autonomous localization technology where it may be triggered and spray the preloaded drug substance past the intestinal barrier. The device design is simple, low-cost, and has the appearance of a typical drug capsule. We initially developed an endoscopically or surgically placed, liquid jet device for optimization and early preclinical work and have since progressed to an autonomous fully integrated prototype device for further evaluation. With the endoscopically or surgically placed device we assessed the potential bioavailability rates that may be achieved with our device in preclinical swine studies with drugs such as human insulin, dulaglutide, and adalimumab. In these studies we have observed bioavailability of approximately 19% (n=18), 29% (n=11), and 27% (n=11), respectively. We believe this technology, if successfully developed, has broad applications beyond GI diseases and can be applied to numerous drugs that currently demand a parenteral route of administration.

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

Our current internal pipeline includes PGN-OB1, an oral version of adalimumab (a drug with approximately $19 billion in annual sales and for which we have produced a GMP batch), and PGN-OB2, an oral version of a GLP-1 analog (a drug with a projected $15 billion market by 2025). As a result of our use of known molecules, we believe that rapid proof of concept and value inflexion with preclinical and phase 1 pharmacokinetic results is possible.

Our lead oral biotherapeutic delivery system programs are in preclinical proof-of-concept stage and we expect to complete a preclinical study demonstrating the first fully autonomous device in the first quarter of 2021. Assuming successful results, we expect to initiate Phase 1 clinical studies followed by Phase 2 studies and subsequent Phase 3 studies to support MAA filings in Europe and NDA or BLA submissions in the United States. We believe certain programs may be eligible for the 505(b)(2) pathway in the United States and/or the hybrid MAA pathway in Europe.

Key Targeted Therapeutic Opportunities in Gastrointestinal Disease

Inflammatory Bowel Diseases

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

Ulcerative Colitis

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

aminosalicylates, more potent systemic therapies such as infliximab and adalimumab are used. The CCF estimates that UC may affect as many as 907,000 Americans.

Crohn's Disease

Similar to UC, Crohn's disease, or CD, is a chronic disorder that causes inflammation of the digestive tract, but unlike UC, CD may involve all layers of the intestine and can affect any part of the intestines. The symptoms of CD range from mild to severe with the most common symptoms being diarrhea, abdominal pain, fever, and sometimes rectal bleeding. Mild symptoms may be treated with topical corticosteroids and aminosalicylates. For moderate to severe CD, the biologics described above are commonly used to treat UC. The CCF estimates as many as 780,000 Americans have CD, and states that it is most often diagnosed in adolescents and young adults between the ages of 20 and 30 years.

Other Diseases of Interest

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

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

Key Features of our Precision Medicine Platform

Our platform is distinguished by several key elements:

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

with a third-party in August 2020 for one of our precision medicine products and we continue to pursue additional collaborations, although none of these relationships are material individually or in the aggregate.

Laboratories

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

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

Avero Diagnostics

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

Laboratory Operations and Processes

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

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

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

After extraction, samples are processed in batches utilizing color coded and barcoded pre-aliquoted reagent plates. Our internally prepared reagent plates reduce technologist time and improve throughput and turnaround time. Use of the color coding system and barcoding allows traceability of all reagents without requiring laborious and error prone manual recording. Continuing with automation islands, steps requiring transfer of samples as well a multi-step process are performed by internally developed automation systems. This includes amplification set-up and sample addition. Each sample plate, reagent plate, liquid handling system, thermocycler, sequencer/detection system, and performing technologist is recorded. After amplification, library preparation and indexing samples are pooled and quantitated to allow for optimal loading on the sequencing instruments. Due to the islands of automation strategy, multiple workflows coexist on common equipment maximizing utilization while ensuring the required

turnaround time. In order to ensure maximum quality during the manual steps, the materials and set-up are verified by a second trained technologist.

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

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

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

Finally, laboratory directors are responsible for ensuring compliance with CLIA regulations, applicable state-specific regulations, and recommendations from professional societies such as CAP, ACMG, and Clinical and Laboratory Standards Institute. The laboratory directors fulfill this requirement by working with the operations department to confirm that all laboratory personnel have the proper credentials and training, procedural requirements are met, and the relevant quality metrics are monitored over time to identify any possible problems that could affect patient results.

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

Laboratory Supplies

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

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

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

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

Sales and Marketing

We have a commercial team of more than 150 individuals in the United States, including the sales force and marketing and health plan market access teams. Our sales force promotes our products across three regions with a focus exclusively on OB/GYNs and maternal-fetal medicine providers in the women's health market and offers our full product portfolio in an effort to maximize cross-selling opportunities. We are expanding into adjacent specialty markets with sales and marketing teams targeting customers in genetic

counseling and reproductive medicine, with further expansion into gastrointestinal medicine planned for 2023. We are also evaluating the expansion of our business internationally to leverage our portfolio, with our Preeclampsia test representing one potential avenue for expansion.

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

Our marketing strategy is focused on driving adoption of genetic testing protocols and educating healthcare professionals on the value of genetic testing for healthcare management decisions. Our marketing activities include presenting clinical research at medical conferences and scientific meetings, conducting provider education campaigns and hosting medical education events through field medical science liaisons and sales representatives, using online advertising, social media, and public relations channels to raise product and company awareness, and developing strategic business partnerships.

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

Reimbursement

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

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

We generate revenue from the sales of our molecular tests and receive payments for such tests from four distinct channels: commercial third-party payors, government health benefits programs such as Medicare and Medicaid, laboratory distribution partners, and individual patients. Reimbursements from payors, including commercial third-party payors and government health benefits programs, constituted more than 95% of our revenue during the year ended December 31, 2020. We are currently contracted with payors representing approximately 146 million covered lives.

We seek to improve reimbursement for our tests through active engagement with payors and patients, with a goal to maximize revenues while ensuring compliance with applicable rules and regulations.

Commercial Third-Party Payors

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

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

We have entered into settlement agreements with commercial third-party payors in order to settle claims related to past billing and coding practices that have been discontinued, including, without limitation: Connecticut General Life Insurance Company and Cigna Health and Life Insurance Company, or Cigna, United HealthCare Services, Inc. and UnitedHealthcare Insurance Company, or United, and Aetna Health Management, Inc., or Aetna. In December 2018, we and Avero Diagnostics entered into settlement agreements with Cigna pursuant to which Avero Diagnostics agreed to pay Cigna $12.0 million in a series of installments and we agreed to guarantee $6.0 million of such payment. We and Avero Diagnostics also agreed to certain covenants regarding our billing practices. As of December 31, 2020, all obligations under such agreement with Cigna were fully settled. In September 2019, we entered into a settlement agreement with United that governs past benefit claims and a corrective action plan which governs future benefit claims that we submit for reimbursement at an arm's length, out-of-network basis to United. The total settlement amount was $30.0 million, to be paid in a series of installments. We have paid $18.0 million under such agreement to date. In November 2019, we entered into a settlement agreement with Aetna, which was amended in April 2020, pursuant to which we agreed to pay Aetna

$15.0 million in a series of installments. We have paid $12.5 million under such agreement to date. As part of the Aetna settlement, we also entered into an in-network participation agreement with Aetna that became effective January 1, 2020. Each of these settlement agreements provides for a release of past claims by all parties.

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 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.

As noted above, 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. In our experience with negotiations with similarly situated commercial payors, a settlement may take six to twelve months to negotiate, and the time period over which a negotiated settlement payment may be paid could extend from one to two years, or longer. Historical settlement amounts and payment time periods may not be indicative of the final settlement terms with Anthem, if any. We intend to negotiate and/or dispute this claim of recoupment with Anthem and seek to offset any amounts owed by Anthem to us. Anthem has indicated a willingness to engage in contract negotiations for in-network status separately and in parallel to discussions regarding its recoupment claim. The resolution of this dispute may or may not include our moving in network with Anthem. As a potential means of making recoupment payments, if any, we may negotiate to apply temporarily lowered contracted rates for a specific period. Such provider-payor disputes are not uncommon and we expect to approach this dispute with an aim to resolve in a mutually satisfactory manner. It is not possible to predict the ultimate outcome of this matter and the timing for resolution (see Note 10).

Government Health Benefits Programs

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

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

For clinical diagnostic laboratory tests furnished on or after January 1, 2017, Medicare reimbursement is paid based upon the weighted median of the reported commercial third-party payor payments for the same test, as calculated using the data collected by applicable laboratories and reported to CMS during the specified data collection and reporting period. For clinical diagnostic laboratory tests that are assigned a new or substantially revised code, initial payment rates are assigned by the cross-walk or gap-fill methodology that existed under the prior law. The cross-walk methodology applies when a new test or substantially revised test is determined to be similar to an existing test, multiple existing test codes, or a portion of an existing test code, which can then be utilized to determine a payment. The gap-fill methodology applies when no comparable, existing test is available. In this case, the Medicare Administrative Contractor, or MAC, develops a local payment amount for the new test code and CMS calculates a national limitation amount after a year of payment at the local MAC rates based on the median of rates for the test code across all MACs. Initial payment rates for new advanced diagnostic laboratory tests are based on the actual list charge for the laboratory test.

The revised reimbursement methodology described above generally results in relatively lower reimbursement amounts under Medicare for clinical laboratory services than has been historically reimbursed. Any reductions to reimbursement rates resulting from the new methodology are limited to 10% per test per year in each of 2018 through 2020 and to 15% per test per year in each of 2021 through 2023. The CARES Act amended the timeline for reporting private payer payment rates and delayed by one year the payment reductions scheduled for 2021.

In addition to the CARES Act, Congress has enacted other laws in response to the COVID-19 pandemic to provide financial relief to healthcare providers and suppliers, including diagnostic laboratories, and encourage implementation of diagnostic testing and treatment for COVID-19. For instance, the Families First Coronavirus Response Act, enacted on March 18, 2020, requires certain governmental and commercial insurance plans to provide coverage of COVID-19 diagnostic testing services without imposing cost-

sharing (e.g., copays, deductibles, or coinsurance) or other utilization management requirements. The CARES Act and the Paycheck Protection Program and Health Care Enhancement Act, enacted on April 24, 2020, each appropriated approximately $100 billion to provide financial relief for certain healthcare providers and to expand treatment and diagnostic testing capacity for COVID-19. The CARES Act and subsequent legislation also suspended, for the period from May 1, 2020 to March 31, 2021, the 2% Medicare payment reduction created under the sequestration required by the Budget Control Act of 2011 (as amended by the American Taxpayer Relief Act of 2012), and extended the sequester by one year, through 2030.

Laboratory Distribution Partners

We have contracted with other clinical and genetic laboratories for distribution of our products. Our reimbursement for these products comes directly from the contracted laboratory. In some instances, our distribution partners will request that we bill the payor for the provided test on their behalf. In these instances, we collect payment directly from the payor.

Individual Patients

We generally seek to collect co-payments and deductibles directly from patients in cases where we have billed the payor. For these patients, we offer a range of flexible payment plans to assist in the payment of co-payments and deductibles. We also seek to collect payment directly from patients for cash paying patients who do not have or have elected not to use medical insurance. Patients paying out of pocket are generally offered a discounted price. We are not currently promoting or offering direct-to-consumer testing products.

We are subject to applicable state and federal laws regarding who should be billed, how they should be billed, how business should be conducted, and how patient obligations regarding cost sharing should be handled.

Competition in Molecular Testing

Women's Health Molecular Testing

We compete with numerous companies that have developed and commercialized some combination of our core product portfolio: NIPT; carrier screening; and hereditary cancer screening. Our primary competitors include Invitae, Myriad Genetics (which acquired Counsyl in 2018), and Natera. Secondary competitors include Ambry Genetics, GeneDx (a subsidiary of Bio-Reference Laboratories), LabCorp, Quest Diagnostics, Roche Diagnostics, Sema4, and other commercial and academic laboratories. We expect additional competition as other established and emerging companies enter the women's health molecular testing market, including through business combinations.

We believe the principal competitive factors in our market include the following:

- test performance, including sensitivity, specificity, failure rates, and turnaround time, as demonstrated in clinical validation;
- value of product offerings, including pricing and impact on healthcare spending;
- coverage and reimbursement arrangements with third-party payors;
- convenience of testing;
- additional value-added services and digital healthcare tools;
- effectiveness of sales and marketing efforts;
- development and introduction of new, innovative products;
- key opinion leader support;
- brand awareness; and
- ease of integration with healthcare provider practices.

We believe that we compete favorably on the basis of the factors above, particularly in test performance, additional value-added services, and digital healthcare tools, value of product offerings, and effectiveness of sales and marketing efforts.

Preeclampsia

The U.S. market for preeclampsia tests currently includes certain positive or predictive tests such as the predictive Preeclampsia Screen T1 offered by NTD Labs (purchased from Perkin Elmer in 2016) and the GestAssured preeclampsia test using congo red staining offered by GestVision. We expect to offer a noninvasive biomarker test designed to rule out preeclampsia. We anticipate that our test would compete favorably by providing superior sensitivity, specificity, and high NPV to rule out preeclampsia in symptomatic women as compared to existing clinical assessment tools, including those discussed above.

Testing Services

The market for anatomic pathology and molecular testing is highly competitive. We compete with a vast network of local and regional pathology groups, national laboratories, hospital-based laboratories, and physician-owned laboratories. Competition in the industry is based on several factors including price, quality of service, accuracy of results, clinical expertise, test menu, turnaround time of test results, commercial strategy and execution, ability to retain high-quality staff, client relationships, and reputation.

Competition in Precision Medicine

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

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

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

Recoverable Sampling System

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

PIL Dx—Progenity Ingestible Laboratory Diagnostics

Although we believe that they are comparatively limited in functionality and capability, we face competition from a small number of currently marketed or in-development diagnostic devices and tests specifically targeting GI disorders, such as those from Medtronic and Commonwealth Diagnostics International. Additionally, we will similarly face competition from new entrants as advances in diagnostics and engineering bring new technologies to market.

Drug Delivery System

The current IBD market is both established and mature, comprised of a range of therapeutic agents including branded and generic small molecules, biologics, biosimilars, and involving multiple mechanisms of action as well as routes of administration. Although we believe our technology platform will provide us with a competitive advantage in its ability to enable targeted delivery of therapeutic agents (and, in particular, biologics) via oral administration, we will face competition from several companies whose current R&D efforts will likely result in the emergence of newer pharmaceuticals touting oral administration, more convenient dosing frequency, novel mechanisms of action, and improved safety profiles and drug availability. We believe that the majority of competition will come from those companies marketing or developing biologics and small molecule therapeutics, such as AbbVie, Eli Lilly, Galapagos, Gilead, J&J, Pfizer, Roche, Takeda, and UCB.

Oral Biotherapeutic Delivery System

We expect to face competition from a number of technologies currently marketed or being developed to enhance or facilitate the oral administration of therapeutic agents. There is a wide range of competitive technologies and mechanisms that may challenge us.

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

- Functional excipients designed to enhance the solubility and/or permeability of peptides and small molecules: Enteris Biopharma and Novo Nordisk;
- Enteric coating technologies designed to prevent gastric degradation of active pharmaceutical ingredients and facilitate GI delivery: Assembly Biosciences, Catalent, Cosmo Pharmaceuticals, Intract Pharma, Lonza, and Tillotts Pharma; and

- Ingestible devices designed for the targeted delivery of a therapeutic payload: Lyndra Therapeutics and Rani Therapeutics.

Intellectual Property

The proprietary nature of, and intellectual property protection for, our existing and future products, processes, and know-how are important to our business. Our success depends in part on our ability to obtain patent and other legal protection for our products, technology, and know-how, to operate without infringing on the proprietary rights of others, and to prevent others from infringing on our proprietary rights. We rely on a combination of patents, trade secrets, know-how, license agreements, and nondisclosure and other contractual provisions to protect our intellectual property rights. These rights cover our proprietary tests, processes, databases, information, and materials across our different businesses. We seek and maintain patent protection in the United States and internationally for our over 600 issued patents and pending patent applications, while also in-licensing technology, inventions, and improvements that we consider important to the success of our business. In addition to patent protection, we intend to use other means to protect our products, technology and know-how, including pursuing terms of marketing or data exclusivity for our products, orphan drug status (if applicable) and similar rights that are available under regulatory provisions in certain territories, including the United States and Europe. We also rely on know-how and continuing technological innovation that are protected as trade secrets to develop and maintain our competitive position.

Molecular Testing Technology Patent Portfolio

Intellectual property rights relating to the molecular testing technology include a patent portfolio consisting of 27 distinct patent families comprising more than 150 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 2040, 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 allele dosages;
- determining methylation status;
- isolating and analyzing rare cells; and
- diagnosing pregnancy-associated conditions like preeclampsia and preterm birth.

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

- Proprietary NGS and highly multiplexed polymerase chain reaction assays and panels;
- Discovery and diagnostic algorithms;
- Laboratory, billing, and reimbursement information systems; and
- Variant classification, annotation, and reporting systems.

Precision Medicine Technology Patent Portfolio

Intellectual property rights relating to our precision medicine technology include a patent portfolio consisting of more than 70 distinct patent families comprising more than 500 issued or 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 be projected to expire in 2040, in each case, subject to potential term extensions. Thirty of the families were acquired in connection with the acquisition of certain tangible and intangible assets relating to the business formerly operated by Medimetrics GmbH, Medimetrics Personalized Drug Delivery B.V., and Medimetrics Personalized Drug Delivery Inc. In general, we file our precision medicine patent applications in the following patent jurisdictions: the United States, Australia, China, Canada, Europe, and Japan; and sometimes in these additional jurisdictions: Brazil, Eurasia, Hong Kong, Israel, India, South Korea, Mexico, and Singapore.

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

- autonomous localization of an ingestible device in the GI tract using visible or infrared light;
- GI sampling mechanisms and compositions, including preservatives for GI analytes;

- ingestible device assays, optics and analytics for detecting and quantifying GI analytes;
- ingestible device drug delivery mechanisms and systems;
- targeted topical and systemic delivery of therapeutics, including biologics, peptides, small molecules, nucleic acids, or cells for the treatment of GI conditions;
- ingestible devices for diagnosing, treating, and aiding in the treatment of GI conditions; and
- GI-specific drug formulations and dosing regimens.

Trademarks

Our reputation and brand awareness are very important to us. Accordingly, we invest significant resources in the protection of our trademarks. We have and will continue to pursue the registration of our trademarks, including trademarks for the name Progenity, our logo, and certain of our products, in relevant jurisdictions.

Government Regulation

Regulations Related to Clinical Laboratories

Clinical Laboratory Improvement Amendments of 1988 and State Regulation

As a clinical laboratory, we are required to hold certain federal certifications under the CLIA to conduct our business. Our clinical laboratory facility located in Ann Arbor, Michigan is CLIA certified and is accredited by CAP, a CLIA-approved accrediting organization, which means that our laboratory has been certified as following CAP guidelines in operating the laboratory and in performing tests that ensure the quality of our results.

Under CLIA, a laboratory is any facility that performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, or treatment of disease or the impairment or assessment of health. CLIA requires that such laboratories obtain certification from the federal government and maintain compliance with various operational, personnel qualification, facilities administration, quality control and assurance, and proficiency testing requirements intended to ensure the accuracy, reliability, and timeliness of patient test results. CMS administers the CLIA certification program. CLIA certification is also necessary to bill state and federal healthcare programs, as well as many commercial third-party payors, for laboratory testing services.

CLIA requires that we hold a certificate that specifies the types of testing we perform and that we comply with certain standards applicable to such tests. In addition, CLIA specifies certain testing categories requiring periodic proficiency testing, and certified laboratories performing these tests must enroll in an approved proficiency testing program. To demonstrate proficiency, such laboratories must test specimens received from an outside proficiency testing organization, such as CAP, and then, submit the results back to that organization for evaluation. Failing to achieve a passing score on a proficiency test may lead to loss of certification to perform testing in the corresponding category. Furthermore, failure to comply with other proficiency testing regulations, can result in revocation of the referring laboratory's entire CLIA certification.

In addition, as a condition of CLIA certification, our laboratory is subject to survey and inspection every other year, as well as random inspections at CMS's discretion. The biannual survey is conducted by CMS, a CMS agent (typically a state agency), or, if the laboratory holds a CLIA Certificate of Accreditation, a CMS-approved accreditation organization. Because CLIA is user-fee funded, all costs of administering the program must be covered by the regulated facilities such as ours, including certification and survey costs.

Laboratories performing high-complexity testing are required to meet more stringent requirements than laboratories performing less complex tests. A high-complexity laboratory like ours that is certified under CLIA may develop, validate, and use proprietary tests referred to as LDTs. Under current federal policy, FDA premarket review of LDTs is not required, but laboratories may voluntarily submit 510(k) or PMA applications, or *de novo* classification requests, for LDTs to obtain FDA clearance or approval following a demonstration of clinical validity. On the other hand, the CLIA program requires laboratories to demonstrate the analytical validity of any LDT used in clinical testing. All of our current products are LDTs.

CLIA provides that a state may adopt laboratory regulations that are more stringent than those under federal law, and a number of states have implemented their own more stringent laboratory regulatory requirements. State laws may require that laboratory personnel meet certain qualifications, specify certain quality control procedures, facility requirements, or prescribe record maintenance requirements.

California Laboratory Licensing

In addition to federal certification requirements for laboratories under CLIA, licensure is required and maintained for our clinical laboratory under California law because we receive specimens for testing from California. The California licensure law establishes standards for the day-to-day operation of a clinical laboratory, including the training and skills required of personnel and quality control. In addition, California law mandates proficiency testing, which involves testing of specimens that have been specifically prepared for the laboratory.

If a clinical laboratory is out of compliance with California standards, the California Department of Public Health, Laboratory Field Services branch, may suspend, restrict, or revoke its license to operate the clinical laboratory, assess substantial civil money penalties, or impose specific corrective action plans.

New York Laboratory Licensing

Our laboratory receives specimens from New York state, and so we are required to maintain a New York clinical laboratory license, under New York laws and regulations, which establish standards for: (1) day-to-day operation of a clinical laboratory, including training and skill levels required of laboratory personnel; (2) physical requirements of a facility; (3) equipment; and (4) validation and quality control.

New York law also mandates proficiency testing for laboratories licensed under New York state law, regardless of whether or not such laboratories are located in New York. If a laboratory is out of compliance with New York statutory or regulatory standards, the New York State Department of Health may suspend, limit, revoke or annul the laboratory's New York license, censure the holder of the license or assess civil money penalties. Statutory or regulatory noncompliance may result in a laboratory's operator being found guilty of a misdemeanor under New York law. The New York State Department of Health also must approve each specific LDT before the test is offered in New York.

Other State Laboratory Licensing Laws

In addition to New York and California, other states, including Maryland, Pennsylvania, and Rhode Island, require licensing of out-of-state laboratories under certain circumstances. We have obtained licenses in these additional states and believe we are in compliance with applicable licensing laws.

Potential sanctions for violation of state statutes and regulations include significant fines, the disapproval of licensure applications and the suspension or loss of various licenses, certificates and authorizations, which could harm our business. CLIA does not preempt state laws that have established laboratory quality standards that are at least as stringent as federal law.

State Genetic Testing Laws

Many states have implemented genetic testing and privacy laws imposing specific patient consent requirements and protecting test results. In some cases, we are prohibited from conducting certain tests without a certification of patient consent by the physician ordering the test. Requirements of these laws and penalties for violations vary widely.

Federal Oversight of Laboratory Developed Tests

The laws and regulations governing the marketing of diagnostic products are evolving, extremely complex, and in many instances, there are no significant regulatory or judicial interpretations of these laws and regulations. Clinical laboratory tests are regulated under CLIA, as administered by CMS, as well as by applicable state laws In addition, pursuant to its authority under the FD&C Act, the FDA has jurisdiction over medical devices, which include, among other things, in vitro diagnostic devices, or IVDs, intended for clinical purposes. LDTs are diagnostic tests that are designed, manufactured, and used within a single laboratory, and the FDA has regulated LDTs as a subset of IVDs. The FDA regulates, among other matters, the research, testing, manufacturing, safety, labeling, storage, recordkeeping, premarket clearance or approval, marketing and promotion and sales and distribution of medical devices, including IVDs, in the United States to ensure that such products on the domestic market are safe and effective for their intended uses. In addition, the FDA regulates the import and export of medical devices.

Although the FDA has statutory authority to assure that medical devices, are safe and effective for their intended uses, the FDA has historically exercised its enforcement discretion and not enforced applicable provisions of the FD&C Act and regulations with respect to LDTs. We believe our tests fall within the scope of the agency's LDT definition. As a result, we believe our molecular tests are not currently subject to the FDA's regulations and the FD&C Act provisions applicable to medical devices and IVDs.

Legislative and administrative proposals to amend FDA's oversight of LDTs have been introduced in recent years and we expect that new legislative and administrative proposals will continue to be introduced from time to time. It is possible that legislation could be enacted into law or regulations or guidance could be issued by the FDA which may result in new or increased regulatory requirements

for us to continue to offer our LDTs or to develop and introduce new tests as LDTs. For example, in recent years, FDA stated its intention to modify its enforcement discretion policy with respect to LDTs. Specifically, on July 31, 2014, the FDA notified Congress of its intent to modify, in a risk-based manner, its policy of enforcement discretion with respect to LDTs. On October 3, 2014, the FDA issued two draft guidance documents outlining a method for extending regulatory oversight to LDTs. These draft guidance documents were titled "Framework for Regulatory Oversight of Laboratory Developed Tests," or Framework Guidance, and "FDA Notification and Medical Device Reporting for Laboratory Developed Tests," or Notification Guidance. The Framework Guidance stated that FDA intended to end its policy of enforcement discretion with respect to most LDTs and apply a risk-based regulatory compliance and enforcement approach consistent with the classification of medical devices generally in Classes I through III. The Notification Guidance would have further enabled FDA to collect information regarding the LDTs currently being offered for clinical use through a notification process, as well as to enforce its regulations for reporting safety issues and collecting information on any known or suspected adverse events related to the use of an LDT. The 2014 Framework and Notification Guidances were the subject of much controversy among the device and laboratory industries, healthcare providers, the U.S. Congress, and other stakeholders, and on November 18, 2016, the FDA announced that it would not finalize either guidance document. On January 13, 2017, FDA released a document titled "Discussion Paper on Laboratory Developed Tests," or the Discussion Paper, which stated that the agency had declined to finalize the LDT guidances to allow for additional discussion on appropriate regulatory oversight. The Discussion Paper presented a more focused approach to LDT oversight, and stated that under the FDA's current thinking, LDTs marketed before any regulatory framework becomes effective would not be expected to comply with the requirements. In addition, the FDA continued to caution against the use of pharmacogenetic tests that had not been reviewed by the FDA and raised concerns about the clinical validation of high-risk tests that purport to predict a drug response but that may be inconsistent with FDA-approved drug labeling.

In April 2017, Congress released a discussion draft of the Diagnostic Accuracy and Innovation Act, or DAIA, the first legislative attempt to reform the regulatory framework for LDTs and IVDs since the FDA proposed to overhaul its policy of enforcement discretion with respect to LDTs. DAIA sought to carve LDTs and certain IVDs out of the current definition of "medical devices" by codifying a new defined term, in vitro clinical tests, or IVCTs. IVCTs would constitute products currently regulated as IVDs and LDTs, and such products would be regulated differently from medical devices. DAIA proposed a three-tiered risk classification system with corresponding premarket review pathways for each tier. It also sought to establish jurisdictional boundaries between the FDA, CMS, and the states, with FDA oversight over development and manufacturing, CMS oversight over laboratory operations, and individual state oversight over medical use and interpretation. In August 2018, the FDA provided technical drafting assistance on DAIA, issuing comments in the form of a revised version of the draft legislation. Unlike DAIA, the FDA's technical assistance proposed a bifurcated risk classification for IVCTs that would eliminate the middle-risk tier, subject most high-risk IVCTs to premarket approval, and exempt most low-risk IVCTs from premarket review. It would also establish a precertification program that would enable an IVCT developer to be certified by the FDA, or potentially by an FDA-accredited body, as having sufficient skill at developing IVCTs, so as to not require premarket review for each individual test marketed by a certified developer. If included in any enacted law, the FDA's recommendations would also centralize the FDA's jurisdiction, giving the FDA authority to withdraw approvals, request raw data, and take corrective action against test developers. In December 2018, legislators released a discussion draft of a new bill, the Verifying Accurate, Leading-edge IVCT Development, or VALID, Act, which largely incorporated the FDA's proposals, and in April 2019, HHS, issued technical assistance comments on the VALID Act, which largely expressed support for maintaining the FDA's jurisdiction over IVCTs and the proposed precertification program. Even if passed by Congress and signed in to law, many of the proposals in the VALID Act, including the proposed requirements for premarket review and precertification of IVCTs, may take time to be worked out and fully implemented by the FDA, CMS and other regulatory authorities.

In August 2020, HHS announced that the FDA will not require premarket review for any LDTs without first conducting notice-and-comment rulemaking proceedings. As a result, the FDA may not rely on guidance documents, policy statements, or other informal decision-making to impose premarket review requirements on LDTs. It remains to be seen whether the Biden administration will continue this HHS policy. The HHS announcement applies to all LDTs, including LDTs relating to the COVID-19 pandemic, and the FDA subsequently announced that it would no longer review EUA requests for COVID-19 LDTs. While the HHS announcement permits laboratories to use LDTs without an EUA or FDA premarket clearance or approval, such use will not be protected by the federal Public Readiness Emergency Preparedness (PREP) Act, which provides immunity from tort liability claims (except willful misconduct) to individuals or organizations involved in the manufacture, distribution, or dispensing of medical countermeasures. Further, such use remains subject to regulation by CMS under the CLIA.

Advertising of Laboratory Services or LDTs

Whether regulated by the FDA as a Class I or Class II device or subject to FDA's enforcement discretion as an LDT, our advertising for laboratory services and tests is subject to federal truth-in-advertising laws enforced by the Federal Trade Commission, or FTC, as well as comparable state consumer protection laws. Under the Federal Trade Commission Act, or FTC Act, the FTC is empowered, among other things, to (a) prevent unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce; (b) seek monetary redress and other relief for conduct injurious to consumers; and (c) gather and compile information and conduct investigations relating to the organization, business, practices, and management of entities engaged in commerce. The FTC has very broad enforcement authority, and failure to abide by the substantive requirements of the FTC Act and other consumer protection laws

can result in administrative or judicial penalties, including civil penalties, injunctions affecting the manner in which we would be able to market services or products in the future, or criminal prosecution.

Medical Device Regulation

Pursuant to its authority under the FD&C Act, the FDA has jurisdiction over medical devices, including IVDs and other products we are currently developing. The FDA regulates, among other things, the research, design, development, 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. Although the tests we currently market are LDTs, which are subject to the recent announcement by HHS and FDA's enforcement discretion, we intend to develop certain product candidates, such as ingestible diagnostic products, that are subject to the FDA's premarket review requirements applicable to medical devices.

Device Classification

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

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

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

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

510(k) Pathway

To obtain 510(k) clearance, we must submit a premarket notification under Section 510(k) of the FD&C Act demonstrating that the proposed device is "substantially equivalent" to a predicate device. A predicate device is a legally marketed device that is not subject to premarket approval, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was found substantially equivalent through the 510(k) process. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data is sometimes required to support substantial equivalence. The FDA's 510(k) clearance pathway usually takes from three to 12 months from the date the notification is submitted, but it can take considerably longer, depending on the extent of FDA's requests for additional information and the amount of time a sponsor takes to fulfill them. After a 510(k) is submitted, the FDA determines whether to accept it for substantive review. If it lacks necessary information for substantive review, the FDA will refuse to accept the 510(k) submission. If it is accepted for filing, the FDA begins a substantive review. By statute, the FDA is required to complete its review of a 510(k) premarket notification within 90 days of receiving the 510(k) submission. As a practical matter, clearance often takes longer, and clearance is never assured.

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

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

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

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

PMA Pathway

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

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

- the device may not be shown safe or effective to the FDA's satisfaction;
- the data from 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 maintain customer complaint files, record all lot numbers of disposable products, and conduct periodic audits to assure compliance with applicable regulations. We will place special emphasis on customer training and advise all customers that device operation should be undertaken only by qualified personnel. In addition to laws and regulations in the United States, we are subject to a variety of laws and regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our product candidates.

Postmarket Requirements—EU

The regulatory review process varies from country to country and may in some cases require the submission of clinical data. Our international sales will be subject to regulatory requirements in the countries in which our product candidates are sold. These regulations will be significantly modified in the next couple of years. For example, in April 2017, the new EU Medical Devices Regulation (Regulation EU 2017/745) was adopted. The EU Medical Devices Regulation, or EU MDR, repeals and replaces the

existing EU Medical Devices Directive (Council Directive 93/42/EEC) after a certain transition period. The EU MDR, among other things, is intended to establish a uniform, transparent, predictable, and sustainable regulatory framework across the EEA for medical devices and ensure a high level of safety and health while supporting innovation. The EU MDR was originally scheduled to become applicable three years after publication (in May 2020). However, due to the uncertainty surrounding the COVID-19 pandemic, the date of application was postponed by one year to May 26, 2021. Once applicable, the new regulation will among other things:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities;
- improve the traceability of medical devices;
- set up a central database to provide comprehensive information on products available in the EU; and
- strengthen rules for the assessment of certain high-risk devices before they are placed on the market.

In the meantime, the current EU Medical Devices Directive continues to apply.

Drug and Biologics Regulation

Premarket Requirements—U.S.

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

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

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

Preclinical Testing

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

IND Submission

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

Clinical Trials

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

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

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

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

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

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

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

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

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

NDA/BLA Submission and Review

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

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

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

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

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

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

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

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

Expedited Development and Review Programs

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

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

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

The FDA also designates certain products as “breakthrough therapies,” if the product is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as

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

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

Hatch-Waxman Act

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

Generic Drugs

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

505(b)(2) NDAs

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

RLD Patents

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

Regulatory Exclusivities

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

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

Other Exclusivities

Pediatric Exclusivity. Section 505A of the FD&C Act provides for six months of additional exclusivity or patent protection if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show that the product is effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or *Orange Book* listed patent protection that cover the drug are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve an ANDA or 505(b)(2) application owing to regulatory exclusivity or listed patents. If and when any drug or biologic product candidate is approved, we will evaluate seeking pediatric exclusivity as appropriate.

