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

☐ **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: 001-39049

EXAGEN INC.

(Exact name of registrant as specified in its charter)

Delaware	**20-0434866**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1261 Liberty Way	
Vista California	**92081**
(Address of Principal Executive Offices)	**(Zip Code)**

(760) 560-1501
(Registrant's Telephone Number, Including Area Code)

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	**XGN**	**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 Section 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 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 during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and "emerging growth company" in Rule 12b-2 of the Securities Exchange Act of 1934.

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 Securities Act ☐

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

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

As of June 30, 2020 (the last business day of the registrant's most recently completed second fiscal quarter), the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $83.4 million, based on the closing price of the registrant's common stock on the Nasdaq Global Market of $12.41 per share.

Total shares of common stock outstanding as of the close of business on March 12, 2021 was 12,669,816.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required to be disclosed in Part III of this report is incorporated by reference from the registrant's definitive Proxy Statement for the 2021 Annual Meeting of Stockholders, which proxy statement will be filed not later than 120 days after the end of the fiscal year covered by this Form 10-K.

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Part I.

Forward-Looking Statements and Market Data

This Annual Report on Form 10-K, or this Annual Report, contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical facts contained in this Annual Report, including statements regarding our future results of operations and financial position, business strategy, the impact of the COVID-19 pandemic, current and future product offerings, reimbursement and coverage, our ability to implement an integrated testing with therapeutics strategy, the expected benefits from our partnership or promotion arrangements with third parties, research and development costs, timing and likelihood of success and plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. This Annual Report also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

In some cases, you can identify forward-looking statements by terms such as "believe," "may," "will," "should," "predict," "goal," "strategy," "potentially," "estimate," "continue," "anticipate," "intend," "could," "would," "project," "plan," "expect," "seek," and similar expressions that convey uncertainty of future events or outcomes, are intended to identify forward-looking statements.

The forward-looking statements in this Annual Report are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Annual Report and are subject to a number of risks, uncertainties and assumptions described under the sections “Risk Factors” and elsewhere in this Annual Report. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we undertake no obligation to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

We use our trademarks in this Annual Report as well as trademarks, tradenames and service marks that are the property of other organizations. Solely for convenience, certain trademarks and tradenames referred to in this Annual Report appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or that the applicable owner will not assert its rights, to these trademarks and tradenames.

Item 1. Business

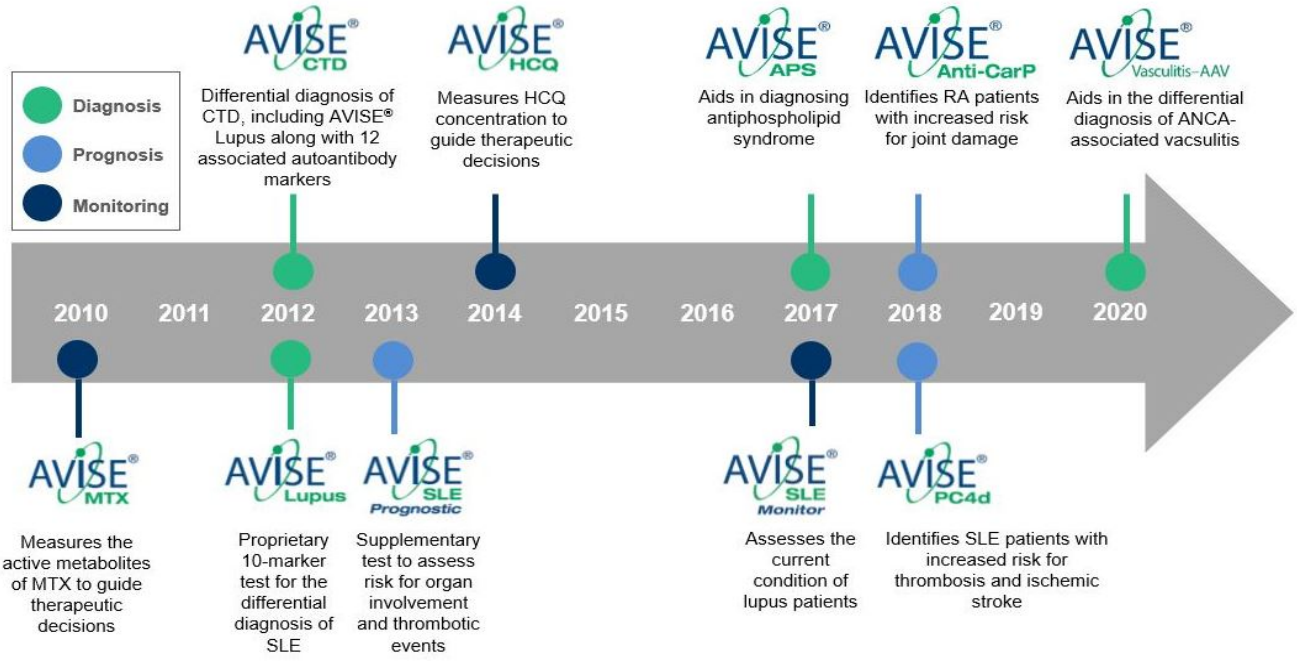
Company Overview

Exagen is dedicated to transforming the care continuum for patients suffering from debilitating and chronic autoimmune diseases by enabling timely differential diagnosis and optimizing therapeutic intervention. We have developed and are commercializing a portfolio of innovative testing products under our AVISE® brand, several of which are based on our proprietary Cell-Bound Complement Activation Products, or CB-CAPs, technology. CB-CAPs assess the activation of the complement system, a biological pathway that is widely implicated across many autoimmune and autoimmune-related diseases, including systemic lupus erythematosus, or SLE. Our goal is to enable rheumatologists to improve care for patients through the differential diagnosis, prognosis and monitoring of complex autoimmune and autoimmune-related diseases, including SLE and rheumatoid arthritis, or RA. Our strategy includes leveraging our portfolio of testing products to market therapeutics through our sales channel, targeting the approximately 5,000 rheumatologists across the United States. Our business model of integrating testing products and therapeutics positions us to offer targeted solutions to rheumatologists and, ultimately, better serve patients.

We currently market 10 testing products under our AVISE® brand that allow for the differential diagnosis, prognosis and monitoring of complex autoimmune and autoimmune-related diseases. Our lead testing product, AVISE® CTD, enables differential diagnosis for patients presenting with symptoms indicative of a wide variety of connective tissue diseases, or CTDs, and other related diseases with overlapping symptoms. The comprehensive nature of AVISE® CTD allows for the testing of a number of relevant biomarkers in one convenient blood draw, as opposed to testing serially for individual biomarkers, which adds time and cost to the diagnostic process. We believe AVISE® CTD may provide clinical utility for over 23 million patients in the United States suffering from these diseases, which include SLE, RA, Sjögren's syndrome, antiphospholipid syndrome, or APS, other autoimmune-related diseases such as autoimmune thyroid, and other disorders that mimic these diseases, such as fibromyalgia. There is an unmet need for rheumatologists to add clarity in their CTD clinical evaluation, and we believe there is a significant opportunity for our tests that enable the differential diagnosis of these diseases, particularly for potentially life-threatening diseases such as SLE.

We are leveraging our portfolio of testing products to establish partnerships with leading pharmaceutical companies, academic research centers and patient advocacy organizations. In December 2018, we entered into a co-promotion agreement, or the Janssen Agreement, with Janssen Biotech, Inc., or Janssen, to exclusively promote SIMPONI® (golimumab) in order to advance our integrated testing and therapeutics strategy, and we began direct promotion of SIMPONI® in January 2019. We also have agreements with other leading pharmaceutical companies and clinical research organizations, including GlaxoSmithKline LLC, or GSK, Covance Inc. and Parexel that leverage our testing products and/or the data generated from such tests. We provide GSK, a leader in lupus therapeutics, our test result data to provide market insight into and help increase awareness of the benefits of an early and accurate diagnosis of SLE and lupus nephritis, and monitoring disease activity. We partner with academic research centers and patient advocacy organizations, such as Brigham and Women's Hospital, Hospital for Special Surgery, and Duke University as well as the Lupus Foundation of America, to help improve the quality of life for people affected by autoimmune diseases through programs of research, education, support and advocacy. We plan to pursue additional partnerships that are synergistic with our evolving portfolio of testing products.

We have demonstrated a strong track record of developing innovative testing products that meet the needs of diagnosing, prognosing and monitoring CTDs, as illustrated below:



AVISE® CTD leverages our proprietary CB-CAPs technology to enable the differential diagnosis SLE. AVISE® CTD provides rheumatologists and their patients with sensitive and specific results that allow for potentially faster and more accurate differential diagnosis of SLE as compared to other currently-marketed testing methods. Beyond SLE, AVISE® CTD allows rheumatologists to accurately diagnose other overlapping autoimmune and autoimmune-related diseases, including RA, with the same blood sample.

Our AVISE® SLE Monitor testing product also leverages our proprietary CB-CAPs technology by measuring two CB-CAPs biomarkers that offer insight into a patient's disease activity. This test is designed to enable rheumatologists to effectively assess and optimize therapeutic intervention in patients diagnosed with SLE. Depending on disease severity, AVISE® SLE Monitor may be utilized by patients multiple times a year throughout their lives.

We market our AVISE® testing products using our specialized salesforce. Since the launch of AVISE® CTD in 2012 and through December 31, 2020, we have delivered over 487,000 of these tests. For the year ended December 31, 2020, 100,450 AVISE® CTD tests were delivered, representing an approximate 5% decline over the same period in 2019. The number of ordering healthcare providers reached a record of 2,500 for the year ended December 31, 2020, representing approximately 5% growth over the same period in 2019. In the fourth quarter of 2020, the number of ordering healthcare providers reached 1,690 compared to 1,707 in the same period in 2019, and we reached a record 635 adopting healthcare providers (defined as those who previously prescribed at least 11 diagnostic tests in the corresponding period) compared to 572 in the same period in 2019. A high percentage of adopting healthcare providers continue to order tests in subsequent quarters, including a retention rate of approximately 99% among adopting healthcare providers from the third quarter of 2020 that order at least one diagnostic test in the fourth quarter of 2020.

In addition, we continue to populate a growing proprietary database of de-identified patient test results from our clinical studies and our clinical laboratory. We believe the insight emerging from these results has the potential to unlock value for pharmaceutical and biotechnology companies in the development and commercialization of therapeutics. We believe we also have the ability to further leverage our database to optimize patient selection in clinical trials for companies developing therapeutics for autoimmune and autoimmune-related diseases. We plan to collaborate with our existing and future pharmaceutical and biotechnology partners to help maximize the full value of our in-house database.

We believe our integrated testing and therapeutics strategy differentiates us from other diagnostic and pharmaceutical companies, and results in a unique opportunity to promote and sell targeted therapies in patient focused sales calls with rheumatologists, including those with whom we have a longstanding relationship and who have a history using our portfolio of testing products. We intend to leverage our integrated testing and therapeutics strategy to establish additional partnerships.

We are led by an experienced management team with unique capabilities to execute on our strategy of integrating the promotion of testing products and therapeutics. Our senior management has an average of over 20 years of experience in the healthcare industry with a focus on integrating diagnostics and therapeutics.

Our Strategy

We develop and commercialize next-generation testing products and promote synergistic therapeutics to ultimately improve the continuum of care for patients suffering from debilitating and chronic autoimmune diseases. The key tenets of our business strategy include:

- ***Continue our track record of developing innovative testing products.*** Since inception, we have demonstrated a strong track record of developing testing products that address the challenges in the differential diagnosis, prognosis and monitoring of patients with autoimmune and autoimmune-related diseases. We are leveraging our proprietary CB-CAPs and methotrexate polyglutamate, or MTXPG, technologies to develop additional testing products designed to have superior clinical utility for CTDs. We believe our commitment to innovating our portfolio of testing products will further strengthen our relationships with rheumatologists and our value proposition to our existing and future pharmaceutical and biotechnology partners.
- ***Drive additional market penetration for our testing products.*** Our portfolio of testing products enables the differential diagnosis, prognosis and monitoring of complex autoimmune and autoimmune-related diseases. We have demonstrated a strong track record of commercial growth from our testing products, leveraging our specialized salesforce and expansive network of relationships with rheumatologists across the United States. We believe we are uniquely positioned to continue expanding our commercial presence within the autoimmune disease market and plan to continue to invest in our salesforce in order to achieve the optimal reach and frequency with rheumatologists. This will support our strategy of integrating the promotion of testing products and therapeutics. In addition, we will continue to expand our efforts in the targeted promotion and education of rheumatologists and payors as to the clinical and cost benefits of our testing products. We believe these efforts will position us to capture additional market share for our portfolio of testing products.
- ***Integrate the promotion of testing products and therapeutics for autoimmune and autoimmune-related diseases and establish additional partnerships.*** Our integrated testing and therapeutics strategy leverages our sales and marketing efforts, targeting rheumatologists for the commercialization of our testing products to promote therapeutics. In January 2019, we began our exclusive promotion of SIMPONI® in the United States. In addition, we believe our agreements with leading pharmaceutical companies and clinical research organizations validate our unique value proposition to partners seeking a competitive edge for developing and commercializing therapeutics for autoimmune and autoimmune-related diseases. We intend to leverage our integrated testing and therapeutics strategy to establish additional partnerships with a focus on the development and commercialization of therapeutics that are synergistic with our testing products.
- ***Maintain meaningful margin.*** We realized an increase to our gross margins beginning in the first quarter of 2020 following the expiration of a 10% annual royalty on our CB-CAPs technology. We believe we are well positioned to maintain meaningful margin through a continued focus on increasing operating leverage through the implementation of certain internal initiatives, such as conducting additional validation and reimbursement oriented clinical studies to facilitate payor coverage of our testing products, capitalizing on our growing reagent purchasing to negotiate improved volume-based pricing and automation in our clinical laboratory to reduce material and labor costs. However, our efforts to maintain a meaningful margin may be partially offset by our ability to generate meaningful co-promotion revenue in 2021.

Autoimmune and Connective Tissue Diseases

Autoimmune diseases encompass a broad range of serious, chronic and debilitating conditions in which a person's immune system creates antibodies that mistakenly react against normal healthy tissues causing inflammation and irreversible tissue damage. These antibodies are called autoantibodies and their detection through blood tests can help diagnose, prognose and monitor the course of autoimmune diseases. However, knowing when and which autoantibody to test for is challenging due to the vagueness of symptoms, the unexplained flaring and remission of symptoms, and the many conditions which can mimic autoimmune disease. Early and accurate diagnosis of the conditions causing these overlapping symptoms is critical as an incorrect diagnosis can lead to toxicity from inappropriate medications, irreversible tissue damage and other comorbidities associated with uncontrolled disease. There is no known cause or cure for these chronic conditions and current treatment interventions are targeted at managing symptoms and limiting disease progression.

CTDs are a sub-category of autoimmune diseases involving inflammation of the joints, tissues and internal organs. Persons with CTDs often present to their rheumatologist with complaints of joint pain, fatigue, unexplained fever,

inflammation, rash, stiffness and muscle aches. These symptoms overlap among numerous CTDs, including SLE, one of the most severe CTDs and historically difficult to rule out, as well as other autoimmune-related diseases and other disorders that mimic these diseases, such as fibromyalgia. Based on a study we commissioned in 2014, we estimate that there are approximately 23 million undiagnosed patients in the United States who are symptomatic of these conditions and who may benefit from the differential diagnosis of CTDs. Of these patients, we estimate approximately seven million are potentially referable to rheumatologists and would be candidates for an AVISE® CTD test, representing a total addressable market of approximately $3.7 billion, based on the current Medicare allowable reimbursement rate. We estimate the total addressable market for our AVISE® testing products to be approximately $5 billion, based on estimated patient populations, the current Medicare allowable reimbursement rate and testing frequencies.

Systemic Lupus Erythematosus

SLE, the most common and severe form of lupus, is a chronic, inflammatory disorder that can damage any part of the body, including the skin, joints and internal organs. The blood of a person afflicted with SLE contains autoantibodies, which are the cause of the inflammation and organ damage and are one indicator of immune system abnormalities. SLE is characterized by a rise in symptoms and/or abnormal laboratory test results. SLE varies in severity, from mild cases to those in which significant and potentially fatal damage occurs to vital organs such as the brain, heart, kidneys and lungs. Detection of these autoantibodies can assist rheumatologists in the diagnosis of SLE. Diagnosis of SLE allows rheumatologists to initiate the most appropriate therapy to minimize irreversible organ damage and reduce morbidity and mortality. Current treatment for SLE involves the use of antimalarials, corticosteroids, immunosuppressants and biologic agents to prevent or suppress active disease or flares.

Standard laboratory tests for diagnosing SLE include measuring immunological biomarkers, such as antinuclear antibodies, or ANA, anti-double stranded DNA, or anti-dsDNA, and other autoantibody tests. ANA are a group of autoantibodies produced by a person's immune system when it fails to adequately distinguish between self and non-self. The ANA test detects these autoantibodies in the blood and is a useful screening tool for SLE and other autoimmune and autoimmune-related diseases. The vast majority of SLE patients test positive for ANA. However, the high sensitivity of ANA for SLE is counterbalanced by somewhat poor specificity. Sensitivity measures the proportion of patients who are correctly identified as having a particular condition, while specificity measures the proportion of patients who are correctly identified as not having a particular condition. Therefore, the majority of individuals who test positive for ANA do not have SLE. Only approximately 11-13% of individuals with a positive ANA test have SLE. This lack of specificity leads to many inappropriate non-autoimmune referrals to the rheumatologist from primary care physicians. For example, it has been reported that 30% of fibromyalgia patients may test positive for ANA, potentially generating as many as four million inappropriate rheumatology referrals. In addition, a study published in 2012 reported the estimated prevalence of a positive ANA test in the normal, healthy, U.S. population to be 13.8%, or 32 million people, indicating a significant need for a highly-specific test for this disease.

Anti-dsDNA are autoantibodies that target a person's double stranded DNA. The anti-dsDNA antibody test is a very specific test for SLE as anti-dsDNA antibodies are rarely found in autoimmune diseases other than SLE. A strongly positive anti-dsDNA antibody test makes it very likely that a person has SLE, although if the test is negative it does not necessarily rule out SLE. Approximately 30-70% of people with SLE have a negative anti-dsDNA antibody test, reaffirming the need for an effective testing product which adds clarity to the rheumatologist's clinical assessment.

Activation of the complement system is an integral part of the disease process of SLE. Thus, rheumatologists measure components of the complement system, including serum levels of C3 and C4, to help diagnose SLE and monitor SLE disease activity. In 2012, the Systemic Lupus Collaborating Clinics added low C3 and low C4 as immunologic criteria for classifying SLE. In active SLE, C3 and C4 complement proteins are consumed and broken down to fragments, known as complement activation products. Therefore, low levels of C3 and C4 suggest a diagnosis of SLE and that the disease is active. However, variability in the levels of C3 and C4 can occur due to factors unrelated to SLE disease presence or disease activity, making them less reliable as biomarkers for SLE. For example, C3 and C4 are acute phase reactants and produced during inflammation. As a result, many SLE patients have normal complement levels even when the disease is active. Although relatively specific for SLE, low complement levels can also be seen in certain chronic infections, including non-lupus related kidney inflammation, severe liver disease and other autoimmune diseases. CB-CAPs are formed when the fragments of complement activation products from C4 bind permanently to circulating cells such as red blood cells, b-cells and platelets. This binding lasts for the life of the cell and represents a more stable and reliable indicator of complement activation than measuring C3 and C4 alone.

In March 2011, the first new biologic targeting treatment of SLE in over 50 years, GSK's Benlysta®, was approved by the U.S. Food and Drug Administration, or the FDA, and in December 2020, the FDA approved this biologic drug

for the treatment of lupus nephritis. It is the only approved biologic for the treatment of active, antibody-positive SLE who are receiving standard therapy, and in December 2020, the FDA approved this biologic for the treatment of adult patients with active lupus nephritis who are receiving standard therapy. Since Benlysta®'s approval, there have been a number of drug development programs that have failed in SLE, which may suggest that guidelines for classifying SLE patients and the endpoints used to determine clinical effectiveness have not adequately addressed the complexity of the disease process and its heterogeneous population. We believe biopharmaceutical companies would benefit from the differential diagnosis enabled by our AVISE® testing products in order to better identify sub-populations of SLE patients for targeted therapies.

Rheumatoid Arthritis

RA is a chronic, systemic autoimmune disease in which the immune system attacks the joints and can also affect other organ systems. The annual incidence and prevalence of RA in the United States is estimated to be 75,000 and 1.75 million, respectively. Patients suffering from RA develop joint damage that is associated with painful inflammation which often progresses to irreversible damage of cartilage and bone leading to significant disability and a reduction in quality of life and the ability to work. Early diagnosis and effective treatment of RA is critically important to prevent erosive bone or joint damage and disability. Rheumatologists are compelled to reach a definitive diagnosis quickly and administer effective treatment.

Diagnosis of RA involves performing a complete medical history with physical and/or radiographic examination of the number and distribution of swollen, tender and painful joints that have persisted for more than six weeks. Laboratory testing for rheumatoid factor, or RF, anti-cyclic citrullinated peptide, or CCP, antibodies, and testing for general, nonspecific inflammation with erythrocyte sedimentation rate, or the ESR, and C-reactive protein tests are used to assist in the diagnosis.

The standard of care for the treatment for RA involves the use of Disease Modifying Anti-Rheumatic Drugs, or DMARDs, which have shown, in clinical studies, the ability to slow or stop disease progression. Methotrexate remains the most commonly used DMARD, due to its low cost, effectiveness, and the extensive clinical experience with its use. It is estimated that approximately 74% of RA patients in the United States, or 1.3 million patients, are treated with methotrexate, either as a monotherapy or in combination with another DMARD.

Biologics DMARDs are proteins that have been genetically modified to target cellular components of the immune system that attack healthy tissues causing the symptoms of RA. They are a targeted form of therapy, which makes them different from traditional RA treatments, such as methotrexate. The first FDA approved biologics for RA were the anti-TNFs. ENBREL® was approved for RA in 1998 and the latest, SIMPONI®, was approved in 2009. The anti-TNFs dominate the therapy for RA and generally are the first biologics chosen to augment methotrexate when patients are not achieving a satisfactory response.

Our Solution

We currently market 10 testing products under our AVISE® brand that allow for the differential diagnosis, prognosis and monitoring of complex autoimmune and autoimmune-related diseases, including SLE and RA. Our product portfolio integrates our proprietary CB-CAPs technology, which is a stable and reliable method for differentially diagnosing SLE. We are focused on leveraging our portfolio of testing products to co-promote therapeutics with existing partners and future partners through our sales channel targeting the approximately 5,000 rheumatologists across the United States.

Our Proprietary Technologies

We have two core proprietary technologies, CB-CAPs and MTXPGs, which form the backbone of several of our testing products.

CB-CAPs

Our proprietary CB-CAPs technology determines the blood levels of complement activation proteins permanently deposited on hematopoietic cells. The determination of complement proteins in a patient’s blood is a mainstay in clinical laboratory science, and state-of-the-art methods traditionally rely on measurement of serum or plasma levels of soluble complements. C3 and C4 are the most commonly determined complement proteins in the blood and the precursors to activation of complement proteins into biologically active breakdown products. However, there are limitations with measuring C3 and C4 blood levels as indicators of complement activation. For example, increased synthesis of C3 and C4 by the liver can offset increased C3 and C4 breakdown during activation of the complement cascade, resulting in no change in serum levels. While the limitations and drawbacks of measuring standard

components of the complement system, such as C3 and C4, are well recognized by the medical community, these laboratory biomarkers are part of international guidelines for the classification of SLE.

We believe the availability of novel complement biomarkers supporting or replacing standard C3 and C4 measures will be of great value for rheumatologists and ultimately their patients. Our CB-CAPs technology directly measures protein products of complement activation, such as C4d, the product of C4 activation. These complement activation products become stably attached to surfaces of circulating blood cells to become CB-CAPs. As such, the determination of CB-CAPs in the blood provides benefits when compared to the traditional complement measurement. These include the stable, accurate and unequivocal information of complement activation that enable consistent measurement and an improved ability to assess and monitor changes in biological activity related to activation of the complement system. In a head-to-head study published in 2014, CB-CAPs (EC4d or BC4d) showed 22% higher sensitivity (66%) than C3 and C4 (44%) in diagnosing SLE, with specificity fixed at 91%.

MTXPGs

Methotrexate is the standard of care and first-line treatment of many autoimmune diseases including RA and psoriatic arthritis. Our proprietary technology measures blood levels of MTXPGs, which are the active metabolite of methotrexate. The technology uses a dried capillary blood-based collection method coupled with liquid chromatographic tandem mass spectrometry and quantifies nanomolar concentrations of MTXPG using at least two orders of magnitude lower blood volume than venipuncture. MTXPG blood levels are actionable clinical utility checkpoints and can help clinicians identify causes for a lack of response to methotrexate, such as poor activation to active metabolites, underexposure secondary to poor absorption or poor compliance, all of which are limiting factors to the achievement of a robust clinical response with this first-line treatment. We believe we can leverage this technology to optimize anti-TNF treatment by reducing the formation of anti-drug antibodies that are known to impact the clinical efficacy of these drugs.

Testing Products

Since inception, we have been committed to developing and commercializing innovative testing products that address the challenges rheumatologists face in differentially diagnosing, prognosing and monitoring complex autoimmune and autoimmune-related diseases. We estimate the total addressable market for our AVISE® testing products to be approximately $5 billion, based on estimated patient populations, the current Medicare allowable reimbursement rate and testing frequencies.

Diagnosis

AVISE® CTD

Our lead testing product, AVISE® CTD, is a comprehensive test that aids in the differential diagnosis of SLE versus other common CTDs. The SLE portion of the test employs our proprietary CB-CAPs technology and specifically measures activation of the complement system by quantifying the level of two CB-CAPs biomarkers in the patient's blood, B-cell C4d, or BC4d, and erythrocyte bound C4d, or EC4d, which are higher in patients with SLE compared to patients with other CTDs. In addition, the comprehensive nature of AVISE® CTD enables testing for a series of biomarkers (23 as of December 31, 2020) in one convenient blood draw to further aid in the differential diagnosis of a wide variety of CTDs and other diseases which can be challenging to diagnose as a result of overlapping symptoms. These diseases include SLE, RA, Sjögren's syndrome, APS, other autoimmune-related diseases such as autoimmune thyroid, and other disorders that mimic these diseases, such as fibromyalgia. Our test's ability to allow rheumatologists to effectively rule out SLE and differentially diagnose other CTDs such as RA adds clarity to the rheumatologist's assessment, thereby making the evaluation process more efficient and accurate. The clinical performance of our proprietary biomarkers and the convenience of a single blood draw make AVISE® CTD an attractive choice among rheumatologists.

AVISE® Lupus

The AVISE® Lupus test employs our proprietary CB-CAPs technology and is the cornerstone of the SLE assessment within our more comprehensive AVISE® CTD testing product. AVISE® Lupus measures activation of the complement system by quantifying the level of BC4d and EC4d in the patient's blood. Rheumatologists choose to order the comprehensive AVISE® CTD test or the more focused AVISE® Lupus test based on medical necessity, which is determined by each patient's symptoms and medical history.

AVISE® APS

AVISE® APS consists of a specialized panel of eight autoantibody tests. This test aids in both the diagnosis and management of APS, a hyper-coagulation state leading to thrombosis, pregnancy complications, and even death. Rheumatologists would typically request the AVISE® APS test in patients who initially tested positive for one or more APS biomarkers contained in AVISE® CTD, or in the management of patients experiencing a high-risk pregnancy.

AVISE® Vasculitis AAV

In September 2020, we launched AVISE® Vasculitis AAV which utilizes a testing panel of individual analytes designed to provide physicians with rapid and reliable results in the assessment and monitoring of anti-neutrophil cytoplasmic antibody, or ANCA, associated vasculitis, or AAV. AAV is a group of autoimmune diseases characterized by vascular inflammation and damage. Early signs and symptoms vary greatly and are not always indicative of the severity of the disease. Rapid and accurate testing is essential to prevent death and long-term disability.

Prognosis

AVISE® SLE Prognostic

AVISE® SLE Prognostic is a ten-biomarker panel of autoantibodies that have established predictive value for assessing the potential for complications affecting the kidney, brain and cardiovascular system, including lupus nephritis, lupus psychosis, strokes and heart attacks related to lupus. Rheumatologists rely on insights from the AVISE® SLE Prognostic test to help tailor their treatment approach.

AVISE® Anti-CarP

AVISE® Anti-CarP, which measures anti-carbamylated protein antibody, or anti-CarP, was developed by the Leiden University Medical Center, and we introduced it as a biomarker-driven RA prognostic test through a distribution agreement with Inova Diagnostics, Inc. with the goal of identifying patients prone to more severe disease. We were the first commercial laboratory to make testing for anti-CarP available in the United States with the introduction of AVISE® Anti-CarP in 2018. This test uniquely addresses two major challenges facing rheumatologists today – (1) patients presenting with RA symptoms but lacking the common confirmatory blood tests for anti-RF or anti-CCP, known as sero-negative patients, and (2) the lack of a serologic indicator, which indicates a poor prognosis and helps guide treatment decisions. Anti-CarP can be positive in up to 26% of RA patients who are negative for anti-CCP. Furthermore, RA patients positive for Anti-CarP have an increased risk for more severe RA disease, including permanent joint damage.

AVISE® PC4d

AVISE® PC4d, introduced in 2018, reflects over 10 years of research efforts and employs our proprietary CB-CAPs technology. This proprietary CB-CAP biomarker measures platelet- bound C4d, or PC4d, and has been shown in clinical studies to have significant association with thrombosis and ischemic stroke in SLE. These thrombotic events can be among the most damaging and deadly forms of lupus flares and often strike without warning. Because of its strong association with thrombosis, we believe AVISE® PC4d promises to be a valuable tool for SLE disease monitoring.

Monitoring

AVISE® SLE Monitor

AVISE® SLE Monitor is a six-biomarker blood test that employs our proprietary CB-CAPs technology and is intended to assess the condition of a patient that has been diagnosed with SLE. It offers a unique combination of biomarkers that measure for EC4d, which has shown greater accuracy in tracking disease activity than C3 and C4, and PC4d, which is associated with thrombosis risk in SLE. AVISE® SLE Monitor offers additional insight into a patient's disease activity as well as possible adverse events. Rheumatologists have limited methods for evaluating the extent of disease activity taking place inside the body of an SLE patient. They rely on imperfect biomarkers, overt symptoms or flares, and patient reported history, all of which leave the rheumatologists looking for greater insights. In surveys conducted with SLE patients, it has been reported that patients tend to under report their symptoms and over 70% of healthcare providers are unaware of this bias. AVISE® SLE Monitor demonstrates correlation to SLE disease activity and is therefore designed to enable rheumatologists to effectively assess and optimize therapeutic intervention in patients diagnosed with SLE. Additionally, AVISE® SLE Monitor measures EC4d, anti-C1q, C3, C4 and anti-dsDNA which can assist physicians with managing their lupus nephritis patients. Depending on disease severity, our AVISE® SLE Monitor testing product may be utilized by patients multiple times a year and throughout their lives. We believe AVISE® SLE Monitor will play an increasingly important role in the management of SLE patients and further solidify the role and relationship of AVISE® testing products for these patients.