Orphan Drug Exclusivity. Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States or, if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making a drug or biologic product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan designation must be requested before submitting an NDA or BLA. After the FDA grants orphan designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug or biological product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity or inability to manufacture the product in sufficient quantities. The orphan designation of such drug or biologic also entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user fee waivers. However, competitors, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Orphan exclusivity also could block the approval of one of our product candidates for seven years if a competitor obtains approval of the same drug or biologic as defined by the FDA or if our product candidate is determined to be contained within the scope of the orphan exclusivity of the competitor's product for the same indication or disease. Orphan drug status in the European Union has similar but not identical benefits in that jurisdiction.

The Biologics Price Competition and Innovation Act

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

Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being addressed by the FDA.

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

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

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

Post-Approval Regulation of Drug and Biologic Products

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

Once we are engaged in manufacturing approved drug or biologic products or their components, we must comply with applicable cGMP requirements and product-specific regulations enforced by the FDA and other regulatory agencies. Compliance with cGMP includes adhering to requirements relating to organization and training of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, quality control and quality assurance, packaging and labeling controls, holding and distribution, laboratory controls, and records and reports. The FDA regulates and inspects equipment, facilities, and processes used in manufacturing pharmaceutical or biologic products prior to approval. If, after receiving approval, a company makes a material change in manufacturing equipment, location, or process (all of which are, to some degree, incorporated in the NDA or BLA), additional regulatory review and approval may be required. The FDA also conducts regular, periodic visits to re-inspect equipment, facilities, and processes following the initial approval of a product. Failure to comply with applicable cGMP requirements and conditions of product approval may lead the FDA to seek sanctions, including fines, civil penalties, injunctions, suspension of manufacturing operations, operating restrictions, withdrawal of FDA approval, seizure, or recall of products, and criminal prosecution.

The FDA and other federal regulatory agencies closely regulate the marketing and promotion of drugs and biologics through, among other things, standards and regulations for direct-to-consumer advertising, advertising and promotion to healthcare professionals, communications regarding unapproved uses, industry-sponsored scientific and educational activities, and promotional activities involving the Internet. A product candidate cannot be promoted as safe or effective for any use before it is approved. After approval, product promotion can include only those claims relating to safety and effectiveness that are consistent with the labeling approved by the FDA. Healthcare providers are permitted to prescribe drugs and biologics for "off-label" uses—that is, uses not approved by the FDA and therefore not described in the product's labeling—because the FDA does not regulate the practice of medicine. However, FDA regulations impose stringent restrictions on manufacturers' communications regarding off-label uses. Broadly speaking, a manufacturer may not promote a drug or biologic for off-label use, but under certain conditions may engage in non-promotional, balanced, scientific communication regarding off-label uses. Failure to comply with applicable FDA requirements and restrictions in

this area may subject a company to adverse publicity and enforcement action by the FDA, the DOJ, or the HHS Office of Inspector General, or OIG, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug or biological products.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- adverse publicity, fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

Other Requirements

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

EU Requirements

We must obtain the requisite marketing authorizations from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of a product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application, or CTA, much like an IND, prior to the commencement of clinical trials. In the EU, for example, a CTA must be submitted to the national health authority of each EU Member State in which the clinical trial is to be conducted and to an independent ethics committee, much like the FDA and an IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed.

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

Since the United Kingdom, or UK, has formally left the EU on January 31, 2020 and the transition period, during which EU pharmaceutical laws continued to apply to the United Kingdom, has expired on December 31, 2020, the EU pharmaceutical laws now only apply to the United Kingdom in respect of Northern Ireland as laid out in the Protocol on Ireland and Northern Ireland. The EU and the United Kingdom have concluded a trade and cooperation agreement, or TCA, which is provisionally applicable since January 1, 2021. The TCA was ratified by the UK Parliament on December 30, 2020 and awaits the final agreement of the remaining 27 EU member states.

The TCA includes provisions affecting pharmaceutical businesses (including on customs and tariffs). In addition, there are some specific provisions concerning pharmaceuticals, including the mutual recognition of Good Manufacturing Practice, or GMP, inspections of manufacturing facilities for medicinal products and GMP documents issued. The TCA does not, however, contain wholesale mutual recognition of UK and EU pharmaceutical regulations and product standards.

Since January 1, 2021, the EU laws which have been transposed into UK law through secondary legislation continue to be applicable as "retained EU law." As there is no general power to amend these regulations, the UK government has introduced the "Medicines and Medical Devices Bill 2019 – 2021," which seeks to address this regulatory gap through introducing regulation-making, delegated powers covering the fields of human medicines, clinical trials of human medicines, veterinary medicines and medical devices. The purpose of the bill is to enable the existing regulatory frameworks to be updated. If the bill is enacted, the powers granted under it will

only be exercisable in relation to four pieces of legislation: the Human Medicines Regulations 2012, the Medicines for Human Use (Clinical Trials) Regulations 2004, the Medicines (Products for Human Use) Regulations 2016 and limited parts of the Medicines Act 1968 (specifically those parts which make provision related to pharmacies). It is then further restricted to amending or updating only those provisions stated in the bill, which include clinical trials.

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

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

Combination Products

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

To determine which the FDA center or centers will review a combination product candidate submission, companies may submit a request for assignment to the FDA. Those requests may be handled formally or informally. In some cases, jurisdiction may be determined informally based on FDA experience with similar products. However, informal jurisdictional determinations are not binding on the FDA. Companies also may submit a formal Request for Designation to the FDA Office of Combination Products. The Office of Combination Products will review the request and make its jurisdictional determination within 60 days of receiving a Request for Designation.

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

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

The post-market requirements that apply to the cleared or approved product will largely be aligned with the agency center determined to have primary jurisdiction over the product candidate and that provided marketing authorization, but manufacturers must also comply with certain post-market requirements with respect to the constituent parts of combination products. In April 2019, FDA published a final guidance document entitled Compliance Policy for Combination Product Postmarketing Safety Reporting, which is intended to assist manufacturers of combination products comply with reporting requirements applicable to such products. 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 (which includes collection, analysis and transfer of) personal data, 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. Further, the GDPR prohibits the transfer of personal data to countries outside of the EU that are not considered by the European Commission to provide an adequate level of data protection, including to the United States, except if the data controller meets very specific requirements. Following the Schrems II decision of the Court of Justice of the European Union on July 16, 2020, there is considerable uncertainty as to the permissibility of international data transfers under the GDPR. The European Data Protection Board has adopted draft recommendations for data controllers and processors who export personal data to third countries regarding supplementary measures to ensure compliance with the GDPR when transferring personal data outside of the European Union. These recommendations were submitted to public consultation until December 21, 2020, however it is unclear when and in which form these recommendations will be published in final form.

Failure to comply with the requirements of the GDPR and the related national data protection laws of the EU Member States may result in significant monetary fines and other administrative penalties as well as civil liability claims from individuals whose personal data was processed. Data protection authorities from the different EU Member States may still implement certain variations, enforce the GDPR and national data protection laws differently, and introduce additional national regulations and guidelines, which adds to the complexity of processing personal data in the EU. Guidance developed at both EU level and at the national level in individual EU Member States concerning implementation and compliance practices is often updated or otherwise revised.

There is, moreover, a growing trend towards required public disclosure of clinical trial data in the EU which adds to the complexity of obligations relating to processing health data from clinical trials. Such public disclosure obligations are provided in the new Regulation (EU) No 536/2014, EMA disclosure initiatives and voluntary commitments by industry. Failing to comply with these obligations could lead to government enforcement actions and significant penalties against us, harm to our reputation, and adversely impact our business and operating results. The uncertainty regarding the interplay between different regulatory frameworks, such as the Regulation (EU) No 536/2014 and the GDPR, further adds to the complexity that we face with regard to data protection regulation.

Healthcare Fraud and Abuse Laws

The federal Anti-Kickback Statute, or AKS, makes it a crime for a provider or supplier, including a laboratory, to knowingly and willfully offer, pay, solicit, or receive renumeration, directly or indirectly, in order to induce business reimbursable under any federal healthcare program. An intentional violation of the AKS may result in imprisonment for up to ten years and/or significant criminal fines. The U.S. government may also assess civil monetary penalties under AKS and seek to exclude the provider from participation in Medicare, Medicaid, and other federal healthcare programs.

Actions that violate the federal AKS or similar laws may also involve liability under the federal False Claims Act, or FCA, which prohibits knowingly presenting or causing to be presented a false or fraudulent claim for payment of U.S. government funds. Although the AKS and FCA apply only to federal healthcare programs, a number of states have passed substantially equivalent laws in which similar types of prohibitions are made applicable to other, non-federal health plans and third-party payors.

Federal and state law enforcement authorities scrutinize arrangements between healthcare providers and potential referral sources to ensure that the arrangements are not designed as a mechanism to induce patient care referrals and opportunities. The law enforcement authorities, the courts, and Congress have also demonstrated a willingness to look behind the formalities of a transaction to determine the underlying purpose of payments between healthcare providers and actual or potential referral sources. Generally, courts have taken a broad interpretation of the scope of the federal AKS. “Renumeration” is defined broadly to include anything of value, and some courts have held that the AKS may be violated if merely one purpose of a payment arrangement is to induce future referrals.

In December 1994 and in June 2014, the OIG issued Special Fraud Alerts on arrangements for the provision of clinical laboratory services and relationships between laboratories and referring physicians. The alerts described multiple practices allegedly employed by some clinical laboratories and healthcare providers that potentially violate federal fraud and abuse laws, including the AKS. The

OIG emphasized that when a purpose of such arrangements is to induce referrals for reimbursed laboratory testing, both the clinical laboratory and the healthcare provider may be liable under the AKS, and may be subject to criminal prosecution and exclusion from participation in Medicare and Medicaid.

Recognizing that the AKS is broad and may technically prohibit innocuous or beneficial arrangements for the provision of healthcare services, HHS developed a series of regulatory "safe harbors." These safe harbor provisions assure healthcare providers and other parties that they may not be prosecuted under the AKS, as long as all applicable requirements are met. Although full compliance with these provisions protects against prosecution under the AKS, the failure of a transaction or arrangement to fit squarely within a specific safe harbor does not necessarily mean that it is illegal or that the OIG will pursue prosecution under the AKS. While we believe we are not in violation of the AKS, we cannot provide assurance that our relationships with healthcare professionals, hospitals, and other customers will not be subject to scrutiny or will survive regulatory challenge. If imposed for any reason, sanctions under the AKS could have a negative effect on our business.

In addition to the requirements that are discussed above, there are several other healthcare fraud and abuse laws that could have an impact on our business. The federal FCA prohibits a person from knowingly submitting or causing to be submitted false claims or making a false record or statement in order to secure payment by the federal government. In addition to actions initiated by the government itself, the statute's "whistleblower," or "*qui tam*," provisions authorize actions to be brought on behalf of the federal government by a private party having knowledge of the alleged fraud, also known as a relator. Because a *qui tam* complaint is initially filed under seal, the action may be pending for some time before the defendant is even aware of the action. If the government is ultimately successful in obtaining monetary damages in the matter, or if the relator succeeds in obtaining monetary damages without the government's involvement, the relator will receive a percentage of the recovery. Violation of the FCA may result in fines of up to three times the actual damages sustained by the government, plus significant mandatory civil penalties for each separate false claim, imprisonment, or both, and possible exclusion from government healthcare programs, including Medicare and Medicaid.

In October 2018, the Eliminating Kickbacks in Recovery Act of 2018, or EKRA, was passed as part of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (the SUPPORT Act). The EKRA creates criminal penalties for knowingly and willfully paying, offering to pay, soliciting, or receiving any remuneration (including any kickback, bribe, or rebate), whether directly or indirectly, overtly or covertly, in cash or in kind, to induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory, or in exchange for an individual using the services of that recovery home, clinical treatment facility, or laboratory, unless a specific exception applies. Unlike the federal AKS, the EKRA applies to all "health care benefit programs," including private health care programs, and is not limited to government health care programs. Most of the safe harbors available under the federal AKS are not reiterated under the EKRA's exceptions. Therefore, compliance with a federal AKS safe harbor does not guarantee protection under the EKRA. As such, the EKRA potentially expands the universe of arrangements that could be subject to enforcement under federal fraud and abuse laws. Violation of the EKRA may result in significant fines and imprisonment up to 10 years for each occurrence. Because the EKRA is a new law, there is very little additional guidance to indicate how and to what extent it will be applied and enforced by government agencies in our industry. Our relationships with healthcare professionals, sales representatives, hospitals, or customers may be subject to scrutiny under the EKRA. If imposed for any reason, sanctions under the EKRA could have a negative effect on our business.

We are also subject to a federal law called the Physician Self-Referral Law, or "Stark Law", which prohibits, with certain exceptions, "self-referrals," which in our case means payments made by a laboratory to a physician in exchange for the provision of clinical laboratory services, presenting or causing to be presented claims to Medicare and Medicaid for laboratory tests referred by physicians who personally, or through a family member, have an investment interest in, or a compensation arrangement with, the clinical laboratory performing the tests. A person who attempts to circumvent the Stark Law may be subject to significant fines 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 on a per violation basis, plus up to three times the amount of reimbursement claimed, and possible exclusion from government healthcare programs, including Medicare and Medicaid. Claims that violate the Stark Law may not be paid by Medicare or Medicaid, and any person collecting any amounts under such claims is obligated to refund the payment. Various states have also enacted self-referral restrictions with which we have to comply and which differ from those imposed by the federal Stark Law.

While we have attempted to comply with the federal fraud and abuse laws, and similar laws of other states, some of our arrangements could be subject to regulatory scrutiny, and we cannot provide assurance that we will be found to be in compliance with these laws following regulatory review.

Further, in addition to the privacy and security regulations stated above, HIPAA created two federal crimes: (1) healthcare fraud and (2) false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully defrauding a healthcare benefit program, including private payors. A violation of this statute may result in fines, imprisonment, or exclusion from government healthcare programs. The false statements statute prohibits knowingly and willfully falsifying, concealing, or covering up

a material fact or making a materially false, fictitious, or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items, or services. A violation of this statute may result in fines or imprisonment.

Finally, federal law prohibits any entity from offering or transferring to a Medicare or Medicaid beneficiary any remuneration that the entity knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of Medicare or Medicaid payable items or services, including waivers of copayments and deductible amounts (or any part thereof) and transfers of items or services for free or for other than fair market value. Any violation of these prohibitions may result in significant civil monetary penalties for each wrongful act. Although we believe that our sales and marketing practices comply in all materials respects with all applicable federal and state laws and regulations, regulatory authorities may disagree. Any identified violation of applicable fraud and abuse laws could result in significant fines or our exclusion from Medicare, Medicaid, and other governmental programs, which could have a material adverse effect on our business, results of operations, financial condition, and cash flows.

Regulations Related to Our Precision Medicine Business

Due to the variety of product candidates that we are developing, we and our product candidates will be subject to a wide variety of regulations promulgated by the FDA. Specifically, our product candidates are subject to regulation by the FDA's Center for Biologics Evaluation and Research, Center for Devices and Radiological Health and Center for Drug Evaluation and Research, as well as other non-U.S. regulatory bodies (should we develop the product candidates and seek to obtain regulatory clearances or approvals to market outside of the United States).

Avero Diagnostics Relationship and the Corporate Practice of Medicine

Through one of our wholly-owned subsidiaries, we have a contractual relationship with Mattison Pathology, LLP, dba Avero Diagnostics, a professional partnership organized in Texas. In accordance with the terms of a management services agreement, we provide certain management services, including required office functions, to Avero Diagnostics and we also agree that Avero Diagnostics will be solely and exclusively in control of its provision of professional medical services and we will neither have nor exercise any control or discretion over the methods by which the physicians employed by Avero Diagnostics practice medicine. For additional information regarding our relationship with Avero Diagnostics, please see Note 3. Variable Interest Entity to our audited financial statements for the year ended December 31, 2019, included in this prospectus. A separate nominee agreement provides us the right, but not the obligation, to designate persons to purchase the stock of Avero Diagnostics at any time for a nominal amount. We receive a management fee equal to the net operating income of Avero Diagnostics. In the event that Avero Diagnostics incurs losses, we have no obligation to absorb those losses or provide additional cash support to Avero Diagnostics, but we may choose to do so and have done so in the past. We have determined that Avero Diagnostics is a variable interest entity and that Progenity is the primary beneficiary, resulting in the consolidation of Avero Diagnostics as required by the accounting guidance for consolidation.

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

Environmental Matters

Our operations require the use of hazardous materials (including biological materials), which materials subject us to a variety of federal, state, and local environmental and safety laws and regulations. Some of these laws and regulations provide for strict liability, potentially holding a party liable without regard to fault or negligence. We could be held liable for damages and fines as a result of our, or others', business operations should contamination of the environment or individual exposure to hazardous materials occur. We cannot predict how new, or changes in, laws or regulations will affect our business, operations, or the cost of compliance.

Facilities

Our headquarters are located in San Diego, California, where we lease 25,795 square feet of office space. Our lease expires in June 2023.

We own property in Ann Arbor, Michigan that we use for laboratory testing and research and such property is subject to a mortgage. We also lease approximately 26,000 square feet of office space in Ann Arbor, Michigan. Our lease expires in October 2023, and we have an option to extend it through at least October 2028.

We own property located in Lubbock, Texas that we use for the purpose of laboratory testing for Avero Diagnostics and such property is subject to a mortgage. We also lease approximately 42,000 square feet of laboratory testing and research space for Avero Diagnostics in Irving, Texas. Our lease expires in November 2022, and we have an option to extend it through November 2027.

We believe that our current facilities are adequate for our needs. We also believe we will be able to obtain additional space, as needed, on commercially reasonable terms.

Employees

As of December 31, 2020, we had 649 employees, 635 of which are 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.

Corporate Information

We were incorporated in Delaware in January 2012 under the name Ascendant MDx, Inc., and we later changed our name in August 2013 to Progenity, Inc. Through our predecessor, Ascendant MDx, a California corporation, we commenced our operations in 2010. Our principal executive offices are located at 4330 La Jolla Village Drive, Suite 200, San Diego, CA 92122, and our telephone number is (855) 293-2639. Our website is www.progenity.com. 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 our 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.

Risk Factor Summary

- The recent and 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 currently receive and expect to continue to receive a significant portion of our revenues from our women's health-related NIPT and carrier screening products, and if our efforts to further increase the use and adoption of these products fail, our business will be harmed.
- We have incurred losses in the past, and we may not be able to achieve or sustain profitability in the future.
- We operate in a highly competitive business environment.
- Our success depends on our ability to improve and enhance our current products and develop new product candidates, which is complex and costly and the results are uncertain.
- We are still developing our precision medicine platform and to date have generated no 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.
- 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.
- Our outstanding debt, and any new debt, may impair our financial and operating flexibility.
- Although we have implemented compliance policies and have an internal audit function, we cannot ensure that our employees will fully adhere to such policies.
- We have increased the size of our organization and expect to further increase it in the future, and we may experience difficulties in managing this growth. If we are unable to manage the anticipated growth of our business, our future revenue and operating results may be adversely affected.
- We may not be able to obtain and maintain the third-party relationships that are necessary to develop, commercialize, and manufacture some or all of our product candidates.
- We rely on a limited number of suppliers or, in some cases, single suppliers, for some of our laboratory instruments and materials and may not be able to find replacements or immediately transition to alternative suppliers on a cost-effective basis, or at all.
- If third-party payors do not adequately reimburse for our products, they might not be purchased or used, which may adversely affect our revenue and profitability.
- We may be unable to expand or maintain third-party payor coverage and reimbursement for our Innatal, Preparent, and other tests.
- 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

The recent and 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 our laboratory operations, sales and marketing efforts, 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, 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. For example, in December 2019, a novel strain of coronavirus, SARS-CoV-2, causing a disease referred to as COVID-19, was reported to have surfaced in Wuhan, China. Since then, COVID-19 has spread to other countries and throughout the United States. In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic, and the U.S. government imposed restrictions on travel between the United States, Europe, and certain other countries. Since March 2020, numerous state and local jurisdictions, including the jurisdictions where our headquarters and laboratories are located, have imposed, and others in the future may impose, quarantines, shelter-in-place orders, executive, and similar government orders for their residents to control the spread of COVID-19.

In response to these public health directives and orders, we have implemented work-from-home 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 the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition. We continue to monitor state and local quarantine, shelter-in-place, executive, and similar government orders and will reopen our offices to allow employees to return to the office, as needed, in accordance with our reopening plan, which is based on a phased approach that is appropriately tailored for each of our offices, with a focus on 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 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. In addition, reimbursements for our tests have been delayed and may continue to be delayed if third-party payors' processing continues to be impacted by the COVID-19 pandemic and work-from-home policies and other operational limitations mandated by federal, state, and local governments as a result of the pandemic. While the potential economic impact brought by COVID-19, and the duration of such impact, may be difficult to assess or predict, the widespread pandemic has resulted in significant disruption of global financial markets, which could reduce our ability to access capital and negatively affect our future liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 and related government orders and restrictions could materially affect our business and the value of our common stock.

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 and we now expect to instead commence this study in 2021. If COVID-19 continues to spread in the United States and elsewhere, we may experience additional disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- delays in receiving authorization from local regulatory authorities to initiate our planned clinical trials;
- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials, including interruption in global shipping that may affect the transport of clinical trial materials;
- changes in local regulations as part of a response to the COVID-19 pandemic 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. The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems, or the global economy as a whole.

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

We currently receive and expect to continue to receive a significant portion of our revenues from the sales of our women's health-related NIPT product, Innatal, and our carrier screening products, including Preparent. We undertake efforts to increase the awareness and adoption of Innatal and Preparent among laboratories, clinics, clinicians, physicians, payors, and patients. Continued and additional market acceptance of Innatal and Preparent and our ability to attract new customers are key elements to our future success. The market demand for NIPT and carrier screening tests has grown in recent years and is evolving. For example, in August 2020, ACOG issued a new set of guidelines recommending that prenatal aneuploidy screening be offered to all pregnant women regardless of their age or other risk factors. However, this market trend may not continue. Demand for Innatal and Preparent is affected by a number of factors, many of which are beyond our control, including the recommendation of our products by physicians, the timing and development of new products by our competitors, and reimbursement from payors. Despite the recent ACOG guidelines, payors may elect not to cover prenatal aneuploidy screening for average risk women and such recommendations may not result in an increase in market demand.

Our ability to increase sales of our products and establish greater levels of adoption and reimbursement for our products is

uncertain for many reasons, including, among others:

- we may be unable to demonstrate to laboratories, clinics, clinicians, physicians, payors, and patients that our products are superior to alternatives with respect to value, convenience, accuracy, scope of coverage, and other factors;
- third-party coverage and reimbursement are currently primarily limited to high-risk pregnancies and, despite recent ACOG guidelines regarding average-risk pregnancies, may not gain acceptance for use in the average-risk pregnancy population or for the screening of microdeletions, limiting the overall addressable market;
- third-party payors may set the amounts of reimbursement at prices that reduce our profit margins or do not allow us to cover our expenses;
- we may not be able to maintain and grow effective sales and marketing capabilities;
- our sales and marketing efforts may fail to effectively reach customers or communicate the benefits of our products;
- superior alternatives to our products may be developed and commercialized;
- we may experience supply constraints, including due to the failure of our key suppliers to provide required sequencing instruments and reagents;
- the FDA may initiate rulemaking to impose premarket review, clearance, or approval or other requirements over laboratory developed tests, or LDTs; and
- the FDA or other U.S. or foreign regulatory or legislative bodies may adopt new regulations or policies or take other actions that impose significant restrictions on our ability to market our products.

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

In addition, as our products may have different reimbursement rates and reimbursement amounts, a change in product mix could negatively impact our average selling price and total revenue. For example, during the COVID-19 pandemic, which has caused an overall decrease in demand for our products, demand for our NIPT product has been more resilient than for our carrier screening products, leading to a higher proportion of NIPT tests in our product mix. The average reimbursement rate for our NIPT product tends to be slightly lower than for our carrier screening products. In addition, we added COVID-19 testing to our product mix, which has a lower reimbursement amount per test. As a result, our average selling price and revenue was negatively impacted.

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

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

Other than revenues from our laboratory testing business, we do not expect to generate revenues from other sources in the immediate future. It is possible that we will not generate sufficient revenue from the sale of our products to cover our costs, including research and development expenses related to furthering our product pipeline, and achieve or sustain profitability. A significant element of our business strategy is to increase and maintain our in-network coverage with third-party payors; however, the negotiated fees under our contracts with third-party payors are typically lower than the list price of our tests, and in some cases the third-party payors with whom we contract may have negative coverage determinations for some of our offerings. Therefore, being in-network with third-party payors has had, and may continue to have, an adverse impact on our revenues especially if we are unable to increase the adoption of, and obtain favorable coverage determinations and reimbursement for, our products.

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

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

- we acquire or in-license additional technologies, product candidates, products, or businesses.

We operate in a highly competitive business environment.

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

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

Moreover, established, traditional first-line testing prenatal methods, such as serum protein measurement, where doctors measure certain hormones in the blood, and invasive prenatal diagnostics tests like amniocentesis, have been used for many years and are therefore practices that are difficult to change or supplement. Our conception and pre-implantation genetic screening products face competition from various laboratories that offer or seek to offer similar solutions. We also compete against companies providing hereditary cancer screening tests. For more information on our molecular testing competitors, see Part I, Item 1. "Business—Competition in Molecular Testing."

We expect any of our future precision medicine products to face substantial competition from major pharmaceutical companies, biotechnology companies, academic institutions, government agencies, and public and private research institutions. The larger competitors have substantially greater financial and human resources, as well as a much larger infrastructure than we do. For more information on our precision medicine competitors, see 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 portfolio. 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 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 our existing products and any future products may decline rapidly if a new product is introduced by a competitor, particularly if a new product represents a substantial improvement over any of our existing products. In addition, the high level of competition in our industry could force us to reduce the price at which we sell our products or require us to spend more to market our products.

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

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

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

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

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

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

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

Our operations with respect to our precision medicine platform to date have been limited to developing our platform technology, undertaking preclinical studies and clinical trials, and conducting research to identify potential product candidates. To date, we have only conducted clinical trials to evaluate whether our platform localization technology enables identification of the location of our ingestible medical devices within the gastrointestinal tract as well as the function of our DDS device.

We seek to develop a suite of ingestible capsules for both diagnostic and therapeutic solutions. However, medical device and related diagnostic and therapeutic product development is a highly speculative undertaking and involves a substantial degree of uncertainty. Our precision medicine platform has not yet demonstrated an ability to generate revenue or successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields such as ours 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 products may have undesirable side effects or other unexpected characteristics.

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

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

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

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

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

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

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

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

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

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product, and our 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 tests and other product candidates, or may not be replicated in later studies required for marketing authorizations.

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

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

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

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

In response to the COVID-19 pandemic, we are providing molecular testing for diagnosing COVID-19 through Avero Diagnostics. The demand for such testing may decrease in the future and our investment in such testing capabilities may not pay off.

The COVID-19 pandemic has created an opportunity for our diagnostic tests and the Avero Diagnostics laboratory is providing molecular testing for diagnosing COVID-19. Avero Diagnostics' molecular testing utilizes certain third-party in-vitro diagnostics that have received Emergency Use Authorization, or EUA, from the FDA. The FDA has the authority to issue an EUA during a public health emergency if it determines that based on the totality of the scientific evidence that it is reasonable to believe that the product may be effective, that the known and potential benefits of a product outweigh the known and potential risks, that there is no adequate, approved, and available alternative, and if other regulatory criteria are met. These standards for marketing authorization are lower than if FDA had reviewed these tests under its traditional marketing authorization pathways, and we cannot assure you that these would be cleared or approved under those more onerous clearance and approval standards. Moreover, FDA's policies regarding EUAs can change unexpectedly, and FDA may revoke an EUA where it determines that the underlying health emergency no longer exists or warrants such authorization or if problems are identified with the authorized product. We cannot predict how long these authorizations will remain in place. FDA policies regarding diagnostic tests, therapies and other products used to diagnose, treat or mitigate COVID-19 remain in flux as the FDA responds to new and evolving public health information and clinical evidence. Changes to FDA regulations or requirements could require changes to authorized tests, necessitate additional measures, or make it impractical or impossible for Avero Diagnostics to continue utilizing these tests. The termination of any of the EUAs for the COVID-19 testing being run by Avero Diagnostics could adversely impact our business, financial condition and results of operations. There is no assurance that our COVID-19 diagnostic testing program will continue to be accepted by the market or that, when compared to our COVID-19 tests, other diagnostic tests will not become more accepted, produce quicker results, or be more accurate. Further, the longevity and extent of the COVID-19 pandemic is uncertain. Future demand for COVID-19 testing is becoming increasing difficult to predict due to various factors including but not limited to the availability of vaccinations, the number of individuals who choose to be vaccinated, the effectiveness of the various vaccinations against variants, the rate of new cases, and evolving government directives, laws, regulations and rules related to COVID-19 testing. In the long term, we expect that the COVID-19 pandemic will eventually dissipate and, as a result, the significance of COVID-19 testing to our business and financial results will decrease. As a result, the increase in revenue due to any increase in demand for these diagnostic tests may not be indicative of our future revenue.

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.

In the future, we expect to incur significant costs in connection with our operations, including but not limited to the development, marketing authorization, and commercialization of new tests, medical devices, therapeutics, and other products. These development activities generally require a substantial investment before we can determine commercial viability, and the proceeds from our initial public offering, or IPO, in June 2020 and concurrent equity and convertible debt offerings in December 2020 will not be sufficient to fully fund these activities. We expect to need to raise additional funds through public or private equity or debt financings, collaborations or licensing arrangements to continue to fund or expand our operations.

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

- the scope and duration of and expenditures associated with our discovery efforts and research and development programs, including for our precision medicine platform;
- the costs to fund our commercialization strategies for any product candidates for which we receive marketing authorization or otherwise launch and to prepare for potential product marketing authorizations, as required;

- the costs of any acquisitions of complementary businesses or technologies that we may pursue;
- potential licensing or partnering transactions, if any;
- our facilities expenses, which will vary depending on the time and terms of any facility lease or sublease we may enter into, and other operating expenses;
- the scope and extent of the expansion of our sales and marketing efforts;
- potential and pending litigation, potential payor recoupments of reimbursement amounts, and other contingencies;
- the commercial success of our products;
- our ability to obtain more extensive coverage and reimbursement for our tests and therapeutic products, if any, including in the general, average-risk patient population; and
- our ability to collect our accounts receivable.

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

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

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

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

As of each of December 31, 2020, we had approximately $171.6 million of outstanding indebtedness, composed of the amount due under our convertible notes payable and mortgages payable. Certain of our debt agreements contain various restrictive covenants and our mortgages are secured by real estate assets.

The indenture for the 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 $15,000,000 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.

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

We have implemented compliance policies and procedures intended to train and monitor our sales, billing, marketing and other personnel. Our efforts to implement appropriate monitoring of such personnel are ongoing and we have identified and are analyzing situations in which employees may have failed to fully adhere to our policies and applicable laws in the past. For example, as part of our work to improve our compliance program and our obligations under our Corporate Integrity Agreement (as defined below), including our internal auditing and monitoring function, we commissioned a third-party analysis of our coding and billing processes. In connection with that audit, we identified that we had not timely and appropriately transitioned to the implementation of a new CPT code in 2019, and as a result we received an overpayment of approximately $10.0 million from government payors during 2019 and early 2020. We also conducted a similar review of our historic practices regarding the collection of patient responsibility amounts, including copayments and deductibles, from government health program beneficiaries between May 2018 and May 2020. We reported the overpayments identified in both audits to the Office of Inspector General of the Department of Health and Human Services, or the OIG, in compliance with our Corporate Integrity Agreement. For additional information on our transition for this CPT code, see Notes 4 and 10 to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. There can be no assurance that we will not identify further compliance, billing, or other failures or experience similar issues in the future. Failure by our sales, billing, marketing, or other personnel to follow our policies and comply with applicable laws may subject us to administrative, civil, and criminal actions, penalties, damages, fines, individual imprisonment, exclusion from participation in federal healthcare programs, refunding of payments received by us, and curtailment or cessation of our operations. For additional information regarding recent government investigations regarding our compliance with certain policies and laws, see Part I, Item 3. “Legal Proceedings.” In addition, in the event of failure by our sales, billing, marketing, or other personnel to follow our policies and comply with applicable laws, commercial third-party payors may refuse to provide all or any reimbursement for tests administered and seek repayment from us of amounts previously reimbursed, which failures may harm our ability to secure network contracts with third-party payors. For additional information regarding recent claims by and settlement agreements with commercial payors, see Part I, Item 1. “Business—Reimbursement—Payor Dispute” and “—Commercial Third-Party Payors.” Any of the foregoing could adversely affect our revenue, cash flow, and financial condition, and reduce our growth prospects. For additional information regarding these risks, see the risk factor titled “If we or our commercial partners act in a manner that violates healthcare laws or otherwise engage in misconduct, we could face substantial penalties and damage to our reputation, and our business operations and financial condition could be adversely affected.”

Compliance with the terms and conditions of our Corporate Integrity Agreement requires significant resources and, if we fail to comply, we could be subject to penalties or excluded from participation in government healthcare programs, which could harm our results of operations, liquidity and financial condition.

In connection with settlement of the government investigations described in Part I, Item 3. “Legal Proceedings,” effective July 21, 2020, we entered into a five-year corporate integrity agreement, or the Corporate Integrity Agreement, with the OIG. The Corporate Integrity Agreement requires, among other matters, that we maintain a Compliance Officer, a Compliance Committee, board review and oversight of 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; implement a risk assessment and internal review process; and submit periodic reports to the OIG regarding our compliance program and Corporate Integrity Agreement implementation. The Corporate Integrity Agreement requires us to report substantial overpayments that we discover we have received from federal health care programs, as well as probable violations of federal health care laws. See “Risk Factors—Although we have implemented compliance policies and have an internal audit function, we cannot ensure that our employees have adhered or will fully adhere to such policies.” We are in the process of implementing the processes, policies and procedures required under the Corporate Integrity Agreement. Implementing and administering such processes, policies and procedures will require significant management attention and cash and other resources. Furthermore, while we have developed and instituted a corporate compliance program, we cannot guarantee that we, our employees, our consultants or our contractors are or will be in compliance with all potentially applicable federal healthcare laws or all requirements of the Corporate Integrity Agreement. Our failure to comply with our obligations under the Corporate Integrity Agreement could result in monetary penalties and our exclusion from participating in federal healthcare programs. The costs associated with compliance with the Corporate Integrity Agreement, or any liability or consequences associated with its breach, could have an adverse effect on our operations, liquidity and financial condition.

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.

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

In addition, our direct communications with patients may be scrutinized under the laws and regulations governing such communications. The interpretation of many of these statutes, regulations and rulings is evolving in the courts and administrative agencies and an inability to comply may have an adverse impact on our business. For example, the Telephone Consumer Protection Act, or TCPA, imposes significant restrictions on utilizing text messages to mobile telephone numbers as a means of communication, when the prior express consent of the person being contacted has not been obtained or proof of such consent is not properly maintained. Our ability to communicate with patients may be affected by the TCPA, its implementing regulations and litigation pursuant to the TCPA. The determination by a court or regulatory agency that our SMS text messaging violates the TCPA could subject us to civil penalties, could require us to change some portions of our business and could otherwise harm our business.

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

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

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

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

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

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

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

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

As of December 31, 2020, we had 635 full-time employees worldwide. We have significantly expanded the size of our organization over the past several years, particularly personnel within our sales and marketing and research and development groups, and we expect to continue to do so in the future. As we transition into operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial, and other personnel. Future growth would impose significant added responsibilities on members of management, including:

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

Our future financial performance and our ability to successfully develop, market, and sell our products and product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities. As we continue to grow our sales force, the impact of such growth on our revenue may be delayed as a result of time needed for onboarding and training of new sales force members.

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

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

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

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

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

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

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

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

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

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

A portion of our tests are performed by third-party CLIA certified laboratories. These third-party laboratories are subject to contractual obligations but are not otherwise under our control. We, therefore, do not control the capacity and quality control efforts of

these third-party laboratories other than through our ability to enforce contractual obligations on volume and quality systems. In the event of any adverse developments with these third-party laboratories or their ability to perform this testing in accordance with the legal, regulatory, or commercial standards, our ability to provide test results to customers may be delayed, interrupted, or suspended. Any natural or other disasters, pandemics, acts of war or terrorism, shipping embargoes, labor unrest, or political instability or similar events at our third-party laboratories' facilities that cause a loss of testing capacity would heighten the risks that we face.

Changes to or termination of our agreements or inability to renew our agreements with these parties or enter into new agreements with other laboratories that are able to perform such testing could impair, delay, or suspend our efforts to market and commercialize our tests. Such interruption could harm our reputation and lead to the loss of customers, and we may be unable to regain those customers in the future. In addition, certain third-party payors may take the position that sending out this testing to third-party laboratories is contrary to the terms of their coverage policies and/or our contract in cases where we are in-network with the payor, and may refuse to pay us for testing that we have outsourced. If any of these events occur, our business, operating results, and financial condition could suffer.

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

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

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

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

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

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

through a pre-market approval application, or PMA, we may also be required to obtain approval of a PMA supplement prior to making any changes to Innatal or Preparent as a result of implementing an alternative sequencing platform.

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

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

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

In addition, we or third parties may experience other problems with the manufacturing, quality control, storage or distribution of our products, including equipment breakdown or malfunction, failure to follow specific protocols and procedures, problems with suppliers and the sourcing or delivery of raw materials and other necessary components, problems with software, labor difficulties, and natural disaster-related events or other environmental factors. These problems can lead to increased costs, lost sales, damage to customer relations, failure to supply penalties, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches of products. If problems are not discovered before the product is released to the market, recalls, corrective actions, or product liability-related costs also may be incurred. Problems with respect to the manufacture, storage, or distribution of products could materially disrupt our business and have a material and adverse effect on our operating results and financial condition. For additional information regarding our third-party suppliers and manufacturers, see Part I, Item 1. "Business—Laboratories—Laboratory Supplies."

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Failure to successfully discover, develop, manufacture, and sell biologics could adversely impact our business, operating results, and financial condition.

Even if we are able to successfully develop biologics in the future, the Biologics Price Competition and Innovation Act, or BPCIA, created a framework for the approval of biosimilars in the United States that could allow competitors to reference data from any future biologic products for which we receive marketing approvals and otherwise increase the risk that any product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the original biologic was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full Biologics License Application, or BLA, for the competing product containing the sponsor’s own 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 products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences. Expiration or successful challenge of our applicable patent rights could also trigger competition from other products, assuming any relevant exclusivity period has expired. As a result, we could face more litigation and administrative proceedings with respect to the validity and/or scope of patents relating to our biologic products.

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

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

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

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

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

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

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

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

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

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

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

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

The use of our current products and precision medicine product candidates could be associated with side effects or adverse events, which can vary in severity (from minor reactions to death) and frequency (infrequent or prevalent). Side effects or adverse events associated with the use of our product candidates may be observed at any time, including in clinical trials or when a product is commercialized. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory authorization by the FDA or other comparable foreign authorities. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects such

as toxicity or other safety issues and could require us or our collaboration partners to perform additional studies or halt development or sale of these product candidates or expose us to product liability lawsuits, which would harm our business and financial results. In such an event, we may be required by regulatory agencies to conduct additional animal or human studies regarding the safety and efficacy of our product candidates, which we have not planned or anticipated or our studies could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny or withdraw approval of our product candidates for any or all targeted indications. There can be no assurance that we will resolve any issues related to any product-related adverse events to the satisfaction of the FDA or any other regulatory agency in a timely manner, if ever, which could harm our business, operating results, financial condition and prospects.

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

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

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

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

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

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

The FDA and similar foreign governmental authorities have the authority to require the recall of certain commercialized products over which they exercise oversight in the event of material deficiencies or defects in design or manufacture or a public health/safety issue. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture or a public health/safety issue. Manufacturers may, under their own initiative, recall a product if any material deficiency is found. The FDA requires that certain recalls of medical devices be reported to the FDA within 10 working days after the recall is initiated. We may initiate voluntary recalls involving our products in the future that we determine do not require us to notify the FDA. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. In addition, the FDA could bring an enforcement action against us based on our failure to report the recalls when they were conducted. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Once marketed, recalls of any of our products, including our precision medicine products, would divert managerial and financial resources and could have a material and adverse effect on our business, operating results, and financial condition. A future recall announcement could harm our reputation with customers and negatively affect our sales.

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

We provide anatomic and molecular pathology testing through our affiliation with Mattison Pathology, LLP, a Texas limited liability partnership doing business as Avero Diagnostics, located in Lubbock and Irving, Texas. The laws of certain states in which we operate or may operate in the future prohibit non-physician entities from practicing medicine, exercising control over physicians or engaging in certain practices such as fee-splitting with physicians. Although we believe that we have structured our affiliation with Avero Diagnostics to ensure that the physicians maintain exclusive authority regarding the delivery of medical care, there can be no assurance that these laws will be interpreted in a manner consistent with our practices or that other laws or regulations will not be enacted in the future that could have a material and adverse effect on our business, operating results, and financial condition. Regulatory authorities and other parties, including our associated physicians, may assert that, despite the management service agreement and other arrangements through which we operate, we are engaged in the prohibited corporate practice of medicine, and/or that our arrangement with Avero Diagnostics constitutes unlawful fee-splitting. If a corporate practice of medicine or fee-splitting law is interpreted in a manner that is inconsistent with our practices, we would be required to restructure or terminate our relationship with Avero Diagnostics to bring its activities into compliance with such law. A determination of noncompliance, the termination of or failure to successfully restructure this relationship could result in disciplinary action, penalties, damages, fines, and/or a loss of revenue, any of which could have a material and adverse effect on our business, operating results, and financial condition. For more information regarding our relationship with Avero Diagnostics, see Part I, Item 1. “Business—Government Regulation—Avero Diagnostics Relationship and the Corporate Practice of Medicine.”

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

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

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

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

adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

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

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

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

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

In addition, we may be subject to product liability claims and lawsuits, including potential class actions, alleging that our products have resulted in or could result in an unsafe condition or injury. The product candidates we are developing using our precision medicine platform are designed to be ingested, and there are a number of factors that could result in an unsafe condition or injury to, or death of, a patient with respect to these or other products that we sell. A product liability or professional liability claim could result in substantial damages and be costly and time-consuming for us to defend. Although we maintain product and professional liability insurance, our insurance may not fully protect us from the financial impact of defending against product liability or professional liability claims or any judgments, fines or settlement costs arising out of any such claims. Any product liability or professional liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any product liability or professional liability lawsuit could harm our reputation, result in a cessation of our testing, or cause our partners to terminate existing agreements and potential partners to seek other partners, any of which could adversely impact our business, operating results, and financial condition.

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

Our operating results, including our revenues, gross margin, profitability, and cash flows, have varied in the past and may vary significantly in the future, and period-to-period comparisons of our operating results may not be meaningful. Accordingly, our results should not be relied upon as an indication of future performance. Our operating results, including quarterly financial results, may fluctuate as a result of a variety of factors, many of which are outside of our control. Fluctuations in our results may adversely impact the value of our common stock. Factors that may cause fluctuations in our financial results include, without limitation, those listed elsewhere in this "Risk Factors" section. In addition, our results may fluctuate due to the fact that we recognize costs as they are incurred, but there is typically a delay in the related revenue recognition as we record most revenue only upon receipt of payment.

Accordingly, to the extent our revenues increase, we may experience increased costs unless and until the related revenues are recognized. In addition, as we increase our internal sales and marketing and research and development efforts, we expect to incur costs in advance of achieving the anticipated benefits of such efforts. We also may face competitive pricing or reimbursement rate pressures, and we may not be able to maintain our sales volume and/or reimbursement rates in the future, which would adversely affect our business, operating results, and financial condition.

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

We have in the past entered into, and may in the future enter into, transactions to acquire other businesses, products, or

technologies. Successful acquisitions require us to correctly identify appropriate acquisition candidates and to integrate acquired products or operations and personnel with our own.

Should we make an error in judgment when identifying an acquisition candidate, should the acquired operations not perform as anticipated, or should we fail to successfully integrate acquired technologies, operations, or personnel, we will likely fail to realize the benefits we intended to derive from the acquisition and may suffer other adverse consequences. Acquisitions involve a number of other risks, including:

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

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

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.

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

DNA testing, such as testing that is conducted using Innatal, Preparent and our other products, has raised ethical, legal and social issues regarding privacy and the appropriate uses of the resulting information. Governmental authorities could, for social or other purposes, limit or regulate the use of genomic information or genomic testing or prohibit testing for genetic predisposition to certain conditions, particularly for those that have no known cure. Patients may also refuse to use genetic tests even if permissible, for similar reasons; they may also refuse genetic testing due to concerns regarding eligibility for life or other insurance. Ethical and social concerns may also influence U.S. and foreign patent offices and courts with regard to patent protection for technology relevant to our business.

Although the Genetic Information Non-discrimination Act has criminalized the disallowance of health insurance on the basis of genetic information, modification or retraction of this federal law could dramatically reduce public demand for genetic testing. These and other ethical, legal and social issues may limit market acceptance of our tests or reduce the potential markets for products enabled by our technology platform, either of which could harm our business, operating results, and financial condition.

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

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

is unclear how these U.S. federal income tax changes will affect state and local taxation. Generally, future changes in applicable tax laws and regulations, or their interpretation and application, could have a material and adverse effect on our business, operating results, and financial condition.

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

As of December 31, 2020, we had net operating loss, or NOL, carryforwards of approximately $271.1 million for federal income tax purposes, and $200.0 million for state income tax purposes. The federal NOLs will be carried forward indefinitely and the state NOLs began expiring in 2019. Utilization of these NOLs depends on many factors, including our future income, which cannot be assured. Some of these NOLs could expire unused and be unavailable to offset our future income tax liabilities. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50 percentage point change, by value, in its equity ownership by 5% stockholders over a rolling three-year period, the corporation's ability to use its pre-change NOLs and other pre-change tax attributes to offset its post-change income may be limited. If we determine that an ownership change has occurred and our ability to use our historical NOLs is materially limited, it could harm our future operating results by effectively increasing our future tax obligations. In addition, under the TCJA, federal NOLs incurred in 2018 and in future years may be carried forward indefinitely but generally may not be carried back and the deductibility of such NOLs is limited to 80% of taxable income. On March 27, 2020, Congress enacted the Coronavirus Aid, Relief and Economic Security Act, known as the CARES Act, which provides some relief from the limitations on the utilization of NOLs and certain other tax attributes described above. During the three months ended March 31, 2020, we recorded a discrete tax benefit of $37.7 million related to the NOL carryback provisions available under the CARES Act for taxes paid in years 2013, 2014, 2015, and 2017, which we refer to as the CARES Act Tax Benefit. 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."

Reimbursement Risks Related to Our Business

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

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

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

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

and/or imperfections in Medicare, Medicaid or other data used to calculate these rates. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or by any future relaxation of laws that restrict imports of certain medical products from countries where they may be sold at lower prices than in the United States.

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

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

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

Our business depends on our ability to obtain or maintain adequate reimbursement coverage from third-party payors. Third-party reimbursement for our testing represents a significant portion of our revenues, and we expect third-party payors such as third-party commercial payors and government healthcare programs to continue to be our most significant sources of payments in the foreseeable future. In particular, we believe that for us to achieve commercial success it will be necessary to gain acceptance from third-party payors for the screening of microdeletions and for use of NIPT in the average-risk pregnancy population, which population represents roughly 80% of the U.S. pregnancy market, and to obtain positive coverage determinations and favorable reimbursement rates from third-party payors for our tests. We did not receive reimbursement for a significant number of Innatal tests for average-risk patients that we performed in the year ended December 31, 2020. In addition, it is to be determined whether and to what extent certain of our other products, including those under development, will be covered or reimbursed. If we are unable to obtain or maintain coverage or adequate reimbursement from, or achieve in-network status with, third-party payors for our existing or future tests or other products, our ability to generate revenues will be limited. For example, healthcare providers may be reluctant to order our tests or other products due to the potential of a substantial cost to the patient if coverage or reimbursement is unavailable or insufficient.

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

In making coverage determinations, third-party payors often rely on practice guidelines issued by professional societies. ACOG has issued updated guidelines recommending informing pregnant women that Non-Invasive Prenatal Screening, or NIPS, is the most sensitive screening option for trisomy 13, trisomy 18, and Down syndrome, as well as of the availability of the expanded use of NIPT to screen for clinically relevant copy number variants, or CNVs, in the context of counseling that includes the risks/benefits and limitations of screening for CNVs. A CNV is a genetic mutation in which a segment of the genome has been deleted or duplicated, including microdeletions in which a small segment of a chromosome is deleted. The International Society for Prenatal Diagnosis has issued guidelines that are supportive of performing NIPT in average-risk pregnancies, as well as high-risk pregnancies. ACOG and the American College of Medical Genetics, or ACMG, have also provided support for the use of NIPT in the general population, with ACOG noting, however, that NIPT is not equivalent to diagnostic testing because of its potential for false-positive and false-negative results. However, the Society for Maternal Fetal Medicine, or SMFM, has issued guidelines for NIPT stating that, while all pregnant women should be informed of the option to receive NIPT, conventional screening methods, such as traditional serum screening, rather than NIPT, remain the most appropriate choice for first-line screening for average-risk pregnancies. Therefore, while we expect the ACOG and SMFM guidelines to result in an increase in the number of average-risk women who are informed of NIPT and that may request it as a result, not all third-party payors reimburse for NIPT for these average-risk patients.

In December 2020, Aetna finalized its reimbursement policy to cover NIPT in the average-risk population. UnitedHealthcare and a number of other third-party payors have also made a similar change to cover NIPT in the average-risk population. This leaves only some regional plans and some Medicaid plans with negative coverage determinations for NIPT in average-risk patient populations, meaning that their policy is not to reimburse for NIPT for patients in the average-risk or general population. The SMFM guidelines also echoed a previous statement from SMFM that routine screening for microdeletions should not be performed. Many third-party payors do not cover microdeletions screening. We have experienced, and may continue to experience, a negative impact on third-party payors' coverage for Innatal for microdeletions, at least until additional validation data on the sensitivity and specificity of our tests becomes available. We may not be able to obtain positive coverage determinations for our tests. If third-party payors do not reimburse for NIPT for average-risk pregnancies or microdeletions in the future, our operating results would be adversely affected, particularly to the extent that we continue to perform large volumes of

tests for which third-party payors do not cover.

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

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

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

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

Payors dispute our billing or coding from time to time and we deal with requests for recoupment from third-party payors from time to time in the ordinary course of our business, and we expect these disputes and requests for recoupment to continue. Third-party payors may decide to deny payment or recoup payment for testing that they contend to have been not medically necessary, against their coverage determinations, or for which they have otherwise overpaid, and we may be required to refund reimbursements already received. We have entered into settlement agreements with 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 third-party payors deny payment for testing, reimbursement revenue for our testing could decline. 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, and it may decrease reimbursement going forward. We may also decide to negotiate and settle with a third-party payor in order to resolve an allegation of overpayment. 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.

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

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

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

If a third-party payor denies coverage, or if the patient has a large deductible or co-insurance amount, it may be difficult for us to collect from the patient, and we may not be successful in doing so. If we are in-network, we are often contractually prohibited from seeking payment from the patient. If we are out-of-network, we are often unable to collect the full amount of a patient's responsibility, despite our good faith efforts to collect. As a result, we cannot always collect the full amount due for our tests when third-party payors deny coverage, cover only a portion of the invoiced amount or the patient has a large deductible, which may cause payors to raise questions regarding our billing policies and patient collection practices. We have in the past received, and we may in the future receive, inquiries from third-party payors regarding our billing policies and collection practices in these circumstances. Guidance from third-party payors regarding billing and patient collection practices will continue to evolve and may also impact our compliance with applicable requirements. While we have addressed these inquiries as and when they have arisen, there is no guarantee that we will be successful in addressing such concerns, and if we are unsuccessful, this may result in a third-party payor deciding to reimburse for our tests at a lower rate or not at all, seeking recoupment of amounts previously paid to us, or bringing legal action to seek reimbursement of previous amounts paid. Any of such occurrences could cause reimbursement revenue for our testing, which constitutes the large majority of our revenue, to decline. Additionally, if we were required to make a repayment, such repayment could be significant, which could have a material and adverse effect on our business, operating results, and financial condition.

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

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

We have experienced, and may continue to experience, delays in reimbursement when we transition to being an in-network provider with a third-party payor. In addition, while we expect to gradually see an increase in test volume through broader access to in-network patients and an increase in percentage of tests paid upon transitioning to in-network status with a payor, we also expect to experience a negative impact in revenues per test due to lower rates. We can provide no assurance that we will see the benefits of this transition to in-network status and that the increase in volume of tests and tests paid will be sufficient to compensate for the decrease in per test revenues.

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

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

Reduced reimbursement of our tests may harm our business, operating results, and financial condition. Billing for clinical laboratory testing services is complex. We perform tests in advance of payment and without certainty as to the outcome of the billing process. In cases where we expect to receive a fixed fee per test due to our reimbursement arrangements, we may nevertheless encounter variable reimbursement, leading to disputes over pricing and billing. Each third-party payor typically has different billing requirements, and the billing requirements of many payors have become increasingly difficult to meet. Among the factors complicating our billing of third-party payors are:

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

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

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

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

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

The U.S. government has shown significant interest in pursuing healthcare reform and reducing healthcare costs. Government healthcare policy has been and will likely continue to be a topic of extensive legislative and executive activity in the U.S. federal government and many U.S. state governments. As a result, our business could be affected by significant and potentially unanticipated changes in government healthcare policy, such as changes in reimbursement levels by government third-party payors. Any such changes could substantially impact our revenues, increase costs, and divert management attention from our business strategy. We cannot predict the impact of governmental healthcare policy changes on our future business, operating results, and financial condition. In the United States, the ACA was signed into law in March 2010 and significantly impacted the U.S. pharmaceutical and medical device industries, including the diagnostics sector, in a number of ways. Among other things, the ACA expanded healthcare fraud and abuse laws such as the False Claims Act and the Anti-Kickback Statute, including but not limited to required disclosures of financial arrangements with physician customers, required reporting of discovered overpayments, lower thresholds for violations, new government investigative powers, and enhanced penalties for such violations. The ACA restricts insurers from charging higher premiums or denying coverage to individuals with pre-existing conditions, and requires insurers to cover certain preventative services without charging any copayment or coinsurance, including screening for lung, breast, colorectal and cervical cancers. The ACA also created a new system of health insurance "exchanges" designed to make health insurance available to individuals and certain groups through state- or federally-administered marketplaces in addition to existing channels for obtaining health insurance coverage. In connection with such exchanges, certain "essential health benefits" are intended to be made more consistent across plans, setting a baseline coverage level. The states (and the federal government) have some discretion in determining the definition of "essential health benefits" and we do not know whether our tests or other products will fall into a benefit category deemed "essential" for coverage purposes across the plans offered in any or all of the exchanges. If any of our tests are not covered by plans offered in the health insurance exchanges, our business, operating results, and financial condition could be adversely affected. There have been multiple attempts to repeal ACA or significantly scale back its applicability, which could negatively impact reimbursement for our testing, adversely affect our test volumes, and adversely affect our business, operating results, and financial condition. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or Texas District Court Judge, ruled that the entire ACA is invalid based primarily on the fact that the legislation enacted on December 22, 2017, informally known as the Tax Cuts and Jobs Act, repealed the tax-based shared responsibility payment imposed by the ACA, on certain individuals who fail to maintain qualifying

health coverage for all or part of a year, which is commonly referred to as the "individual mandate." On December 18, 2019, the 5th Circuit Court of Appeals upheld the Texas District Court's ruling that the individual mandate was unconstitutional, but remanded the case back to the Texas District Court to determine whether the remaining provisions of the ACA were nonetheless valid. On March 2, 2020, the U.S. Supreme Court granted the petitions for writs of certiorari to review the case and a decision is expected by mid-2021, although it is unclear how the Supreme Court will rule. The repeal of this mandate would mean that fewer consumers will carry insurance coverage and therefore may be less likely to elect to receive our testing because they would be required to pay out of pocket for such tests. The attempts to repeal the ACA have resulted in considerable uncertainty and concern regarding, for example, a patient's election to undergo genetic screening and whether doing so may impact health insurance eligibility. Because it is unclear whether or how the ACA may change, and whether and to what extent NIPT, cancer screening or other genetic screening may be affected, we are uncertain how our business may be impacted.

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

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

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

Our revenues from Medicare are currently very small and were only 4.2% of our total revenues in 2020, given our current product mix and the fact that our testing generally is not received by Medicare beneficiaries. As a result, we do not expect those revenues to change materially with regard to our current commercial products. However, our other products in development may be used by Medicare beneficiaries in the future. Medicare reimbursement can affect both Medicaid reimbursement, which is relevant to NIPT and carrier screening, and reimbursement from commercial third-party payors. Specifically, fee-for-service Medicaid programs generally do not reimburse at rates that exceed Medicare's fee-for-service rates, and many commercial third-party payors set their payment rates at a percentage of the amounts that Medicare pays for testing services. Medicare reimbursement rates are typically based on the CLFS, set by CMS pursuant to a statutory formula established by Congress. Our current Medicare Part B coverage was not set pursuant to a national coverage determination by CMS. Although we believe that coverage is available under Medicare Part B even without such a determination, we currently lack the certainty afforded by a formal national coverage determination by CMS. Thus, CMS or a regional Medicare Administrative Contractor, or MAC, could issue an adverse coverage determination as to Innatal or Preparent or our future products, if any, which could influence other third-party payors, including Medicaid, and could have a material and adverse effect on our business, operating results, and financial condition.

It is estimated that nearly half of all births in the United States are to state Medicaid program recipients. Each state's Medicaid program has its own coverage determinations related to our testing, and many state Medicaid programs do not provide their recipients with coverage for our testing. Even if our testing is covered by a state Medicaid program, we must be recognized as a Medicaid provider by the state in which the Medicaid recipient receiving the services resides in order for us to be reimbursed by a state's Medicaid program. In addition, many Medicaid programs have entered into agreements with managed care plans to have the managed care plans manage the provision of healthcare to that Medicaid program's beneficiaries. In order for us to enter into contracts to offer our tests to beneficiaries who are enrolled with a Medicaid managed care plan, we must first be recognized as a Medicaid provider in that state, and then contract with the applicable Medicaid managed care program. We are currently recognized by a vast majority of states as a Medicaid provider. It is likely that we will not be able to be recognized as a provider by additional Medicaid programs because some states require that a provider maintain a physical laboratory in that state in order to be recognized; furthermore, some states have closed provider panels, which means that the state does not intend to expand its current provider network and therefore does not intend to recognize additional Medicaid providers. Even if we are recognized as a provider in a state, if Medicare's CLFS rate

for our tests are low, the Medicaid reimbursement amounts are sometimes as low, or lower, than the Medicare reimbursement rate. In addition, as noted above, each state's Medicaid program has its own coverage determinations related to our testing, and many state Medicaid programs do not provide their recipients with coverage for our testing. As a result of all of these factors, our testing is not reimbursed or only reimbursed at a very low amount by many state Medicaid programs. In some cases, a state Medicaid program's reimbursement rate for our testing might be zero dollars. Low or zero-dollar Medicaid reimbursement rates for our tests could have a material and adverse effect on our business, operating results, and financial condition.

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

The Medicare Modernization Act, or MMA, changed the way Medicare covers and reimburses for pharmaceutical products. The legislation introduced a new reimbursement methodology based on average sales prices for pharmaceutical products that are used in hospital settings or under the direct supervision of a physician and, starting in 2006, expanded Medicare coverage for pharmaceutical product purchases by the elderly. In addition, the MMA requires the creation of formularies for self-administered pharmaceutical products and provides authority for limiting the number of pharmaceutical products that will be covered in any therapeutic class and provides for plan sponsors to negotiate prices with manufacturers and suppliers of covered pharmaceutical products. As a result of the MMA and the expansion of federal coverage of pharmaceutical products, we expect continuing pressure to contain and reduce costs of pharmaceutical products. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we may receive for any pharmaceutical product candidates that we may develop using our precision medicine platform in the future and could materially adversely affect our business, operating results and overall financial condition. While the MMA generally applies only to pharmaceutical product benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement policies and any reduction in coverage or payment that results from the MMA may result in a similar reduction in coverage or payments from private payors.

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

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

Regulatory and Legal Risks Related to Our Business

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

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

- federal and state laws and regulations governing the submission of claims, as well as billing and collection practices, for healthcare services;
- the federal Anti-Kickback Statute, which prohibits, among other things, the knowing and willful solicitation, receipt, offer or payment of remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as Medicare and Medicaid; a person does not need to have knowledge of the statute or specific intent to violate it to have committed a violation; a violation of the Anti-Kickback Statute may result in imprisonment for up to ten years and 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;
- 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, 2020, we have paid approximately $36.9 million towards this amount. We will pay the remaining portion of the settlement over an approximately three-year period, structured as follows: $5.0 million in December 2021; 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 to our current offerings, could adversely affect our future product commercialization and operating results.

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

We may develop new medical devices in connection with our precision medicine platform and new molecular test candidates that are regulated by the FDA as medical devices. Unless otherwise exempted, medical devices must receive one of the following marketing authorizations from the FDA before being marketed in the United States: "510(k) clearance," *de novo* classification, or PMA. The FDA determines whether a medical device will require 510(k) clearance, *de novo* classification, or the PMA process based on statutory criteria that include the risk associated with the device and whether the device is similar to an existing, legally marketed product. In the 510(k) clearance process, before a device may be marketed, the FDA must determine that a proposed device is "substantially equivalent" to a legally-marketed "predicate" device, which includes a device that has been previously cleared through the 510(k) process, a device that was legally marketed prior to May 28, 1976 (pre-amendments device), a device that was originally on the U.S. market pursuant to an approved PMA and later down-classified, or a 510(k)-exempt device. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data are sometimes required to support substantial equivalence. In the process of obtaining PMA approval, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, 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 existing tests and other products. Delays in receipt of, or failure to obtain, marketing authorizations could materially delay or prevent us from commercializing our products or result in substantial additional costs that could decrease our profitability. In addition, even if we receive FDA 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.

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

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

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

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

Any sanction imposed under CLIA, its implementing regulations, or state or foreign laws or regulations governing licensure, or our failure to renew a CLIA certificate, a state license or accreditation, could have a material and adverse effect on our business, operating results and financial condition. For a discussion of an inquiry from the State of Texas regarding our CLIA certification, see Part I, Item 3. "Legal Proceedings—Texas OIG Inquiry." CMS also has the authority to impose a wide range of sanctions, including revocation of the CLIA certification along with a bar on the ownership or operation of a CLIA-certified laboratory by any owners or operators of the deficient laboratory. If we were to lose our CLIA certification or required state licensure, we would not be able to operate our clinical laboratory and conduct our tests, in full or in particular states, which would adversely impact our business, operating results, and financial condition.

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

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

Both before and after a product is commercially released, we and our products are subject to ongoing and pervasive oversight of government regulators. For instance, in the case of any product candidates subject to regulation by the FDA, including those products candidates in connection with our precision medicine platform, our facilities and procedures and those of our suppliers will be subject to periodic inspections by the FDA to determine compliance with applicable regulations. The results of these inspections can include inspectional observations on FDA's Form-483, warning letters, or other forms of enforcement. If the FDA 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.

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

Even after authorization, any medical products we develop will be subject to ongoing regulatory review, including requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. Any marketing authorizations that we obtain for our product candidates may also be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate.

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

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

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

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

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

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

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

compliance with the regulations applicable to the activities being conducted. Although we oversee our contract manufacturers, we cannot control the manufacturing process of, and are completely dependent on, such contract manufacturing partners for compliance with these regulatory requirements. If these facilities do not pass a pre-approval plant inspection, marketing authorizations for the products may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever.

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

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

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

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

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

The FDA may initiate rulemaking to impose premarket review, clearance, or approval or other requirements on LDTs, and we may become subject to extensive regulatory requirements and may be required to conduct additional clinical trials prior to continuing to sell our existing tests or launching any other tests we may develop, which may increase the cost of conducting, or otherwise harm, our business.

We currently market all of our commercial molecular tests as LDTs and may in the future market other tests as LDTs. Under current federal policy, FDA premarket review of LDTs is not required, but laboratories may voluntarily submit 510(k) or PMA applications, or de novo classification requests, for LDTs to obtain FDA clearance or approval following a demonstration of clinical validity. If there are changes in FDA regulations, particularly under the new Biden administration, or if the FDA disagrees that our marketed tests are LDTs or determines that we are marketing our tests outside the scope of the FDA's current policy of enforcement discretion, we may become subject to extensive regulatory requirements and may be required to stop selling our existing tests or launching any other tests we may develop and to conduct additional clinical trials or take other actions prior to continuing to market our tests. If the FDA allows our tests to remain on the market but there is uncertainty about our tests, if they are labeled investigational by the FDA or if labeling claims the FDA allows us to make are very limited, orders from physicians or reimbursement may decline. If required, the regulatory authorization process may involve, among other things, successfully completing additional clinical trials and submitting a 510(k) notice, or filing a *de novo* classification request or a PMA application with the FDA. If the FDA adopts regulations requiring premarket review, our tests may not be cleared or approved on a timely basis, if at all. This could significantly increase the costs and expenses of conducting, or otherwise harm, our business.

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

On July 31, 2014, the FDA notified Congress of its intent to modify, in a risk-based manner, its policy of enforcement discretion with respect to LDTs. On October 3, 2014, the FDA issued two draft guidances, entitled "Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)," or the Framework Guidance, and "FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)." The Framework Guidance stated that the FDA intended to modify its policy of enforcement discretion with respect to LDTs in a risk-based manner consistent with the existing classification of medical devices. Thus, pursuant to the Framework Guidance, the FDA planned to begin to enforce its medical device requirements, including premarket submission requirements, on LDTs that have historically been marketed without FDA premarket review and oversight. In August 2020, HHS

announced that the FDA will not require premarket review for any LDTs without first conducting notice-and-comment rulemaking proceedings. Although, as a result of this decision, the FDA may not rely on guidance documents, policy statements, or other informal decision-making to impose premarket review requirements on LDTs, the FDA could ultimately adopt rules that modify its current approach to LDTs in a way that would subject our products marketed as LDTs to the enforcement of regulatory requirements. Additionally, if and when the FDA begins to actively enforce its premarket submission regulations with respect to LDTs, we may be required to obtain premarket clearance or approval for our currently marketed tests and other products we plan to commercialize as LDTs. Moreover, legislative measures have recently been proposed in Congress that, if ultimately enacted, could provide the FDA with additional authority to require premarket review of and regulate LDTs. For example, in late 2018, the FDA proposed to Congress significant reforms to the agency's regulation of LDTs that would bring all *in vitro* clinical tests, including LDTs, under a unified framework and would dramatically increase FDA oversight of LDTs. The FDA's proposal included premarket review for certain tests, a precertification program to permit approval or clearance of a group of tests based on the review of a representative test, registration and notification requirements, quality system requirements, adverse event reporting, labeling requirements, and explicit authorities for the FDA to revoke the marketing authorization of tests and to take corrective action against test developers. However, in August 2020, the HHS issued a rescission order stating that the FDA will not require premarket review of LDTs absent changes in policy implemented through formal notice-and-comment rulemaking procedures. It remains to be seen whether the Biden administration will continue this HHS policy. The outcome and ultimate impact of such proposals on our business is difficult to predict at this time. Potential future increased regulation of our LDTs could also result in increased costs and administrative and legal actions for noncompliance, including warning letters, fines, penalties, product suspensions, product recalls, injunctions and other civil and criminal sanctions, which could have a material and adverse effect upon our business, operating results, and financial condition.