In the first quarter of 2021, physicians will have the option to obtain complete blood counts with differential (CBC+diff) and serum creatinine and C-reactive protein measurements for their patients along with their AVISE® SLE Monitor test order.

AVISE® MTX

AVISE® MTX is a patented and validated blood test that precisely measures blood levels of MTXPG, the active metabolite of methotrexate linked to disease control in RA patients. There is large variability in the way patients absorb and metabolize methotrexate, leaving rheumatologists unsure of what steps to take when a patient has an inadequate response. Methotrexate is the most widely prescribed drug by rheumatologists in the treatment of RA. Measuring MTXPGs allows rheumatologists to identify patients presenting with inadequate exposure to methotrexate enabling them to optimize dosing and achieve therapeutic levels commensurate with adequate disease control. When faced with a patient who is not responding to methotrexate therapy, the options include increasing the dose, switching to a parenteral delivery method and/or advancing to a more costly biologic therapy. AVISE® MTX provides crucial information as to whether a patient has achieved MTXPG blood levels consistent with an appropriate response to methotrexate, also known as the therapeutic level, or if the MTXPG blood levels are too low to produce adequate effects. The rheumatologists can then make informed therapeutic decisions to optimize methotrexate therapy and give patients their best chance at achieving an optimal response.

AVISE® MTX is compatible with AVISE® Touch, our low-volume test sample collection method that allows for a micro-volume blood sample to be collected anywhere from a simple fingerstick. AVISE® Touch has a number of advantages, including empowering rheumatologists to collect and submit samples without full phlebotomy services, convenience for patients who have trouble with venipuncture and potential patient self-collection.

AVISE® HCQ

AVISE® HCQ is a blood test designed to help rheumatologists objectively monitor levels of hydroxychloroquine, or HCQ, in whole blood as they treat patients with SLE and other CTDs, including RA. HCQ is typically prescribed to patients to control SLE disease activity and prevent flares. However, there is large variability in the response to HCQ therapy, the drug can sometimes take weeks or months to have a therapeutic effect and compliance has been documented to be an issue in CTD patients. We believe measuring HCQ makes the patient accountable, and also helps to determine whether HCQ blood levels are adequate and consistent with clinical efficacy. The addition of new and costly biologic therapies approved for the treatment of SLE may drive interest by all healthcare stakeholders, especially payors, to adopt an approach that optimizes a generic drug before advancing to a costlier alternative. AVISE® HCQ is also compatible with AVISE® Touch.

Test Reports

We provide the results of our AVISE® testing products in a comprehensive and easy-to-understand test report typically sent to rheumatologists within five business days following receipt of the blood specimen. As shown below, the result of the AVISE® Lupus portion of the AVISE® CTD report displays a gradient illustrating the likelihood of the presence of lupus, which facilitates interpretation and discussion of the result with the patient versus only reporting a numerical value. In addition, all biomarker results for AVISE® CTD are reported and organized by disease state, providing clarity and convenience for the rheumatologists. A sample of the full AVISE® CTD report is shown below:

AVISE® CTD Report

AVISE CTD

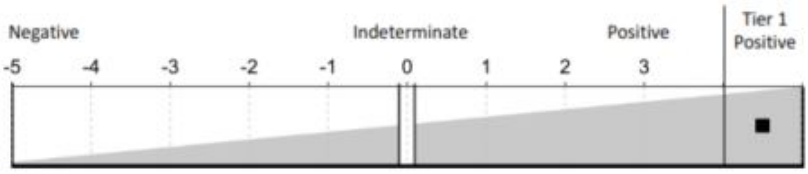
Order ID 611111
Provider Sample Provider MD

Specimen	
Collected	01/28/2021
Received	01/29/2021
Test Order	
Created	01/29/2021
Reported	02/09/2021

Patient	Test, Patient
Gender - DOB	Female - 01/01/2000
Identifier Received	
Exagen ID	111111

AVISE CTD Test Report

AVISE Lupus Result: **Tier 1 Positive**



Tier 1 Analytes	Value	Interpretation	Reference Range	Tier 1 Assessment
Anti-dsDNA IgG	413 IU/mL	POSITIVE	<302 - Negative | ≥302 - Positive	Positive
Confirmation by Crithidia luciliae		Positive dsDNA confirmed by Crithidia		
Anti-Smith IgG	1 U/mL	Negative	<5 - Negative | 5-10 - Equivocal | >10 - Positive	
CB-CAP: EC4d - Erythrocyte-bound C4d	8 Net MFI	Negative	<15 - Negative | 15-75 - Positive | >75 - Strong Positive	
CB-CAP: BC4d - B-lymphocyte-bound C4d	125 Net MFI	POSITIVE	<61 - Negative | 61-200 - Positive | >200 - Strong Positive	

Note:

The Tier 1 result is associated with an increased likelihood of SLE and is the product of the following analyte values meeting the Tier 1 criteria: Anti-dsDNA, confirmed by Crithidia IFA

Tier 2 Analytes	Value	Interpretation	Reference Range	Tier 2 Assessment
ANA IgG	>150 Units	STRONG POSITIVE	<20 - Negative | 20-59 - Positive | ≥60 - Strong Positive	Not assessed due to Tier 1 Positive
CB-CAP: EC4d - Erythrocyte-bound C4d	8 Net MFI	Negative	<15 - Negative | 15-75 - Positive | >75 - Strong Positive	
CB-CAP: BC4d - B-lymphocyte-bound C4d	125 Net MFI	POSITIVE	<61 - Negative | 61-200 - Positive | >200 - Strong Positive	
Anti-SS-B/La IgG	<1 U/mL	Negative	<7 - Negative | 7-10 - Equivocal | >10 - Positive	
Anti-Scl-70 IgG	<1 U/mL	Negative	<7 - Negative | 7-10 - Equivocal | >10 - Positive	
Anti-Centromere Protein B (CENP) IgG	<1 U/mL	Negative	<7 - Negative | 7-10 - Equivocal | >10 - Positive	
Anti-Jo-1 IgG	<1 U/mL	Negative	<7 - Negative | 7-10 - Equivocal | >10 - Positive	
Anti-CCP IgG	<1 U/mL	Negative	<7 - Negative | 7-10 - Equivocal | >10 - Positive	

Note:

Approved by: R. Harper Summers, MD

Date: 01-31-2021

Results were obtained using flow cytometry for complement C4d fragment bound to erythrocytes (EC4d) and B-lymphocytes (BC4d). Autoantibodies were determined using solid phase immunoassays. ANA was determined by indirect immunofluorescence and solid phase assays. ANA by solid phase assay was used for the index calculation. In a study of 794 subjects comprising 304 SLE patients, 285 patients with other rheumatic diseases and 205 normal healthy controls, positivity for Tier 1 markers (anti-dsDNA, confirmed using Crithidia, anti-Sm or elevated EC4d and BC4d) was associated with a sensitivity of 46% and a specificity of 97%. Among the 440 subjects negative in Tier 1, a positive index score composite of ANA (by ELISA), EC4d/BC4d and positivity for anti-citrullinated peptide antibodies, SS-B/La, CENP, Jo-1 or Scl-70 resulted in sensitivity of 62% for SLE and specificity of 89%. Two tier combination yielded 80% sensitivity for SLE and 86% specificity for other rheumatic diseases (98% specificity vs. healthy).

AVISE CTD

Order ID 611111
Provider Sample Provider MD

Specimen
Collected 01/28/2021
Received 01/29/2021

Test Order
Created 01/29/2021
Reported 02/09/2021

Patient **Test, Patient**
Gender - DOB Female - 01/01/2000
Identifier Received
Exagen ID 111111

SLE-Associated Analytes	Value		Interpretation	Reference Range
++ ANA IgG	>150	Units	STRONG POSITIVE	ELISA: <20 - Negative | 20-59 - Positive | ≥60 - Strong Positive
+ ANA by HEp-2 *Titer:*	1:320		POSITIVE	IFA: <1:80 - Negative | ≥1:80 - Positive
Nuclear Pattern: Homogeneous				
Cytoplasmic Pattern: Observed				
+ Anti-dsDNA IgG	413	IU/mL	POSITIVE	ELISA: <302 - Negative | ≥302 - Positive
+ Anti-dsDNA by Crithidia (confirmatory)	POSITIVE			IFA: Negative
Anti-Smith IgG	1	U/mL	Negative	ELISA: <5 - Negative | 5-10 - Equivocal | >10 - Positive
CB-CAP: EC4d - Erythrocyte-bound C4d	8	Net MFI	Negative	FACS: <15 - Negative | 15-75 - Positive | >75 - Strong Positive
+ CB-CAP: BC4d - B-lymphocyte-bound C4d	125	Net MFI	POSITIVE	FACS: <61 - Negative | 61-200 - Positive | >200 - Strong Positive

Other Autoimmune Disease Auto-Antibodies	Value		Interpretation	Reference Range
Anti-U1RNP IgG	3	U/mL	Negative	ELISA: <7 - Negative | 7-10 - Equivocal | >10 - Positive
Anti-RNP70 IgG	<1	U/mL	Negative	ELISA: <7 - Negative | 7-10 - Equivocal | >10 - Positive
Anti-Ro52 IgG	5	CU	Negative	CIA: <20 - Negative | ≥20 - Positive
+ Anti-Ro60 IgG	116	CU	POSITIVE	CIA: <20 - Negative | ≥20 - Positive
Anti-SS-B/La IgG	<1	U/mL	Negative	ELISA: <7 - Negative | 7-10 - Equivocal | >10 - Positive
Anti-Scl-70 IgG	<1	U/mL	Negative	ELISA: <7 - Negative | 7-10 - Equivocal | >10 - Positive
Anti-RNA Pol III IgG	10	Units	Negative	ELISA: <20 - Negative | 20 - 80 - Equivocal* | >80 - Strong Positive
Anti-Centromere Protein B (CENP) IgG	<1	U/mL	Negative	ELISA: <7 - Negative | 7-10 - Equivocal | >10 - Positive
Anti-Jo-1 IgG	<1	U/mL	Negative	ELISA: <7 - Negative | 7-10 - Equivocal | >10 - Positive

Rheumatoid Arthritis Auto-Antibodies	Value		Interpretation	Reference Range
Rheumatoid Factor IgM	<1.0	U/mL	Negative	ELISA: <3.5 - Negative | 3.5-5 - Equivocal | >5 - Positive
Rheumatoid Factor IgA	2	U/mL	Negative	ELISA: <14 - Negative | 14-20 - Equivocal | >20 - Positive
Anti-CCP IgG	<1	U/mL	Negative	ELISA: <7 - Negative | 7-10 - Equivocal | >10 - Positive

Antiphospholipid Syndrome Auto-Antibodies	Value		Interpretation	Reference Range
Anti-Cardiolipin IgM	<1	CU	Negative	CIA: <20 - Negative | ≥20 - Positive
+ Anti-Cardiolipin IgG	25	CU	POSITIVE	CIA: <20 - Negative | ≥20 - Positive
Anti-β2 Glycoprotein 1 IgM	<1	CU	Negative	CIA: <21 - Negative | ≥21 - Positive
+ Anti-β2 Glycoprotein 1 IgG	61	CU	POSITIVE	CIA: <21 - Negative | ≥21 - Positive

Thyroid Auto-Antibodies	Value		Interpretation	Reference Range
Anti-Thyroglobulin IgG	<12	IU/mL	Negative	ELISA: <40 - Negative | 40-60 - Equivocal | >60 - Positive
Anti-Thyroid Peroxidase IgG	<4	IU/mL	Negative	ELISA: <25 - Negative | 25-35 - Equivocal | >35 - Positive

Notes:

*Interpretation of the reference range has been changed effective 10/19/2020

References

1) Kalunian K, et al. Measurement of CB-CAPs enhances diagnostic performance in SLE. Arthritis Rheum. 2012 Dec;64(12):4040-7. 2) Wallace D, et al. Systemic lupus erythematosus and primary fibromyalgia can be distinguished by testing for cell-bound complement activation products. Lupus Sci Med., 2016 Feb;3(1):e000127. 3) Putterman C, et al. CB-CAPS in SLE: comparison with anti-ds DNA and standard complement measurements. Lupus Sci Med. 2014 Oct;1(1):e000056

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Laboratory Directors:
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Therapeutics

In December 2018, we entered into the Janssen Agreement to exclusively promote SIMPONI® in the United States for the treatment of adult patients with moderate to severe RA and for other indicated rheumatic diseases, and we began direct promotion of SIMPONI® to rheumatologists with our specialized salesforce in January 2019. We believe our salesforce allows us to reach the approximately 5,000 rheumatologists in the United States. Additionally, we believe that educating providers regarding SIMPONI® has and will continue to facilitate greater acceptance of SIMPONI®.

Our AVISE® MTX test can identify methotrexate patients with inadequate methotrexate exposure who are potential candidates for SIMPONI® therapy. Our AVISE® Anti-CarP test can identify RA patients with more severe disease requiring more aggressive therapy, such as anti-TNF biologics like SIMPONI®. We believe our strategy of integrating the promotion of testing products and therapeutics, combined with our specialized salesforce, uniquely position us to expand SIMPONI®'s U.S. market share. We recognized co-promotional revenue of approximately $5.1 million and $1.5 million during the years ended December 31, 2020 and 2019, respectively. For more information regarding the Janssen Agreement, including predetermined baselines and minimum promotion fee levels for 2021, see "—Agreements with Pharmaceutical Companies."

In recent years, advancements in the understanding of the autoimmune and autoimmune-related disease process have led to a significant number of novel biologic drugs and drug development initiatives, especially in RA and SLE, and we intend to leverage our integrated testing and therapeutics strategy to establish additional partnerships with a focus on the development and commercialization of therapeutics that are synergistic with our testing products.

Our Pipeline and Growth Opportunities

In December 2019, we formed a Scientific Advisory Board consisting of national experts in the clinical management of rheumatic autoimmune diseases including RA and lupus to help guide the organization's leadership team on the design and execution of research projects as well as weigh-in on known and anticipated advances in technologies affecting clinical management of autoimmune diseases. We believe there is significant potential to capitalize on our proprietary CB-CAPs and MTXPG technologies by integrating those technologies with commercially validated biomarkers to develop testing products with superior clinical utility. The complement pathway is widely implicated in the pathogenesis of a variety of conditions, including autoimmune diseases and organ transplant rejection, and emerging data suggests its implication in cancer development. We believe that our proprietary CB-CAPs technology, owing to its stability and reliability, will allow us to produce meaningful and differentiated proprietary solutions for rheumatologists. For example, we are focused on leveraging our proprietary CB-CAPs technology by developing a thrombosis risk score with PC4d in prognosing cardiovascular events in SLE. In addition, we are developing a panel of assays that we believe may have high diagnostic and/or prognostic value in patients with fibromyalgia, RA, Sjögren's and myositis, and we continue to evaluate the use of AVISE® Touch and microfluidics for our broader portfolio of testing products to increase convenience and cost-effectiveness.

Sales and Marketing

Our specialized salesforce is focused on targeting the approximately 5,000 rheumatologists across the United States. Our sales representatives generally have extensive experience in healthcare sales with backgrounds in rheumatology, biologics, specialty therapeutics and/or testing. In addition, our sales representatives complete a comprehensive disease-level sales training program and are required to participate in regular, ongoing training activities and certifications.

Our sales model involves integrating the promotion of testing products and therapeutics in a unique approach that will enable our sales representatives to gain greater access and time with rheumatologists. The test information available to our sales representatives creates a different dynamic as compared to a traditional drug sales representative's product detail. It enables a timely, extended, patient-focused discussion that naturally transitions to a therapeutic discussion during the same sales call. Our goal is for our sales representative to be viewed as a collaborative consultant versus a traditional drug sales representative. We intend to capitalize on our established reputation, market presence and expertise to sell additional products and services into the autoimmune and autoimmune-related disease market. We believe that a collaborative relationship with rheumatologists helps build a lasting sales channel through which additional products and services can be introduced.

As of December 31, 2020, our overall sales team consisted of approximately 66 members. We have a salesforce of 53 representatives, who are managed by a team of seven regional sales directors. Our salesforce is organized into seven regions which include, Pacific, Southwest, Midwest, Great Lakes, Southeast, Atlantic and Northeast. As of December 31, 2020, our salesforce was covering a total of 56 territories within the seven regions. We expanded the reach and frequency of our salesforce by adding seven new territories in 2021 for a total of 63 territories, as well as the creation of an inside salesforce to further our reach with rheumatologists in white space, complementing our

decentralized salesforce and covering vacant territories. In addition, we expect to increase our salesforce in 2021, which is expected to significantly increase the number of sales calls made per year, helping us to cultivate a strong collaborative relationship with rheumatologists through increased interactions. To further support our promotional efforts, we have a centralized, dedicated client services department with a high level of technical training that augments our specialized salesforce and marketing activities and enhances sales efficiency and customer satisfaction by providing personalized customer support. We believe our salesforce allows us to reach the approximately 5,000 rheumatologists in the United States.

Right Doctor, Right Message, Right Frequency

We believe our sales model of integrating the promotion of testing products and therapeutics will be complemented by our focused "high-touch" selling approach that emphasizes execution in three core areas: *targeting, messaging and call frequency*. We strategically *target* the highest-potential practices by utilizing various data sources (e.g., market analytics, demographic data, historical biologic and diagnostic product usage trends). Furthermore, we believe the increased access afforded by our testing products will allow for patient-focused *messaging* and the increased accuracy of our testing products over current standard of care diagnostic methodologies. Finally, we execute a high-*frequency* promotional strategy for our top targeted rheumatologists and their office personnel to build knowledge, understanding and retention of the benefits of our testing products.

We plan to leverage core channels for building awareness and adoption including our participation with multiple patient advocacy organizations, such as the Lupus Foundation of America, or LFA, and medical societies, such as the American College of Rheumatology, or ACR. We have also established strong relationships with multiple rheumatology care management organizations, or super groups, which can be key in influencing favorable reimbursement. Our AVISE® MTX testing product has been included in the clinical guidelines for two of these groups. We believe our experience with advancing a testing product from initial development through clinical adoption differentiates us and uniquely positions us to replicate success with our other testing products. Beyond working with these groups, we intend to continue to augment field selling activity with a balanced marketing mix including print and digital advertising, direct marketing, continuing medical education programs and working with key opinion leaders to support peer-to-peer educational events.

Reimbursement, Clinical Validation and Clinical Utility

Reimbursement

We seek reimbursement for our testing products from several sources, including commercial third-party payors, government payors and patients. Payment from commercial third-party payors differs depending on whether we have entered into a contract with the payor as a participating provider or do not have a contract and are considered to be an out-of-network provider. When we contract to serve as a participating provider, reimbursements are made pursuant to a percentage of our charges or a negotiated fee schedule amount. Where we are not reimbursed in full, we may elect to appeal the insurer's underpayment or denial of payment or seek payment from the patient. We continue to focus on expanding coverage among existing contracted providers and achieving coverage with commercial payors, laboratory benefit managers and evidence review organizations. We employ a multi-pronged strategy designed to achieve broad coverage and reimbursement for our AVISE® testing products:

- *Meet the evidence standards necessary to be consistent with leading clinical guidelines.* We believe inclusion in leading clinical guidelines plays a critical role in payors' coverage decisions. In order to change clinical guidelines, tests must carry a high level of published evidence demonstrating analytical validity, clinical validity, clinical utility and cost effectiveness. When studies with such evidence are published in peer-reviewed journals, the authors of clinical guidelines may assess the level of evidence and determine whether modifying existing guidelines to include new technology is warranted. For example, we previously conducted peer-reviewed, published clinical studies for AVISE® Lupus which helped us secure favorable coverage from various commercial plans. We have conducted, and continue to conduct, clinical validation and clinical utility studies for AVISE® Lupus, which we believe will provide a basis for the ACR White Paper and/or UpToDate to consider inclusion of AVISE® Lupus in their respective guidelines. In the future, we also intend to conduct similar studies in order to develop similar supporting literature with respect to our other testing products.
- *Execute an internal managed care policy and claims adjudication function as part of our core business operations.* We employ a team of in-house claims processing and reimbursement specialists who work with patients and payors to obtain maximum reimbursement. In parallel, a managed care team collaborates with our reimbursement specialists to ensure our payor outreach strategy reacts and anticipates the changing needs of our customer base. Our customer service team is an integral part of our reimbursement strategy, working with patients and rheumatologists to navigate the claims process.

- *Cultivate a network of key opinion leaders.* Key opinion leaders are able to influence clinical practice by publishing research and determining whether new tests should be integrated into clinical guidelines. We collaborate with key opinion leaders early in the development process to ensure our clinical studies are designed and executed in a way that clearly demonstrates the benefits of our testing products to healthcare providers and payors.

Clinical Validation

We demonstrated the clinical validity of AVISE® Lupus in a study of 794 patients conducted from 2010 to 2014 across multiple leading academic centers. The primary endpoint of the study was the specificity and sensitivity of AVISE® Lupus compared to common autoantibodies used to diagnose SLE and other CTDs, such as ANA and anti-dsDNA. The final results of this study showed that AVISE® Lupus demonstrated 86% specificity and 80% sensitivity in distinguishing SLE from other CTDs and fibromyalgia, was 33% more specific than ANA (53% specificity/89% sensitivity) and was 48% more sensitive than anti-dsDNA (32% sensitivity/97% specificity).

We further demonstrated the clinical validity of AVISE® Lupus for detection of probable SLE, or pSLE, in a 246 subject multi-center, prospective, cross-sectional study, first published in the Arthritis & Rheumatology Journal in September 2019. The objective of this study was to evaluate the frequency of AVISE® Lupus and CB-CAPs as a marker of complement activation in patients with pSLE and the usefulness of the AVISE® Lupus test as a predictor of the evolution of pSLE into classified SLE by the ACR criteria. Of the 92 pSLE patients, more pSLE were positive for CB-CAPs (28%) or AVISE® Lupus (40%) than for low complement (9%) at the enrollment visit ($p=0.0001$, for each) and an AVISE® Lupus index score >0.08 prospectively associated with the development from pSLE to SLE by ACR classification criteria within 18 months (hazard ratio = 3.11, $p<0.01$).

Clinical Utility

We have collaborated with both academic and community clinicians to demonstrate the clinical utility of AVISE® Lupus versus standard diagnostic tests in physician diagnosis, impact on patient management decisions, patient reported outcomes and health economics.

We sponsored a longitudinal, case-control, retrospective review of medical charts in 2016 to assess the value and clinical utility of AVISE® Lupus to rheumatologists. The results of this study were published in the Open Rheumatology Journal in 2016 and suggested that a positive AVISE® Lupus test aids in the diagnosis of SLE versus standard diagnostic tests.

In early 2018, we initiated CARE for Lupus, a prospective, randomized, multi-site study to assess the performance of AVISE® Lupus versus standard diagnostic laboratory tests, or SDLT. A total of 145 patients were enrolled across 32 sites between July 2017 and December 2018, with 73 patients enrolled in the SDLT group and 72 patients in the AVISE® Lupus group. The CARE study was published in September 2019 in Lupus Science & Medicine. Results showed among patients who tested positive for AVISE® Lupus (n=9), 44% in the AVISE® Lupus group had a higher likelihood of SLE, compared with 9% in the SDLT group ($p=0.127$), whereas among patients who tested negative for AVISE® Lupus (n=63), 60% in the AVISE® Lupus group had a lower likelihood of SLE, compared with 37% in the SDLT group ($p=0.012$). In the group of patients randomized to the AVISE® Lupus group, positive test results associated significantly with initiation of prednisone ($p=0.03$) and a similar trend was observed with HCQ therapy ($p=0.11$). Finally, in the group of patients randomized to the AVISE® Lupus group, a positive test result associated with an increase in patient-reported outcomes measuring health-related quality of life using five-level EQ-5D, or EQ5D-5L index score, from enrollment to visit 2 ($p=0.028$), and greater improvements were detectable when compared to the group of patients positive for AVISE® Lupus and randomized to the SDLT arm ($p=0.049$).

Healthcare Economics

In October 2020, a study in collaboration with leading health economic experts was published in the journal ACR Open Rheumatology, titled "Evaluation of the Economic Benefit of Earlier Systemic Lupus Erythematosus (SLE) Diagnosis using a Multivariate Assay Panel (MAP)." This was the first ever evaluation of the economics of diagnosing SLE with AVISE® Lupus (MAP) compared to standard diagnostic laboratory tests in a hypothetical cohort of 1,000 suspected SLE patients. Over the four-year time horizon, AVISE® Lupus demonstrated an estimated total direct cost savings of approximately $2.0 million, or $1,991 per patient. In addition, the year one savings was $655,403, or $655 per eligible patient, with the use of AVISE® Lupus, which aligns with early benefit to health plans looking for savings in the first year.

The above referenced studies are included in the AVISE® Lupus Dossier. In March 2020, we announced coverage and in-network contract with three California Medical Groups followed by coverage and an in-network agreement

with TRICARE East Humana Military and Highmark BCBS coverage policy. We anticipate continued coverage determinations and in-network contracting announcements in 2021 and beyond.

We believe our reimbursement strategy, including establishing the clinical validation, clinical utility and health economics of our testing products will continue to allow us to drive an expansion in reimbursement coverage for our testing products.

Laboratory Operations

We perform all of our AVISE® tests in our approximately 8,000 square foot clinical laboratory, which is certified by the Clinical Laboratory Improvement Amendments of 1988, or CLIA, and accredited by the College of American Pathologists, or CAP, and located in Vista, California. Our laboratory is certified for the performance of high-complexity testing by the Centers for Medicare and Medicaid Services, or CMS, in accordance with CLIA. We are approved to offer our products in all 50 states. Our clinical laboratory reports all AVISE® testing product results within five business days. In the fourth quarter of 2020, we completed the build-out of approximately 2,000 additional square feet to our clinical laboratory. We believe that our existing laboratory facilities are adequate to meet our business needs for at least the next 12 months and that additional laboratory space will be available on commercially reasonable terms, if required.

Quality Assurance

Our quality assurance function oversees the quality of our laboratory as well as research and development, client services, billing, sales and marketing operations. We have established oversight for systems implementation and maintenance procedures, document control processes, supplier qualification, preventive or corrective actions, and employee training processes that we believe achieves excellence in operations. We continuously monitor and improve our processes and procedures and believe this high-quality service leads to customer satisfaction and retention.

Competition

Our principal competition for our AVISE® testing products is traditional methods used by healthcare providers to test patients with CTD like symptoms. Such traditional methods include testing for a broad range of diagnostic, immunology and chemistry biomarkers, such as ANA and anti-dsDNA, and serum complement biomarkers, such as C3 and C4. We also face competition from commercial laboratories, such as Laboratory Corporation of America Holdings, Quest Diagnostics Incorporated, ARUP Laboratories, Inc. and the Mayo Clinic, all of which have existing infrastructures to support the commercialization of diagnostic services. Large, multispecialty group medical clinics, health systems and academic medical university-based clinics may provide in-house clinical laboratories offering autoimmune and autoimmune-related disease testing services. Additionally, we compete against regional clinical laboratories providing testing in the autoimmune and autoimmune-related disease field, including Rheumatology Diagnostics Laboratories, Inc. (acquired by Laboratory Corporation of America in June 2020). Other potential competitors include companies that might develop diagnostic or disease or drug monitoring products, such as Myriad Genetics, Inc., Progentec Diagnostics Inc., Scipher Medicine Corporation, Genalyte Inc., Oncimmune plc, DxTerity Diagnostics Inc. and Immunovia AB. In the future, we may also face competition from companies developing new products or technologies.

Direct competition for the promotion of SIMPONI® includes all other companies with anti-TNF biologics and the marketing companies supporting their distribution and promotion. These products include HUMIRA® from Abbvie Inc., ENBREL® from Amgen Inc., CIMZIA® from UCB, INFLECTRA® from Pfizer Inc., or Pfizer, (biosimilar REMICADE®) and RENFLEXIS® from Merck & Co. (biosimilar REMICADE®). Additionally, we are restricted from promoting any other biologic or Janus kinase inhibitor, or JAK inhibitor, used for treatment of indications covered by the Janssen Agreement without Janssen's consent. Additional competitors include companies with other biologic drugs indicated for RA that have significant sales or sales potential. Specifically, these include ORENCIA® from Bristol-Myers Squibb Company, ACTEMRA® from Roche Holding AG, or Roche, RITUXAN® from Roche, XELJANZ® from Pfizer, KEVZARA® from Sanofi S.A., RINVOQ™ from Abbvie Inc. and OLUMIANT® from Eli Lilly and Company. There are also several late-stage RA drug and biosimilar development programs and several additional RA products that have minimal sales to date or that are indicated for other rheumatic indications competitive to SIMPONI® such as psoriatic arthritis and ankylosing spondylitis.

We believe the principal competitive factors in our target market include: quality and strength of clinical and analytical validation data; confidence in diagnostic results; safety and efficacy with respect to promoted therapeutics; sales and marketing capabilities; the extent of reimbursement; inclusion in clinical guidelines; cost-effectiveness; and ease of use.

Many of our potential competitors have widespread brand recognition and substantially greater financial, technical and research and development resources and selling and marketing capabilities than we do. Others may develop products with prices lower than ours that could be viewed by rheumatologists and payors as functionally equivalent to our solution or offer solutions at prices designed to promote market penetration, which could force us to lower the list price of our products and affect our ability to achieve profitability. If we are unable to change clinical practice in a meaningful way or compete successfully against current and future competitors, we may be unable to increase market acceptance and sales of our products, which could prevent us from increasing our revenue or achieving profitability and could cause the market price of our common stock to decline.

Agreements with Pharmaceutical Companies

Janssen Agreement

In December 2018, we and Janssen entered into the Janssen agreement to co-promote SIMPONI® in the United States. We are responsible for the costs associated with our salesforce over the course of such co-promotion. Janssen is responsible for all other aspects of the commercialization of SIMPONI® under the Janssen agreement. In exchange for our sales and co-promotional services, we are entitled to a quarterly tiered promotion fee ranging from $750 to $1,250 per prescription based on the incremental increase in total prescribed units of SIMPONI® for that quarter over a predetermined baseline for the quarters ended March 31, 2019 to December 31, 2020. The predetermined average baseline for quarters ended March 31, 2019 to March 31, 2020 was approximately 29,000 prescribed units per quarter, subject to adjustment under certain circumstances. In June 2020, due in part to COVID-19, we amended the Janssen Agreement, pursuant to which the predetermined average baseline for total prescribed units of SIMPONI® for each remaining quarter in 2020, starting with the quarter ending June 30, 2020, was adjusted from approximately 29,000 to approximately 26,000 prescribed units per quarter, and subject to adjustment under certain circumstances. For each of the third and fourth quarters of 2020, we received a minimum promotion fee of $0.3 million and the fee was capped at 5% above the adjusted predetermined baseline. In December 2020, we further amended the Janssen Agreement, pursuant to which the predetermined average baseline for total prescribed units of SIMPONI® for the quarters ending December 31, 2020, March 31, 2021 and June 30, 2021 was adjusted to approximately 28,750 prescribed units per quarter, subject to further adjustment under certain circumstances. For the first and second quarter of 2021, we will be entitled to an amended quarterly tiered promotion fee ranging from $500 to $1,000 per prescription based on the incremental increase in total prescribed units of SIMPONI® for that quarter over the predetermined baseline. We refer to the Janssen Agreement, as amended in June 2020 and December 2020, as the Amended Janssen Agreement. Pursuant to the Amended Janssen Agreement, for each of the first and second quarters of 2021, we will receive a minimum promotion fee of $0.3 million and the fee will be capped at 10% above the adjusted predetermined baseline. We continued to receive a minimum promotion fee of $0.3 million and the fee was capped at 5% above the adjusted predetermined baseline for the quarter ended December 31, 2020. The quarterly tiered promotion fee for the remaining term of the Amended Janssen Agreement beginning with the quarter ended September 30, 2021 will revert to the terms set forth in the Janssen Agreement prior to the amendment, with no minimum promotion fee and no cap on predetermined baseline units.