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

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

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

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

While we have a compliance plan intended to address compliance with government laws and regulations, including applicable fraud and abuse laws and regulations such as those described in this risk factor, the evolving commercial compliance environment and the need to build and maintain robust and scalable systems to comply with regulations in multiple jurisdictions with different compliance and reporting requirements increases the possibility that we could inadvertently violate one or more of these requirements.

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

Many of the sequencing instruments, reagents, kits and other consumable products used to perform our testing, as well as the instruments and other capital equipment that enable the testing, are offered for sale as analyte specific reagents, or ASRs, or for research use only, or RUO. ASRs are medical devices and must comply with FDA QSR provisions and other device requirements, but most are exempt from 510(k) and PMA review. Products that are intended for RUO and are labeled as RUO, including our epigenetics platform, are exempt from compliance with FDA requirements, including the approval or clearance and other product quality requirements for medical devices. A product labeled RUO but which is actually intended for clinical diagnostic use may be viewed by

the FDA as adulterated and misbranded under the FD&C Act and subject to FDA enforcement action. The FDA has said that when determining the intended use of a product labeled RUO, it will consider the totality of the circumstances surrounding distribution and use of the product, including how the product is marketed and to whom. The FDA could disagree with a supplier's assessment that the supplier's products are RUOs, or could conclude that products labeled as RUO are actually intended for clinical diagnostic use, and could take enforcement action against the supplier, including requiring the supplier to cease offering the product while it seeks clearance or approval. Suppliers of RUO products that we employ in our other tests may cease selling their respective products, and we may be unable to obtain an acceptable substitute on commercially reasonable terms or at all, which could significantly and adversely affect our ability to provide timely testing results to our customers or could significantly increase our costs of conducting business.

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

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

Separately, in response to the COVID-19 pandemic, the FDA temporarily postponed routine surveillance inspections of domestic and foreign manufacturing facilities and inspections of foreign products. The FDA is only conducting prioritized domestic inspections, where possible to do so safely, and, on a case-by-case basis, "mission-critical" inspections. The FDA has also expanded its use of other tools, when possible, to ensure the quality and safety of products being imported into the United States. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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

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

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

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

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

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

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

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

Risks Related to Our Intellectual Property

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

Our success depends in part on our freedom-to-operate with respect to the patents or intellectual property rights of third parties. We operate in industries in which there have been substantial litigation and other proceedings regarding patents and other intellectual property rights. For example, we have identified a number of third-party patents that may be asserted against us with respect to certain of our current molecular testing products and certain of our future products in the molecular testing and precision medicine space. 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 prevent us from offering our tests, which would have a material and adverse effect on our business, operating results, and financial condition. See Part I, Item 3. "Legal Proceedings—Natera Lawsuit" and "—Ravgen Lawsuit" for more information regarding patent infringement suits filed by Natera and Ravgen, Inc., respectively.

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

Because the industries in which we operate are particularly litigious, we are susceptible to intellectual property suits that could cause us to incur substantial costs or pay substantial damages or prohibit us from selling our products 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 current or 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 diagnostics area where the U.S. Supreme Court has issued a series of decisions setting forth limits on the patentability of natural phenomena, natural laws, abstract ideas and their applications (see, *Mayo Collaborative v. Prometheus Laboratories (2012), Association for Molecular Pathology v. Myriad Genetics (2013), and Alice Corporation v. CLS Bank (2014),* which has made it difficult to obtain certain patents and to assess the validity of previously issued patents). This uncertainty may materially affect our ability to defend or obtain patents or to address the patents and patent applications owned or controlled by our collaborators and licensors.

We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies are covered by valid and enforceable patents or are effectively maintained as trade secrets. Any finding that our patents or patent applications are invalid or unenforceable could harm our ability to prevent others from practicing the related technology. We cannot be certain that we were the first to invent the inventions covered by pending patent applications or that we were the first to file such applications, and a finding that others have claims of inventorship or ownership rights to our patents and applications could require us to obtain certain rights to practice related technologies, which may not be available on favorable terms, if at all. There may be times when we choose to retain advisors with academic employers who limit their employees' rights to enter into agreements which provide the kind of confidentiality and assignment provisions congruent with our consulting agreements. We may decide that

obtaining the services of these advisors is worth any potential risk, and this may harm our ability to obtain and enforce our intellectual property rights. In addition, our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing similar or alternative competing products, or design around our patented technologies, and may therefore fail to provide us with any competitive advantage. Furthermore, as our issued patents expire, we may lose some competitive advantage as others develop competing products that would have been covered by the expired patents, and, as a result, may adversely affect our business, operating results, and financial condition.

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

Further, preliminary injunctions that bar future infringement by the competitor are not often granted; therefore, remedies for infringement are not often immediately available. Even if we prevail in an infringement action, we cannot assure you that we would be fully or partially financially compensated for any harm to our business. We may be forced to enter into a license or other agreement with the third parties on terms less profitable or otherwise less commercially acceptable to us than those negotiated between a willing licensee and a willing licensor. Any inability to stop third-party infringement could result in loss in market share of some of our products, or lead to a delay, reduction, and/or inhibition of our development, manufacture, or sale of some of our products. A product produced and sold by a third-party infringer may not meet our or other regulatory standards or may not be safe for use, which could cause irreparable harm to the reputation of our products, which in turn could result in substantial loss in our market share and profits. See Part I, Item 3. “Legal Proceedings—Natera Lawsuit” and “—Ravgen Lawsuit” for more information regarding patent infringement suits filed by Natera and Ravgen, Inc., respectively.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The issuance of shares of our common stock upon conversion of the convertible notes 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 in shares of our common stock, together with cash in lieu of issuing any fractional share. The issuance of shares of our common stock upon conversion of the convertible notes 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 may occur could depress the trading price of our common stock even in the absence of actual conversions. Moreover, the expectation of conversions 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 could depress the trading price of our common stock.

We expect that many investors in our outstanding convertible notes will seek to employ a convertible note 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. 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. 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, 2020, our current directors and executive officers, together with their affiliates, beneficially own, in the aggregate, a majority 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.

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

While we have paid dividends to our stockholders in the past, we currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, our ability to pay cash dividends on our capital stock may be prohibited or limited by the terms of any current or future debt financing arrangement. Any return to stockholders may therefore be limited to the increase, if any, of the 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 have and will continue to incur significantly increased costs and devote substantial management time to reporting and other requirements as a result of operating as a public company.

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

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

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

For as long as we continue to be an emerging growth company, however, we intend to take advantage of certain other exemptions from various reporting requirements that are applicable to other public companies including, but not limited to, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we will rely on

these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile and experience decreases.

We will remain an emerging growth company until the earliest of (a) the end of the fiscal year (i) following the fifth anniversary of the closing of 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 or significant deficiencies in our internal control over financial reporting are discovered or occur in the future, our consolidated financial statements may contain material misstatements and we could be required to restate our financial results, which could adversely affect our stock price and result in an inability to maintain compliance with applicable stock exchange listing requirements.

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

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

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 current stockholders hold in excess of 50% of our outstanding common stock;
- prohibit stockholders from calling special meetings of stockholders;
- establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon by stockholders at annual stockholder meetings;
- provide the board of directors with sole authorization to establish the number of directors and fill director vacancies; and
- provide that the board of directors is expressly authorized to make, alter, or repeal our amended and restated bylaws.

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

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. We also own approximately 26,500 square feet of laboratory space in Ann Arbor, Michigan. Additionally, our subsidiary, Avero Diagnostics, owns a 14,000 square feet of property located in Lubbock, Texas, which is used primarily for laboratory testing. We believe our existing facilities will be sufficient for our needs for the foreseeable future.

Item 3. Legal Proceedings.

Federal Investigations

In April 2018, we received a civil investigative demand from an Assistant U.S. Attorney for the Southern District of New York, 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.

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 Office of Inspector General of the Department of Health and Human Services, or 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;
- 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, or the State Settlement Agreements.

We refer to the SDNY Civil Settlement Agreement, the SDCA Civil Settlement Agreement, the Non-Prosecution Agreement, the Corporate Integrity Agreement, and the State Settlement Agreements collectively as the Agreements.

SDNY Civil Settlement Agreement

Pursuant to the SDNY Civil Settlement Agreement, we are required to pay a settlement amount of approximately $19.4 million, which includes approximately $9.7 million designated as restitution to the U.S. federal government. During the year ended December 31, 2020, we paid approximately $14.7 million. The outstanding settlement amount is payable in two installments as follows:

- approximately $2.0 million on or before December 31, 2021; and
- approximately $2.8 million on or before December 31, 2022.

The remaining amounts payable to the government will be subject to interest at a rate of 1.25% per annum, and any or all amounts may be paid earlier at our option.

Furthermore, we have agreed that, if during calendar years 2020 through 2023, and so long as amounts payable to the government remain unpaid, we receive any civil settlement, damages awards, or tax refunds, to the extent that the amounts exceed $5.0 million in a calendar year, we will pay 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, we received tax benefit payments of approximately $37.7 million and made accelerated payments of $4.1 million.

Additionally, under the SDNY Civil Settlement Agreement, the U.S. federal government and the relator agreed to dismiss all civil claims asserted by the relator under the qui tam provisions of the federal False Claims Act.

SDCA Civil Settlement Agreement

Pursuant to the SDCA Civil Settlement Agreement, we are required to pay a settlement amount of approximately $16.4 million, which includes approximately $10.0 million designated as restitution to the U.S. federal government. During the year ended December 31, 2020, we paid approximately $12.5 million. The outstanding settlement amount is payable in two installments as follows:

- approximately $1.7 million on or before December 31, 2021; and
- approximately $2.2 million on or before December 31, 2022.

The remaining amounts payable to the government will be subject to interest at a rate of 1.25% per annum, and any or all amounts may be paid earlier at our option.

On July 21, 2020, we issued a promissory note to the U.S. federal government for the full settlement amount in connection with the SDCA Civil Settlement Agreement, or the Promissory Note. The Promissory Note contains customary events of default and related acceleration of payment provisions. In addition, the Promissory Note provides, among other terms, that, if during calendar years 2020 through 2023, and so long as amounts payable to the government remain unpaid, we receive any civil settlement, damages awards, or tax refunds, to the extent that the amounts exceed $5.0 million in a calendar year, we will pay 22% 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 approximately $3.4 million. During the year ended December 31, 2020, we received tax benefit payments of approximately $37.7 million and made accelerated payments of $3.4 million.

Non-Prosecution Agreement

Effective July 21, 2020, we entered into the Non-Prosecution Agreement, pursuant to which we 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 our operations and (iv) fulfill certain other disclosure, reporting and cooperation obligations. The DOJ agreed that it will not prosecute us for any conduct described in the Non-Prosecution Agreement provided that we perform our obligations under the Non-Prosecution Agreement during the period from July 21, 2020 through July 21, 2021. The Non-Prosecution Agreement provides that the DOJ may unilaterally, upon notice to us, extend the term of the agreement in 6-month increments, for a maximum total term of 24 months (that is, two 6-month extensions).

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 us from participating in federal healthcare programs, effective July 21, 2020, we entered into a five-year Corporate Integrity Agreement with the OIG. The Corporate Integrity Agreement requires, among other matters, that we 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. If we fail to comply with our obligations under the Corporate Integrity Agreement, we could face monetary penalties and/or be excluded from participating in federal healthcare programs.

State Settlement Agreements

Effective October 1, 2020, we entered into agreements with the State AGs with respect to the investigated matters. The State Settlement Agreements require the Company to pay a settlement amount of approximately $13.2 million to the participating states. The State Settlement Agreements include acceleration provisions similar to the SDNY Civil Settlement Agreement and the SDCA Civil Settlement Agreements described above upon our receipt of civil settlements, damages awards, and tax refunds, with the amount to be accelerated and the timing of accelerated payment subject to such receipts. During the year ended December 31, 2020, we received tax benefit payments of approximately $37.7 million and made accelerated payments of $9.7 million. The outstanding settlement amount is payable in three installments as follows:

- approximately $1.4 million on or before December 31, 2021;
- approximately $1.9 million on or before December 31, 2022; and
- approximately $0.2 million on or before December 31, 2023.

Settlement Accruals

As of December 31, 2019, we had accrued an aggregate of $35.8 million associated with a potential settlement with the DOJ and the participating State AGs within accrued expenses and other current liabilities and as a reduction of revenue as reflected on the consolidated balance sheet of the Company as of December 31, 2019 and consolidated statement of operations for the year ended December 31, 2019. As of December 31, 2020, the Company's accrual consists of $5.0 million included in accrued expenses and other current liabilities and $7.1 million included in other long-term liabilities.

OIG Inquiry

On October 16, 2019, we received an inquiry from the Texas Health & Human Services Commission Office of Inspector General, or the TX OIG, alleging that we did not hold the required CLIA Laboratory Certificate of Accreditation to perform, bill for, or be reimbursed by the Texas Medicaid Program for certain tests performed by us from January 1, 2015 through December 31, 2018. Although we believe that we hold and have held all required CLIA certificates and/or subcontract with third-party laboratories that hold and have held such certificates to perform all of the tests subject to the TX OIG inquiry, there can be no assurance that the TX OIG will agree with this position. We submitted a written response to the inquiry on October 23, 2019 and are awaiting a response from the TX OIG on the matter. It is not possible to predict the outcome of these matters and the timing for resolution.

Natera Lawsuit

On June 17, 2020, Natera, Inc., or Natera, filed suit in the Western District of Texas (W.D. Texas Civil Action No. 6:20-cv-532) asserting our infringement of six Natera patents based on a portion of our NIPT product offering. On June 19, 2020, Natera filed a substantially similar second suit in the Northern District of Texas (N.D. Texas Civil Action No. 3:20-cv-1634). On July 31, 2020, Progenity filed a motion to dismiss the Western District of Texas case based on improper venue. The motion is fully briefed and

remains pending before the Court. The Northern District of Texas case has been stayed until a decision with respect to the motion to dismiss is made.

On July 2, 2020, we filed a Complaint for Declaratory Judgment of Non-Infringement against Natera in the Southern District of California (S.D. California Civil Action No. 3:20-cv-1252). This case has been stayed pending the outcome of our venue motion in the Western District of Texas.

We believe that the claims in Natera's complaints are without merit, and we are vigorously defending against them.

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. We have not yet responded to the complaint.

We believe the claims in Ravgen's complaint are without merit, and we intend to vigorously defend against them.

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 amended complaint on February 4, 2021. 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 we (i) had overbilled government payors by $10.3 million and thus overstated our revenues for the full fiscal year 2019 and first quarter of 2020, and (ii) were allegedly 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. Our response to the amended complaint is due by April 5, 2021. We intend to vigorously defend against these claims. Given the uncertainty of litigation, the preliminary stages of these cases, 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 this action, and therefore cannot estimate the reasonably possible loss or range of loss, if any, that may result from these actions. Subject to a reservation of rights, we are advancing expenses subject to indemnification to the underwriters of the IPO.

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 12, 2021, there were approximately 55 stockholders of record of our common stock.

Dividends

We anticipate that we will retain earnings, if any, to support operations 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.

Use of Proceeds from IPO

On June 23, 2020, we completed our initial public offering, or IPO, pursuant to which we issued and sold an aggregate of 6,666,667 shares of our common stock at the IPO price of $15.00 per share.

The offer and sale of all of the shares of our common stock in the IPO were registered under the Securities Act pursuant to our Registration Statement on Form S-1, as amended (File No. 333-238738), which was declared effective on June 18, 2020. Piper Sandler & Co. and Wells Fargo Securities, LLC acted as joint book-running managers for the IPO. Robert W. Baird & Co. Incorporated and Raymond James & Associates, Inc. acted as book-running managers for the IPO. BTIG, LLC acted as the lead manager for the IPO.

We received gross proceeds from our IPO of $100.0 million, and net proceeds of $88.7 million after deducting $7.0 million in underwriting discounts and commissions and $4.3 million of other offering expenses. None of the underwriting discounts and commissions or other offering expenses were incurred or paid, directly or indirectly, to any of our directors or officers or their associates or to persons owning 10% or more of our common stock or to any of our affiliates.

The net proceeds from our IPO have been used and will be used, to support our operations, to invest in our molecular testing research and development program, to invest in research and development with respect to our precision medicine platform, and for working capital and general corporate purposes. There has been no material change in our intended use of proceeds from our IPO as described in our final prospectus filed with the SEC pursuant to Rule 424(b)(4) on June 22, 2020.

Item 6. Selected Financial Data.

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 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 and Recent Developments

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

Our internal core competencies, deep research and development pipeline and strategic acquisitions of novel technologies have fueled our innovation in women's health, supporting the development and launch of complementary molecular testing products that inform critical healthcare decision-making across a woman's lifetime.

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

We generate revenue by providing tests. Our molecular tests are provided through our certified Clinical Laboratory Improvement Amendments, or CLIA, and College of American Pathologists, or CAP, accredited laboratory located in Ann Arbor, Michigan. We also provide anatomic and molecular pathology tests through our affiliation with Mattison Pathology, LLP, a Texas limited liability partnership doing business as Avero Diagnostics, located in Lubbock and Irving, Texas. The focus of our commercial operations is to distribute our molecular tests and our anatomic and molecular pathology tests through our dedicated direct sales force. Distribution of our tests is supported by a field operations team who provide all logistical functions in receiving clinical samples at the laboratory for analysis. 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. Future demand for COVID-19 testing is becoming increasing difficult to predict due to various factors, including but not limited to, the availability of vaccinations, the number of individuals who choose to be vaccinated, the effectiveness of the various vaccinations against variants, the rate of new cases, and evolving government directives, laws, regulations and rules related to COVID-19 testing. In the long term, we expect that the COVID-19 pandemic will eventually dissipate and, as a result, the significance of COVID-19 testing to our business and financial results will decrease.

During the years ended December 31, 2020 and 2019, we accessioned approximately 320,000 and 329,000 tests, respectively.

We generate revenue through providing our tests and receiving payments for such tests from payors, laboratory distribution partners, and self-paying individuals. More than 95% of payments for our tests are received through reimbursement. We receive reimbursement from several distinct channels: commercial third-party payors, laboratory distribution partners, and government health benefits programs such as Medicare and Medicaid.

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

In the third quarter of 2020, we successfully achieved a key milestone in the verification phase of our rule out assay for preeclampsia and held a preeclampsia research and development day.

In February 2021, we entered into a Securities Purchase Agreement for a private placement with certain institutional and accredited investors, or the Purchasers. Pursuant to the Securities Purchase Agreement, the Purchasers purchased an aggregate of 4,370,629 units, or the Units, representing (i) 4,370,629 shares of our common stock 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 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 December 2020, we issued and sold 8,792,047 shares of our common stock in an underwritten public offering, at a price of $3.27 per share. We received approximately $26.9 million in net proceeds, after deducting underwriting discounts and commissions and other offering expenses payable by us.

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

In November 2020, we approved a reduction in force that resulted in the termination of approximately 9.5% of our workforce, or approximately 67 employees. The reduction in force was implemented in order to enable us to decrease its costs and more effectively align resources to business priorities. 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.

Factors Affecting Our Performance

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

Report Volume

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

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

Reimbursement

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

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

Gross Margin

Our gross margin is an important indicator of the operating performance of our business. Higher gross margins reflect the average selling price of our tests, as well as the operating efficiency of our laboratory operations. Reducing the costs of goods sold for our tests represents another important opportunity for innovation and is a significant area of focus for our research and development organization. We regularly evaluate our operations in order to determine whether we can reduce costs by developing new technologies, improving the efficiency of our assay and laboratory processes, modifying our processes to use materials and technologies that provide equal or greater quality at lower cost, and improving how we manage our inventory and negotiating favorable terms for our materials purchases. We are currently developing our next generation Innatal Prenatal Screen (Innatal 4th Generation), an improved platform with simplified and more cost-effective assay workflow, which we believe will allow us to substantially improve the gross margin of our NIPT. We also work with partner laboratories that complement our test portfolio offering, while developing in parallel new technologies that we expect could, over time, reduce our cost structure by internalizing the production of those tests when the commercial benefits dictate such conversion. We are now predominantly an in-network provider, with approximately 146 million covered lives nationwide under our agreements with commercial third-party payors following the recent additions of in-network contracts with Aetna and Cigna. While we continue our contract negotiation process with several additional large commercial third-party payors, the transition to establishing ourselves as an in-network provider is expected to lead to an increase in the proportion of tests paid and allow us to gain access to a larger in-network patient base.

New Product Development

Our business involves significant investment in research and development activities for the development of new products which we believe are strategic complements to our product portfolio and drive long-term revenue growth. We intend to continue investing in our pipeline of new products and technologies. We expect our investment in research and development to increase as we pursue regulatory approval of our product candidates and as we seek to expand our pipeline of product candidates. Due to the impact of the COVID-19 pandemic and resulting work-from-home policies and other operational limitations mandated by federal, state, and local governments, certain of our research and development activities have been delayed and may be further delayed until such operational limitations are lifted. While we are implementing mitigation strategies, where possible, certain preclinical and clinical activities were suspended during the implementation of these policies and will necessarily incur some delay following the resumption of normal operations. While some of our research and development laboratory work was impacted by the stay-at-home shutdown, especially in

our Michigan facilities, our preeclampsia test verification work restarted in June and has now migrated to the operations laboratory, which is part of our essential services, and is, therefore, less exposed to further shutdowns caused by the COVID-19 pandemic. However, the development of our new products could continue to be delayed if any stay-at-home orders in the State of Michigan are reinstated.

The achievement of key development milestones (e.g., clinical verification and validation and CLIA certification for our molecular tests and clinical studies and regulatory approval for our precision medicine product platform) is a key factor in evaluating our performance.

Key Components of Our Results of Operations.

Revenue

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

Due to potential future changes in insurance coverage policies, contractual rates, and other trends in the reimbursement of our tests, payments received for our tests may fluctuate significantly over time. Our revenue incorporates an estimate of variable consideration, which is adjusted for estimates of disallowed cases, discounts, and refunds. We have established an accrual for refunds of payments previously made by healthcare insurers based on historical experience and executed settlement agreements with healthcare insurers. The refunds are accounted for as reductions in revenues in the statement of operations as an element of variable consideration. Our estimate of variable consideration included in the transaction price is also impacted by our ongoing transition to in-network contracts with commercial payors.

Currently, we operate primarily as an in-network provider of molecular tests and we continually seek to transition to in-network coverage with additional third-party payors, which we believe is crucial to our growth and long-term success. This transition is ongoing, and we are actively negotiating with a few remaining commercial payors. We are currently contracted with payors representing an estimated 146 million covered lives.

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

Delays to third-party payors' processing due to the impact of the COVID-19 pandemic and resulting work-from-home policies and other operational limitations mandated by federal, state, and local governments have and may continue to extend the typical timelines. These factors might delay the time period in which cash is collected from payors and impact our revenue recognition. We believe that the full impact of these delays may not yet have been reflected in our financial performance, as we customarily receive payment several months after completion of a molecular test.

Cost of Sales

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

Research and Development

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

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

Selling and Marketing

Selling and marketing expenses consist primarily of personnel costs, including salaries, commissions, bonuses, stock-based compensation expense, and benefits for our sales and marketing team. Selling and marketing expenses also include costs for communication, advertising, conferences, other marketing events, and allocated overhead costs. We expect selling and marketing expense to continue to increase as we increase the size of our selling and marketing function to support the growth of our business. We have implemented and continue to monitor mitigation strategies to address the work-from-home policies and other operational limitations mandated by federal, state, and local governments as a result of the COVID-19 pandemic. While largely yet to be determined, these mitigation strategies include virtual meetings and mobile phlebotomy services for patients preferring not to visit a physician’s office. These strategies and others may cause increases in our sales and marketing costs.

General and Administrative

General and administrative expenses consist primarily of personnel costs, including salaries, bonuses, stock-based compensation expense, and benefits, for our finance and accounting, legal, human resources, and other administrative teams. Additionally, these expenses include professional fees of audit, legal, and recruiting services. Following the listing of our common stock on Nasdaq, we expect to continue to incur additional expenses as a result of operating as a public company, including costs to comply with the rules and regulations applicable to companies listed on a U.S. securities exchange and costs related to compliance and reporting obligations pursuant to the rules and regulations of the SEC. In addition, as a public company, we expect to incur increased expenses in the areas of insurance, investor relations, and professional services. Furthermore, we expect to incur expenses related to maintaining compliance with the stipulations of the government settlement and the legal costs associated with the Natera lawsuit, the Ravgen lawsuit and IPO related litigation described in Part I, Item 3. “Legal Proceedings” in this Annual Report. As a result, we expect the dollar amount of our general and administrative expenses to increase for the foreseeable future. We expect, however, that our general and administrative expenses will decrease as a percentage of our revenue over time, although the percentage may fluctuate from period to period depending on fluctuations in our revenue and the timing and extent of our general and administrative expenses.

Interest Expense

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

Interest and Other Income (Expense), Net

Interest and other income, net primarily consists of changes in 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 and interest income earned from our cash and cash equivalents, 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.

Results of Operations.

Comparison of Years Ended December 31, 2020 and 2019

	Year Ended December 31,	
	2020	2019
	(in thousands)	
Statement of Operations Data:		
Revenues	$ 74,313	$ 143,985
Cost of sales	93,433	100,492
Gross profit (loss)	(19,120)	43,493
Operating expenses:		
Research and development	47,743	63,400
Selling and marketing	52,887	58,888
General and administrative	75,438	61,324
Total operating expenses	176,068	183,612
Loss from operations	(195,188)	(140,119)
Interest expense	(9,984)	(9,199)
Interest and other income (expense), net	(24,888)	575
Loss before income taxes	$ (230,060)	$ (148,743)
Income tax benefit	(37,532)	(706)
Net loss	(192,528)	(148,037)

	Year Ended December 31,	
	2020	2019
Percentage of Revenue Data:		
Revenues	100%	100%
Cost of sales	126	70
Gross profit (loss)	(26)	30
Operating expenses:		
Research and development	64	44
Selling and marketing	71	41
General and administrative	102	43
Total operating expenses	237	128
Loss from operations	(263)	(97)
Interest expense	(13)	(6)
Interest and other income (expense), net	(34)	—
Loss before income taxes	(310)	(103)
Income tax benefit	(51)	(0)
Net loss	(259)%	(103)%

Revenue

	Year Ended December 31,		Increase/	
	2020	2019	(Decrease)	% Change
	(in thousands) (unaudited)			
Revenues	$ 74,313	$ 143,985	$ (69,672)	(48.4)%

Revenue was $74.3 million for the year ended December 31, 2020, compared to $144.0 million for the year ended December 31, 2019, a decrease of $69.7 million, or 48.4%. This decrease was largely attributable to a decrease in test volumes as a result of the COVID-19 pandemic during the second, third, and fourth quarters of 2020, rate degradation due to payor policy changes, partially offset by a decrease of $6.2 million in revenue reserve accruals for payor settlements compared to the prior period.

In addition, revenue was $14.3 million for the three months ended December 31, 2020, compared to $25.9 million for the three months ended September 30, 2020, a decrease of $11.6 million, or 44.8%.

Cost of Sales

	Year Ended December 31,		Increase/	
	2020	2019	(Decrease)	% Change
	(in thousands) (unaudited)			
Cost of sales	$ 93,433	$ 100,492	$ (7,059)	(7.0)%

Cost of sales was $93.4 million for the year ended December 31, 2020, compared to $100.5 million for the year ended December 31, 2019, a decrease of $7.1 million, or 7.0%.

The decrease in cost of sales was primarily due to a decrease in test volumes in the second, third, and fourth quarters of 2020 as a result of the COVID-19 pandemic, partially offset by an increase in stock-based compensation expense following the IPO in June 2020.

Research and Development Expenses

	Year Ended December 31,		Increase/	
	2020	2019	(Decrease)	% Change
	(in thousands) (unaudited)			
Research and development	$ 47,743	$ 63,400	$ (15,657)	(24.7)%

Research and development expenses were $47.7 million for the year ended December 31, 2020, compared to $63.4 million for the year ended December 31, 2019, a decrease of $15.7 million, or 24.7%. The decrease in research and development expenses was primarily attributable to a $14.7 million decrease in consulting costs, as well as a $4.5 million decrease in supplies costs and other expenses, partially offset by a $4.2 million increase in salaries and stock-based compensation expenses.

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

	Year Ended December 31,	
	2020	2019
	(in thousands) (unaudited)	
Molecular testing	$ 26,080	$ 31,562
Precision medicine	21,663	31,838
Total research and development expenses	$ 47,743	$ 63,400

In addition, research and development expenses were $11.2 million for the three months ended December 31, 2020, compared to $13.0 million for the three months ended September 30, 2020, a decrease of $1.8 million, or 13.8%.

Selling and Marketing Expenses

	Year Ended December 31,		Increase/	
	2020	2019	(Decrease)	% Change
	(in thousands) (unaudited)			
Selling and marketing	$ 52,887	$ 58,888	$ (6,001)	(10.2)%

Selling and marketing expenses were $52.9 million for the year ended December 31, 2020, compared to $58.9 million for the year ended December 31, 2019, a decrease of $6.0 million, or 10.2%.

The decrease in selling and marketing expenses was primarily attributable to a $4.7 million decrease in travel and entertainment costs due to a reduction in travel during the year ended December 31, 2020 as a result of the COVID-19 related restrictions and associated work-from-home policies, a decrease of $0.7 million in advertising and promotion costs, and a decrease of $0.4 million in salaries and stock-based compensation expenses.

In addition, selling and marketing expenses were $12.5 million for the three months ended December 31, 2020, compared to $13.2 million for the three months ended September 30, 2020, a decrease of $0.7 million, or 5.3%.

General and Administrative Expenses

	Year Ended December 31,		Increase/	
	2020	2019	(Decrease)	% Change
	(in thousands) (unaudited)			
General and administrative	$ 75,438	$ 61,324	$ 14,114	23.0%

General and administrative expenses were $75.4 million for the year ended December 31, 2020, compared to $61.3 million for the year ended December 31, 2019, an increase of $14.1 million, or 23.0%.

The increase in general and administrative expenses was primarily attributable to a $7.4 million increase in salaries and stock-based compensation expenses, a $5.4 million increase in consulting and professional costs, primarily related to legal costs associated with our government settlement negotiations and litigation, and a $3.6 million increase in business insurance costs. These increases were partially offset by a decrease of $3.2 million in supplies costs.

In addition, general and administrative expenses were $20.5 million for the three months ended December 31, 2020, compared to $20.6 million for the three months ended September 30, 2020.

Interest Expense

	Year Ended December 31,		Increase/ (Decrease)	% Change
	2020	2019		
	(in thousands) (unaudited)			
Interest expense	$ (9,984)	$ (9,199)	$ (785)	8.5%

Interest expense increased by $0.8 million, or 8.5%, from the year ended December 31, 2019 to the year ended December 31, 2020.

Interest and Other Income (Expense), Net

	Year Ended December 31,		Increase/ (Decrease)	% Change
	2020	2019		
	(in thousands) (unaudited)			
Interest and other income (expense), net	$ (24,888)	$ 575	$ (25,463)	*

* - The change is more than 100%

Interest and other expense, net, was $24.9 million for the year ended December 31, 2020, compared to interest and other income, net of $0.5 million for the year ended December 31, 2019.

This change was primarily due to a $13.7 million increase in fair value of our embedded derivative liability related to the convertible notes, a $7.6 million 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, a $3.6 million loss on extinguishment of debt associated with the conversion of an unsecured promissory note into shares of common stock upon completion of the IPO.

Income Tax Benefit

	Year Ended December 31,		Increase/ (Decrease)	% Change
	2020	2019		
	(in thousands) (unaudited)			
Income tax provision (benefit)	$ (37,532)	$ (706)	$ (36,826)	*

* - The change is more than 100%

Income tax benefit was $37.5 million for the year ended December 31, 2020, compared to income tax benefit of $0.7 million for the year ended December 31, 2019. 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. The tax benefit recorded during the year ended December 31, 2019 was recorded due to refunds received during 2019.

Liquidity and Capital Resources.

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

As of December 31, 2020, we had $92.1 million of cash and cash equivalents, convertible notes outstanding of $168.5 million, and mortgages outstanding of $3.1 million. Our accumulated deficit as of December 31, 2020, was $541.3 million. For the year ended December 31, 2020, we had a net loss of $192.5 million and cash used in operations of $165.7 million. Our primary requirements for liquidity have been to fund our working capital needs, capital expenditures, dividends, research and development, and general corporate needs. In addition, in February 2021, we entered into a Securities Purchase Agreement for a private placement with certain institutional and accredited investors and sold an aggregate of 4,370,629 units representing (i) 4,370,629 shares of our common stock and (ii) warrants to purchase up to 4,370,629 shares of common stock for an aggregate purchase price of approximately $25.0 million.

Based on our planned operations, we do not expect that our current cash and cash equivalents will be sufficient to fund our operations for at least 12 months from the issuance date of the consolidated financial statements for the year ended December 31, 2020. We 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, or the Credit Agreement, with a fund managed by Athyrium, as collateral agent and a lender. The Credit Agreement provided for a term loan of $75.0 million, the issuance of Series B Preferred Stock, and the issuance of a warrant to purchase Series B Preferred Stock, or 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 years ended December 31, 2020 and 2019, we recognized interest expense on the term loan of $7.5 million and $8.9 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 August 27, 2019, we entered into a Series B Preferred Stock Purchase Agreement with Athyrium Opportunities III Acquisition LP, a fund managed by Athyrium, pursuant to which we issued 9,090,910 shares of Series B Preferred Stock at $2.75 per share for an aggregate purchase price of $25.0 million. A 1.283636364-for-1 stock split for our Series B Preferred Stock shares and Series B Preferred Stock Purchase Warrant issued and outstanding previously was effected on August 27, 2019 pursuant to an amendment and restatement of our amended and restated certificate of incorporation. As a result of the stock split, we issued an additional 4,017,512 shares of Series B Preferred Stock and adjusted the Series B Preferred Stock Purchase Warrant to be a warrant to purchase 1,818,182 shares of Series B Preferred Stock. On August 27, 2019, we executed an exchange agreement with our Series A-1 Preferred Stock holders, pursuant to which 1,500,000 outstanding shares of Series A-1 Preferred Stock were exchanged for 35,664,240 shares of Series B Preferred Stock.

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

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

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

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

On March 31, 2020, we entered into the First Amendment to the Credit Agreement, or the Credit Agreement Amendment, with the collateral agent and lender party thereto, providing for the payment of interest due and payable as of March 31, 2020 in shares of our Series B Preferred Stock, and further providing for the payment of interest due and payable as of June 30, 2020 in shares of our Series B Preferred Stock in the event 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, or the Subscription Agreement, with the lender, which provided for the issuance of 967,130 shares of Series B Preferred Stock at a subscription price of $2.25 per share, as payment for interest due and payable as of March 31, 2020 and all applicable fees as set forth in the Credit Agreement Amendment. The Subscription Agreement further provided for a potential additional issuance of shares of Series B Preferred Stock as payment for the interest due and payable under the Credit Agreement as of June 30, 2020, in the event 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, or the Convertible Note, with an annual interest rate of 8.0% and in an aggregate principal amount of $15.0 million. The Convertible Note 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, dated May 6, 2020, or the Second Credit Agreement Amendment, allowing for the creation or incurrence of certain indebtedness and the making of payments, in each case, in respect of the Convertible Note, among other matters, and (ii) the Second Amendment to Series B Preferred Stock Warrant, dated May 8, 2020, providing for the removal of certain restrictive exercise provisions in the Series B Preferred Stock Purchase Warrant. 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 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, or the Indenture. The Convertible Notes are due on December 1, 2025, unless earlier repurchased,

redeemed or converted, and accrue interest at a rate per annum equal to 7.25% payable semi-annually in arrears on June 1 and December 1 of each year, with the initial payment on June 1, 2021.

The Convertible Notes are our senior, unsecured obligations and are (i) equal in right of payment with our existing and future senior, unsecured indebtedness; (ii) senior in right of payment to our existing and future indebtedness that is expressly subordinated to the 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, 2020, we were in compliance with all such covenants.

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 and $1.4 million as of December 31, 2020 and December 31, 2019, respectively. The mortgage matures in 2024 and requires monthly principal and interest payments at a fixed interest rate of 2.94% plus a floating rate at LIBOR. We also have a mortgage with American Bank of Commerce (originally executed in February 2008) outstanding on Avero Diagnostic's property located in Lubbock, Texas, which is used primarily for laboratory testing. The outstanding balance was $1.7 million and $1.9 million as of December 31, 2020 and December 31, 2019, respectively. The mortgage matures in 2029 and requires monthly principal and interest payments at an interest rate of 3.25%.

Cash Flows

Our primary uses of cash are to fund our operations and research and development as we continue to grow our business. We expect to continue to incur operating losses in future periods as our operating expenses increase to support the growth of our business. We expect that our research and development, selling and marketing, and general and administrative expenses will continue to increase as we expand our marketing efforts and increase our internal sales force to drive increased adoption of and reimbursement for our tests, continue our research and development efforts with respect to our current tests and further develop our product pipeline, including our preeclampsia test and precision medicine products under development. 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,	
	2020	2019
Cash used in operating activities	$ (165,744)	$ (106,124)
Cash (used in) provided by investing activities	(4,944)	16,525
Cash provided by financing activities	229,722	73,636

Operating Activities

Net cash used in operating activities in the year ended December 31, 2020 of $165.7 million was primarily attributable to a $192.5 million net loss, adjusted for $78.0 million of non-cash charges, primarily driven by $33.5 million of noncash revenue reserve, $13.9 million of expense related to change in the fair value of derivative liability, $11.0 million of loss on extinguishment of debt, $10.7 million of stock-based compensation expense and $5.1 million of depreciation and amortization expense. The net cash outflow from changes in operating assets and liabilities of $51.1 million was primarily attributable to a $61.5 million decrease in accrued expenses and other liabilities, offset by an $9.5 million decrease in accounts receivable.

Net cash used in operating activities for the year ended December 31, 2019 of $106.1 million was primarily attributable to a $148.0 million net loss. This was partially offset by a $17.8 million increase in accrued expenses and other current liabilities as well as a $9.1 million increase in other long-term liabilities primarily as a result of noncash revenue accrual for settlement negotiations with the Assistant U.S. Attorney for the Southern District of New York for $39.7 million. The net loss was also partially offset by a $3.4 million increase in accounts receivable primarily as a result of the adoption of ASC 606.

Investing Activities

Net cash used in investing activities during the year ended December 31, 2020 of $4.9 million was attributable to the purchase of property and equipment. Net cash provided by investing activities during the year ended December 31, 2019 of $16.5 million was primarily driven by $31.4 million from the sale of short-term investments. The cash inflow was partially offset by cash outflows of $11.2 million for purchases of short-term investments and $3.7 million for purchases of property and equipment.

Financing Activities

Net cash provided by financing activities during the year ended December 31, 2020 of $229.7 million was primarily attributable to $116.4 million in net proceeds from the issuance of common stock, $99.7 million in net proceeds from the 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 coverage financing, $0.7 million in principal payments on capital lease obligations and $0.3 million in principal payments on mortgages payable. Net cash provided by financing activities during the year ended December 31, 2019 of $73.6 million was primarily attributable to $79.0 million in proceeds from the issuance of Series B Preferred Stock and $0.5 million in proceeds from issuance of common stock, partially offset by $4.5 million in dividends paid, $1.0 million in principal payments on capital lease obligations, and $0.2 million in principal payments on mortgages payable, and $0.2 million in payments for deferred costs.

Contractual Obligations and Commitments

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.

Off-Balance Sheet Arrangements

As of December 31, 2020, we did not have any relationships with unconsolidated organizations or financial partnerships, such as structured finance or special purpose entities, that would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

Critical Accounting Policies and Significant Judgments and Estimates

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

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

Revenue Recognition

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

We adopted the new revenue recognition guidance, ASC Topic 606, *Revenue from Contracts with Customers*, or ASC 606, on January 1, 2019 using the modified retrospective transition method. The transition method was applied to all contracts that were not yet complete as of January 1, 2019. The cumulative impact of adoption was recorded as an adjustment of $23.7 million to increase the opening balance of accounts receivable and decrease accumulated deficit as of January 1, 2019.

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.

Embedded Derivative Related to Convertible Notes

The Convertible Notes due in December 2025 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, 2020, the fair value of the embedded derivative was $18.4 million 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 generally four years.

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

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

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

	Year ended December 31,	
	2020	2019
Risk-free interest rate	0.4% - 1.7%	1.4% - 2.4%
Expected volatility	57.0% - 71.0%	57.0% - 71.0%
Expected dividend yield	—	—
Expected life (years)	4.0 - 6.3 years	6.25 years

Goodwill and Intangible Assets

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

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

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

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, 2020 and 2019, the related consolidated statements of operations, stockholders' deficit, and cash flows for each of the years in the two-year period ended December 31, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2020, 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 raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

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

San Diego, California
March 18, 2021

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

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 92,076	$ 33,042
Accounts receivable, net	12,682	22,189
Inventory	12,219	10,937
Income tax receivable	—	634
Prepaid expenses and other current assets	9,361	7,846
Total current assets	126,338	74,648
Property and equipment, net	17,842	15,891
Other assets	198	198
Goodwill	6,219	6,219
Other intangible assets, net	3,843	4,771
Total assets	$ 154,440	$ 101,727
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 17,410	$ 15,754
Accrued expenses and other current liabilities	54,677	83,615
Current portion of mortgages payable	271	241
Current portion of capital lease obligations	312	727
Total current liabilities	72,670	100,337
Capital lease obligations, net of current portion	46	358
Mortgages payable, net of current portion	2,795	3,081
Convertible notes, net of unamortized discount of $9,614 as of December 31, 2020	158,886	—
Note payable to related party, net of unamortized discount of $6,034 as of December 31, 2019	—	68,966
Embedded derivative liability	18,370	—
Other long-term liabilities	8,667	12,859
Total liabilities	$ 261,434	$ 185,601
Commitments and contingencies (Note 10)		
Stockholders' deficit:		
Common stock – $0.001 par value. 350,000,000 and 300,000,000 shares authorized as of December 31, 2020 and December 31, 2019, respectively; 59,287,331 and 8,451,415 shares issued as of December 31, 2020 and December 31, 2019, respectively; 55,772,303 and 4,976,843 shares outstanding as of December 31, 2020 and December 31, 2019, respectively	59	9
Series A Preferred Stock – $0.001 par value. 4,120,000 shares authorized, issued and outstanding as of December 31, 2019; no shares authorized, issued and outstanding as of December 31, 2020	—	4
Series B Preferred Stock – $0.001 par value. 126,035,000 shares authorized as of December 31, 2019; 101,867,405 shares issued and outstanding as of December 31, 2019, respectively. No shares authorized, issued and outstanding as of December 31, 2020	—	102
Additional paid-in capital	452,992	283,260
Accumulated deficit	(541,274)	(348,478)
Treasury stock – at cost; 3,515,028 shares of common stock as of December 31, 2020 and 3,474,572 shares of common stock as of December 31, 2019	(18,771)	(18,771)
Total stockholders' deficit	(106,994)	(83,874)
Total liabilities and stockholders' deficit	$ 154,440	$ 101,727

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,	
	2020	2019
Revenues	$ 74,313	$ 143,985
Cost of sales	93,433	100,492
Gross profit (loss)	(19,120)	43,493
Operating expenses:		
Research and development	47,743	63,400
Selling and marketing	52,887	58,888
General and administrative	75,438	61,324
Total operating expenses	176,068	183,612
Loss from operations	(195,188)	(140,119)
Interest expense	(9,984)	(9,199)
Interest and other income (expense), net	(24,888)	575
Loss before income taxes	(230,060)	(148,743)
Income tax benefit	(37,532)	(706)
Net loss	(192,528)	(148,037)
Dividend paid to preferred stockholders	(268)	(3,652)
Stock dividend on exchange of Series A-1 to Series B Preferred Stock	—	(27,637)
Stock dividend on Series B Preferred Stock	—	(49,501)
Net loss attributable to common stockholders	$ (192,796)	$ (228,827)
Net loss per share attributable to common stockholders, basic and diluted	$ (7.01)	$ (46.87)
Weighted average number of shares outstanding used in calculating net loss per share attributable to common stockholders, basic and diluted	27,512,876	4,882,662

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, 2018	**8,112,581**	**$ 8**	**5,620,000**	**$ 6**	**14,164,306**	**$ 14**	**$ 124,244**	**$ (142,469)**	**(3,474,572)**	**$ (18,771)**	**$ (36,968)**
Adoption of accounting standard (Note 2)	—	—	—	—	—	—	—	23,666	—	—	23,666
Issuance of common stock upon exercise of options	338,834	1	—	—	—	—	550	—	—	—	551
Exchange of Series A-1 Preferred Stock for Series B Preferred Stock	—	—	(1,500,000)	(2)	35,664,240	36	27,603	(27,637)	—	—	—
Issuance of Series B Preferred Stock, net of issuance cost	—	—	—	—	34,035,354	34	79,005	—	—	—	79,039
Stock dividend on Series B Preferred Stock	—	—	—	—	18,003,505	18	49,483	(49,501)	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	2,375	—	—	—	2,375
Dividends paid	—	—	—	—	—	—	—	(4,500)	—	—	(4,500)
Net loss	—	—	—	—	—	—	—	(148,037)	—	—	(148,037)
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)**
Issuance of common stock upon exercise of options	543,218	—	—	—	—	—	626	—	—	—	626
Issuance of common stock upon initial public offering, net	6,666,667	7	—	—	—	—	88,658	—	—	—	88,665
Issuance of common stock upon secondary public offering, 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 Warrant	—	—	—	—	—	—	268	(268)	—	—	—
Issuance of common stock upon vesting of restricted stock unit awards	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)**

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,	
	2020	2019
Operating Activities:		
Net loss	$ (192,528)	$ (148,037)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash revenue reserve	33,549	39,703
Depreciation and amortization	5,059	4,679
Stock-based compensation expense	10,668	2,375
Loss on extinguishment of debt	10,952	—
Amortization of debt discount	3,656	1,670
Inventory write-down	143	535
Loss on disposal of property and equipment	67	—
Change in fair value of derivative liability	13,860	—
Changes in operating assets and liabilities:		
Accounts receivable, net	9,508	3,429
Inventory	(1,425)	(3,857)
Income tax receivable	635	5,560
Prepaid expenses and other current assets	(2,564)	(3,867)
Other assets	—	(54)
Accounts payables	2,857	4,383
Accrued expenses and other liabilities	(61,424)	18,001
Other long-term liabilities	1,243	(30,644)
Net cash used in operating activities	(165,744)	(106,124)
Investing Activities:		
Purchases of property and equipment	(4,944)	(3,725)
Purchases of short-term investments	—	(11,214)
Proceeds from sale of short-term investments	—	31,414
Proceeds from sale of equity method investment	—	50
Net cash (used in) provided by investing activities	(4,944)	16,525
Financing Activities:		
Proceeds from issuance of common stock, net	116,435	551
Proceeds from issuance of Series B Preferred Stock and warrant, net of issuance cost	21,307	79,039
Proceeds from issuance of convertible notes, net	99,708	—
Payments for financing of insurance premiums	(6,745)	—
Dividends paid	—	(4,500)
Payments for deferred offering costs	—	(179)
Principal payments on mortgages payable	(256)	(228)
Principal payments on capital lease obligations	(727)	(1,047)
Net cash provided by financing activities	229,722	73,636
Net increase (decrease) in cash and cash equivalents	59,034	(15,963)
Cash and cash equivalents at beginning of period	33,042	49,005
Cash and cash equivalents at end of period	$ 92,076	$ 33,042

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,	
	2020	**2019**
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 3,927	$ 7,529
Cash paid for income taxes	62	6
Supplemental schedule of non-cash investing and financing activities:		
Exchange of note payable for convertible notes	$ 75,000	$ —
Conversion of convertible note	18,750	—
Issuance of preferred stock in settlement of interest payable	2,698	—
Equity financing issuance costs incurred but not paid	205	871
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	1,204	337
Capital lease obligations	—	241
Stock dividend on exchange of Series A-1 to Series B Preferred Stock	—	27,637
Stock dividend on Series B Preferred Stock	—	49,501

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 primary operations include a licensed Clinical License Improvement Amendment and College of American Pathologists certified laboratory located in Michigan specializing in the molecular testing markets serving women's health providers in the obstetric, gynecological, fertility, and maternal fetal medicine specialty areas in the United States.

The Company has expertise in the national reference laboratory, clinical genetics, laboratory molecular testing, and biotechnology markets. Distribution is managed by a dedicated women's health physician sales force and a field operations team who support all logistical functions in receiving clinical samples to the laboratory for analysis. The Company's core business is focused on the prenatal carrier screening and noninvasive prenatal test market, targeting preconception planning, and routine pregnancy management for genetic disease risk assessment. Through its affiliation with Mattison Pathology, LLP ("Mattison"), a Texas limited liability partnership doing business as Avero Diagnostics ("Avero"), located in Lubbock and Dallas, Texas, the Company's operations have expanded to provide anatomic and molecular pathology testing products in the United States.

On June 10, 2020, the Company amended its certificate of incorporation to reflect a one-for-6.178 reverse stock split of the Company's common stock. The par value and the number of authorized shares of common stock were not adjusted as a result of the reverse stock split. All issued and outstanding shares of common stock and related per share amounts contained in the accompanying consolidated financial statements have been adjusted to reflect this reverse stock split for all periods presented. The reverse stock split resulted in an adjustment to the respective Series A and B preferred stock conversion prices to reflect a proportional decrease in the number of shares of common stock to be issued upon conversion.

On June 23, 2020, the Company completed the initial public offering of its common stock (the "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 underwriting discounts and commissions and other offering expenses payable by the Company. In connection with the IPO, on June 23, 2020, all outstanding Series A and B preferred stock and the outstanding convertible promissory note converted into shares of common stock and the outstanding warrant to purchase shares of convertible preferred stock became exercisable for shares of common stock.

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. Concurrently with this underwritten public offering, the Company completed a private offering of $168.5 million principal amount of its 7.25% Convertible Senior Notes due 2025 (the "Convertible Notes") pursuant to Rule 144A under the Securities Act. Included in the principal amount was $78.5 million of Convertible Notes issued to Athyrium Capital Management, L.P. ("Athyrium"), which were exchanged for discharge of amounts and any obligations outstanding under the Company's existing credit and security agreement with a fund managed by Athyrium (see Note 8).

Liquidity

As of December 31, 2020, the Company had cash and cash equivalents of $92.1 million and an accumulated deficit of $541.3 million. For the year ended December 31, 2020, the Company reported a net loss of $192.5 million and cash used in operating activities of $165.7 million. The Company's primary sources of capital have historically been the sale of common stock, private placements of preferred stock and incurrence of debt. As of December 31, 2020, the Company had $168.5 million of convertible notes outstanding (see Note 7), and mortgages outstanding of $3.1 million (see Note 9). Management does not believe that the current available cash and cash equivalents will be sufficient to fund the Company's planned expenditures and meet its obligations for at least 12 months following the financial statement issuance date without raising additional funding. As a result, there is substantial doubt about the Company's ability to continue as a going concern for 12 months following the issuance date of the consolidated financial statements for the year ended December 31, 2020. 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 provides sufficient runway to achieve critical research and development pipeline milestones and show continued progress in the molecular testing activities into mid-2021. 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. 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 recent 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 spread of the pandemic and related restrictions on travel and transports, all of which are 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 COVID-19 is unknown at this time, the Company has made appropriate estimates based on the facts and circumstances available as of the reporting date. These estimates may change as new events occur and additional information is obtained.

Note 2. Summary of Significant Accounting Guidance

Basis of Presentation

The Company's financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP") and include the accounts of Progenity, Inc., its wholly owned subsidiaries, and an affiliated professional partnership with Avero with respect to which the Company currently has a specific management arrangement. The Company has determined that Avero is a variable interest entity and that the Company is the primary beneficiary resulting in the consolidation of Avero as required by the accounting guidance for consolidation. All significant intercompany balances and transactions have been eliminated in consolidation (see Note 3).

Use of Estimates

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

Operating Segments

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

Revenue Recognition

Revenue is recognized in accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). In accordance with ASC 606, the Company follows a five-step process to recognize revenues: 1) identify the contract with the customer, 2) identify the performance obligations, 3) determine the transaction price, 4) allocate the transaction price to the performance obligations and 5) recognize revenues when the performance obligations are satisfied.

Revenue is primarily derived from providing molecular testing products, which are reimbursed through arrangements with third-party payors, laboratory distribution partners, and amounts from individual patients. Third-party payors include commercial payors, such as health insurance companies, health maintenance organizations and government health benefit programs, such as Medicare and Medicaid. The Company's contracts generally contain a single performance obligation, which is the delivery of the test results, and the Company satisfies its performance obligation at a point in time upon the delivery of the results, which then triggers the billing for the product. The amount of revenue recognized reflects the amount of consideration the Company expects to be entitled 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 have been 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, 2020	December 31, 2019
Blue Shield of Texas	17.8%	*
Aetna	4.0%	6.0%
Cigna	2.6%	*
United Healthcare	6.6%	31.5%
Government Health Benefits Programs	26.2%	16.7%
Anthem	3.5%	*

* Less than 1%.

	Percentage of Revenue	
	Year Ended December 31,	
	2020	2019
Blue Shield of Texas	35.6%	21.3%
Aetna	11.0%	9.2%
Cigna	7.6%	4.5%
United Healthcare	6.7%	30.8%
Government Health Benefits Programs	3.7%	*
Anthem(1)	(6.7)%	6.1%

(1) The negative amounts presented in the percentage of revenues include accruals for reimbursement claims and settlements included in the estimates of variable consideration recorded during the year ended December 31, 2020. Revenue recognized consider 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, as described in Notes 4 and 10.
* Less than 1%.

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.

Cost of Sales

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

Cash and Cash Equivalents including Concentration of Credit Risk

The Company considers all highly liquid investment instruments purchased with an initial maturity of three months or less to be cash equivalents. The Company limits its exposure to credit loss by placing its cash and cash equivalents in financial institutions with high credit ratings. The Company's cash and cash equivalents may consist of deposits held with banks, money market funds, or other highly liquid investments that may at times exceed federally insured limits. Cash equivalents are financial instruments that potentially subject the Company to concentrations of risk, to the extent of amounts recorded in the balance sheets. The Company performs evaluations of its cash equivalents and the relative credit standing of these financial institutions and limits the amount of credit exposure with any one institution. Management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held.

Investments

All investments have been classified as "available-for-sale" and are carried at fair value as determined based upon quoted market prices or pricing models for similar securities at period end. Investments with contractual maturities less than 12 months at the balance sheet date are considered short-term investments. Those investments with contractual maturities 12 months or greater at the balance sheet date are considered long-term investments. A decline in the fair value of any security below cost that is deemed other than temporary results in a charge to earnings and the corresponding establishment of a new cost basis for the security. Dividend and interest income are recognized when earned. Realized gains and losses are included in earnings and are derived using the specific identification method for determining the cost of the securities sold.

Inventory

Inventory is stated at lower of cost (first-in, first-out method) or net realizable value. Inventory consists entirely of supplies, which are consumed when the Company is providing its test reports, and therefore the Company does not maintain any work in process or finished goods inventory. The Company reviews its inventory on a regular basis for excess and obsolete inventory based on an estimate for future consumption. Write-downs or losses of inventory are generally due to technological advances or new product introductions in the Company's laboratory testing products. The Company believes that the estimate used in calculating the inventory provision are reasonable and properly reflect the risk of excess and obsolete inventory. If laboratory operation demand is significantly less than inventory levels, inventory write-downs may be required, which could have a material adverse effect on the Company's consolidated financial statements. Inventory write-downs amounted to $0.1 million and $0.5 million in the years ended December 31, 2020 and 2019, respectively.

Property and Equipment, Net

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

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

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

Goodwill

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

If, after assessing qualitative factors, an entity determines it is not more likely than not that the fair value of a reporting unit is less than its carrying amount, then performing the two-step impairment test is unnecessary. If deemed necessary, a two-step test is used to identify the potential impairment and to measure the amount of goodwill impairment, if any. The first step is to compare the fair value of the reporting unit with its carrying amount, including goodwill. If the fair value of the reporting unit exceeds its carrying amount, goodwill is considered not impaired; otherwise, there is an indication that goodwill may be impaired and the amount of the loss, if any, is measured by performing step two. Under step two, the impairment loss, if any, is measured by comparing the implied fair value of the reporting unit goodwill with the carrying amount of goodwill. No impairment was recorded for the years ended December 31, 2020 and 2019.

Intangible Assets

Intangible assets consist of identifiable intangible assets acquired through acquisitions. Identifiable intangible assets include payor relationships, trade names, and noncompete agreements. The Company amortizes payor relationships and trade names using the straight-line method over their useful lives. The Company amortizes noncompete covenants using the straight-line method over the terms of the related agreements. The Company reviews impairment for intangible assets with definite useful lives whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. Recoverability of these assets is measured by a comparison of the carrying amounts to the undiscounted future cash flows the assets are expected to generate. If such review indicates that the carrying amount of intangible assets is not recoverable, the carrying amount of such assets is reduced to fair value. No impairment was recorded for the years ended December 31, 2020 and 2019.

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

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, 2020 and 2019.

Embedded Derivative Related to Convertible Notes

During 2020, the Company issued convertible notes with an embedded derivative that is required to be bifurcated from their 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 on the consolidated statements of operations. Changes in the Company’s 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 improve the Company's tests, to reduce costs, and to develop new products. Research and development expenses also consist of personnel expenses, including salaries, bonuses, stock-based compensation expense, and benefits, and allocated overhead costs. Research and development expenses are expensed as incurred.

Selling and Marketing

Selling and marketing expenses consist primarily of costs for communication, advertising, conferences, and other marketing events. Selling and marketing expenses also consist of personnel expenses, including salaries, bonuses, stock-based compensation expense, benefits, and allocated overhead costs. Selling and marketing expenses are expensed as incurred. Advertising expense for the years ended December 31, 2020 and 2019 amounted to $1.6 million and $2.2 million, respectively.

General and Administrative

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

Stock-Based Compensation

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. The Company accounts for the forfeitures in the period in which they occur. The fair value of each restricted stock unit award is estimated based on the market price of the underlying common stock on the date of the grant.

The determination of the fair value of each stock award using the option-pricing model is affected by the Company's assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, the fair value of the common stock at the date of grant, the expected term of the awards, the expected stock price volatility over the term of the awards, risk-free interest rate, and dividend rate. The Company's 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 selling price per share of its common stock as reported on the Nasdaq Global Market 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 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 with to the expected term of the awards.

Risk-Free Interest Rate—The risk-free interest rate is calculated using the average of the published interest rates of U.S. Treasury zero-coupon issues with maturities that are commensurate with the expected term.

Dividend Rate—The dividend yield assumption is zero, as the Company has no plans to make dividend payments.

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 (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. 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 May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* (*ASC 606*), which supersedes the revenue recognition requirements in ASC Topic 605, *Revenue Recognition* ("ASC 605"), and requires entities to recognize revenue when they transfer control of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services. The Company adopted ASC 606 as of January 1, 2019, using the modified retrospective transition method applied to those contracts which were not completed as of January 1, 2019. Upon adoption, the Company recognized the cumulative effect of adopting this guidance as an adjustment to its opening accumulated deficit balance. The Company recorded a one-time increase to opening accounts receivable, net, and a reduction to opening accumulated deficit of $23.7 million as of January 1, 2019. The adjustment was primarily related to the recognition of variable consideration the Company expected to receive that was previously recognized as cash was received under ASC 605.

In June 2018, the FASB issued Accounting Standards Update ("ASU") No. 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*. The standard simplifies the accounting for share-based payments granted to nonemployees for goods and services and aligns most of the guidance on such payments to the nonemployees with the requirements for share-based payments granted to employees. The Company adopted the new accounting standard in fiscal year 2020 using the retrospective transition method for each period presented, which did not have a material impact on the consolidated financial statements.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* which removes certain exceptions to the general principles of Topic 740, *Accounting for Income Taxes* ("ASC 740") and is intended to improve consistency and simplify GAAP in several other areas of ASC 740 by clarifying and amending existing guidance. The Company early adopted ASU No. 2019-12 for the quarter ended March 31, 2020, which did not have a material impact on the consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-04, *Intangibles—Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment*. The new standard simplifies the measurement of goodwill by eliminating step two of the two-step impairment test. Step two measures a goodwill impairment loss by comparing the implied fair value of a reporting unit's goodwill with the carrying amount of that goodwill. The new guidance requires an entity to compare the fair value of a reporting unit with its carrying amount and recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value. Additionally, an entity is required to consider income tax effects from any tax-deductible goodwill on the carrying amount of the reporting unit when measuring the goodwill impairment loss, if applicable. The Company adopted the new accounting standard in fiscal year 2020, 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 now effective for EGCs for fiscal years beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022. If Company maintains EGC status, it will adopt the new standard in the fourth quarter of 2022 using the modified retrospective method, under which the Company will apply the new lease standard to existing and new leases as of January 1, 2022, but prior periods will not be restated and will continue to be reported under Topic 840 guidance in effect during those periods. The Company plans to elect 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.

The Company continues to monitor FASB activity to assess certain interpretative issues and the associated implementation of the new standard and is in the process of reviewing its lease arrangements, including property, equipment and vehicle leases. The Company is not yet able to estimate the anticipated impact to its consolidated financial statements from the implementation of the new standard as it continues to interpret the principles of the new 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.

Note 3. Variable Interest Entity

In June 2015, the Company entered into a series of agreements with Avero. The Company entered into a purchase agreement to acquire certain assets from Mattison used in the 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 Company entered into a nominee agreement which provides it with the right, but not the obligation, to purchase, or to designate a person(s) to purchase, the stock of Avero at any time for a nominal amount.

The Company also entered into a management services arrangement that authorizes the Company to perform the management services in the manner that it deems reasonably appropriate to meet the day-to-day business needs of Avero. The Company's

management services include 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 is entitled to receive an annual management fee equal to the amount of the net operating income of Avero. The term of the agreement with Avero is 10 years, subject to automatic renewals. The agreement can be terminated by either party with a 90-day notice before the end of the term.

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

In December 2018, Avero entered into a settlement agreement with Cigna (the "Cigna settlement obligation") whereby Avero agreed to pay an aggregate amount of $12.0 million with an upfront payment of $6.0 million and the remaining $6.0 million to be paid over 24 months, beginning in February 2019. The Company guaranteed the $12.0 million Cigna settlement obligation. The Company provided financial support to Avero in the amount of $3.0 million and $3.0 million during the years ended December 31, 2020 and 2019, respectively, related to the Cigna settlement obligation (see Note 10), 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, 2020 and 2019, 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 and 2019, in thousands. The creditors of Avero have no recourse to the general credit of the Company, with the exception of $1.7 million and $1.9 million in mortgage payable guaranteed by the Company as of December 31, 2020 and 2019, respectively (see Note 9), and $3.0 million in remaining Cigna settlement obligation guaranteed by the Company as of December 31, 2019. The assets and liabilities exclude intercompany balances that eliminate in consolidation:

	December 31, 2020	December 31, 2019
Assets of Avero that can only be used to settle obligations of Avero		
Cash and cash equivalents	$ 556	$ 1,837
Accounts receivable, net	6,047	4,269
Inventory	3,382	2,572
Prepaid expenses and other current assets	1,254	1,181
Property and equipment, net	5,436	5,586
Other assets	30	30
Goodwill	6,219	6,219
Other intangible assets, net	3,843	4,771
Total assets of Avero that can only be used to settle obligations of Avero	$ 26,767	$ 26,465
Liabilities of Avero		
Accounts payable	$ 4,722	$ 2,450
Accrued expenses and other accrued liabilities	3,472	5,630
Current portion of capital lease obligations	46	59
Current portion of mortgage payable	199	173
Capital lease obligations, net of current portion	4	50
Mortgage payable, net of current portion	1,520	1,733
Other long-term liabilities	428	467
Total liabilities of Avero	$ 10,391	$ 10,562

Note 4. Revenues

Revenue is derived from contracts with healthcare insurers, government payors, laboratory partners and patients in connection with sales of prenatal genetic, anatomic or molecular pathology tests. The Company enters into contracts with healthcare insurers related to tests provided to patients who have health insurance coverage. Insurance carriers are considered third-party payors on behalf of the patients, and the patients who receive genetic, anatomic or molecular pathology test products are considered the customers. Tests may be billed to insurance carriers, patients, or a combination of insurance carriers and patients. The Company also sells tests to laboratory partners, which are also considered to be customers. The Company's test volumes began to decrease in the second half of March 2020 as a result of the COVID-19 pandemic spreading in the United States and resulting limitations and reordering of priorities

across the U.S. healthcare system. The Company expects test volumes to continue to be adversely affected by COVID-19 and cannot predict when volumes will return to normal.

In accordance with ASC 606, a performance obligation represents a promise in a contract to transfer a distinct good or service to a customer and the consideration should be allocated to each distinct performance obligation and recognized as revenue when or as the performance obligation is satisfied. The Company has evaluated its contracts with healthcare insurers, government payors, laboratory partners and patients and identified a single performance obligation in those contracts, the delivery of a test result. The Company satisfies its performance obligation at a point in time upon the delivery of the test result, at which point the Company can bill for its products. The amount of revenue recognized reflects the transaction price and considers the effects of variable consideration, which is discussed below.

Once the Company satisfies its performance obligations upon delivery of a test result and bills for the product, the timing of the collection of payments may vary based on the payment practices of the third-party payor. The Company bills patients directly for co-pays and deductibles that they are responsible for and also bills patients directly in cases where the customer does not have insurance.

The Company has established an accrual for refunds of payments previously made by healthcare insurers based on historical experience and executed settlement agreements with healthcare insurers. The refunds are accounted for as reductions in revenues in the statement of operations as an element of variable consideration. For example, during the three months ended June 30, 2020, the Company accrued $10.3 million for refunds to government payors related to reimbursement for the Company's Preparent expanded carrier screening tests during 2019 and early 2020. 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 $10.3 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 and will continue to settle any future obligation as they arise.

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 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 a reduction of $26.9 million of revenue reported for year ended December 31, 2020 and a reduction of $16.0 million for the year ended December 31, 2019. These amounts included (i) adjustments for actual collections versus estimated variable consideration as of the beginning of the reporting period and (ii) cash collections and the related recognition of revenue in the current period for tests delivered in prior periods due to the release of the constraint on variable consideration, offset by (iii) reductions in revenue for the accrual for reimbursement claims and settlements described in Note 10.

Disaggregation of Revenues

The following table shows a further disaggregation of revenues by payor type (in thousands):

	Year Ended December 31,	
	2020	2019
Commercial third-party payors	$ 64,433	$ 139,051
Government health benefit programs(1)	2,731	195
Patient/laboratory distribution partners	7,149	4,739
Total revenues	$ 74,313	$ 143,985

(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, 2020 and 2019. Revenue 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.

Note 5. Balance Sheet Components

Prepaid Expenses and Other Current Assets

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

	December 31, 2020	December 31, 2019
Prepaid expenses	$ 9,116	$ 6,476
Other current assets	245	1,370
Total	$ 9,361	$ 7,846

Property and Equipment, Net

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

	December 31, 2020	December 31, 2019
Computers and software	$ 14,591	$ 13,913
Building and leasehold improvements	9,458	9,491
Laboratory equipment	7,678	5,580
Furniture, fixtures, and office equipment	1,686	1,633
Construction in progress	2,784	1,493
Land	1,091	1,091
Total property and equipment	37,288	33,201
Less accumulated depreciation and amortization	(19,446)	(17,310)
Property and equipment, net	$ 17,842	$ 15,891

Capital leases included in property and equipment, net consisted of the following (in thousands):

	December 31, 2020	December 31, 2019
Capital leases	$ 2,467	$ 3,692
Less accumulated depreciation and amortization	(1,954)	(2,239)
Capital leases included in property and equipment, net	$ 513	$ 1,453

Depreciation expense was $4.1 million and $3.7 million for the years ended December 31, 2020 and 2019, respectively.