The Janssen Agreement expires on December 31, 2021, unless extended by us for an additional 12 months upon 180 days written notice prior to the end of the current term. If we elect to extend the term, the predetermined baseline for 2022 will be subject to future agreement by us and Janssen. Janssen can terminate the agreement at any time for any reason upon 30 days' notice to us, and we can terminate the agreement for any reason at the end of any calendar quarter upon 30 days' notice to Janssen. Either party may terminate the agreement in the event of the other party's default of any of its material obligations under the agreement if such default remains uncured for a specified period of time following receipt of written notice of such default.

Collaboration Agreement with GSK

In January 2018, we entered into a collaboration agreement with GSK, pursuant to which we provide GSK with our test result data to provide market insight into and help increase awareness on the benefits of an early and accurate diagnosis of SLE. The agreement was amended in November 2018 to, among other things, include data from our AVISE® Prognostic and AVISE® HCQ testing products and extend the term of the agreement through December 31, 2019. The agreement was further amended in November 2019 and November 2020 to, among other things, extend the term of the agreement through December 31, 2020 and December 31, 2021, respectively.

Under the agreement, we are required to deliver weekly de-identified data files to GSK covering all data obtained from the performance of certain AVISE® testing products, subject to applicable requirements under the Federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, internal policy requirements and other applicable laws. During the term of the agreement, the data we provide to GSK may not be provided, directly or through a third party, to any other pharmaceutical company that is marketing or developing a product for the

treatment of SLE. GSK made a single upfront payment in exchange for the right to receive the applicable data files. In addition, GSK has agreed to create a joint steering committee to cooperate with us in order to raise awareness and physician support for our AVISE® testing products, including through the development and delivery of approved promotional materials and the implementation of a related training plan for each party's sales personnel.

The joint committee will meet at least 120 days prior to the end of the term of the agreement in order to discuss renewal options. Either party may terminate the agreement for breach and, in certain cases, such breach must remain uncured for a certain period of time following receipt of written notice of such breach. In addition, GSK may terminate the agreement immediately if we become insolvent or for convenience upon 60 days' prior written notice.

Intellectual Property Overview

We strive to protect and enhance the proprietary technologies that we believe are important to our business and seek to obtain and maintain patents for any patentable aspects of our testing products and services and any other inventions that are important to the development of our business. Our success will depend on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, to defend and enforce our patents, to maintain our licenses to use intellectual property owned by third parties, to preserve the confidentiality of our trade secrets and to operate without infringing the valid and enforceable patents and other proprietary rights of third parties. We also rely on continuing technological innovation and in-licensing opportunities to develop, strengthen, and maintain our proprietary position in the fields targeted by our testing products and services.

We are the owner or licensee of a portfolio of patents and patent applications and possess substantial know-how and trade secrets which protect various aspects of our business. The patent families comprising our patent portfolio are primarily focused on our AVISE® testing products for the diagnosis, prognosis and monitoring of autoimmune and autoimmune-related diseases, and are generally directed to CB-CAPs, red blood cell MTXPG exposure assessments, and anti-MCV antibodies. We intend to leverage the intellectual property surrounding our AVISE® testing products as an important component of our business strategy.

Patent Protection for our AVISE® Testing Products

Our portfolio of patents and patent applications related to our AVISE® testing products generally relates to three aspects: CB-CAPs, red blood cell MTXPG exposure assessments, and anti-MCV antibodies. The patent families which we believe are important for the protection of AVISE® are summarized below in the section entitled "—License Agreements." As of February 8, 2021, our portfolio primarily consisted of the following:

CB-CAPs

We are the exclusive licensee of five patent families related to CB-CAPs technology from the University of Pittsburgh, or UPitt. We expect that these patent families (U.S. Patent Nos. 7,361,517; 7,390,631; 7,585,640; 7,588,905; 8,080,382; and 8,126,654) will expire in 2024 or 2025. A foreign patent corresponding to U.S. Patent No. 7,361,517 has issued in Europe (EP 1,756,571). Foreign patents corresponding to U.S. Patent No. 7,390,631 have issued in Japan (JP 4570872 and JP 4906898). Foreign patents corresponding to U.S. Patent No. 7,585,640 have issued in Australia (AU 2005242719) and Canada (CA 2,564,492). A foreign patent corresponding to U.S. Patent Nos. 7,588,905 and 8,126,654 has issued in Japan (JP 4550051). We also own one issued patent (US 10,132,813), two pending U.S. nonprovisional patent applications, a pending PCT application, and a pending U.S. provisional application that relate to our AVISE® Lupus products. Foreign patents corresponding to US 10,132,813 have issued in Europe (EP 2,673,644) and Japan (JP 5,990,542) and Hong Kong (HK112316). In order to manage our foreign filing costs and focus on the U.S. market, we made the decision to cease the prosecution and maintenance of several of our foreign patents and patent applications related to our CB-CAPs technology, including EP 1,432,731; EP 1,618,379; EP 1,635,692; EP 1,745,287; EP 2,214,014; EP 2,216,650, and certain of their corresponding family members.

MTX Exposure Assessment Products and Services

We are the exclusive licensee of four patents that relate to our AVISE® MTX product and methods for monitoring methotrexate therapy using red blood cell MTXPG exposure assessments. These patents and patent applications are owned by Prometheus and are exclusively licensed to us for all uses except for use in gastrointestinal diseases. These patents include U.S. Patent Nos. 6,921,667; 7,563,590; 7,582,282 and 7,695,908, which are expected to expire between 2023 and 2027. We also are the exclusive licensee of two issued US patents (US 9,261,509 and US 9,822,391) that relate to our AVISE® MTX product.

Proprietary Rights and Processes

We may rely, in some circumstances, on proprietary technology and processes (including trade secrets) to protect our technology. However, these can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with those who have access to our confidential information, including our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our proprietary technology and processes by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any such breach. In addition, our proprietary technology and processes may otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants, scientific advisors, contractors, or any future collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. For this and more comprehensive risks related to our proprietary technology and processes, please see “Risk Factors—Risks Related to our Intellectual Property.”

License Agreements

Amended and Restated Exclusive License Agreement with the University of Pittsburgh

In August 2011, we entered into an amended and restated exclusive license agreement with UPitt, to amend and restate the exclusive license agreement we obtained by our purchase of the medical diagnostics division of Cypress Bioscience, Inc., or Cypress, in 2010, or the Cypress Purchase, and to obtain an exclusive license to UPitt’s patent rights in certain inventions, or the UPitt Patent Rights, related to the use of CB-CAPs technology in the diagnosis, prognosis and monitoring of diseases, including certain patents related to our AVISE® testing products. The agreement was amended three times, once in May 2012 to, among other things, limit the territory of the license to the United States and exclude certain foreign patents and applications from the agreement, once in September 2013 to add (1) an additional U.S. patent to the UPitt Patent Rights licensed under the agreement and (2) the field of monitoring of organ transplantation and organ rejection to the scope of the license, and once in June 2016 to, among other things, clarify the definition of combination products for determining royalties due under the license.

Under the agreement, we are permitted to make, use and sell products and services utilizing the UPitt Patent Rights in the field of SLE and the field of monitoring of organ transplantation and organ rejection, and to sublicense such rights. UPitt retained the right to practice under the UPitt Patent Rights and to use such rights for non-commercial education and research purposes. In addition, this agreement is subject to the rights of the United States government, if any, as set forth in 35 U.S.C. §200, et seq. Pursuant to this law, the U.S. government may have acquired a nonexclusive, nontransferable, paid up license to practice or have practiced for or on behalf of the U.S. government the inventions described in the UPitt Patent Rights throughout the world.

In consideration for the rights granted to us under the agreement, we made certain upfront payments to UPitt on the first and second anniversaries of the agreement that increased on the third and subsequent anniversaries of the agreement until the first sale of products or services utilizing the UPitt Patent Rights. We are required to pay UPitt a low single-digit royalty on net sales of products or services utilizing the UPitt Patent Rights sold by us or our affiliates, subject to minimum annual royalty payments and other adjustment in certain circumstances. We also made a $0.2 million milestone payment to UPitt with the achievement of certain levels of net sales which we met in 2014. Our royalty obligations continue for each licensed product or service on a country-by-country basis until the expiration of the last licensed patent covering the applicable licensed product or service in such country.

In the event we sublicense any of the UPitt Patent Rights, we are obligated to pay UPitt a low single-digit percentage sublicense royalty on net sales of products or services sold by our sublicensees that utilize the sublicensed UPitt Patent Rights and a low double-digit percentage of all non-royalty sublicensing income received by us.

The agreement requires that we diligently develop and commercialize products that are covered by the UPitt Patent Rights, and we have agreed to meet certain development and commercial milestones. UPitt may terminate the agreement if we fail to meet such milestones. In addition, if we fail to meet a milestone relating to development of the UPitt Patent Rights in the monitoring of organ transplantation and organ rejection field, UPitt may remove that field from our licensed rights. We are currently in compliance with these milestone requirements.

We may terminate the agreement upon six months’ written notice to UPitt. UPitt may terminate the agreement in the event of our nonperformance of any of our obligations under the agreement if such nonperformance remains uncured for a certain period of time following our receipt of written notice of such nonperformance or in the event of our insolvency. Absent early termination, the agreement will continue until the expiration date of the longest-lived patent right included in the UPitt Patent Rights.

Exclusive License Agreement with the University of Pittsburgh

We made an economic decision to cease the maintenance and licensing of UPitt Patent Rights outside the United States, which led to such rights returning to UPitt. We subsequently made the determination to re-license these foreign patent rights from UPitt, but at the time of re-licensing these patent rights, a number of the foreign patent rights had permanently lapsed. Accordingly, in September 2013, we entered into an exclusive license agreement with UPitt to obtain an exclusive license to UPitt's remaining ex-U.S. patent rights in certain inventions, or the ex-U.S. UPitt Patent Rights, related to the use of CB-CAPs technology in the diagnosis, prognosis and monitoring of diseases, including certain patents related to our AVISE® testing products.

Under the agreement, we are permitted to make, use and sell products and services utilizing the ex-U.S. UPitt Patent Rights in the field of SLE and the field of monitoring of organ transplantation and organ rejection outside of the United States, and to sublicense such rights. UPitt retained the right to practice under the ex-U.S. UPitt Patent Rights and to use such rights for non-commercial education and research purposes. In addition, this agreement is subject to the rights of the U.S. government, if any, as set forth in 35 U.S.C. §200, et seq.

In consideration for the rights granted to us under the agreement, we paid an initial license fee to UPitt. We are also required to pay UPitt a low single-digit royalty on net sales of products or services utilizing the ex-U.S. UPitt Patent Rights sold by us or our affiliates, subject to adjustment in certain circumstances. Our royalty obligations continue for each licensed product or service on a country-by-country basis until the expiration of the last licensed patent covering the applicable licensed product or service in such country.

In the event we sublicense any of the ex-U.S. UPitt Patent Rights, we are obligated to pay UPitt a low single-digit percentage sublicense royalty on net sales of products or services sold by our sublicensees that utilize the sublicensed ex-U.S. UPitt Patent Rights and a low double-digit percentage of all non-royalty sublicensing income received by us.

The agreement requires that we diligently develop and commercialize products that are covered by the ex-U.S. UPitt Patent Rights, and we have agreed to meet certain commercial milestones. UPitt may terminate the agreement if we fail to meet such milestones. We are currently in compliance with these milestone requirements.

We may terminate the agreement upon six months' written notice to UPitt. UPitt may terminate the agreement in the event of our nonperformance of any of our obligations under the agreement if such nonperformance remains uncured for a certain period of time following our receipt of written notice of such nonperformance or in the event of our insolvency. Absent early termination, the agreement will continue until the expiration date of the longest-lived patent right included in the UPitt Patent Rights.

License Agreement with Prometheus Laboratories, Inc.

In connection with the Cypress Purchase, we acquired a license agreement, dated September 2007, between Prometheus Laboratories, Inc., or Prometheus, and Proprius Pharmaceuticals, Inc., or Proprius, a company which had been previously acquired by Cypress. Pursuant to this agreement, we obtained an exclusive, worldwide license to Prometheus's patent rights in certain inventions, or the Prometheus Patent Rights, related to the diagnosis, prognosis and monitoring of diseases, including certain patents related to our AVISE® testing products and services. This agreement was subsequently amended in October 2013.

Under the agreement, we are permitted to research, develop, manufacture and commercialize products utilizing the Prometheus Patent Rights and to sublicense such rights; provided, however, that any such sublicenses may only be granted with Prometheus's consent. We are not permitted to develop or commercialize products utilizing the Prometheus Patent Rights for use in diagnosing or treating any gastrointestinal diseases or to promote any such products to gastroenterologists. Pursuant to the agreement, we are obligated to use reasonable commercial efforts to undertake certain development activities with respect to products utilizing the Prometheus Patent Rights, including the completion of certain clinical studies. In addition, in the event that we do not timely complete these studies or approved substitute studies, we will become obligated to pay to Prometheus a one-time payment of $50,000.

We are required to make a milestone payment of $2.0 million upon the achievement of certain net sales. In addition, we are required to pay Prometheus tiered royalties in the mid-single-digit range on sales of any products utilizing the Prometheus Patent Rights by us, our affiliates or our sublicensees. Our royalty obligations continue on a licensed-product-by-licensed-product and country-by-country basis until the expiration, lapse or invalidation of the last valid claim in a licensed patent covering the applicable licensed product in such country.

In the event we sublicense any of the Prometheus Patent Rights, we are obligated to pay to Prometheus a fee based on a percentage of sublicense fees received by us, which percentage is in the mid-twenties. In addition, we

are also required to pay to Prometheus a percentage of the royalty payments we receive from our sublicensees, which may not be less than a certain low single-digit percentage of net sales of products or services sold by our sublicensees that utilize the sublicensed Prometheus Patent Rights, nor more than a certain mid-single digit percentage of such net sales.

We may unilaterally terminate the agreement for any reason upon 60-days' written notice to Prometheus. Either party may terminate the agreement in the event of the other party's material breach of the agreement if such breach remains uncured for a certain period of time following receipt of written notice of such breach or in the event of the other party's insolvency. Absent early termination, the agreement will continue until the expiration date of the longest-lived patent right included in the Prometheus Patent Rights.

Asset Purchase Agreement with Cypress (Royalty Pharma) and Proprius

In October 2010, we completed the Cypress Purchase pursuant to an asset purchase agreement with Cypress and its wholly-owned subsidiary, Proprius, under which we obtained certain assets related to our AVISE® testing products and services. The agreement was amended six times, once in March 2011 to change certain obligations relating to certain accounts receivable we acquired from Cypress, once in August 2012 to convert a one-time payment obligation to a payment plan over four years with interest, once in February 2013 to convert a one-time contingent milestone payment obligation concerning a CB-CAPs monitoring assay to a payment plan over two years with interest, once in October 2013 to, among other things, provide consent for Exagen to use its IP as collateral on a financing round, once in January 2016 to restate an annual sales milestone, and once in February 2017 to restate specifics of the monitoring assay royalty.