Intangible Assets, Net

Intangible assets, net consisted of the following (in thousands):

December 31, 2020	Cost	Accumulated amortization	Net
Payor relationships	$ 7,230	$ (4,037)	$ 3,193
Trade names	1,410	(787)	623
Noncompete agreements	384	(357)	27
Intangible assets, net	$ 9,024	$ (5,181)	$ 3,843

December 31, 2019	Cost	Accumulated amortization	Net
Payor relationships	$ 7,230	$ (3,314)	$ 3,916
Trade names	1,410	(646)	764
Noncompete agreements	384	(293)	91
Intangible assets, net	$ 9,024	$ (4,253)	$ 4,771

Amortization expense of intangible assets was $0.9 million for each of the years ended December 31, 2020 and 2019.

The future amortization of intangible assets at December 31, 2020 was (in thousands):

Year ending December 31,	
2021	$ 891
2022	864
2023	864
2024	864
2025	360
Thereafter	—
Total future minimum lease payments	$ 3,843

Accrued Expenses and Other Current Liabilities

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

	December 31, 2020	December 31, 2019
Accrual for reimbursement claims and settlements, current	$ 30,487	$ 60,386
Commissions and bonuses	4,619	6,357
Vacation and payroll benefits	8,896	5,506
Accrued professional services	3,385	5,322
Contract liabilities	378	—
Other	6,912	6,044
Total	$ 54,677	$ 83,615

Other Long-term Liabilities

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

	December 31, 2020	December 31, 2019
Accrual for reimbursement claims and settlements, net of current portion	$ 7,053	$ 12,205
Other	1,614	654
Total	$ 8,667	$ 12,859

Note 6. Fair Value Measurements

The Company's financial assets and liabilities carried at fair value are comprised of investment assets that include money market funds. 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 reporting 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. 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.

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

	Quoted Prices for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
December 31, 2020			
Money market funds(1)	$ 90,254	$ —	$ —
Embedded derivative liability	—	—	18,370
December 31, 2019			
Money market funds(1)	$ 24,432	$ —	$ —

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

The Company's policy is to recognize transfers between levels at the end of the reporting period. There were no transfers between Level 1 and Level 2 during the years ended December 31, 2020 and 2019.

The carrying value of the Company's accounts receivable, income tax receivable, accounts payable, and accrued expenses and other current liabilities are considered to be representative of their respective fair values because of their short-term nature.

The carrying value of the Company's mortgages payable approximates their estimated fair value because the instruments bear interest at rates and have terms that are comparable to those available to the Company for similar loan instruments at December 31, 2020 and 2019.

The carrying value of the Company's convertible senior notes (the "Convertible Notes") at December 31, 2020 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 conversion feature assessed at inception. The carrying value and the fair value of the Company's Convertible Notes, net of discount, was $158.9 million at December 31, 2020. The Company periodically assesses the fair value of the conversion feature related to the Convertible Note. The conversion feature was bifurcated and recorded as an embedded derivative liability in the consolidated balance sheet 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. 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 $250.2 million at December 31, 2020.

The carrying value of the Company's note payable to a related party at December 31, 2019 did not approximate its fair value because the instrument bears interest at a rate that was not comparable to those available to the Company for a similar loan instrument at December 31, 2019. The carrying value and the fair value of the Company's term loan (the "2017 Term Loan") was $75.0 million

and $79.8 million, respectively, at December 31, 2019. The carrying value of the 2017 Term Loan is presented on the accompanying consolidated balance sheets net of discount on the note and debt issuance cost.

Note 7. Convertible Notes

In December 2020, the Company issued a total of $168.5 million principal amount of its Convertible Notes in a private offering of the convertible notes 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 (the "Indenture"). The Convertible Notes are due on December 1, 2025, unless earlier repurchased, redeemed or converted, and accrue interest at a rate per annum equal to 7.25% payable semi-annually in arrears on June 1 and December 1 of each year, with the initial payment on June 1, 2021.

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

At any time, noteholders may convert their Convertible Notes at their option into shares of the Company's common stock, together, if applicable, with cash in lieu of any fractional share, at the then-applicable conversion rate. The initial conversion rate is 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 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) 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 $7,500,000; (vi) the rendering of certain judgments against the Company or any of its 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 the Company or any of the Company's significant subsidiaries. As of 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 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 non-cash gain or loss related to the change in the fair value being charged to interest and other income (expense) in the accompanying 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 expense in the consolidated statements of operations.

Note 8. Related Party Transactions

On October 27, 2017, the Company entered into a Credit and Security Agreement and a Series B Convertible Preferred Stock Purchase Agreement with a private equity firm (the "2017 Transaction"). The 2017 Transaction provided for the 2017 Term Loan, the issuance of Series B Preferred Stock (the "Series B Preferred Stock"), and the issuance of a warrant to purchase Series B Preferred Stock (the "Series B Preferred Stock Purchase Warrant"). The 2017 Term Loan 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.

As of December 31, 2019, the outstanding unpaid principal under the 2017 Term Loan was $75.0 million. As of December 31, 2019, the balance of unamortized discount and issuance costs on the 2017 Term Loan was $6.0 million. During the years ended December 31, 2020 and 2019, the Company recognized interest expense on the 2017 Term Loan of $7.5 million and $8.9 million, respectively, inclusive of $2.1 million and $1.7 million of discount amortization for the years ended December 31, 2020 and 2019, 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 March 31, 2020, the Company entered into the First Amendment to the Credit Agreement (the "Credit Agreement Amendment"), with the collateral agent and lender party thereto, providing for the payment of interest due and payable as of March 31, 2020 in shares of Series B Preferred Stock, and further providing for the payment of interest due and payable as of June 30, 2020 in shares of 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 (the "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 interest and 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 the interest and 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's as described in Note 7. The exchange was accounted as extinguishment of the 2017 Term Loan and resulted in $7.6 million of loss on extinguishment, which was included in the interest and other income (expense), net in the accompanying consolidated statement of operations for the year ended December 31, 2020. This private equity firm also acquired additional $25.0 million principal amount of the Company's Convertible Notes for cash in this private offering, which resulted in $103.5 million aggregate principal amount of the Convertible Notes described in Note 7 acquired by this private equity firm. For the year ended December 31, 2020, the accrued interest expense related to the Convertible Notes held by this private equity firm was $0.5 million. Also in December 2020, the same private equity firm participated in the 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.

Note 9. 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 matures in 2024 and requires monthly principal and interest payments at a fixed interest rate of 2.94% plus a floating rate at LIBOR. As of December 31, 2020 and December 31, 2019, the outstanding balance of this mortgage was $1.3 million and $1.4 million, respectively. The Company also has a mortgage with American Bank of Commerce (originally executed in February 2008) outstanding on Avero's property located in Lubbock, Texas, which is used primarily for laboratory testing. The mortgage matures in 2029 and requires monthly principal and interest payments at an interest rate of 3.25%. As of December 31, 2020 and December 31, 2019, the outstanding balance of this mortgage was $1.7 million and $1.9 million, respectively.

As of December 31, 2020, the minimum principal payments under the mortgages payable were as follows (in thousands):

Year ending December 31,	Minimum Mortgages Payable Payments Obligations
2021	$ 271
2022	281
2023	292
2024	1,338
2025	884
Thereafter	—
Total future minimum payments	3,066
Less current portion of mortgages payable	(271)
Mortgages payable, net of current portion	$ 2,795

Note 10. 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 two to four years. Minimum rent payments under operating leases are recognized on a straight-line basis over the term of the lease. Rent expense for operating leases was $7.6 million and $8.9 million, for the years ended December 31, 2020 and 2019, respectively.

As of December 31, 2020, net minimum payments under the non-cancelable operating leases were as follows (in thousands):

Year ending December 31,	Minimum Operating Lease Payments
2021	$ 5,750
2022	3,017
2023	1,036
2024	38
2025 and thereafter	—
Total future minimum lease payments	$ 9,841

Capital Leases

The Company has entered into various capital lease agreements, primarily for equipment. The outstanding leases have a weighted average imputed interest rate of 5.98% per annum. As of December 31, 2020, the future minimum payments under the capital leases were as follows (in thousands):

Year ending December 31,	Minimum Capital Lease Payments
2021	$ 324
2022	47
2023 and thereafter	—
Total minimum lease payments	371
Less amounts representing interest	(13)
Present value of minimum capital lease payments	358
Less current portion of capital lease obligations	(312)
Capital lease obligations, net of current portion	$ 46

Contingencies

The Company, in the ordinary course of its business, can be involved in lawsuits, threats of litigation, and audit and investigative demands from third parties. While management is unable to predict the exact outcome of such matters, it is management's current belief, that any potential liabilities resulting from these contingencies, individually or in the aggregate, could have a material impact on the Company's financial position and results of operations.

The regulations governing government reimbursement programs (e.g., Medicaid, Tricare, and Medicare) and commercial payor reimbursement programs are complex and may be subject to interpretation. As a provider of services to patients covered under government and commercial payor programs, post payment review audits, and other forms of reviews and investigations are routine. The Company believes it complies in all material respects with the statutes, regulations, and other requirements applicable to its laboratory operations.

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"). 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 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. Specifically, the Company has entered into:

- a civil settlement agreement, effective July 23, 2020, with the DOJ through the AUSA for SDNY, and on behalf of the Office of Inspector General of the Department of Health and Human Services (the "OIG"), and with the relator named therein (the "SDNY Civil Settlement Agreement");

- a civil settlement agreement, effective July 23, 2020, with the DOJ through the AUSA for 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 (the "SDCA Civil Settlement Agreement");
- a non-prosecution agreement, effective July 21, 2020, with the AUSA for SDCA (the "Non-Prosecution Agreement") in resolution of all criminal allegations;
- a corporate integrity agreement, effective July 21, 2020, with the OIG (the "Corporate Integrity Agreement"); and
- civil settlement agreements, effective October 1, 2020, with the State AGs ("the State Settlement Agreements").

The Company refers to the SDNY Civil Settlement Agreement, the SDCA Civil Settlement Agreement, the Non-Prosecution Agreement, the Corporate Integrity Agreement and the State Settlement Agreements collectively as the Agreements.

SDNY Civil Settlement Agreement

Pursuant to the SDNY Civil Settlement Agreement, the Company is required to pay a settlement amount of approximately $19.4 million, which includes approximately $9.7 million designated as restitution to the U.S. federal government. During the year ended December 31, 2020, the Company paid approximately $14.7 million. The outstanding settlement amount is payable in two installments as follows:

- approximately $2.0 million on or before December 31, 2021; and
- approximately $2.8 million on or before December 31, 2022.

The remaining amounts payable to the government will be subject to interest at a rate of 1.25% per annum, and any or all amounts may be paid earlier at the option of the Company.

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 $37.7 million related to the NOL carryback provisions available under the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act") for taxes paid by the Company in years 2013, 2014, 2015 and 2017 (the "CARES Act Tax Benefit") and made accelerated payments of approximately $4.1 million under the SDNY Civil Settlement Agreement.

Additionally, under the SDNY Civil Settlement Agreement, the U.S. federal government and the relator agreed to dismiss all civil claims asserted by the relator under the *qui tam* provisions of the federal False Claims Act.

SDCA Civil Settlement Agreement

The SDCA Civil Settlement Agreement requires the Company to pay a settlement amount of approximately $16.4 million, which includes approximately $10.0 million designated as restitution to the U.S. federal government. During the year ended December 31, 2020, the Company paid approximately $12.5 million. The outstanding settlement amount is payable in two installments as follows:

- approximately $1.7 million on or before December 31, 2021; and
- approximately $2.2 million on or before December 31, 2022.

The remaining amounts payable to the government, will be subject to interest at a rate of 1.25% per annum, and any or all amounts may be paid earlier at the option of the Company.

On July 21, 2020, the Company issued a promissory note to the U.S. federal government for the full settlement amount in connection with the SDCA Civil Settlement Agreement (the "Promissory Note"). The Promissory Note contains customary events of default and related acceleration of payment provisions. In addition, the Promissory Note provides, among other terms, 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 22% 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 approximately $3.4 million. During the year ended December 31, 2020, the Company received a tax refund of $37.7 million and made accelerated payments of approximately $3.4 million under the SDCA Civil Settlement Agreement.

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 provides that the DOJ may unilaterally, upon notice to the Company, extend the term of the agreement in 6-month increments, for a maximum total term of 24 months (that is, two 6-month extensions).

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. The Company's failure to comply with its obligations under the Corporate Integrity Agreement could result in monetary penalties and/or the Company being excluded from participating in federal healthcare programs.

State Settlement Agreements

Effective October 1, 2020, the Company entered into agreements with the State AGs with respect to the investigated matters. The State Settlement Agreements require the Company to pay a settlement amount of approximately $13.2 million to the participating states. The State Settlement Agreements include acceleration provisions similar to the SDNY Civil Settlement Agreement and the SDCA Civil Settlement Agreements described above upon the Company's receipt of civil settlements, damages awards, and tax refunds, with the amount to be accelerated and the timing of accelerated payment subject to such receipts. Because the Company received the June 2020 and September 2020 tax benefits totaling approximately $37.7 million, the initial payment to the participating states included added payments reflecting 17% of that amount, for a total initial payment on October 2, 2020 of approximately $8.7 million. During the year ended December 31, 2020, the Company paid approximately $9.7 million. The outstanding settlement amount is payable in three installments as follows:

- approximately $1.4 million on or before December 31, 2021;
- approximately $1.9 million on or before December 31, 2022; and
- approximately $0.2 million on or before December 31, 2023.

Settlement Accruals

As of December 31, 2019, the Company had accrued an aggregate of $35.8 million associated with a potential settlement with the DOJ and the participating State AGs within accrued expenses and other current liabilities and as a reduction of revenue as reflected on the consolidated balance sheet of the Company as of December 31, 2019 and consolidated statement of operations for the year ended December 31, 2019. In addition, in the quarter ended March 31, 2020, the Company accrued an additional $13.2 million with respect to the total amount to be paid under the agreement in principle to the DOJ and the participating State AGs, and additional amounts for related costs as of and for the quarterly period ended March 31, 2020. As of December 31, 2020, the Company's accrual consists of $5.0 million in accrued expenses and other current liabilities and $7.1 million in other long-term liabilities.

Payor Settlement Agreements

On June 21, 2018, the Company received a letter from Cigna alleging damages related to contract terms. On December 5, 2018, Cigna and the Company entered into a settlement agreement whereby Avero agreed to pay an aggregate amount of $12.0 million with an upfront payment of $6.0 million and the remaining $6.0 million to be paid over 24 months. For the year ended December 31, 2018, the Company recorded a charge of $12.0 million associated with this claim in its consolidated statements of operations as a reduction to revenue. As of December 31, 2020, the Cigna settlement obligation was fully settled.

On June 25, 2018, the Company received a letter from Aetna's external legal counsel that included various allegations relating to the Company's past practices. In November 2019, the Company and Aetna entered into a settlement agreement for $15.0 million, to be paid in installment payments through December 2020. During the year ended December 31, 2018, the Company recorded a charge of $15.0 million associated with this claim in its consolidated statements of operations as a reduction to revenue. As of December 31, 2020, the Company's accrual consists of $2.5 million included in accrued expenses and other current liabilities.

On October 18, 2018, the Company received a letter from UnitedHealth Group that included various allegations relating to the Company's past practices. On September 30, 2019, the Company entered into a settlement agreement with United HealthCare Services, Inc. and UnitedHealthcare Insurance Company ("United") in which the Company agreed to pay an aggregate amount of $30.0 million. The settlement is to be paid with an upfront payment of $2.0 million, and the remaining balance to be paid every six months starting December 31, 2019, with the first two installment payments of $5.0 million each, and $6.0 million each thereafter. As of December 31, 2020, the remaining settlement accrual related to United of $12.0 million is included in accrued expenses and other current liabilities.

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 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 4, 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., or 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 NIPT and microdeletion tests and secondarily to the implementation of the new CPT code for reimbursement for the Company's 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. In management's experience with negotiations with similarly situated commercial payors, a settlement may take six to twelve months to negotiate, and the time period over which a negotiated settlement payment may

be paid could extend from one to two years, or longer. Historical settlement amounts and payment time periods may not be indicative of the final settlement terms with Anthem, if any. Management intends to negotiate and/or dispute this claim of recoupment with Anthem and seek to offset any amounts owed by Anthem to the Company. Anthem has indicated a willingness to engage in contract negotiations for in-network status separately and in parallel to discussions regarding its recoupment claim. The resolution of this dispute may or may not include our moving in network with Anthem. As a potential means of making recoupment payments, if any, the Company may negotiate to apply temporarily lowered contracted rates for a specific period. Such provider-payor disputes are not uncommon and the Company expects to approach this dispute with an aim to resolve in a mutually satisfactory manner. The Company has recorded an accrual for the estimated probable loss for this matter as of December 31, 2020.

OIG Inquiry

On October 16, 2019, the Company received an inquiry from the Texas Health & Human Services Commission Office of Inspector General (the "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. 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 submitted a written response to the inquiry on October 23, 2019 and are awaiting a response from the TX OIG on the matter. It is not possible to predict the outcome of these matters and the timing for resolution.

Natera Lawsuit

On June 17, 2020, Natera, Inc. ("Natera") 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. On June 19, 2020, Natera filed a substantially similar second suit in the Northern District of Texas (N.D. Texas Civil Action No. 3:20-cv-1634). On July 31, 2020, the Company filed a motion to dismiss the Western District of Texas case based improper venue. The motion is fully briefed and remains pending before the Court. The Northern District of Texas case has been stayed until a decision with respect to the motion to dismiss is made.

On July 2, 2020, the Company filed a Complaint for Declaratory Judgment of Non-Infringement against Natera in the Southern District of California (S.D. California Civil Action No. 3:20-cv-1252). This case has been stayed pending the outcome of the Company's venue motion in the Western District of Texas. Management believes that the claims in Natera's complaints are without merit and the Company is vigorously defending against them.

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 the Company's infringement of two Ravgen patents. The Company has not yet responded to the complaint. Management believes the claims in Ravgen's complaint are without merit, and the Company intends to vigorously defend against them.

IPO Litigation

On June 23, 2020, the Company closed an initial public offering of its common stock ("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 amended complaint on February 4, 2021. 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 the Company (i) had overbilled government payors by $10.3 million and thus overstated its revenues for the full fiscal year 2019 and first quarter of 2020, and (ii) was allegedly suffering from material negative trends with respect to testing volumes, average selling prices for its tests, and revenues. Lead Plaintiffs seek certification as a class, unspecified compensatory damages, interest, costs and expenses including attorneys' fees, and unspecified extraordinary, equitable, and/or injunctive relief. The Company's response to the amended complaint is due by April 5, 2021. The Company intends to vigorously defend against these claims. Given the uncertainty of litigation, the preliminary stages of these cases, and the legal standards that must be met for, among other things, success on the merits, the Company is unable to predict the ultimate outcome of this action, and therefore cannot estimate the reasonably possible loss or range of loss, if any, that may result from these actions. Subject to a reservation of rights, the Company is advancing expenses subject to indemnification to the underwriters of the IPO.

Note 11. 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 million shares of common stock and 10 million 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. As of December 31, 2019, $1.1 million of deferred offering costs were included in prepaid expenses and other current assets in the accompanying consolidated balance sheet.

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.

Treasury Stock

In June 2014, the Company authorized an Equity Repurchase Program for Key Employees (the "Repurchase Program"). The Repurchase Program allowed the Company to repurchase for cash a portion of the common stock equity interests of certain employees, provided that (i) no more than 25% of the equity interest of any employee was repurchased under the Repurchase Program, (ii) the purchase price paid for each share of common stock equaled the most recent appraisal valuation of the Company's common stock, and (iii) the aggregate repurchases did not exceed the lesser of (a) equity interest representing, in the aggregate, 0.8 million shares of common stock, (b) a purchase price, in the aggregate, of more than $6.0 million, and (c) the maximum repurchases permitted under the General Corporation Law of the State of Delaware. In addition, it was the Company's practice to require individuals exercising stock options to hold the shares received upon exercising for a reasonable period of time in order for the holder to be exposed to the economic risks and rewards of share ownership prior to participating in the Repurchase Program. A reasonable period of time was defined as a period of at least six months and that covered at least two common stock appraisal valuations. The Repurchase Program has been discontinued.

Convertible Preferred Stock

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

On August 27, 2019, the Company issued 9,090,910 shares of Series B Preferred Stock at an issuance price of $2.75 per share for an aggregate consideration of $25.0 million (the "August 2019 Financing") pursuant to a Series B Preferred Stock Purchase Agreement with a private equity firm. In addition, the Company amended the Series B Preferred Stock Purchase Warrant dated October 27, 2017 to increase the Series B Preferred Stock underlying the Series B Preferred Stock Purchase Warrant from 1,416,431 shares to 1,818,182 shares and adjust the exercise price to $2.75 per share. The $25.0 million of proceeds from the August 2019 Financing were allocated among the newly issued Series B Preferred Stock shares and additional shares of Series B Preferred Stock Purchase Warrant based on their relative fair values.

In connection with the August 2019 Financing, the Board of Directors and stockholders approved a 1.28-for-1 stock split for the Company's Series B Preferred Stock and Series B Preferred Stock Purchase Warrant issued and outstanding prior to the August 2019 Financing, which was effected on August 27, 2019 pursuant to an amendment to the amended and restated certificate of incorporation. The conversion price of the Series B Preferred Stock and exercise price of the outstanding Series B Preferred Stock Purchase Warrant was lowered from $3.53 to $2.75 per share. As a result, the Company issued 4,017,512 additional shares of Series B Preferred Stock as a stock dividend to the preferred stockholders, which was recorded as a $13.1 million increase to accumulated deficit in the consolidated statements of stockholders' deficit during the year ended December 31, 2019.

On August 27, 2019, the Company entered into an Exchange Agreement with holders of Series A-1 Preferred Stock (the "Exchange Agreement") pursuant to which the outstanding 1,500,000 shares of Series A-1 Preferred Stock were exchanged for 35,664,240 shares of Series B Preferred Stock. The exchange ratio was 1.2 to 1 on as-if converted to 4,810,651 shares of common stock that the Series A-1 Preferred Stock can be converted to, based on the conversion rate of 3.2 to 1. The Company determined that such exchange constituted a modification to the Series A-1 Preferred Stock. Accordingly, the increase comparing the fair value of the Series B Preferred Stock with the fair value of the Series A-1 Preferred Stock represented a dividend to the preferred stockholders of approximately $27.6 million, which was recorded as an increase to accumulated deficit in the consolidated statements of stockholders' deficit during the year ended December 31, 2019.

On November 12, 2019, the Company entered into a Series B Preferred Stock Purchase Agreement (the "November Series B Preferred Stock Purchase Agreement") with a private equity firm and received $25.0 million (the "November 2019 Financing") in exchange for the issuance of 11,111,111 shares of Series B Preferred Stock at $2.25 per share. In connection with the November 2019 Financing, the Board of Directors and stockholders approved a 1.22-for-1 stock split for the Company's Series B Preferred Stock and Series B Preferred Stock Purchase Warrant issued and outstanding prior to the November 2019 Financing. The conversion price of the Series B Preferred Stock and exercise price of the outstanding Series B Preferred Stock Purchase Warrant was lowered from $2.75 to $2.25 per share. As a result, the Company issued 13,985,993 additional shares of Series B Preferred Stock and adjusted the Series B Preferred Stock Purchase Warrant to purchase up to 2,222,222 shares of Series B Preferred Stock. The issuance of additional shares represented a stock dividend to the preferred stockholders, which was recorded as a $36.4 million increase to accumulated deficit in the consolidated statements of stockholders' deficit during the year ended December 31, 2019. In connection with the November 2019 Financing, the Company amended the certificate of incorporation. Following the amendment, there are no authorized or outstanding shares of Series A-1 Preferred Stock.

On November 22, 2019, the Company completed an additional equity financing pursuant to the November Series B Preferred Stock Purchase Agreement with certain existing, accredited investors for an aggregate of $6.1 million in exchange for the issuance of an aggregate of 2,722,222 shares of Series B Preferred Stock at $2.25 per share.

On December 19, 2019, the Company completed an additional equity financing pursuant to the November Series B Preferred Stock Purchase Agreement with the same private equity firm as the November 2019 Financing for $25.0 million in exchange for the issuance of 11,111,111 shares of Series B Preferred Stock at $2.25 per share.

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

On March 31, 2020, in connection with the Credit Agreement Amendment, which 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.

Preferred stock outstanding as of December 31, 2019 consisted of the following (in thousands, except share and per share data):

December 31, 2019	Shares Authorized	Shares Issued and Outstanding	Per Share Price at Issuance	Aggregate Liquidation Preference
Series A	4,120,000	4,120,000	$ 0.48543	$ 2,000
Series B	126,035,000	101,867,405	2.25000	229,202
Total preferred stock	130,155,000	105,987,405		$ 231,202

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, 2020	December 31, 2019
Outstanding stock options to purchase common stock	4,268,945	2,561,866
Restricted stock units outstanding	1,468,765	322,608
Available for future issuance under equity incentive plan	2,938,616	—
Common stock warrant	400,160	—
Common stock issuable upon conversion of convertible notes	51,529,036	—
Series A Preferred Stock	—	13,213,254
Series B Preferred Stock	—	16,488,731
Series B Preferred Stock Purchase Warrant	—	359,699
Total	60,605,522	32,946,158

Note 12. Stock-Based Compensation

In February 2018, the Company adopted the 2018 Equity Incentive Plan (the "2018 Plan"). The 2018 Plan is the successor to and continuation of the Second Amended and Restated 2012 Stock Plan (the "2012 Plan") and the 2015 Consultant Stock Plan (the "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 1.1 million 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 2.7 million shares. On March 4, 2020, the Board of Directors adopted the Third Amended and Restated 2018 Equity Incentive Plan (the "2018 Third Amended Plan"), which increased the number of shares available for future grant to a total of 7,615,733 shares and was approved by stockholders on March 5, 2020. As of December 31, 2020, the number of shares available for grant under the 2018 Third Amended Plan was 2,938,616. 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.

Stock Options

The following table summarizes stock option activity under the 2012 Plan, the 2015 Plan, and the 2018 Third Amended Plan during the year ended December 31, 2020 (in thousands, except share and per share data):

	Stock Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Balance at December 31, 2019	2,561,866	$ 9.01		
Options granted	2,652,102	8.22		
Options exercised	(543,218)	1.15		
Options forfeited/cancelled	(401,805)	11.24		
Balance at December 31, 2020	4,268,945	$ 8.14	7.74	$ 2,527
Vested and expected to vest at December 31, 2020	4,268,945	$ 8.14	7.74	$ 2,527
Vested and exercisable at December 31, 2020	1,748,573	$ 8.18	5.40	$ 1,708

The aggregate intrinsic value in the above table is calculated as the difference between the closing price of our common stock at December 31, 2020, of $5.31 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, 2020 was $4.2 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, 2020 and 2019:

	Year ended December 31,	
	2020	2019
Risk-free interest rate	0.4% - 1.7%	1.4% - 2.4%
Expected volatility	57.0% - 71.0%	57.0% - 71.0%
Expected dividend yield	—	—
Expected life (years)	4.0 - 6.3 years	6.25 years

Restricted Stock Units

The following table summarizes restricted stock unit activity for the year ended December 31, 2020:

	Number of Shares	Weighted-Average Grant Date Fair Value
Balance at December 31, 2019	323,671	$ 15.19
Granted	1,389,919	8.10
Vested	(140,422)	14.93
Forfeited/cancelled	(104,403)	12.06
Balance at December 31, 2020	1,468,765	$ 8.73

2020 Employee Stock Purchase Plan

In June 2020, the Company's board of directors adopted the ESPP. At December 31, 2020, 510,000 shares of common stock were 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. 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 stock-based compensation expense related to stock options, RSUs and the ESPP is included in the accompanying consolidated statements of operations as follows (in thousands):

	Year Ended December 31,	
	2020	2019
Cost of sales	$ 867	$ 207
Research and development	2,804	851
Selling and marketing	1,633	501
General and administrative	5,364	816
Total stock-based compensation expense	$ 10,668	$ 2,375

The weighted-average grant date fair value of options granted during the years ended December 31, 2020 and 2019 was $5.15 per option and $7.35 per option, respectively. At December 31, 2020, there was $12.8 million and $10.5 million, of compensation cost related to unvested stock options and RSUs, respectively, expected to be recognized over a remaining weighted average vesting period of 2.93 years. The total unrecognized compensation costs will be adjusted for forfeitures in future periods as they occur. No tax benefits related to stock-based compensation were recorded in the statements of operations because during the years ended December 31, 2020 and 2019 as the Company is in a net operating loss position with a full valuation allowance on net deferred tax assets.

Note 13. Income Taxes

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

	Year Ended December 31,	
	2020	2019
Current provision:		
Federal	$ (37,697)	$ (638)
State	82	(104)
	(37,615)	(742)
Deferred expense:		
Federal	22	36
State	61	—
	83	36
Net income tax provision	$ (37,532)	$ (706)

The components of income tax expense relate to the following (in thousands):

	Year Ended December 31,	
	2020	2019
Income tax benefit at U.S. federal statutory rate	$ (48,313)	$ (31,236)
State income tax benefit, net of federal benefit	(5,469)	(4,538)
NOL carryback and other true ups	(15,517)	—
Government litigation settlements	4,611	—
Federal research and development credit	(3,573)	(3,232)
Convertible debt	740	—
Stock-based compensation	84	(87)
Meals and entertainment	—	367
Change in valuation allowance	29,845	38,514
Other	60	(494)
Total income tax expense	$ (37,532)	$ (706)

Deferred income taxes reflect the net tax effects of (a) temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, and (b) operating losses and tax credit carryforwards. The tax effects of temporary differences that give rise to portions of the deferred tax assets and deferred tax liabilities as of December 31, 2020 and 2019 are presented below (in thousands):

	December 31, 2020	December 31, 2019
Deferred tax assets:		
Net operating losses and carryforwards	$ 87,329	$ 51,768
Reserves	7,211	17,287
Intangible assets	3,878	3,982
Accrued expenses	1,816	3,025
Stock-based compensation	2,289	194
Convertible debt	3,290	—
Total deferred tax assets	105,813	76,256
Deferred tax liabilities:		
Fixed assets	(1,698)	(1,705)
Prepaid expenses	(1,146)	(138)
Goodwill	(402)	(205)
Adoption of ASC 606	(2,824)	(4,227)
Total deferred tax liabilities	(6,070)	(6,275)
Net deferred tax assets	99,743	69,981
Less: valuation allowance	(99,862)	(70,017)
Net deferred tax assets (liabilities)	$ (119)	$ (36)

Due to the losses generated in 2020 and 2019 and projected future taxable losses, management concluded that it is not more likely than not that the Company will realize the benefits of its deferred tax assets. As such, the Company recorded a valuation allowance of $99.9 million and $70.0 million, respectively, on its net deferred tax assets as of December 31, 2020 and 2019.

At December 31, 2020, the Company had federal and state income tax net operating loss (“NOL”) carryforwards of approximately $271.1 million and $200.0 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 $11.6 million and $2.5 million, respectively, as of December 31, 2020. 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 and determined future utilization of tax attribute carryforwards are not limited per Section 382 of the Internal Revenue Code.

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, 2020.

The Company’s policy is to recognize interest and penalties related to income tax matters in the provision for income taxes. At December 31, 2020, there were no interest and penalties related to uncertain tax positions.

The Company is subject to taxation in the United States, various US state jurisdictions and the United Kingdom. Multiple tax years remain open to examination depending on the applicable jurisdiction.

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 10). During the year ended December 31, 2020, we received a full tax refund related to the NOL carryback provisions available under the CARES Act.

On December 27, 2020, President Trump signed into law the Consolidated Appropriations Act, 2021 ("CAA 2021"), which included a number of provisions including, but not limited to the extension of numerous employment tax credits, the extension of the Section 179D deduction, enhanced business meals deductions, and the deductibility of expenses paid with Paycheck Protection Program ("PPP") loan funds that are forgiven. Accordingly, the effects of the CAA 2021 have been incorporated into the income tax provision for the year ended December 31, 2020. These provisions did not have a material impact on the Company's income tax provision.

Note 14. 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,	
	2020	2019
Stock options to purchase common stock	4,268,945	2,561,866
Restricted stock units	1,468,765	322,608
Common stock warrant	400,160	—
Stock issuable upon conversion of convertible notes	51,529,036	—
Series A Preferred Stock	—	13,213,254
Series B Preferred Stock	—	16,488,731
Series B Preferred Stock Purchase Warrant	—	359,699
Total	57,666,906	32,946,158

Note 15. Employee Benefit Plan

The Company has a qualified 401(k) employee savings plan for the benefit of its employees (the "plan"). Substantially all employees are eligible to participate in the plan. Under the plan, employees can contribute and defer taxes on compensation contributed. The Company has the option to make discretionary profit-sharing contributions to the plan. The Company made employer contributions to the plan of $2.9 million and $2.5 million for the years ended December 31, 2020 and 2019, respectively.

Note 16. Quarterly Financial Data (Unaudited)

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

	Three Months Ended			
2020	**December 31,**	**September 30,**	**June 30,**	**March 31,**
Revenues	$ 14,276	$ 25,943	$ 17,266	$ 16,828
Loss from operations	(51,371)	(44,571)	(46,720)	(52,526)
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)
2019				
Revenues	$ 20,476	$ 18,772	$ 57,230	$ 47,507
Loss from operations	(48,973)	(54,841)	(14,298)	(22,007)
Net loss	(50,476)	(57,133)	(16,409)	(24,019)
Net loss attributable to common stockholders	(86,840)	(97,907)	(16,409)	(27,671)
Net loss per share, basic and diluted	(17.46)	(19.85)	(3.34)	(5.88)

Note 17. Subsequent Events

On February 22, 2021, the Company entered into a Securities Purchase Agreement for a private placement with certain institutional and accredited investors (the “Purchasers”). Pursuant to the Securities Purchase Agreement, the Purchasers have agreed to purchase an aggregate of 4,370,629 units (the “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 is $5.72, for an aggregate purchase price of approximately $25.0 million. This 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 the Company of approximately $30.0 million.