In 2011, Royalty Pharma Collection Trust, or Royalty Pharma, acquired Cypress and became its successor-in-interest under the agreement. In consideration for the acquisition, we made certain initial cash payments to Cypress and we are currently making payments to Royalty Pharma, as a successor-in-interest to Cypress, pursuant to the August 2012 amendment, which payments are subject to acceleration in certain circumstances. Under our agreements with Royalty Pharma, we are required to pay Royalty Pharma a low double-digit royalty on the world wide net sales of CB-CAPs products and a low double-digit royalty on the net sales of certain new products in each case, for a period of eight years, which eight year period expired in January 2020.

In addition, we are required to make certain one-time contingent milestone payments for two third-party commercial programs, for the launch of a CB-CAPs monitoring assay, and for the achievement of an annual, worldwide net sales level for CB-CAPs products. Our agreement with Royalty Pharma requires that we use commercially reasonable efforts to cause each of the milestones to be achieved. In December 2015, we achieved the specified annual world-wide nets sales of CB-CAPs products which required us to make a $2.0 million milestone payment to Royalty Pharma. We paid the applicable $2.0 million milestone payment in 2016. In February 2017, we amended our agreements with Royalty Pharma relating to the launch of a monitoring product using CB-CAPs technology. As a result of this amendment, a prior obligation to make a one-time payment of $1.0 million upon the launch of a monitoring product incorporating CB-CAPs technology was replaced with an agreement to pay Royalty Pharma a one-time payment of $100,000 upon the launch of such a product, plus a 2.5% royalty based on future cash collections from sales of that product which incorporate the licensed technology. Future royalties under this arrangement are limited to the lesser of $1,200,000 (including the upfront payment of $100,000) or the total royalty earned through January 1, 2024.

Dr. Thierry Dervieux and De Novo Diagnostics, Inc.

In September 2011, we entered into a license agreement with Dr. Thierry Dervieux, our former Chief Scientific Officer, and his company De Novo Diagnostics, Inc., under which we obtained an exclusive, worldwide (except for Australia and New Zealand) license to Dr. Dervieux's patent rights and know-how in certain inventions, or the Dervieux Patent Rights, related to the diagnosis, prognosis and monitoring of diseases, including certain patents related to our AVISE® testing products and services.

Under the agreement, we are permitted to develop, manufacture and commercialize products utilizing the Dervieux Patent Rights in the human healthcare market, and to sublicense such rights.

In considerations for the rights granted to us under the agreement, we are required to make milestone payments, up to an aggregate of $600,000, upon achievement of certain sales milestones. In addition, we are required to pay Dr. Dervieux a mid-single-digit royalty on net sales by us or our affiliates of any products utilizing the Dervieux Patent Rights, subject to adjustment in certain circumstances. We are also obligated to pay Dr. Dervieux a percentage in the mid-twenties of sublicense fees and royalties received by us.

The agreement requires that we diligently develop and commercialize products that are covered by the Dervieux Patent Rights, and we have agreed to use commercially reasonable efforts to bring technology covered by the Dervieux Patent Rights to market as soon as practicable.

We may unilaterally terminate the agreement upon 12 months' written notice to Dr. Dervieux. Either party may terminate this agreement in the event of the other party's nonperformance of any of its obligations under the agreement if such nonperformance remains uncured for a specified period of time following receipt of written notice of such nonperformance or in the event of the other party's insolvency. Absent early termination, the agreement will continue until the expiration date of the longest-lived patent right included in the Dervieux Patent Rights.

Regulations

Clinical Laboratory Improvement Amendments of 1988

As a clinical reference laboratory, we are required to hold certain federal, state and local licenses, certifications and permits to conduct our business. Under CLIA, we are required to hold a certificate applicable to the type of laboratory tests we perform and to comply with standards applicable to our operations, including test processes, personnel, facilities administration, equipment maintenance, recordkeeping, quality systems and proficiency testing. We must maintain CLIA compliance and certification to be eligible to bill for diagnostic services provided to Medicare beneficiaries.

We have current certification under CLIA to perform testing at our Vista facility. To renew our CLIA certificate, we are subject to survey and inspection every two years to assess compliance with program standards. The regulatory and compliance standards applicable to the testing we perform may change over time, and any such changes could have a material effect on our business.

Penalties for non-compliance with CLIA requirements include suspension, limitation or revocation of the laboratory's CLIA certificate, as well as directed plan of correction, state on-site monitoring, civil money penalties, civil injunctive suit or criminal penalties.

State Laboratory Licensing

In addition to federal certification requirements of laboratories under CLIA, licensure is required and maintained for our Vista clinical reference laboratory under California law. Such laws establish standards for the day-to-day operation of a clinical reference laboratory, including the training and skills required of personnel and quality control. In addition, California laws mandate proficiency testing, which involves testing of specimens that have been specifically prepared for the laboratory.

Because we receive specimens from New York, our clinical reference laboratory is required to be licensed by New York, under New York laws and regulations, which establish standards for:

- day-to-day operation of a clinical laboratory, including training and skill levels required of laboratory personnel;
- physical requirements of a facility;
- equipment; and
- validation and quality control.

New York law also mandates proficiency testing for laboratories licensed under New York state law, regardless of whether such laboratories are located in New York. If a laboratory is out of compliance with New York statutory or regulatory standards, the New York Department of Health, or NYDOH, 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. NYDOH also must approve the LDT before the test is offered in New York. We have received written approval from NYDOH to offer our products in New York.

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.

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 like AVISE® CTD, AVISE® SLE Prognostic and AVISE® MTX are regulated under CLIA, as administered by CMS, as well as by applicable state laws. In addition, the Federal Food, Drug and Cosmetic Act, or

FDCA, defines a medical device to include any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals. Our in vitro testing products are considered by the FDA to be subject to regulation as medical devices. Among other things, pursuant to the FDCA and its implementing regulations, the FDA regulates the research, testing, manufacturing, safety, labeling, storage, recordkeeping, pre-market clearance or approval, marketing and promotion, and sales and distribution of medical devices in the United States to ensure that medical products distributed domestically are safe and effective for their intended uses. In addition, the FDA regulates the export of medical devices manufactured in the United States to international markets.

Although the FDA has statutory authority to assure that medical devices are safe and effective for their intended uses, the FDA has generally exercised its enforcement discretion and not enforced applicable regulations with respect to in vitro diagnostics that are designed, manufactured, and used within a single laboratory for use only in that laboratory, which are referred to as laboratory developed tests, or LDTs. We believe that the AVISE® CTD and AVISE® MTX are LDTs, as are our near-term pipeline candidate tests. As a result, we believe many of our diagnostic services are currently subject to the FDA's enforcement discretion and are not subject to the FDA's oversight. However, reagents, instruments, software or components provided by third parties and used to perform LDTs may be subject to regulation.

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

For example, in recent years, FDA has stated its intention to modify its enforcement discretion policy with respect to LDTs. For example, 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 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)," or the Reporting Guidance. The Framework Guidance stated that FDA intends to modify its policy of enforcement discretion with respect to LDTs in a risk-based manner consistent with the classification of medical devices generally in Classes I through III. The Reporting 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. On November 18, 2016, the FDA announced that it would not finalize either guidance document to allow for further public discussion on an appropriate oversight approach to LDTs and to give Congressional authorizing committees the opportunity to develop a legislative solution, and the FDA issued a discussion paper on possible approaches to LDT regulation in January 2017. Moreover, in August 2020, the U.S. Department of Health and Human Services announced that FDA will not require premarket review of LDTs absent notice-and-comment rulemaking, as opposed to through guidance documents and other informal issuances.

The FDA could ultimately modify its current approach to LDTs in a way that would subject LDTs to additional regulatory requirements. Moreover, legislative measures have could likewise result in a change to the approach to FDA's regulation over LDTs, including a requirement for premarket review of LDTs, among other things.

Medical Device Regulatory Framework

Although we currently market our proprietary testing products as LDTs, which are currently subject to enforcement discretion, we could be subject to more onerous FDA compliance obligations in the future. Specifically, if the FDA begins to actively regulate LDTs, then, unless an exemption applies, each new or significantly modified medical device we seek to commercially distribute in the U.S. will require either a premarket notification to the FDA requesting permission for commercial distribution under Section 510(k) of the FDCA, also referred to as a 510(k) clearance, or approval from the FDA of a premarket approval, or PMA, application. Both the 510(k) clearance and PMA processes can be resource intensive, expensive, and lengthy, and require payment of significant user fees.

Device Classification

Under the FDCA, 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 a set of FDA regulations, referred to as the General Controls for Medical Devices, which require compliance with the applicable portions of the FDA's quality system regulation, or 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, and 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. Accordingly, a PMA typically includes, but is not limited to, extensive technical information regarding device design and development, pre-clinical and clinical trial data, manufacturing information, labeling and financial disclosure information for the clinical investigators in device studies. The PMA application must provide valid scientific evidence that demonstrates to the FDA's satisfaction a reasonable assurance of the safety and effectiveness of the device for its intended use.

The 510(k) Clearance Process

Under the 510(k) clearance process, the manufacturer must submit to the FDA a premarket notification, demonstrating that the device is "substantially equivalent" to a legally marketed predicate device. A predicate device is a legally marketed device that is not subject to a PMA, 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 previously 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.

After a 510(k) premarket notification 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) notification. 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) notification within 90 days of receiving the 510(k) notification. 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, 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. The de novo classification process is an alternate pathway to classify medical devices that are automatically classified into Class III but which are low to moderate risk. A manufacturer can submit a petition for direct de novo review if the manufacturer is unable to identify an appropriate predicate device and the new device or new use of the device presents a moderate or low risk. De novo classification may also be available after receipt of a "not substantially equivalent" letter following submission of a 510(k) to FDA.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, will require a new 510(k) clearance or, depending on the modification, could require a PMA application. The FDA requires each manufacturer to determine whether the proposed change requires a new submission in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. Many minor modifications are accomplished by a letter-to-file in which the manufacture documents the change in an internal letter-to-file. The letter-to-file is in lieu of submitting a new 510(k) to obtain clearance for such change. The FDA can always review these letters to file in an inspection. If the

FDA disagrees with a manufacturer's determination regarding whether a new premarket submission is required for the modification of an existing 510(k)-cleared device, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or approval of a PMA application is obtained. In addition, in these circumstances, the FDA can impose significant regulatory fines or penalties for failure to submit the requisite application(s).

Over the last several years, the FDA has proposed reforms to its 510(k) clearance process, and such proposals could include increased requirements for clinical data and a longer review period, or could make it more difficult for manufacturers to utilize the 510(k) clearance process for their products. For example, in November 2018, FDA officials announced steps that the FDA intended to take to modernize the premarket notification pathway under Section 510(k) of the FDCA. Among other things, the FDA announced that it planned to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates. These proposals included plans to potentially sunset certain older devices that were used as predicates under the 510(k) clearance pathway, and to potentially publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. These proposals have not yet been finalized or adopted, although the FDA may work with Congress to implement such proposals through legislation.

More recently, in September 2019, the FDA published revised final guidance describing an optional "safety and performance based" premarket review pathway for manufacturers of "certain, well-understood device types" to demonstrate substantial equivalence under the 510(k) clearance pathway by showing that such device meets objective safety and performance criteria established by the FDA, thereby obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. The FDA maintains a list device types appropriate for the "safety and performance based" pathway and continues to develop product-specific guidance documents that identify the performance criteria for each such device type, as well as the recommended testing methods for such device types.

The PMA Approval Process

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 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.

Before approving or denying a PMA, an FDA advisory committee 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 committee, but it considers such recommendations carefully when making decisions.

Prior to approval of a PMA, the FDA may conduct inspections of the clinical trial data and clinical trial sites, as well as inspections of the manufacturing facility and processes to ensure compliance with the QSR. PMA devices are also subject to the payment of user fees, and an annual establishment registration fee.

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 is 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 are required for modification to the manufacturing process, equipment or facility, quality control procedures, sterilization, packaging, expiration date, labeling, device specifications, ingredients, 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 post-approval study or post-market surveillance, whereby the applicant conducts a follow-up study or 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 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. New PMA applications or PMA supplements may also be required for modifications to any approved diagnostic tests, including modifications to our manufacturing processes, device labeling and device design, based on the findings of post-approval studies.

Clinical Trials

Clinical trials are almost always required to support a PMA and are sometimes required to support a 510(k) submission. All clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA's investigational device exemption, or IDE, regulations which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk," to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical trial to proceed under a conditional approval.

In addition, the study must be approved by, and conducted under the oversight of, an Institutional Review Board, or IRB, for each clinical site. The IRB is responsible for the initial and continuing review of the IDE, and may pose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements. Acceptance of an IDE application for review does not guarantee that the FDA will allow the IDE to become effective and, if it does become effective, the FDA may or may not determine that the data derived from the trials support the safety and effectiveness of the device or warrant the continuation of clinical trials. An IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan or the rights, safety or welfare of human subjects.

During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to FDA's regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and recordkeeping requirements. Additionally, after a trial begins, the sponsor, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits.

Post-market Regulation

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;

- labeling regulations and FDA prohibitions against the promotion of investigational products, or the promotion of ‘‘off-label’’ uses of cleared or approved products;
- requirements related to promotional activities;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices, or approval of certain modifications to PMA-approved devices;
- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;
- correction, removal and recall 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 FDCA that may present a risk to health;
- the FDA’s recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and
- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Device manufacturing processes are required to comply with the applicable portions of 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. As a manufacturer, will be subject to periodic scheduled or unscheduled inspections by the FDA. 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 any marketed medical device 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 off-label by a physician in the practice of medicine, could result in restrictions on a medical device, including the removal of the product from the market or voluntary or mandatory device recalls.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that a manufacturer has failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following sanctions:

- warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- recalls, withdrawals, or administrative detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) marketing clearance or PMA approvals of new products or modified products;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export approvals; or
- criminal prosecution.

Federal and State Physician Self-Referral Prohibitions

We are subject to the federal physician self-referral prohibitions, commonly known as the Stark Law, and to similar state law restrictions, such as California’s Physician Ownership and Referral Act, or PORA, and other comparable state laws. Together these restrictions generally prohibit us from billing a patient or any governmental or private payor for certain designated health services, including clinical laboratory services, when the physician ordering the service, or any member of such physician’s immediate family, has a financial interest, such as an ownership or investment interest in or compensation arrangement with us, unless the arrangement meets an exception to the prohibition.

Sanctions for a Stark Law violation include the following:

- denial of payment for the services provided in violation of the prohibition;
- refunds of amounts collected by an entity in violation of the Stark Law;
- significant civil penalties for each bill or claim for a service arising out of the prohibited referral, and additional penalties for each arrangement or scheme that the parties know (or should know) has the principal purpose of circumventing the Stark Law's prohibition;

- the imposition of up to three times the amounts for each item or service wrongfully claimed; and
- possible exclusion from federal healthcare programs, including Medicare and Medicaid.

These prohibitions apply regardless of any intent by the parties to induce or reward referrals or the reasons for the financial relationship and the referral. In addition, knowing violations of the Stark Law may also serve as the basis for liability under the Federal False Claims Act, which can result in additional civil and criminal penalties.

Further, a violation of PORA is a misdemeanor and could result in civil penalties and criminal fines. Other states also have self-referral restrictions with which we have to comply, some of which differ from those imposed by the Stark Law or California law.

Federal and State Anti-Kickback Laws

The Federal Anti-kickback Statute makes it a felony for a person or entity, including a clinical laboratory, to knowingly and willfully offer, pay, solicit or receive any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in order to induce business that is reimbursable under any federal health care program. A violation of the Anti-kickback Statute may result in imprisonment for up to ten years and significant fines for each violation and additional administrative civil money penalties, plus up to three times the amount of the remuneration paid. Convictions under the Anti-kickback Statute result in mandatory exclusion from federal health care programs for a minimum of five years. In addition, The U.S. Department of Health and Human Services, or HHS, has the authority to impose civil assessments and fines and to exclude health care providers and others engaged in prohibited activities from Medicare, Medicaid and other federal health care programs. In addition, the government may assert that a claim that includes items or services resulting from a violation of the Anti-kickback Statute constitutes a false or fraudulent claim under the Federal False Claims Act, which is discussed in greater detail below. Additionally, 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.

Although the Anti-kickback Statute applies only to items and services reimbursable under any federal health care program, a number of states, including California, have passed statutes substantially similar to the Anti-kickback Statute that apply to all third-party payors, including commercial insurers, and in some states, to patients without insurance. The California Attorney General and courts have interpreted the California anti-kickback and fee-splitting laws in substantially the same way as HHS and the courts have interpreted the Anti-kickback Statute. Penalties of such state laws include imprisonment and significant monetary fines.

Federal and state law enforcement authorities scrutinize arrangements between health care providers and potential referral sources to ensure that the arrangements are not designed as a mechanism to induce patient care referrals or induce the purchase or prescribing of particular products or services. Generally, courts have taken a broad interpretation of the scope of the Anti-kickback Statute, holding that the statute may be violated if merely one purpose of a payment arrangement is to induce referrals or purchases.

In addition to statutory exceptions to the Anti-kickback Statute, regulations provide for a number of safe harbors. If an arrangement meets the provisions of a safe harbor, it is deemed not to violate the Anti-kickback Statute. An arrangement must fully comply with each element of an applicable safe harbor in order to qualify for protection.

Failure to meet the requirements of the safe harbor, however, does not render an arrangement illegal. Rather, the government may evaluate such arrangements on a case-by-case basis, taking into account all facts and circumstances. There are no regulatory safe harbors under California laws.

Other Federal and State Health Care Laws

In addition to the requirements discussed above, several other health care fraud and abuse laws could have an effect on our business. For example, provisions of the Social Security Act permit Medicare and Medicaid to exclude an entity that charges the federal health care programs substantially in excess of its usual charges for its services. The terms “usual charge” and “substantially in excess” are subject to varying interpretations.

The Federal False Claims Act prohibits, among other things, a person from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval and from, making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim in order to secure payment or retaining an overpayment by the federal government. In addition to actions initiated by the government itself, the statute authorizes actions to be brought on behalf of the federal government by a private party having knowledge of the alleged fraud. Because the 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 intervenes and is ultimately successful in obtaining redress in the matter or if the plaintiff succeeds in obtaining redress without the government’s involvement, then the plaintiff

will receive a percentage of the recovery. Finally, the Social Security Act includes its own provisions that prohibit the filing of false claims or submitting false statements in order to obtain payment. Violation of these provisions may result in fines, imprisonment or both, and possible exclusion from Medicare or Medicaid programs. Several states, including California, have enacted comparable false claims laws which may be broader in scope and may apply regardless of payor.

The civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. A person who offers or provides to a Medicare or Medicaid beneficiary any remuneration, including waivers of co-payments and deductible amounts (or any part thereof), that the person 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 may be liable for significant civil monetary penalties for each wrongful act and up to three times the amount improperly claimed. Moreover, in certain cases, providers who routinely waive copayments and deductibles for Medicare and Medicaid beneficiaries can also be held liable under the Anti-Kickback Statute and False Claims Act. One of the statutory exceptions to the prohibition is non-routine, unadvertised waivers of copayments or deductible amounts based on individualized determinations of financial need or exhaustion of reasonable collection efforts. The Office of Inspector General of HHS, or OIG, emphasizes, however, that this exception should only be used occasionally to address special financial needs of a particular patient. Although this prohibition applies only to federal healthcare program beneficiaries, applicable state laws related to, among other things, unlawful schemes to defraud, excessive fees for services, tortious interference with patient contracts and statutory or common law fraud, may also be implicated for similar practices offered to patients covered by commercial payors.

HIPAA created new federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the 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.

The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, collectively the Affordable Care Act, or ACA, among other things, also imposed annual reporting requirements on manufacturers of certain devices, drugs and biologics for certain payments and transfers of value by them and in some cases their distributors to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other health care providers beginning in 2022, and teaching hospitals, as well as ownership and investment interests held by physicians (as defined under the statute) and their immediate family members. Any failure to comply with these reporting requirements could result in significant fines and penalties. Because we manufacture our own LDTs solely for use by or within our own laboratory, we believe that we are exempt from these reporting requirements. We cannot assure you, however, that the 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, prospects, results of operations or financial condition.

If our operations are found to be in violation of any of the fraud and abuse laws described above or any other laws that apply to us, we may be subject to penalties, including potentially significant criminal and civil and/or administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

International Regulations

Many countries in which we may offer any of our testing products in the future have anti-kickback regulations prohibiting providers from offering, paying, soliciting or receiving remuneration, directly or indirectly, in order to induce business that is reimbursable under any national health care program. In situations involving physicians employed by state-funded institutions or national health care agencies, violation of the local anti-kickback law may also constitute a violation of the U.S. Foreign Corrupt Practices Act, or FCPA, and/or other applicable anti-corruption laws.

The FCPA prohibits any U.S. individual, business entity or employee of a U.S. business entity from offering or providing, directly or through a third party, including any potential distributors we may rely on in certain markets, anything of value to a foreign official with corrupt intent to influence an award or continuation of business or to gain an unfair advantage, whether or not such conduct violates local laws. In addition, it is illegal for a company that

reports to the SEC to have false or inaccurate books or records or to fail to maintain a system of internal accounting controls. We will also be required to maintain accurate information and control over sales and distributors' activities that may fall within the purview of the FCPA, including its books and records provisions and its anti-bribery provisions.

The standard of intent and knowledge under the FCPA's anti-bribery provisions is minimal intent and knowledge are usually inferred from the fact that bribery took place. The FCPA's accounting provisions do not require intent. Violations of the FCPA's anti-bribery provisions for corporations and other business entities are subject to a fine of up to $2 million and officers, directors, stockholders, employees, and agents are subject to a fine of up to $100,000 and imprisonment for up to five years. Other countries, including the United Kingdom and other OECD Anti-Bribery Convention members, have similar anti-corruption regulations, such as the UK Bribery Act.

When marketing our testing products outside of the U.S., we may be subject to foreign regulatory requirements governing human clinical testing, prohibitions on the import of tissue necessary for us to perform our testing products or restrictions on the export of tissue imposed by countries outside of the U.S. or the import of tissue into the U.S., and marketing approval. These requirements vary by jurisdiction, differ from those in the U.S. and may in some cases require us to perform additional pre-clinical or clinical testing. In many countries outside of the U.S., coverage, pricing and reimbursement approvals are also required.

Privacy and Security Laws

U.S. Data Privacy and Security Laws

Under HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH Act, HHS has issued regulations to protect the privacy and security of protected health information, or PHI, used or disclosed by certain entities including health care providers, such as us. HIPAA also regulates standardization of data content, codes and formats used in certain health care transactions and standardization of identifiers for health plans and providers. Penalties for violations of HIPAA and HITECH laws and regulations include civil and criminal penalties.

The HIPAA privacy regulations cover the use and disclosure of PHI by covered entities as well as business associates, which are defined to include subcontractors that create, receive, maintain, or transmit PHI on behalf of a business associate. They also set forth certain rights that an individual has with respect to his or her PHI maintained by a covered entity, including the right to access or amend certain records containing PHI, or to request restrictions on the use or disclosure of PHI. The HIPAA security regulations establish requirements for safeguarding the confidentiality, integrity, and availability of PHI that is electronically transmitted or electronically stored. The HIPAA breach notification regulations impose certain reporting requirements on covered entities and their business associates in the event of a breach of PHI. The HIPAA privacy and security regulations establish a uniform federal "floor" and do not preempt state laws that are more stringent or provide individuals with greater rights with respect to the privacy or security of, and access to, their records containing PHI or insofar as such state laws apply to personal information that is broader in scope than PHI.

HIPAA authorizes state attorneys general to file suit on behalf of their residents for violations. Courts are able to 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 file suit against us in civil court for violations of HIPAA, its standards have been used as the basis for duty of care cases in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI. In addition, HIPAA mandates that the Secretary of HHS conduct periodic compliance audits of HIPAA covered entities, such as us, and their business associates for compliance with the HIPAA privacy and security standards. It also tasks HHS with establishing a methodology whereby harmed individuals who were the victims of breaches of unsecured PHI may receive a percentage of the civil monetary penalty paid by the violator.

Even when HIPAA does not apply, according to the FTC, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act. 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, certain state laws govern the privacy and security of health-related and other personal information in certain circumstances, some of which are more stringent than HIPAA and many of which 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. The State of California, for example, recently adopted the California Consumer Privacy Act of 2018, or the CCPA, which went into effect January 1, 2020. The CCPA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. It also creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. 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. Although the law includes limited exceptions, including for PHI maintained by a covered entity or business associate, it may regulate or impact our processing of personal information depending on the context. Further, the California Privacy Rights Act, or CPRA, recently passed in California. The CPRA will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required.

GDPR and Foreign Laws

We are also subject to foreign privacy laws in the foreign jurisdictions in which we sell our testing products. The interpretation, application and interplay of consumer and health-related data protection laws in the U.S., Europe and elsewhere are often uncertain, contradictory and in flux. In Europe, the General Data Protection Regulation, or GDPR, went into full effect in May 2018. The GDPR implements stringent operational requirements for processors and controllers of personal data, including, for example, expanded disclosures about how personal information is collected and used, limitations on retention of information, increased requirements pertaining to health data and pseudonymised (i.e., key-coded) data, mandatory data breach notification requirements, more robust rights for individuals in regard to their personal data and higher standards for controllers to demonstrate that they have obtained valid consent for certain data processing activities. It provides that European Union, or EU, and European Economic Area, or EEA, member states may make their own further laws and regulations, which may impose further limitations, including in relation to the processing of biometric or health data, which may result in differences between member state laws, limit our ability to use and share personal data, cause our costs to increase, and/or harm our business and/or financial condition. Among other requirements, the GDPR also regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the European Union, or EU, and the United States remains uncertain. For example, in 2016, the EU and United States agreed to a transfer framework for data transferred from the EU to the United States, called the Privacy Shield, but the Privacy Shield was invalidated in July 2020 by the Court of Justice of the European Union. Further, from January 1, 2021, companies have to comply with the GDPR and also the United Kingdom GDPR, or UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, e.g. fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, and it is unclear how United Kingdom data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the United Kingdom will be regulated in the long term. Currently there is a four to six-month grace period agreed in the EU and United Kingdom Trade and Cooperation Agreement, ending June 30, 2021 at the latest, whilst the parties discuss an adequacy decision. However, it is not clear whether (and when) an adequacy decision may be granted by the European Commission enabling data transfers from EU member states to the United Kingdom long term without additional measures. These changes may lead to additional costs and increase our overall risk exposure.

Billing and Government Reimbursement for Clinical Laboratory Services

Medicare coverage is limited to items and services that are within the scope of a Medicare benefit category that are reasonable and necessary for the diagnosis or treatment of an illness or injury. With respect to Medicare coverage, Palmetto GBA, the Medicare Administrative Contractor, or MAC, responsible for administering Medicare's molecular diagnostic services program, or MolDX Program, issued a local coverage determination, or LCD, that provides coverage for our AVISE® MTX test. The MAC responsible for administering Medicare claims submitted by our laboratory, Noridian Healthcare Solutions, has adopted Palmetto's positive coverage policy, along with a related local coverage article that identifies a unique billing identifier for this test.

Under Medicare, payment for our laboratory tests are generally made under the Clinical Laboratory Fee Schedule, or CLFS, with payment amounts assigned to specific procedure billing codes. In April 2014, Congress passed the Protecting Access to Medicare Act, or PAMA, which included substantial changes to the way in which clinical laboratory services will be paid under Medicare. Under PAMA, laboratories that receive the majority of their Medicare revenue from payments made under the CLFS 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”), private payor payment rates and volumes for their tests. Laboratories that fail to report the required payment information may be subject to substantial civil monetary penalties. As required under PAMA, CMS uses the rates and volumes reported by laboratories to develop Medicare payment rates for laboratory tests equal to the volume-weighted median of the private payor payment rates for the tests.

On June 23, 2016, CMS published the final rule implementing the reporting and rate-setting requirements under PAMA. For tests furnished on or after January 1, 2018, Medicare payments for clinical diagnostic laboratory tests are based upon these reported private payor rates. For clinical diagnostic laboratory tests that are assigned a new or substantially revised CPT code, initial payment rates will be assigned by the gap-fill methodology, as under prior law. Initial payment rates for new advanced diagnostic laboratory tests will be based on the actual list charge for the laboratory test. Any reductions to payment rates resulting from the new methodology are limited to 10% per test per year in each of the years 2018 through 2020 and to 15% per test per year in each of the years 2021 through 2023. At the beginning of 2020, PAMA’s impact on Medicare reimbursement for AVISE® CTD was a reduction of 7.3% compared to levels experienced in 2019. Effective March 2020, as a result of our change in the composition of our AVISE® CTD test, PAMA's impact on Medicare reimbursement for AVISE® CTD was a reduction of 5.3% compared to levels experienced in 2019. We do not expect PAMA to impact Medicare reimbursement for AVISE® CTD in 2021 compared to levels experienced in 2020. The Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, signed into law on March 27, 2020 provides clinical laboratories a one-year reprieve from reporting requirements under the Protecting Access to Medicare Act, as well as a one-year delay of rate cuts scheduled to take place next year. Reporting was not required between January 1, 2020 to December 31, 2020. Instead, it is required between January 1, 2022 and March 31, 2022. Additionally, the next round of rate cuts was pushed from 2021 to 2022, with tests receiving cuts of up to 15% a year from 2022 through 2024.

PAMA also authorizes the adoption of new, temporary billing codes and unique test identifiers for FDA-cleared or approved tests, as well as advanced diagnostic laboratory tests. The AMA’s CPT Editorial Panel has approved a proposal to create a new section of billing codes to facilitate implementation of this section of PAMA. These proprietary laboratory analyses codes, or PLA codes, may be requested by a clinical laboratory or manufacturer to specifically identify their test. If approved, the codes are issued by the AMA on a quarterly basis. While our testing products are not presently identified by any PLA codes, we may seek a specific PLA code or codes to describe some of our testing products in the future.

Billing for diagnostic testing can be complicated. Depending on the billing arrangement and applicable law, we must bill various payors, such as insurance companies, Medicare, Medicaid, physicians, hospitals, employer groups and patients, all of which have different billing requirements. Additionally, compliance with applicable laws and regulations as well as internal compliance policies and procedures adds further complexity to the billing process. Changes in laws and regulations could negatively impact our ability to bill our clients or increase our costs. CMS also establishes new procedures and continuously evaluates and implements changes to the reimbursement process for billing government programs. Missing or incorrect information on test requisitions adds complexity to and slows the billing process, creates backlogs of unbilled tests, and generally increases the aging of accounts receivable and bad debt expense. Failure to timely or correctly bill may lead to our not being reimbursed for our services or an increase in the aging of our accounts receivable, which could adversely affect our results of operations and cash flows. Failure to comply with applicable laws relating to billing federal healthcare programs could also lead to various penalties, including:

- overpayments and recoupments of reimbursement received;
- exclusion from participation in Medicare/Medicaid programs;
- asset forfeitures;
- civil and criminal fines and penalties; and
- the loss of various licenses, certificates and authorizations necessary to operate our business.

Any of these penalties or sanctions could have a material adverse effect on our results of operations or cash flows.

Healthcare Reform

In March 2010, the ACA was enacted in the U.S. The ACA made a number of substantial changes to the way healthcare is financed by governmental and private insurers. The ACA, among other things, included provisions governing enrollment in federal and state healthcare programs, reimbursement matters and fraud and abuse, which we expect will impact our industry and our operations in ways that we cannot currently predict. Additionally, 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 Tax Cuts and Jobs Act of 2017 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 U.S. Court of Appeals for the 5th Circuit upheld the district court’s decision that the individual mandate was unconstitutional but remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing the case, although it is unclear how the Supreme Court will rule. It is also unclear how other efforts, if any, to challenge, repeal or replace the ACA will impact the ACA.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which went into effect on April 1, 2013, and due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021, unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additional state and federal health care reform measures may also be adopted in the future, any of which could have a material adverse effect on the clinical laboratory industry.