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, 2020, 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, 2020 to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and our principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the quarter ended December 31, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management's Annual Report on Internal Control Over Financial Reporting

This Annual Report does not include a report of management's assessment regarding our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) or an attestation report of our independent registered accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

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.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Directors and Executive Officers

The following table sets forth certain information regarding our executive officers and directors as of March 15, 2021.

Name	Age	Position
Executive Officers		
Harry Stylli, Ph.D.	59	Chairman and Chief Executive Officer
Eric d'Esparbes	53	Chief Financial Officer
Damon Silvestry	52	Chief Operating Officer
Sami Shihabi	49	Chief Commercial Officer
Matthew Cooper, Ph.D.	48	Chief Scientific Officer
Troy Seelye	57	Chief Information Officer
Clarke Neumann, J.D.	57	General Counsel and Secretary
George Gianakopoulos	59	Senior Vice President of Sales
Hutan Hashemi, J.D.	42	Chief Compliance Officer
Non-Employee Directors		
Jeffrey D. Alter(1)(2)	58	Director
John T. Bigalke(1)(3)	66	Director
Jeffrey A. Ferrell(2)(3)	46	Director
Brian L. Kotzin, M.D.(2)(4)	72	Director
Samuel R. Nussbaum, M.D.(3)(4)	72	Director
Lynne Powell(1)(4)	54	Director

(1) Member of the Audit Committee.
(2) Member of the Compensation Committee.
(3) Member of the Nominating/Corporate Governance Committee.
(4) Member of the Science Committee.

Our business and affairs are managed under the direction of our Board, which currently consists of seven members. Our entire Board stands for election at each annual meeting of stockholders. Each director holds office for a one-year term and until the election and qualification of his or her successor, or his or her earlier death, resignation or removal.

The following is a biographical summary of the experience of our executive officers and directors:

Executive Officers

Harry Stylli, Ph.D. Dr. Stylli has served as the Chairman of our Board and our Chief Executive Officer since August 2018. Previously, he served as the Executive Chairman of our Board from January 2013 to August 2018 and as the Chairman of our Board from January 2011 to January 2013. He has also served as executive chairman of the board of directors at Immunis.Al (formerly OncoCell MDx), a diagnostic testing company, since April 2019. He previously served as Chief Executive Officer and Chairman of the Board of OncoCell MDx from June 2010 to April 2019. From June 2005 to September 2009, Dr. Stylli was President, Chief Executive Officer, and a member of the board of directors of Sequenom, Inc., a molecular diagnostic testing and genetics analysis company. From December 2003 to February 2005, Dr. Stylli was President and Chief Executive Officer of Xencor, Inc., a biopharmaceutical company. From April 2002 to July 2003, Dr. Stylli served as co-founder, President and Chief Executive Officer of CovX Pharmaceuticals Inc., a biopharmaceutical company. In May 1995, he co-founded Aurora Biosciences Corp., a biotechnology company. From May 1995 to April 2001, when Aurora Biosciences Corp. was acquired by Vertex Pharmaceuticals Incorporated, he held various senior roles at Aurora Biosciences Corp. From April 2001 to June 2002, following the acquisition, Dr. Stylli served as President of Aurora Biosciences Corp. and PanVera Corporation, a biotechnology company. Dr. Stylli received his B.S. from the University of East London, his M.B.A. from Open University in the United Kingdom, and his Ph.D. from London University.

We believe Dr. Stylli is qualified to serve on our Board because of his extensive experience forming and building biotechnology companies.

Eric d'Esparbes. Mr. d'Esparbes has served as our Chief Financial Officer since May 2019. From September 2014 to August 2018, Mr. d'Esparbes served as the Chief Financial Officer of Innoviva, Inc., a biotechnology company, where he was responsible for all aspects of the finance function including financial accounting, capital planning, audit, tax, and investor relations. Mr. d'Esparbes also

served as the interim Principal Executive Officer of Innoviva from February 2018 to June 2018. Prior to Innoviva, he served as Chief Financial Officer for Joule Unlimited, an energy company, from December 2010 to March 2014, Vice President of Finance for AEI, Inc., a global energy company, from February 2010 to December 2010, Chief Financial Officer of AEI Asia Limited from May 2007 to February 2010, and Chief Financial Officer for Meiya Power Company (now CNG New Energy), an energy company, from October 1999 to May 2007. Mr. d'Esparbes earned his bachelor's degree from Hautes Études Commercial in Montréal, Canada.

Damon Silvestry. Mr. Silvestry has served as our Chief Operating Officer since May 2020. Previously, Mr. Silvestry served as the Senior Vice President of Operations and People at Natera, Inc., a cell-free DNA testing company, from April 2018 to May 2020, Senior Vice President of Operations from April 2016 to April 2018, and Vice President of Operations from April 2015 to April 2016. Prior to Natera, Mr. Silvestry was the Senior Vice President of Operations at Miraca Life Sciences (now known as Inform Diagnostics) from June 2011 to October 2014, an anatomic pathology provider. Prior to Miraca, Mr. Silvestry served in a number of roles at Dell, Inc., including as the Executive Director for Latin America & Canada Sales Operations, Director of Dell Americas Engineering, Senior Manager of New Product Introductions and in various leadership roles within engineering. Mr. Silvestry earned his B.S. in Industrial Engineering from Southern Illinois University and his master's degree in Manufacturing Engineering from New York University—Polytechnic School of Engineering.

Sami Shihabi. Mr. Shihabi has served as our Chief Commercial Officer since October 2019. From January 2018 to October 2019, he served as our Senior Vice President of Marketing and Portfolio Strategy, where he was responsible for leading the marketing strategies for our women's health business. Previously, Mr. Shihabi was the Vice President, Head of Commercial for Prometheus Laboratories Inc., a diagnostic company, from October 2016 to January 2018, where he was responsible for leading the commercials sales, marketing, and managed care organizations. Also at Prometheus, he served as Executive Director, Global Strategic Marketing from October 2015 to October 2016. Prior to Prometheus, he served as Global Commercial and Marketing Lead at Nestlé Health Science, a health science company, from January 2014 to October 2015. Mr. Shihabi earned his B.S. in Biological Sciences from the University of California, Davis, his master's degree in Molecular Biology from Pennsylvania State University, and his M.B.A. from the University of California Irvine.

Matthew Cooper, Ph.D. Dr. Cooper has served as our Chief Scientific Officer since March 2015. Previously, Dr. Cooper was the Chief Executive Officer and founder of Carmenta Bioscience, Inc., a biotechnology company, from February 2012 until we acquired Carmenta in March 2015. Prior to Carmenta, he was founding Chief Scientific Officer at Syapse Inc., a precision medicine software platform company, from February 2010 to February 2012. Previously, he served as Head of Non-Clinical Safety Information at Hoffmann-La Roche, a healthcare company, from January 2009 to April 2010 and as Principal Research Scientist at Hoffman-La Roche from February 2006 to January 2009. He was a scientist at Biogen Idec from February 2001 to February 2006. Dr. Cooper has also served as a member of the board of directors of Avails Medical, Inc., an in vitro diagnostics company, since March 2019, and as a member of the board of directors of NeoSeq Healthcare Management Consulting Co., Ltd., a health management company, since November 2018. Dr. Cooper earned his B.S. in Chemistry from the University of Tulsa, dual M.B.A.s from Columbia Business School and the Berkeley Haas School of Business, and his Ph.D. in Toxicology from the University of Kentucky College of Medicine.

Troy Seelye. Mr. Seelye has served as our Chief Information Officer since March 2020. Previously, Mr. Seelye served as Chief Information Officer of Teradata Corp., a provider of data warehousing and analytics solutions, from January 2017 to March 2020. Prior to Teradata, he served in various roles at Illumina Inc., a genetic testing company, including as the Head of Global IT Operations from February 2014 to January 2017 and as the Senior Director of Global Information Systems from September 2008 to February 2014. Prior to Illumina, Mr. Seelye spent 17 years in a number of roles at Amgen Inc., including as Senior Manager, Network Infrastructure Engineering, Senior Manager, Data Center Operations, and Senior Architect, where he led global expansion across Asia and Europe. Mr. Seelye earned his B.S. from California Lutheran University.

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

George Gianakopoulos. Mr. Gianakopoulos has served as our Senior Vice President of Sales since October 2019. He previously served as our Corporate Vice President of Sales from January 2018 to October 2019 and as our Vice President of Sales from September 2014 to January 2018. Prior to joining our company, Mr. Gianakopoulos served as a sales leader in the oncology division of Myriad Genetics, Inc., a diagnostics company, from June 2006 to August 2014, and previously served in various marketing, sales and human resources roles at Eli Lilly. Mr. Gianakopoulos earned his B.S.B.A. and his M.B.A. from Indiana University.

Hutan Hashemi, J.D. Mr. Hashemi has served as our Chief Compliance Officer since July 2020. He previously served as our Chief Compliance Officer and Senior Corporate Counsel from May 2019 to July 2020. Prior to joining our company, Mr. Hashemi served as Chief Compliance Officer and Senior Corporate Counsel at Genoptix, Inc., a clinical oncology laboratory, from March 2017 to May 2019, where he was responsible for all aspects of the healthcare compliance and regulatory functions, as well as lead counsel on various transactional and litigation matters for the company. Mr. Hashemi also served as Corporate Counsel at Genoptix from January 2016 to March 2017. Prior to Genoptix, Mr. Hashemi practiced real estate finance and transactional law at Bryan Cave Leighton Paisner. Mr. Hashemi earned his B.A. in Economics from the University of California, Irvine and his J.D. from the University of Southern California, Gould School of Law.

Non-employee Directors

Jeffrey D. Alter. Mr. Alter has served as a member of our Board since January 2019. Mr. Alter has served as the Executive Vice President, IngenioRX and Anthem Health Solutions, at Anthem, Inc., a health benefits company, since September 2020. Prior to joining Anthem, Inc., from July 2018 to September 2020, Mr. Alter served as President of Arcturus One Consulting, a consulting company. From April 2004 to June 2018, Mr. Alter served in various chief leadership positions at UnitedHealthcare, a health plan business, including as Chief Executive Officer of its commercial group from November 2014 to June 2018, as Chief Executive Officer of its employer and individual business from January 2011 to November 2014, as Chief Executive Officer, Northeast Region from June 2008 to January 2011, as Chief Operating Officer from April 2005 to June 2008, and as Chief Financial Officer, Northeast Region from April 2004 to April 2005. Mr. Alter earned both his B.S. in Marketing and his M.B.A. in Finance from Saint John's University, New York.

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

John T. Bigalke. Mr. Bigalke has served as a member of our Board since January 2019. Mr. Bigalke has served as the Chief Executive Officer of Second Half Healthcare Advisors, a healthcare strategy firm, since its founding by Mr. Bigalke in August 2016. Prior to founding Second Half Healthcare Advisors, he served as Vice Chairman and Senior Partner, Global Health Care Practice at Deloitte USA LLP, an accounting and consulting firm, from April 2012 to August 2016 and as Vice Chairman and National Industry Leader for the Health Care and Life Science Practice at Deloitte USA LLP from June 1998 until April 2012. Mr. Bigalke has served as a member of the board of directors of Premier, Inc., a healthcare improvement company, since October 2019, as a member of the advisory board for Concord Health Partners, a healthcare focused investment firm, since December 2018, and as a director for AdventHealth, a health system company, since June 2012. Since August of 2015, Mr. Bigalke has served as Chairman of the Advisory Board of Vaxcare, Inc., a private healthcare company. He previously served as a member of the board of directors of Deloitte USA, LLP from June 2004 to May 2007. Mr. Bigalke earned his B.S. in Financial Management from Clemson University. Mr. Bigalke is a Certified Public Accountant.

We believe Mr. Bigalke is qualified to serve on our Board because of his extensive experience in the healthcare and life sciences industry and his finance and accounting experience.

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

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

Brian L. Kotzin, M.D. Dr. Kotzin has served as a member of our Board since June 2019. Dr. Kotzin has served in various leadership positions at Nektar Therapeutics, a biopharmaceutical company, including as Chief Medical Officer and Head of Clinical Development since January 2021, and as Senior Vice President, Clinical Development since April 2017. Prior to Nektar, Dr. Kotzin was at Amgen Inc., where he served as Vice President, Global Clinical Development and Head, Inflammation Therapeutic Area from July 2004 to January 2015. During his employment at Amgen Inc., he also served as Vice President, Translational Sciences and Head of Medical Sciences from February 2006 to July 2011. Before joining Amgen, Dr. Kotzin was a faculty member in the Division of Rheumatology of the Department of Medicine and Department of Immunology at the University of Colorado Health Sciences Center in Denver, Colorado from September 1981 to July 2004. During this time at the University of Colorado Health Sciences Center, he was also head of Clinical Immunology in the Department of Medicine and director of the Autoimmunity Center of Excellence from July 1998 to July 2004. Dr. Kotzin has been elected as a Master of the American College of Rheumatology and is an elected Member

of the American Society of Clinical Investigation and the Association of American Physicians. He has served as a member of the board of directors of Kyverna Therapeutics, Inc. since August 2019 and Rigel Pharmaceuticals, Inc. since August 2017. Dr. Kotzin previously served as a member of the board of directors of Vera Therapeutics, Inc. from April 2020 to December 2020. Dr. Kotzin earned his medical degree from Stanford University and his B.S. in Mathematics from the University of Southern California.

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

Samuel R. Nussbaum, M.D. Dr. Nussbaum has served as a member of our Board since January 2019. Dr. Nussbaum has served as a Strategic Consultant for EBG Advisors, the consulting arm for Epstein Becker and Green, since January 2016. Dr. Nussbaum has also served as a Senior Advisor to Sandbox Industries, a venture fund, since January 2017, and Ontario Teachers' Pension Fund since August 2016. From January 2000 until January 2016, Dr. Nussbaum served as Executive Vice President, Clinical Health Policy, and Chief Medical Officer of Anthem, Inc., a health insurance company. Dr. Nussbaum has served as a member of the board of directors of The Able Channel, a streaming and digital health platform company, since January 2020, Atrio Health Plans, a Medicare Advantage health plan provider, since September 2019, Coherus BioSciences, Inc., a biosimilar company, since May 2018, Motus GI Holdings, Inc., a medical technology company, since March 2017, and PhyMed Healthcare Group, an anesthesia management company, since July 2016. Dr. Nussbaum is a Professor of Clinical Medicine at Washington University School of Medicine and an adjunct professor at the Olin School of Business, Washington University and serves as Senior Fellow at the University of Southern California Schaeffer Center for Health Policy and Economics. Dr. Nussbaum earned his B.A. from New York University and his M.D. from Mount Sinai School of Medicine. He trained in internal medicine at Stanford University and Massachusetts General Hospital and in endocrinology at Harvard Medical School and Massachusetts General Hospital.

We believe Dr. Nussbaum is qualified to serve on our Board because of his experience advising life sciences and healthcare companies and his extensive experience as a senior executive and board member in the pharmaceutical and healthcare industries.

Lynne Powell. Ms. Powell has served as a member of our Board since February 2019. Since September 2019 and October 2019, Ms. Powell has served as Chief Executive Officer and as a member of the board of directors, respectively, of Druggability Technologies Holdings Ltd, a specialty pharmaceutical company. In September 2020, Druggability was reorganized into Tavanta Therapeutics, for which Ms. Powell continues to serve as Chief Executive Officer. Prior to joining Tavanta, Ms. Powell served as Senior Vice President and Chief Commercial Officer of BioCryst Pharmaceuticals, Inc., a biotherapeutics company, from January 2015 to July 2019. From January 2010 to October 2014, Ms. Powell served as Senior Vice President of North American Commercial Operations at CSL Behring, a biotherapeutics company. She earned her B.S. in Applied Biology, Pharmacology & Toxicology from the University of East London and her M.B.A. from Monash University (Australia) and Warwick University (UK).

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

Family Relationships

There are no family relationships among any of our directors or executive officers.

Code of Business Conduct and Ethics

Our Board has adopted a Code of Business Conduct and Ethics that establishes the standards of ethical conduct applicable to all our directors, officers, and employees. It addresses, among other matters, compliance with laws and policies, conflicts of interest, corporate opportunities, regulatory reporting, external communications, confidentiality requirements, insider trading, proper use of assets, and how to report compliance concerns. A copy of the code is available on the Corporate Governance section of our website, which is located at *https://investors.progenity.com/corporate-governance/documents-charters*. We intend to disclose any amendments to the Code of Business Conduct and Ethics, or any waivers of its requirements, on our website to the extent required by applicable rules. Our Board is responsible for applying and interpreting our Code of Business Conduct and Ethics in situations where questions are presented to it.

Audit Committee and Audit Committee Financial Expert

We have a separately-designated standing Audit Committee. The members of our Audit Committee are Messrs. Bigalke and Alter and Ms. Powell. Mr. Bigalke and Ms. Powell qualify as an independent director for audit committee purposes, as defined under SEC and Nasdaq listing rules. Mr. Alter no longer qualifies as an independent director, as defined under Nasdaq listing rules, by virtue of his new position at Anthem, Inc. As a result, we are currently relying on Nasdaq transition rules applicable to companies who recently underwent an initial public offering. Each of the members of our Audit Committee has sufficient knowledge in financial and

auditing matters to serve on the audit committee. Mr. Bigalke chairs the Audit Committee. Additionally, Mr. Bigalke qualifies as an “audit committee financial expert” as defined under SEC rules.

Item 11. Executive Compensation.

Our named executive officers, or NEOs, for 2020, which consist of our principal executive officer and the next two most highly-compensated executives, are:

- Dr. Harry Stylli, our Chief Executive Officer, or CEO, and Chairman of our Board;
- Eric d’Esparbes, our Chief Financial Officer; and
- Damon Silvestry, our Chief Operating Officer.

2020 Summary Compensation Table

The following table summarizes the compensation awarded to, earned by, or paid to our NEOs for 2020 and 2019.

Name and Principal Position	Year	Salary ($)	Stock Awards ($) (1)		Option Awards ($) (1)		Non-Equity Incentive Plan Compensation ($) (2)	All Other Compensation ($) (3)	Total ($)
Harry Stylli, Ph.D.	2020	395,000	2,333,660		3,020,843		—	3,819	5,753,322
President, Chief Executive Officer and Chairman of the Board	2019	395,000	—		—		—	—	395,000
Eric d'Esparbes	2020	450,000	769,204	(4)	964,988	(4)	135,000	17,670	2,336,862
Executive Vice President, Chief Financial Officer and Principal Financial Officer									
Damon Silvestry	2020	246,154	611,250		870,152		53,320	39,162	1,820,038
Chief Operating Officer									

(1) Amounts shown in this column represent the aggregate grant date fair value (calculated in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718) of stock awards and stock options granted during the year and the incremental fair value (calculated in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718) of stock options that were repriced on January 9, 2020. A description of the methodologies and assumptions we use to value equity awards and the manner in which we recognize the related expense are described in Note 12 to our consolidated financial statements, Stock-Based Compensation. These amounts may not correspond to the actual value eventually realized by each NEO because the value depends on the market value of our common stock at the time the award vests or is exercised.

(2) Mr. d’Esparbes had a target bonus equal to 50% of base salary and Mr. Silvestry had a target bonus equal to 40% of base salary. Dr. Stylli did not participate in our annual incentive bonus program during 2020 or 2019. Messrs. d’Esparbes and Silvestry will receive their annual non-equity incentive plan compensation awards for 2020 in the form of fully vested shares of common stock.

(3) Amounts shown in this column represent the value of life insurance premiums paid by the Company for each NEO, the value of 401(k) contributions made by the Company for Messrs. d’Esparbes and Silvestry, and the value of relocation and temporary housing costs for Mr. Silvestry.

(4) In lieu of paying cash bonuses for the fiscal year ended December 31, 2019, on March 3, 2020, the compensation committee approved granting Mr. d’Esparbes 4,610 restricted stock units with a fair value on such date of $44,998 and 7,785 stock options with a fair value on such date of $49,184. The grant date for all awards was March 4, 2020. The stock options were fully-vested as of the date of grant and the restricted stock units vested on the one-year anniversary of the date of grant. In accordance with applicable SEC rules, the grant date fair value of each award is included in the 2020 Summary Compensation Table as Stock Awards and Option Awards.

Outstanding Equity Awards at 2020 Fiscal-Year End Table

The following table sets forth information regarding outstanding equity awards at the end of 2020 for each of our NEOs.

	Option Awards					Stock Awards	
Name	Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of shares or units of stock that have not vested (#)	Market value of shares or units of stock that have not vested ($)
Harry Stylli, Ph.D.	2/5/2020 (1)	—	—	—	—	214,174	1,137,264
	2/5/2020 (1)	109,571	368,577	9.76	2/5/2030		
Eric d'Esparbes	6/15/2019 (2)	—	—	—	—	10,653	56,567
	1/9/2020 (3)	10,652	17,754	9.88	6/15/2029	—	—
	1/15/2020 (4)	—	—	—	—	45,564	241,945
	1/15/2020 (4)	—	91,129	9.88	1/15/2030	—	—
	3/4/2020 (5)	—	—	—	—	4,610	24,479
	3/4/2020 (5)	7,785	—	9.76	3/4/2030	—	—
	8/15/2020 (6)	—	—	—	—	36,243	192,450
	8/15/2020 (6)	7,693	66,170	7.71	8/15/2030	—	—
Damon Silvestry	6/15/2020 (7)	—	—	—	—	24,279	128,921
	6/15/2020 (7)	—	48,558	11.37	6/15/2030	—	—
	11/15/2020 (8)	—	—	—	—	75,000	398,250
	11/15/2020 (8)	—	150,000	4.47	11/15/2030	—	—

(1) Dr. Stylli's unvested restricted stock units vest in semi-annual installments on each February 15 and August 15, ending on August 15, 2024, and his stock options vest in equal monthly installments over a four-year period.

(2) These restricted stock units vest over a four-year period, with 25% vesting on the one-year anniversary of the date of grant and then in semi-annual installments beginning on February 15, 2021 and ending on August 15, 2023.

(3) On January 9, 2020, our Board and stockholders approved the reduction of the exercise price of the stock options to $9.88 to reflect the current fair market value of our common stock on such date. The unvested portion of these stock options vest in equal monthly installments through June 15, 2023.

(4) Mr. d'Esparbes's restricted stock units granted on January 15, 2020 vest with 25% vesting on February 15, 2021, and then in semi-annual installments beginning on August 15, 2021 and ending on February 15, 2024 and his stock options granted on such date vest over a four-year period, with 25% vesting on the one-year anniversary of the date of grant and then in equal monthly installments thereafter.

(5) In lieu of paying cash bonuses for the fiscal year ended December 31, 2019, on March 3, 2020, the compensation committee approved granting Mr. d'Esparbes 4,610 restricted stock units with a fair value on such date of $44,998 and 7,785 stock options with a fair value on such date of $49,184. The grant date for all awards was March 4, 2020. The stock options were fully-vested as of the date of grant and the restricted stock units vested on the one-year anniversary of the date of grant.

(6) Mr. d'Esparbes's restricted stock units granted on August 15, 2020 vest with 25% vesting on August 15, 2021, and then in semi-annual installments beginning on February 15, 2022 and ending on August 15, 2024 and his stock options granted on such date vest in equal monthly installments from August 15, 2020 through July 15, 2024.

(7) Mr. Silvestry's restricted stock units granted on June 15, 2020 vest with 25% vesting on August 15, 2021, and then in semi-annual installments beginning on February 15, 2022 and ending on August 15, 2024, and his stock options granted on such date vest over a four-year period, with 25% vesting on the one-year anniversary of the date of grant and then in equal monthly installments thereafter.

(8) Mr. Silvestry's restricted stock units granted on November 15, 2020 vest over a four-year period, with 25% vesting on the one-year anniversary of the date of grant and then in equal semi-annual installments over the following three years, and his stock options granted on such date vest over a four-year period, with 25% vesting on the one-year anniversary of the date of grant and then in equal monthly installments thereafter.

Employment Agreements

We do not have employment agreements with any of our NEOs at this time, but, in connection with Messrs. d'Esparbes's and Silvestry's commencement of employment, we extended offer letters to each of them that provide for base salary, participation in benefit plans and eligibility to earn an annual bonus. In addition, the offer letters provided for the grant of restricted stock units and

stock options to each NEO, which are reflected in the Outstanding Equity Awards at 2020 Fiscal-Year End Table above. The offer letters also included a brief protection of confidential information commitment and related representations.

Incentive Compensation

Annual Incentive. During 2020, our NEOs, other than Dr. Stylli, were eligible to receive an annual incentive bonus determined as a percentage of base salary based upon the achievement of pre-established corporate performance goals, which for 2020 included revenue cycle and volume goals, weighted 40%, managed care goals, weighted 20%, products and launch goals, weighted 25%, and precision medicine goals, weighted 15%, and evaluation of individual performance. For 2020, the target award opportunity for Mr. d'Esparbes was 50% of base salary and the target award opportunity for Mr. Silvestry was 40% of base salary. Performance was measured at fiscal year-end and the compensation committee determined that although the corporate goals were achieved below the target level, individual performance for each of Messrs. d'Esparbes and Silvestry was strong and as a result decided to award bonuses equal to $135,000 and $53,320, respectively. Following the end of the year, the compensation committee decided to award the bonuses in the form of fully vested shares of our common stock. On March 4, 2021, the compensation committee approved granting Mr. d'Esparbes and Mr. Silvestry a number of fully vested shares of common stock equivalent to $135,000 and $53,320, respectively, which will be granted on April 15, 2021 based on the closing price of our common stock on such date.

Equity Incentive. We maintain our 2018 Plan pursuant to which we currently grant stock option and restricted stock unit awards to eligible participants. Each of our NEOs received grants of stock options and restricted stock units under this plan in 2020. As described in our Registration Statement on Form S-1, following the fiscal year ended December 31, 2019, the compensation committee decided to award the 2019 annual incentive bonuses as equity awards granted under the 2018 Plan on March 3, 2020 in the form of fully-vested stock options and restricted stock units that vested on the one-year anniversary of the grant date. In connection therewith, Mr. d'Esparbes received 4,610 restricted stock units with a fair value on such date of $44,998 and 7,785 stock options with a fair value on such date of $49,184. Dr. Stylli received 239,074 restricted stock units and 478,148 stock options on February 5, 2020, which were awarded in recognition of Dr. Stylli's contributions to the Company and in light of the fact that Dr. Stylli had not been granted any equity incentive awards under our various equity compensation plans since the inception of the Company. The compensation committee consulted with its compensation consultant and considered relevant market data in making this award. Mr. d'Esparbes received 64,377 restricted stock units and 91,129 stock options on January 15, 2020 and, on August 15, 2020, in order to bring his compensation closer to the 75th percentile of our peers and, in accordance with the terms of his offer letter, in recognition of the completion of our initial public offering, Mr. d'Esparbes received an additional 36,243 restricted stock units and 73,863 stock options on August 15, 2020. In connection with his commencement of employment, Mr. Silvestry received 24,279 restricted stock units and 48,558 stock options on June 15, 2020 and, pursuant to the terms of his offer letter, an additional 75,000 restricted stock units and 150,000 stock options on November 15, 2020 pursuant to his achievement of certain performance goals related to revenue cycle management process improvements, reducing the rate of missing information on requisitions, savings related to costs of goods sold, implementation of our COVID-19 strategy, and development of a business continuity plan.

Post-Employment Compensation and Change in Control Payments and Benefits

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

401(k) Plan

We offer our eligible full-time employees, including our NEOs, the opportunity to participate in our tax-qualified 401(k) plan. Employees can contribute 1% to 85% of their eligible earnings up to the Internal Revenue Service's annual limits on a before-tax basis, which is generally $19,500 for 2021. We provide a match of 60% of the first 10% contributed. The matches we provided to our NEOs in 2020 are reflected in the "All Other Compensation" column of the 2020 Summary Compensation Table above. The matching funds that we provide are 100% vested after the completion of one year of service.

Other Benefits

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

Clawback Policy

In March of 2021, we adopted a clawback policy applicable to all current and former Section 16 officers, including our NEOs, that will apply if there is an accounting restatement due to material noncompliance with any financial reporting requirement under the securities laws that is caused directly or indirectly by the misconduct of a Section 16 officer. The Company is authorized to recover a portion of any annual cash incentive bonuses, other short-term and long-term cash incentive awards and equity incentive awards paid to current or former executive officers in excess of what would have been paid, settled or issued based upon the restated audited financial statements.

Fiscal Year 2021 Compensation Decisions

Following the end of the fiscal year, in light of Dr. Stylli's historically low compensation as compared to similarly situated executives at our peer companies, in consultation with its compensation consultant and in consideration of relevant market data, the compensation committee recommended to the independent members of the board of directors increasing Dr. Stylli's base salary to $600,000 and approving his participation in the annual bonus program with a target bonus opportunity equal to 50% of base salary to bring him closer to the 25th percentile of our peers. The independent members of the board of directors approved these changes. The compensation committee also approved ordinary course increases in base salary for each of Messrs. d'Esparbes and Silvestry equal to 5% and 3%, respectively. In addition, in light of the fact that many of our existing stock options have an exercise price that exceeds the current market value of our common stock, the compensation committee (or in the case of Dr. Stylli, the independent members of the board of directors) approved awarding stock options to certain executives, including the NEOs, both for retention purposes and to increase their equity-based incentives to improve the Company's return to its stockholders. These stock options have a grant date of March 15, 2021 and a vesting date of March 15, 2022, subject to continued service through such date. The grant date values of the stock options are $522,325, $191,006 and $37,753 for each of Dr. Stylli, Mr. d'Esparbes and Mr. Silvestry, respectively. In addition, each NEO will receive annual equity awards with a grant date of April 15, 2021. The grant date values of the awards are $2,000,000, $729,000 and $500,000 for each of Dr. Stylli, Mr. d'Esparbes and Mr. Silvestry, respectively, and will be granted half in the form of stock options and half in the form of restricted stock units, each subject to our standard four-year vesting schedule.

Director Compensation

Outside Director Compensation Policy

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

Cash Compensation. All non-employee directors are entitled to receive a $50,000 ($90,000 for our Lead Director, Jeffrey D. Alter) annual cash retainer for serving as a member of the board of directors as well as the following additional annual cash retainers for their board committee service:

	Chair	Member
Audit Committee	$ 20,000	$ 8,000
Compensation Committee	15,000	6,000
Nominating/Corporate Governance Committee	10,000	5,000
Science Committee	15,000	6,000

In addition, our Lead Director, Jeffrey D. Alter, receives an additional $40,000 annual cash retainer. Each annual cash retainer and additional annual fee is paid quarterly in advance on a prorated basis. We reimburse all of our directors for their reasonable out-of-pocket expenses, including travel, food, and lodging, incurred in attending meetings of our Board and/or its committees.

Equity Compensation. New non-employee directors are entitled to receive an initial equity grant with a target grant date fair value of $350,000, half of which is awarded in the form of restricted stock units and half of which is awarded in the form of stock options. Subject to the director's continued service, initial equity awards vest in equal installments over a four-year period following the date of grant. In addition, each non-employee director is entitled to receive an annual equity grant with a target grant date fair value of $150,000, half of which is awarded in the form of restricted stock units and half of which is awarded in the form of stock options. The annual equity awards vest in full on the one-year anniversary of the date of grant subject to the director's continued service through such date.

Fiscal Year 2020 Outside Director Compensation Table

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)(1)	Option Awards ($)(1)	Total ($)
Jeffrey D. Alter	$ 97,556	$ 74,999	$ 68,928	$ 241,483
John T. Bigalke	75,000	74,999	68,928	218,927
Jeffrey A. Ferrell(2)	—	—	—	—
Brian L. Kotzin, M.D.	71,000	74,999	46,572	192,571
Samuel R. Nussbaum, M.D.	66,000	74,999	68,928	209,927
Lynne Powell	64,000	74,999	68,928	207,927

(1) Amounts shown in this column represent the aggregate grant date fair value (calculated in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718 "*Compensation - Stock Compensation*") of stock awards and stock options granted during the year and the incremental fair value (calculated in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718) of stock options that were repriced on January 9, 2020. A description of the methodologies and assumptions we use to value equity awards and the manner in which we recognize the related expense are described in Note 12 to our consolidated financial statements, Stock-Based Compensation. These amounts may not correspond to the actual value eventually realized by each director because the value depends on the market value of our common stock at the time the award vests or is exercised. As of December 31, 2020, Mr. Alter held 14,341 restricted stock units and 28,988 stock options, Mr. Bigalke held 14,341 restricted stock units and 28,988 stock options, Mr. Ferrell held no restricted stock units and no stock options, Dr. Kotzin held 15,672 restricted stock units and 28,988 stock options, Dr. Nussbaum held 14,341 restricted stock units and 28,988 stock options, and Ms. Powell held 14,341 restricted stock units and 28,988 stock options.

(2) Mr. Ferrell elected not to receive any compensation from us for his services in 2020.

Directors who are also employees, such as Dr. Stylli, do not receive any compensation for their services as our directors. The compensation received by Dr. Stylli for his services to us as our Chief Executive Officer is presented in the 2020 Summary Compensation Table above.

Indemnification Agreements

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

Compensation Committee Interlocks

None of the members of our Compensation Committee has at any time during the prior three years been one of our officers or employees. None of our executive officers currently serves, or in the past fiscal year has served, as a member of our Board or Compensation Committee of any entity that has one or more executive officers serving on our Board or Compensation Committee. See "Item 13. Certain Relationships and Related Transactions, and Director Independence—Related Party Transactions" below for a description of transactions with Anthem, Inc., where one of the member of our Compensation Committee serves as an executive officer.

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

Security Ownership of Certain Beneficial Owners and Management

The following table presents information regarding beneficial ownership of our equity interests as of February 1, 2021 by:

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

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

The percentage ownership information shown in the column titled "Percentage of Shares Beneficially Owned" in the table below is based on 55,830,087 shares of our common stock outstanding as of February 1, 2021. Unless otherwise indicated, the address of each individual listed in this table is 4330 La Jolla Village Drive, Suite 200, San Diego, CA 92122.

Name and Address of Beneficial Owner	Shares Beneficially Owned	Percentage of Total
Greater than 5% Stockholders		
Entities affiliated with Athyrium Capital Management, LP(1)	56,205,758	66.1%
Named Executive Officers and Directors		
Harry Stylli, Ph.D.(2)	14,563,423	26.0%
Jeffrey D. Alter(3)	51,343	*
John T. Bigalke(4)	31,343	*
Jeffrey A. Ferrell(1)	56,205,758	66.1%
Brian L. Kotzin, M.D.(5)	24,686	*
Samuel R. Nussbaum, M.D.(6)	31,343	*
Lynne Powell(7)	31,343	*
Eric d'Esparbes(8)	79,194	*
Damon Silvestry(9)	121,951	*
All current directors and executive officers as a group (15 persons) (10)	71,508,112	83.4%

* Represents beneficial ownership of less than one percent.

(1) Based on a Schedule 13D/A filed on December 11, 2020 and includes shares of common stock beneficially owned by certain affiliates of Athyrium Capital Management, LP. Consists of (a) 4,211,977 shares of common stock owned by Athyrium Opportunities Fund (A) LP, (b) 2,329,083 shares of common stock owned by Athyrium Opportunities Fund (B) LP, (c) 11,731,480 shares of common stock owned by Athyrium Opportunities III Acquisition 2 LP, (d) 4,175,753 shares of common stock owned by Athyrium Opportunities III Co-Invest 1 LP, (e) 400,160 shares of common stock issuable upon exercise of a warrant held by Athyrium Opportunities III Co-Invest 1 LP, (f) 21,823,737 shares of common stock issuable upon conversion of a convertible note held by Athyrium Opportunities III Co-Invest 1 LP, (g) 4,583,333 shares of common stock owned by Athyrium Opportunities 2020 LP and (h) 6,950,235 shares of common stock issuable upon conversion of a convertible note held by Athyrium Opportunities III Acquisition LP. Voting and investment power with respect to the shares of the Company's common stock held by Athyrium Opportunities Fund (A) LP, Athyrium Opportunities Fund (B) LP, Athyrium Opportunities III Acquisition 2 LP, Athyrium Opportunities III Co-Invest 1 LP, Athyrium Opportunities 2020 LP and Athyrium Opportunities III Acquisition LP (collectively, the "Athyrium Entities") may be deemed to be shared by certain affiliated entities. Athyrium Opportunities Associates Co-Invest LLC is the general partner of Athyrium Opportunities III Co-Invest 1 LP, Athyrium Opportunities Associates III GP LLC is the general partner of Athyrium Opportunities Associates III LP, which is the general partner of each of Athyrium Opportunities 2020 LP and Athyrium Opportunities III Acquisition 2 LP, and Athyrium Opportunities Associates GP LLC is the general partner of Athyrium Opportunities Associates LP, which is the general partner of each of Athyrium Opportunities Fund (A) LP and Athyrium

Opportunities Fund (B) LP. Jeffrey A. Ferrell, a member of the Company's Board, is President of each of Athyrium Opportunities Associates Co-Invest LLC, Athyrium Opportunities Associates III GP LLC, and Athyrium Opportunities Associates GP LLC and in his capacity as such, may be deemed to exercise shared voting and investment power over the shares owned by the Athyrium Entities. Jeffrey A. Ferrell and each of the foregoing entities disclaims beneficial ownership of such shares except to the extent of his or its pecuniary interest therein. The business address of each of the Athyrium Entities is c/o Athyrium Capital Management, LP is 505 Fifth Avenue, Floor 18, New York, New York 10017. As reported in the Schedule 13D/A, each of NB Alternatives Advisers LLC, NB Alternatives GP Holdings LLC, and NB Alternatives Holdings LLC shares voting power with certain Athyrium Entities with respect to 6,541,060 shares of common stock . The business address for NB Alternatives Advisers LLC and NB Alternatives GP Holdings LLC is c/o NB Alternatives Advisers LLC, 325 N. Saint Paul Street, Suite 4900, Dallas, TX 75201 while the business address for NB Alternatives Holdings LLC is c/o NB Alternatives Advisers LLC, 1290 Avenue of the Americas, New York, New York 10104.

(2) Consists of (a) 14,394,085 shares of common stock, (b) 29,884 shares of common stock underlying restricted stock units that will vest within 60 days after the date of this table, and (c) 139,454 shares of common stock underlying options that are exercisable as of the date of this table or will become exercisable within 60 days after such date.

(3) Consists of (a) 23,994 shares of common stock, (b) 9,014 shares of common stock underlying restricted stock units that will vest within 60 days after the date of this table, and (c) 18,335 shares of common stock underlying options that are exercisable as of the date of this table or will become exercisable within 60 days after such date.

(4) Consists of (a) 3,994 shares of common stock, (b) 9,014 shares of common stock underlying restricted stock units that will vest within 60 days after the date of this table, and (c) 18,335 shares of common stock underlying options that are exercisable as of the date of this table or will become exercisable within 60 days after such date.

(5) Consists of (a) 2,663 shares of common stock, (b) 9,014 shares of common stock underlying restricted stock units that will vest within 60 days after the date of this table, and (c) 13,009 shares of common stock underlying options that are exercisable as of the date of this table or will become exercisable within 60 days after such date.

(6) Consists of (a) 3,994 shares of common stock, (b) 9,014 shares of common stock underlying restricted stock units that will vest within 60 days after the date of this table, and (c) 18,335 shares of common stock underlying options that are exercisable as of the date of this table or will become exercisable within 60 days after such date.

(7) Consists of (a) 3,994 shares of common stock, (b) 9,014 shares of common stock underlying restricted stock units that will vest within 60 days after the date of this table, and (c) 18,335 shares of common stock underlying options that are exercisable as of the date of this table or will become exercisable within 60 days after such date.

(8) Consists of (a) 2,322 shares of common stock, (b) 17,776 shares of common stock underlying restricted stock units that will vest within 60 days after the date of this table, and (c) 59,096 shares of common stock underlying options that are exercisable as of the date of this table or will become exercisable within 60 days after such date.

(9) Represents 121,951 shares of common stock.

(10) Consists of (a) those shares described in footnotes (1) through (9) above, (b) 28,263 shares of common stock beneficially owned by our executive officers not named in the table above, (c) 23,286 shares of common stock underlying restricted stock units that will vest within 60 days of the date of this table held by our executive officers not named in the table above, and (d) 316,179 shares of common stock underlying options that are exercisable as of the date of this table or will become exercisable within 60 days after such date held by our executive officers not named in the table above.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table contains information about our equity compensation plans as of December 31, 2020. As of December 31, 2020, we had outstanding awards under five equity compensation plans: our 2011 Incentive Stock Plan, our Second Amended and Restated 2012 Stock Plan, our 2015 Consultant Stock Plan, our Third Amended and Restated 2018 Equity Incentive Plan, and our 2020 Employee Stock Purchase Plan. Current awards may be granted only under our Third Amended and Restated 2018 Equity Incentive Plan and our 2020 Employee Stock Purchase Plan.

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)		Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)	
Equity compensation plans approved by security holders	5,737,710	*	6.01	3,448,616	**
Equity compensation plans not approved by security holders	—		—	—	
Total	5,737,710		6.01	3,448,616	

* Includes stock options to purchase 4,268,945 shares of our common stock with a per share weighted-average exercise price of $6.01 and 1,468,765 restricted stock unit awards with no exercise price.

** Represents 2,938,616 shares of our common stock reserved for future grants under our 2018 Equity Incentive Plan, as amended and restated, and 510,000 shares reserved for issuance under our 2020 Employee Stock Purchase Plan. Excludes 4,537,676 and 557,723 shares that were added to our 2018 Equity Incentive Plan, as amended and restated, and our 2020 Employee Stock Purchase Plan, respectively, on January 1, 2021 pursuant to the evergreen provisions thereunder. As of December 31, 2020, no shares have been issued under the 2020 Employee Stock Purchase Plan.

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

The following is a summary of each transaction or series of similar transactions since January 1, 2019, or any currently proposed transaction, to which we were or are a party in which:

- the amount involved exceeds $120,000 or one percent of the average of our total assets at year-end for the last two completed fiscal years; and
- any of our directors or executive officers, any holder of 5% or more of any class of our voting capital stock or any member of his or her immediate family had or will have a direct or indirect material interest, other than compensation and other arrangements that are described under the section titled “Executive Compensation” or that were approved by our Compensation Committee.

Beneficial ownership of securities is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to such securities.

Related Party Transactions

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

In October 2017, we entered into the Credit Agreement with Athyrium Opportunities III Co-Invest 1 LP, as collateral agent and a lender, which is a fund managed by Athyrium. Athyrium beneficially owns more than 5% of a class of our voting securities and has designated a director on our Board. The Credit Agreement was terminated on December 7, 2020 in connection with the issuance of the Athyrium Notes (as defined below).

The Credit Agreement provided for a term loan of $75.0 million, which accrued interest at a rate of 9.5% and was scheduled to terminate on October 27, 2022. The term loan contained customary covenants, including a requirement that we maintain a minimum unrestricted cash balance at all times of at least $5.0 million. The term loan was secured by all of our tangible and intangible property and assets, with the exception of our intellectual property. As of December 31, 2020, no principal remained outstanding under the term loan. Through December 31, 2020, we paid $21.2 million in interest on the term loan.

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

On May 6, 2020, in connection with the issuance and sale of the Convertible Note described below, we entered into the Second Credit Agreement Amendment allowing for the creation or incurrence of certain indebtedness and the making of payments, in each case, in respect of the Convertible Note, among other matters.

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

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

On May 8, 2020, we entered into a note purchase agreement with Athyrium Opportunities 2020 LP, a fund managed by Athyrium, pursuant to which we issued and sold an unsecured convertible promissory note, or the Convertible Note, with an annual interest rate of 8.0% and in an aggregate principal amount of $15.0 million. The Convertible Note had a maturity date of May 8, 2022 and, in connection with our initial public offering, was converted at the option of the holder into 1,250,000 shares of our common stock. In connection with the issuance and sale of the Convertible Note, we entered into the Second Amendment to Series B Preferred

Stock Warrant, dated May 8, 2020, providing for the removal of certain restrictive exercise provisions in the Series B Preferred Stock Purchase Warrant.

On June 23, 2020, we completed our initial public offering, or IPO, of our common stock. In our initial public offering, we issued and sold 6,666,667 shares of our common stock, at a price to the public of $15.00 per share, of which 3,366,666 shares were purchased by our affiliates, which included 3,333,333 shares purchased by Athyrium and 33,333 shares purchased by Dr. Stylli. In connection with the IPO, on June 23, 2020, all outstanding Series A and B preferred stock and the outstanding convertible promissory note converted into shares of common stock and the outstanding warrant to purchase shares of convertible preferred stock became exercisable for 400,160 shares of our common stock.

On December 7, 2020, we completed a public offering of our common stock and a concurrent offering of convertible notes, or the December 2020 Offerings. In the public offering, we issued and sold 7,645,259 shares of our common stock, at a price to the public of $3.27 per share, of which 4,281,345 shares were purchased by our affiliates, namely 4,128,440 shares purchased by Athyrium and 152,905 shares purchased by Dr. Stylli. The underwriting discount applied with respect to the shares purchased by Athyrium was $0.07267 per share of common stock, as compared to $0.1962 per share of common stock for shares purchased by other investors in the offering.

In the concurrent offering, we issued approximately $168.5 million in aggregate principal amount of our 7.25% Convertible Senior Notes due 2025. Certain entities affiliated with Athyrium acquired $103.5 million in aggregate principal amount of the convertible notes, which we refer to as the Athyrium Notes, of which $25.0 million in aggregate principal amount of the convertible notes was acquired for cash and an additional $78.5 million in aggregate principal amount of the convertible notes was acquired in exchange for the discharge of amounts outstanding under the Credit Agreement. The Athyrium Notes form part of the same series of notes as the other convertible notes issued in the offering. However, the Athyrium Notes were initially issued in certificated form, and are subject to different transfer restrictions than, and will not initially be fungible with, the other convertible notes issued in this offering.

Fourth Amended and Restated Investors' Rights Agreement

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

Demand Registration Rights

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

Piggyback Registration Rights

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

Form S-3 Registration Rights

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

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

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

Guarantee by Dr. Stylli

On May 21, 2020, in connection with settlement discussions related to the federal investigations described under "Part I, Item 3, Legal Proceedings—Federal Investigations," the government required a guarantee of a portion of our obligations to the government by one or more of our significant stockholders, and Dr. Stylli, our Chairman and Chief Executive Officer, reached an agreement with the government to personally guarantee payment of our obligations to the government up to an amount of $5.0 million.

Transactions with Anthem

One of our Board members, Jeffrey Alter, has served as Executive Vice President, IngenioRX and Anthem Health Solutions, at Anthem, Inc., since September 2020. We submit claims for reimbursement and receive associated payments from commercial third-party payors, one of whom is Anthem, Inc. During the years ended December 31, 2019 and 2020, aggregate payments received from Anthem, Inc. were $7.9 million and $5.4 million, respectively.

Related Party Transaction Policy

We have adopted a written related party transaction policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related person transactions. For purposes of our policy, a related person transaction is a transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we and any related person are, were or will be participants in which the amount involved exceeds $100,000. A related person is any executive officer, director, or beneficial owner of more than 5% of any class of our voting securities, including any of their immediate family members and any entity owned or controlled by such persons. Transactions involving compensation for services provided to us as an employee or director, among other limited exceptions, are deemed to have standing pre-approval by the Audit Committee but may be specifically reviewed if appropriate in light of the facts and circumstances.

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

- the risks, costs and benefits to us;
- the impact on a director's independence in the event that the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the availability of other sources for comparable services or products; and

- the terms available to or from, as the case may be, unrelated third parties or to or from employees generally

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

The related party transactions described above, other than the participation by certain of our affiliates in our IPO and December 2020 Offerings, were consummated prior to our adoption of the formal, written policy described above, and, accordingly, the foregoing policies and procedures were not followed with respect to these transactions. However, we believe that the terms obtained or consideration that we paid or received, as applicable, in connection with the transactions described below were comparable to terms available or the amounts that would be paid or received, as applicable, in arms-length transactions at such time.

Board Determination of Independence

Nasdaq listing rules require a majority of a listed company's board of directors to be comprised of independent directors within one year of listing. In addition, the Nasdaq Listing Rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and corporate governance committees be independent under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act, and compensation committee members must also satisfy the independence criteria set forth in Rule 10C-1 under the Exchange Act. Under the Nasdaq listing rules, a director will only qualify as an "independent director" if, in the opinion of our board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee, accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries or otherwise be an affiliated person of the listed company or any of its subsidiaries. In order to be considered independent for purposes of Rule 10C-1, the board must consider, for each member of a compensation committee of a listed company, all factors specifically relevant to determining whether a director has a relationship to such company which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including, but not limited to: (1) the source of compensation of the director, including any consulting advisory or other compensatory fee paid by such company to the director; and (2) whether the director is affiliated with the company or any of its subsidiaries or affiliates.

Our board of directors undertook a review of the composition of our board of directors and its committees and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that Messrs. Bigalke and Ferrell and Dr. Nussbaum, Dr. Kotzin and Ms. Powell qualify as "independent directors" as defined by the Nasdaq listing rules. Dr. Stylli is not deemed to be independent under Nasdaq listing rules by virtue of his employment with the company. Mr. Alter no longer qualifies as an independent director, as defined under Nasdaq listing rules, by virtue of his new position at Anthem, Inc.

Our board of directors also determined that each of the directors currently serving on the audit committee and the compensation committee, except for Mr. Alter, satisfy the independence standards for audit committees and compensation committees, as applicable, established by SEC and Nasdaq listing rules. As a result, we are currently relying on Nasdaq transition rules applicable to companies who recently underwent an initial public offering. In making such determinations, our board of directors considered the relationships that each such non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining independence, including the beneficial ownership of our capital stock by each non-employee director.

Item 14. Principal Accountant Fees and Services.

Audit Fees and Services

KPMG LLP is our independent registered public accounting firm for the year ended December 31, 2020 and 2019. The following table summarizes the fees of KPMG LLP billed to us for each of the last two fiscal years. All of such services and fees were pre-approved by our Audit Committee in accordance with the "Pre-Approval Policies and Procedures" described below.

	Year Ended December 31,	
Fee Category	**2020**	**2019**
Audit Fees(1)	$ 2,320,649	$ 1,497,351
Audit-Related Fees	—	—
Tax Fees(2)	700,752	437,160
All Other Fees	—	—
Total Fees	$ 3,021,401	$ 1,934,511

(1) Consists of aggregate fees billed for professional services related to our initial public offering on $670,649 and $479,351, in 2020 and 2019, respectively, the audit of our annual consolidated financial statements and review of our quarterly condensed consolidated financial statements, and professional consultations with respect to accounting matters. Also includes fees related to comfort letter procedures in connection with follow-on equity and debt offerings and review of registration statements on Forms S-1 and S-8.

(2) Consists of fees billed primarily for professional services for tax compliance, tax advice and tax planning.

Pre-Approval Policies and Procedures

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

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.
4.8	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).
4.9	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).
4.10	Form of warrant (filed with the SEC as Exhibit 4.1 to registrant's Form 8-K filed on February 25, 2021).
4.11*	Description of Securities.
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+	2020 Employee Stock Purchase Plan (filed with the SEC as Exhibit 10.6 to the registrant's Form S-1/A filed on June 15, 2020).
10.7+	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).
10.8+	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).
10.9+	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).
10.10+	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).
10.11+	Offer Letter by and between Progenity, Inc. and George Gianakopoulos, dated as of August 29, 2014 (filed with the SEC as Exhibit 10.11 to the registrant's Form S-1 filed on May 27, 2020).
10.12+	Offer Letter by and between Progenity, Inc. and Troy Seelye, dated as of January 19, 2020 (filed with the SEC as Exhibit 10.12 to the registrant's Form S-1 filed on May 27, 2020).
10.13+	Offer Letter by and between Progenity, Inc. and Damon Silvestry, dated as of March 8, 2020 (filed with the SEC as Exhibit 10.13 to the registrant's Form S-1 filed on May 27, 2020).
10.14+	Severance Plan (filed with the SEC as Exhibit 10.14 to the registrant's Form S-1/A filed on June 4, 2020).
10.15#	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).

10.16#	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).
10.17#	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).
10.18#	Confidential Settlement Agreement and Mutual Release by and among Progenity, Inc., United HealthCare Services, Inc. and UnitedHealthcare Insurance Company, dated as of September 30, 2019 (filed with the SEC as Exhibit 10.18 to the registrant's Form S-1 filed on May 27, 2020).
10.19#	Settlement and General Release Agreement by and among Progenity, Inc., Connecticut General Life Insurance Company and Cigna Health and Life Insurance Company, dated as of December 5, 2018 (filed with the SEC as Exhibit 10.19 to the registrant's Form S-1 filed on May 27, 2020).
10.20#	Settlement and General Release Agreement by and among Mattison Pathology, LLP d/b/a Avero Diagnostics, Connecticut General Life Insurance Company and Cigna Health and Life Insurance Company, dated as of December 5, 2018 (filed with the SEC as Exhibit 10.20 to the registrant's Form S-1 filed on May 27, 2020).
10.21	Management Services Agreement, by and between Mattison Pathology, LLP d/b/a Avero Diagnostics, a Texas limited liability partnership, and Avero Laboratory Holdings, LLC, a Delaware limited liability company, dated as of June 8, 2015 (filed with the SEC as Exhibit 10.24 to the registrant's Form S-1/A filed on June 18, 2020).
10.22	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).
10.23	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).
10.24	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).
10.25	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).
10.26	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).
10.27	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).
10.28	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).
10.29	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).
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	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document

101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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* 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 18, 2021

By: /s/ Harry Stylli, Ph.D.
Harry Stylli, Ph.D.
Chairman and 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/ Harry Stylli, Ph.D. **Harry Stylli, Ph.D.**	Chairman and Chief Executive Officer (principal executive officer)	March 18, 2021
/s/ Eric d'Esparbes **Eric d'Esparbes**	Chief Financial Officer (principal financial and accounting officer)	March 18, 2021
/s/ Jeffrey Alter **Jeffrey Alter**	Director	March 18, 2021
/s/ John Bigalke **John Bigalke**	Director	March 18, 2021
/s/ Jeffrey Ferrell **Jeffrey Ferrell**	Director	March 18, 2021
/s/ Dr. Brian L. Kotzin **Dr. Brian L. Kotzin**	Director	March 18, 2021
/s/ Dr. Samuel Nussbaum **Dr. Samuel Nussbaum**	Director	March 18, 2021
/s/ Lynne Powell **Lynne Powell**	Director	March 18, 2021

Exhibit 4.7

PROGENITY, INC.

AMENDMENT NO. 2 TO
FOURTH AMENDED AND RESTATED INVESTORS' RIGHTS AGREEMENT

December 7, 2020

This Amendment No. 2 (this "**Amendment**") to that certain Fourth Amended and Restated Investors' Rights Agreement, dated as of August 27, 2019 (the "**Agreement**"), by and among Progenity, Inc., a Delaware corporation (the "**Company**"), the investors listed on Exhibit A thereto (each, an "**Investor**" and collectively, the "**Investors**"), and the holders of Common Stock listed on Exhibit B thereto, as previously amended by Amendment No. 1 to the Agreement, dated November 10, 2020. Capitalized terms used in this Amendment that are not otherwise defined herein shall have the respective meanings assigned to them in the Agreement.

RECITALS

WHEREAS, the Company and the Investors desire to amend the Agreement as set forth below;

WHEREAS, the undersigned Investors represent the holders of a majority of the Registrable Securities outstanding on the date of this Amendment and, as such, together with the Company, have the right, power and authority pursuant to Section 4.4 of the Agreement to execute and deliver this Amendment and amend the Agreement in the manner provided herein.

NOW, THEREFORE, in consideration of the mutual promises and covenants contained in this Amendment and other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the parties hereto agree as follows:

AGREEMENT

1. The following defined term on Section 1(a)(xv) of the Agreement is hereby deleted in its entirety and replaced with the following:

> "**Registrable Securities**" means (i) the shares of Common Stock issuable or issued upon conversion of the Preferred Stock, including any shares of Common Stock issued on or before the date hereof, upon conversion of preferred stock of the Company outstanding at any time, other than shares for which registration rights have terminated pursuant to Section 2.15 hereof, (ii) the shares of Common Stock issued pursuant to the Common Stock Purchase Agreement, dated as of August 8, 2016, by and between the Company and BCI, other than shares for which registration rights have terminated pursuant to Section 2.15 hereof, (iii) the shares of Common Stock issuable or issued upon conversion of the Warrant Shares (or, following a Qualified IPO, issuable upon exercise of the Warrant), other than shares for which registration rights have terminated pursuant to Section 2.15 hereof; (iv) shares of Common Stock issuable or issued upon the conversion of the Unsecured Convertible Promissory Note dated May 8, 2020, issued to Athyrium Opportunities 2020 LP; (v) the shares of Common Stock issuable or issued upon exercise of the Convertible Notes, other than shares for which registration rights have terminated pursuant to Section 2.15 hereof; and (vi) any other shares of Common Stock issued as (or issuable upon the conversion or exercise of any warrant, right or other security which is issued as) a dividend or other distribution with respect to, or in exchange for or in replacement of, the shares listed in clauses (i) through (v); provided, however, that the foregoing definition shall exclude in all cases any Registrable Securities sold by

a Person in a transaction in which such Person's rights under this Agreement are not assigned. Notwithstanding the foregoing, such shares of Common Stock shall only be treated as Registrable Securities if and so long as (A) they have not been sold to or through a broker or dealer or underwriter in a public distribution or a public securities transaction, (B) they have not been sold in a transaction exempt from the registration and prospectus delivery requirements of the Securities Act under Section 4(a)(1) or Rule 144 thereof so that all transfer restrictions, and restrictive legends with respect thereto, if any, are removed upon the consummation of such sale, and (C) the Holder thereof is entitled to exercise any right provided in Section 2 in accordance with Section 2.15 below.

2. Section 1 of the Agreement shall be amended by adding the following definition in the alphabetical order, with the remaining definitions and corresponding references adjusted accordingly such that they are in alphabetical order:

"**Convertible Notes**" means the Convertible Senior Notes due 2025 of the Company issued pursuant to an indenture dated as of December 7, 2020.

3. This Amendment may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

4. This Amendment and the rights and obligations of the parties hereunder shall be governed, construed and interpreted in accordance with the laws of the State of Delaware, without giving effect to principles of conflicts of law.

5. Except as expressly provided in this Amendment, all terms and provisions of the Agreement shall remain unmodified and in full force and effect.

(*Signature Page Follows*)

IN WITNESS WHEREOF, the parties have executed this Amendment to the Agreement as of the date first written above.

COMPANY:

PROGENITY, INC.

By: /s/ Harry Stylli
Name: Harry Stylli
Title: Chief Executive Officer

IN WITNESS WHEREOF, the parties have executed this Amendment to the Agreement as of the date first written above.

INVESTORS:

/s/ Harry Stylli

Name: Harry Stylli

IN WITNESS WHEREOF, the parties have executed this Amendment to the Agreement as of the date first written above.

INVESTORS:

ATHYRIUM OPPORTUNITIES FUND (A) LP

By: Athyrium Opportunities Associates LP,
its General Partner

By: Athyrium Opportunities Associates GP LLC,
the General Partner of Athyrium Opportunities Associates LP

_____By /s/ Andrew C. Hyman

_____Name: Andrew C. Hyman

_____Title: Authorized Signatory

ATHYRIUM OPPORTUNITIES FUND (B) LP

By: Athyrium Opportunities Associates LP,
its General Partner

By: Athyrium Opportunities Associates GP LLC,
the General Partner of Athyrium Opportunities Associates LP

_____By /s/ Andrew C. Hyman

_____Name: Andrew C. Hyman

_____Title: Authorized Signatory

ATHYRIUM OPPORTUNITIES III ACQUISITION 2 LP

By: Athyrium Opportunities Associates III LP,
its General Partner

By: Athyrium Opportunities Associates III GP LLC,
the General Partner of Athyrium Opportunities Associates III LP

_____By /s/ Rashida Adams

_____Name: Rashida Adams

_____Title: Vice President

ATHYRIUM OPPORTUNITIES III CO-INVEST 1 LP

By: Athyrium Opportunities Associates Co-Invest LLC,
its General Partner

_____By /s/ Rashida Adams

_____Name: Rashida Adams

_____Title: Vice President

ATHYRIUM OPPORTUNITIES 2020 LP

By: Athyrium Opportunities Associates III LP,
its General Partner

By: Athyrium Opportunities Associates III GP LLC,
the General Partner of Athyrium Opportunities Associates III LP

By /s/ Rashida Adams

_____Name: Rashida Adams

_____Title: Vice President

Exhibit 4.11

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following is a summary of the material terms of our capital stock, as well as other material terms of our eighth amended and restated certificate of incorporation and amended and restated bylaws, and certain provisions of Delaware law. This summary does not purport to be complete and is qualified in its entirety by the provisions of our eighth amended and restated certificate of incorporation and amended and restated bylaws, copies of which are filed as exhibits to our Annual Report on Form 10-K, to which this exhibit is also appended.

Our authorized capital stock consists of 350,000,000 shares of common stock, $0.001 par value per share, and 10,000,000 shares of "blank check" preferred stock, $0.001 par value per share.

Common Stock

Our eighth amended and restated certificate of incorporation authorizes the issuance of up to 350,000,000 shares of our common stock. All outstanding shares of our common stock are validly issued, fully paid and nonassessable, and the shares of our common stock to be issued in connection with this offering will be validly issued, fully paid and nonassessable.

The holders of our common stock are entitled to one vote per share on all matters submitted to a vote of stockholders, and our eighth amended and restated certificate of incorporation does not provide for cumulative voting in the election of directors. The holders of our common stock will receive ratably any dividends declared by our board of directors ("Board") out of funds legally available therefor. In the event of our liquidation, dissolution, or winding-up, the holders of our common stock are entitled to share ratably in all assets remaining after payment of or provision for any liabilities.

Preferred Stock

Our Board may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring, or preventing a change in our control and may adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock.

Warrant

In connection with the Credit and Security Agreement we entered into with Athyrium Opportunities III Co-Invest 1 LP, an affiliate of Athyrium Capital Management, LP, and the other lenders party thereto, we issued to Athyrium Opportunities III Co-Invest 1 LP a warrant to purchase 1,416,431 shares of our Series B Preferred Stock at an initial exercise price of $3.53 per share. The Series B Preferred Stock Purchase Warrant provides for the adjustment of the exercise price and the number of shares issuable upon the exercise of the warrant in the event of certain stock dividends, stock splits, recapitalizations, reclassifications, consolidations and other fundamental transactions. The Series B Preferred Stock Purchase Warrant was originally exercisable for the number of shares of our common stock that would be issuable on conversion of the shares of our Series B Preferred Stock that could otherwise be purchased pursuant to the warrant.

Following the completion of our initial public offering in June 2020, the Series B Preferred Stock Purchase Warrant became exercisable for 400,160 shares of our common stock at an exercise price of $13.90 per share.

Registration Rights

We are party to a fourth amended and restated investors' rights agreement which provides that certain holders of our common stock have certain registration rights described below. The registration of shares of our common stock pursuant to the exercise of registration rights described below would enable holders to sell these shares without restriction under the Securities Act when the registration statement is declared effective. We will pay all expenses related to any demand, piggyback, or Form S-3 registration described below, with the exception of underwriting discounts and commissions.

The registration rights described below will expire (i) five years after the completion of our initial public offering, (ii) with respect to any particular holder, at the time that such holder can sell all its registrable securities under Rule 144 or another similar exemption under the Securities Act without limitation during a three-month period without registration or (iii) upon termination of the fourth amended and restated investors' rights agreement.

Demand Registration Rights

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

Piggyback Registration Rights

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

Form S-3 Registration Rights

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

Our Certificate of Incorporation and Our Bylaws

Special Meetings; Action by Written Consent

Under our eighth amended and restated certificate of incorporation, only a majority of the members of our Board then in office may be able to call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Under our eighth amended and restated certificate of incorporation, stockholders will be permitted to take action by written consent with respect to any matter that can be acted upon at a meeting of our stockholders for so long as Dr. Stylli,

entities affiliated with Athyrium Capital Management, LP and entities affiliated with Andrew Midler collectively own more than 50% of our issued and outstanding common stock. In all other circumstances, our eighth amended and restated certificate of incorporation provides that stockholders may not take any action by written consent in lieu of a meeting. This limit may lengthen the amount of time required to take stockholder actions and would prevent the amendment of our amended and restated bylaws or removal of directors by our stockholders without holding a meeting of stockholders.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Our amended and restated bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors that specify certain requirements as to the timing, form, and content of a stockholder's notice. Business that may be conducted at an annual meeting of stockholders will be limited to those matters properly brought before the meeting. These provisions may make it more difficult for our stockholders to nominate directors at or bring other matters before our annual meeting.

Election and Removal of Directors

Directors will be elected by a plurality vote. Our Board has the exclusive right to increase or decrease the size of the Board and to fill vacancies on the Board. These provisions prevent stockholders from increasing the size of our Board and filling the resulting vacancies. Directors may be removed with or without cause with the approval of the holders of a majority of our outstanding common stock.

Issuance of Undesignated Preferred Stock

Under our eighth amended and restated certificate of incorporation, our Board has the authority, without further action by the stockholders, to issue up to 10,000,000 shares of undesignated preferred stock with rights and preferences, including voting rights, designated from time to time by our Board. Depending on the rights and terms of any new series of preferred stock created, rights of existing stockholders could be negatively affected. The existence of authorized but unissued shares of preferred stock enables our Board to make it more difficult to attempt to obtain control of us by means of a merger, tender offer, proxy contest, or otherwise.

Delaware General Corporation Law Section 203

As a Delaware corporation, we are also subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which prohibits a Delaware corporation from engaging in a business combination specified in the statute with an interested stockholder (as defined in the statute) for a period of three years after the date of the transaction in which the person first becomes an interested stockholder, unless the business combination is approved in advance by a majority of the independent directors or by the holders of at least two-thirds of the outstanding disinterested shares. The application of Section 203 of the Delaware General Corporation Law could also have the effect of delaying or preventing a change of control of us.

Exclusive Forum Selection Clause

Our eighth amended and restated certificate of incorporation 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 fiduciary duty owed by any director, officer or other employee to us or our stockholders; (3) any action asserting a claim against us or any director or officer or other employee arising pursuant to the Delaware General Corporation Law; (4) any action to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or bylaws; or (5) any other action asserting a claim that is governed by the internal affairs doctrine, shall be the Court of Chancery of the State of Delaware (or another state court or the federal court located within the State of Delaware if the Court of Chancery does not have or declines to accept jurisdiction), in all cases subject to the court's having jurisdiction over indispensable parties named as defendants. In addition, our eighth amended and restated certificate of incorporation will provide that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act but the forum selection provisions will not apply to claims brought to enforce a duty or liability created by the Exchange Act. Although we believe these provisions benefit us by providing increased consistency in the application of Delaware law for the

specified types of actions and proceedings, the provisions may have the effect of discouraging lawsuits against us or our directors or officers.

Transfer Agent and Registrar

American Stock Transfer and Trust Company, LLC serves as the transfer agent and registrar for our common stock.

Listing

Our common stock is listed on The Nasdaq Global Market under the symbol “PROG.”

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

The Board of Directors
Progenity, Inc.:

We consent to the incorporation by reference in the registration statement (No. 333-246343) on Form S-8 of Progenity, Inc. of our report dated March 18, 2021, with respect to the consolidated balance sheets of Progenity, Inc. as of December 31, 2020 and 2019, the related consolidated statements of operations, stockholders' deficit, and cash flows for each of the years in the two-year period ended December 31, 2020, and the related notes (collectively, the consolidated financial statements), which report appears in the December 31, 2020 annual report on Form 10-K 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 raise substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of that uncertainty.

/s/ KPMG LLP

San Diego, California
March 18, 2021

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, Harry Stylli, 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)) 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) 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

   (c) 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 18, 2021

By: /s/ Harry Stylli

Harry Stylli, Chairman and 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)) 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) 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

   (c) 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 18, 2021

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, 2020 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 18, 2021

By: /s/ Harry Stylli

Harry Stylli, Ph.D., Chairman and 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.