Human Capital

As of December 31, 2020, we had 181 full-time employees, and 2 part-time employees in the United States. These included 35 in laboratory operations, 12 in research and development, 71 in sales and marketing and 63 in general and administrative functions. None of our employees is represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

We recognize that attracting, motivating and retaining talent at all levels is vital to our continued success. Our employees are a significant asset and we aim to create an equitable, inclusive and empowering environment in which our employees can grow and advance their careers, with the overall goal of developing, expanding and retaining our workforce to support our current pipeline and future business goals. By focusing on employee retention and engagement, we also improve our ability to support our business and operations, our pipeline, and also protect the long-term interests of our securityholders. Our success also depends on our ability to attract, engage and retain a diverse group of employees. Our efforts to recruit and retain a diverse and passionate workforce include providing competitive compensation and benefits packages and ensuring we listen to our employees.

We value innovation, passion, data-driven decision making, persistence and honesty, and are building a diverse environment where our employees can thrive and be inspired to make exceptional contributions to bring novel testing products to patients.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, motivating and integrating our existing and future employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees and directors through grants of stock-based compensation awards and payments of cash-based performance bonus awards, in order to increase stockholder value and the success of our company by motivating our employees to perform to the best of their abilities and achieve our objectives. We are committed to providing a competitive and comprehensive benefits package to our employees. Our benefits package provides a balance of protection along with the flexibility to meet the individual health and wellness needs of our employees. We plan to continue to refine our efforts related to optimizing our use of human capital as we grow, including improvements in the way we hire, develop, motivate and retain employees.

Suppliers

We rely on sole suppliers for the critical supply of reagents, equipment and other materials that we use to perform the tests that comprise our AVISE® testing products. We also purchase components used in our AVISE® testing product transportation kits from sole-source suppliers. Some of these items are unique to these suppliers and vendors.

Financial Information

We manage our operations and allocate resources as a single reporting segment. Financial information regarding our operations, assets and liabilities, including our net loss for the years ended December 31, 2020 and 2019 and our total assets as of December 31, 2020 and 2019, is included in our Financial Statements in Item 8 of this Annual Report.

Corporate Information

We were incorporated under the laws of the state of New Mexico in 2002, under the name Exagen Corporation. In 2003, we changed our state of incorporation from New Mexico to Delaware by merging with and into Exagen Diagnostics, Inc., pursuant to which we change our name to Exagen Diagnostics, Inc. In January 2019, we changed our name to Exagen Inc. Our principal executive offices are located at 1261 Liberty Way, Vista, California 92081. Our telephone number is (760) 560-1501. Our website address is www.exagen.com. The information contained in, or accessible through, our website is not part of, and is not incorporated by reference into, this Annual Report. Investors should not rely on any such information in deciding whether to purchase our common stock.

Available Information

We file Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other information with the Securities and Exchange Commission, or SEC. Our filings with the SEC are available free of charge on the SEC's website at www.sec.gov and on the "Investors" section of our website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. You may also read and copy, at SEC prescribed rates, any document we file with the SEC at the SEC's Public Reference Room located at 100 F Street, N.E., Washington D.C. 20549. You can call the SEC at 1-800-SEC-0330 to obtain information on the operation of the Public Reference Room.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information included in this Annual Report on Form 10-K, including our financial statements and related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before making an investment decision to purchase or sell shares of our common stock. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. In that event, the trading price of our common stock could decline, and you could lose part or all of your investment. The risks described below are not the only ones that we may face, and additional risks or uncertainties not known to us or that we currently deem immaterial may also impair our business and future prospects.

Summary Risk Factors

The risk factors described below are a summary of the principal risk factors associated with an investment in us. These are not the only risks we face. You should carefully consider these risk factors, together with the risk factors set forth in this Item 1A:

- Our business is subject to risks arising from epidemic diseases, such as the global pandemic of the COVID-19 coronavirus;
- We have a history of losses, we expect to incur net losses in the future and we may not be able to generate sufficient revenue to achieve and maintain profitability;
- In the near-term, we expect that our financial results will depend primarily on sales of our testing products, and we will need to generate sufficient revenue from these testing products to grow our business;
- Our future growth depends, in part, on our ability to execute on our strategy of integrating the promotion of our existing and future proprietary testing products with the promotion of therapeutics, and we may be unsuccessful in our promotion efforts for SIMPONI®, which could adversely affect our ability to implement this strategy;
- We may be unable to manage our ongoing growth effectively, which could make it difficult to execute our business strategy;
- If we lose or are unable to secure partners for our integrated testing and therapeutics strategy, or if our partners do not apply adequate resources to their relationships with us or are unable to provide, on a timely basis, an adequate and reliable supply of the therapeutics that we promote, our potential for profitability may be adversely affected;
- Our commercial success depends on attaining and maintaining significant market acceptance of our testing products and promoted therapeutics among rheumatologists, patients, third-party payors and others in the medical community;
- We rely on sole suppliers for some of the reagents, equipment and other materials used in our testing products, and we may not be able to fund replacements or transition to alternative suppliers;

- If we are unable to support demand for our current testing products or any of our future testing products or solutions, our business could suffer;
- If third-party payors do not provide coverage and adequate reimbursement for our testing products, or they breach, rescind or modify their contracts or reimbursement policies or delay payments for our testing products or promoted therapeutics, or if we or our partners are unable to successfully negotiate payor contracts, our commercial success could be compromised;
- If we are unable to compete successfully, we may be unable to increase or sustain our revenue or achieve profitability;
- Developing new testing products involves a lengthy and complex process, and we may not be able to commercialize on a timely basis, or at all, other testing products we are developing;
- If our sole laboratory facility becomes damaged or inoperable, we are required to vacate our existing facility or we are unable to expand our existing facility as needed, we will be unable to perform our testing services and our business will be harmed;
- We may require substantial additional capital to finance our planned operations, which may not be available to us on acceptable terms or at all. Our failure to obtain additional financing when needed on acceptable terms, or at all, could force us to delay, limit, reduce or eliminate our product development programs, commercialization efforts or other operations;
- If we are unable to maintain intellectual property protection our competitive position could be harmed; and
- If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

Risks Related to Our Business and Strategy

Our business is subject to risks arising from epidemic diseases, such as the global pandemic of the COVID-19 coronavirus.

The current COVID-19 worldwide pandemic has presented substantial public health challenges and is affecting our employees, patients, physicians and other healthcare providers, communities and business operations, as well as the U.S. and global economies and financial markets. International and U.S. governmental authorities in impacted regions are taking actions in an effort to slow the spread of COVID-19, including issuing varying forms of "stay-at-home" orders, restricting business functions outside of one's home, restricting gatherings, restricting travel, and mandating social distancing and face coverings. Certain jurisdictions have begun re-opening only to return to restrictions due to increases in new COVID-19 cases. Even in areas where "stay-at-home" restrictions have been lifted and the number of COVID-19 cases have declined, many individuals remain cautious about resuming activities such as preventative-care medical visits. A pandemic, including COVID-19 or other public health epidemic, poses the risk that we or our employees, contractors, suppliers, third-party shipping carries, government and third-party payors and other partners may be prevented from conducting business activities for an indefinite period of time, including due to spread of the disease within these groups or due to shutdowns that may be requested or mandated by governmental authorities. As a result of COVID-19 related limitations and reordering of priorities across the U.S. healthcare system, a reduction in patient flow occurred and our test volumes began to decrease in the second half of March 2020. We experienced an AVISE® CTD volume decrease of approximately 5% in the year ended December 31, 2020 as compared to 2019. By the end of the third quarter of 2020, the number of AVISE® CTD tests delivered substantially recovered to pre-COVID-19 AVISE® CTD tests reported in the first quarter of 2020, and in the fourth quarter of 2020, the number of AVISE® CTD tests delivered exceeded our pre-COVID-19 AVISE® CTD tests reported in the first quarter of 2020. For the three months ended December 31, 2020 as compared to the same period in 2019, we experienced a AVISE® CTD volume increase of approximately 5%. However, the continued spread of COVID-19 may adversely affect testing volumes in future periods, the extent of which is highly uncertain. Healthcare providers and patients have canceled or delayed scheduling, and for an extended period of time may continue to cancel or delay scheduling, standard wellness visits and other non-emergency appointments and procedures, contributing to a decline in orders of our testing products. The economic downturn may also result in closures of the practices of our primary customers. As it relates to our promotion efforts of SIMPONI®, we may experience decreased demand for or discontinued treatment with SIMPONI® from patients who are infected by COVID-19 or who may be at higher risk of infection if it is determined that such patients should minimize exposure to immunosuppressant therapies.

In addition, we believe there are several other important factors that have impacted, and that we expect will impact our operating performance and results of operations, including shutdowns of our facilities and operations as well as those of our suppliers and courier services, disruptions to the supply chain of material needed for our tests, our

sales and commercialization activities and our ability to receive specimens and perform or deliver the results from our tests, delays in reimbursement and coverage decisions from Medicare and third-party payors and in interactions with regulatory authorities, as well as our inability to achieve or re-negotiate volume-based discounts with our key suppliers and to absorb fixed laboratory expenses. For example, we have experienced delays in patient enrollment for ongoing and planned clinical studies involving our tests, which may delay or prevent launch of future test products. Our salesforce has been, and for an extended period of time may continue to be limited to their in-person interactions with healthcare providers, and therefore, also limited their ability to engage in various types of healthcare provider education activities. The portion of our workforce which has been working remotely in an effort to reduce the spread of COVID-19, may be infected from the virus or otherwise distracted. We have also experienced delays in procurement of our testing supplies due to the resurgence of varying forms of "stay-at-home" orders in the fourth quarter of 2020, which may continue into the future, and our partners, including Janssen, may also experience a disruption in their ability to readily obtain supply. We may also face increased competition for laboratory employees due to the increased demand in the industry for such personnel. We may inaccurately estimate the duration or severity of the COVID-19 pandemic, which could cause us to misalign our staffing, spending, activities and precautionary measures with market current or future market conditions.

Our laboratory operations, including laboratory employees and medical directors, may be subject to closure or shut down, either due to the spread of the disease within these individuals, or as part of a larger scale government recommendation or mandate. Any disruption in our laboratory operations would have a material adverse effect on our business and would impede our ability to process tests in a timely manner, or at all.

The occurrence of any of the foregoing events could have a material adverse effect on our business, financial condition and results of operations. The COVID-19 pandemic and mitigation measures have had and may continue to have an adverse impact on global economic conditions which could have an adverse effect on our business and financial condition, including impairing our ability to raise capital on a timely basis or at all. The extent to which the COVID-19 pandemic impacts our results will depend on future developments that are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of the virus and the actions to contain its impact. COVID-19 may also have the effect of heightening many of the other risks described in this section.

We have a history of losses, we expect to incur net losses in the future and we may not be able to generate sufficient revenue to achieve and maintain profitability.

We have incurred net losses since our inception. For the years ended December 31, 2020 and 2019, we incurred net losses of $16.7 and $12.0 million, respectively, and we expect to incur additional losses in 2021 and in future years. As of December 31, 2020, we had an accumulated deficit of $181.3 million. Over the next several years, we expect to continue to devote substantially all of our resources to increase adoption of, and reimbursement for, our testing products, to develop future testing products and to continue to execute our integrated testing and therapeutics strategy. We have experienced and may continue to experience decreases in test volumes due to the impact of the COVID-19 pandemic. We may not be able to generate sufficient revenue to achieve and maintain profitability. Our failure to achieve and maintain profitability in the future could cause the market price of our common stock to decline.

We only recently began transitioning toward an integrated testing and therapeutics strategy, and have experienced material fluctuations in our ability to drive meaningful revenue from the promotion of therapeutics. Consequently, any predictions about our future success, performance or viability may not be as accurate as they could be if we had a longer history of utilizing an integrated testing and therapeutics strategy in addition to the sale of our testing products.

In the near-term, we expect that our financial results will depend primarily on sales of our testing products, and we will need to generate sufficient revenue from these testing products to grow our business.

A significant majority of our historical revenue has been derived from the sale of our AVISE® CTD testing product, which we commercially launched in 2012. In the near term, we expect to continue to derive a majority of our revenue from sales of AVISE® CTD. We are in various stages of research and development with respect to other testing products that we may offer, but there can be no assurance that we will be able to commercialize these testing products.

The demand for our testing products may decrease or may not continue to increase at historical rates for a number of reasons. In addition, at any point in time we may decide to no longer commercialize any of our testing products for any number of reasons. While we have experienced revenue growth from the sale of our testing products, we may not be able to sustain this growth or maintain existing revenue levels. Further, we cannot ensure the continued

availability of our testing products in commercial quantities at acceptable costs. If we are unable to increase sales of our testing products, expand reimbursement for our testing products, or successfully develop and commercialize additional testing products, our revenue and our ability to achieve and sustain profitability would be impaired, and the market price of our common stock could decline.

Our future growth depends, in part, on our ability to execute on our strategy of integrating the promotion of our existing and future proprietary testing products with the promotion of therapeutics, and we may be unsuccessful in our promotion efforts for SIMPONI®, which could adversely affect our ability to implement this strategy.

We are in the process of integrating our historical testing products business with the promotion of therapeutics in an integrated testing and therapeutics strategy. Our integrated testing and therapeutics strategy leverages our sales and marketing efforts, targeting rheumatologists for the commercialization of our testing products to promote therapeutics. As a result, our future growth is dependent, in part, on our ability to leverage our unique commercial model of offering testing products combined with therapeutics, including with respect to the Janssen Agreement, which we entered into in December 2018 to exclusively promote SIMPONI® in the United States. Pursuant to the Janssen Agreement, we are entitled to receive a tiered promotion fee based on the total number of incremental prescriptions written above an established baseline. Our ability to continue to effectively co-promote SIMPONI® will require us to be successful in a range of activities, including creating demand for SIMPONI® through our commercial and sales activities as well as those of Janssen. Moreover, we may encounter difficulties in maintaining an effective salesforce in furtherance of our promotion efforts for SIMPONI®, which could have a material impact on our ability to continue to successfully generate co-promotion revenue. If we encounter difficulties promoting SIMPONI®, our ability to generate significant revenue under the Amended Janssen Agreement will be harmed. In addition, in June 2020 we amended the Janssen Agreement, pursuant to which the predetermined average baseline for each remaining quarter in 2020, starting with the quarter ended June 30, 2020, was adjusted to approximately 26,000 prescribed units per quarter, due in part to COVID-19 and subject to adjustment under certain circumstances. In December 2020, we further amended the Janssen Agreement, pursuant to which the predetermined average baseline for total prescribed units of SIMPONI® for the quarters ending December 31, 2020, March 31, 2021 and June 30, 2021, was adjusted to approximately 28,750 prescribed units per quarter, subject to further adjustment under certain circumstances. Pursuant to the Amended Janssen Agreement, for each of the first and second quarters of 2021, we will receive a minimum promotion fee of $0.3 million and the fee will be capped at 10% above the adjusted predetermined baseline. The quarterly tiered promotion fee for the remaining term of the Amended Janssen Agreement beginning with the quarter ended September 30, 2021 will revert to the terms set forth in the Janssen Agreement prior to the amendment, with no minimum promotion fee and no cap on predetermined baseline units. However, based on the revised predetermined baseline we don't anticipate generating meaningful revenue beyond the minimum promotion fee for the first half of 2021, and may not generate any meaningful revenue thereafter. The Janssen Agreement expires on December 31, 2021, unless extended by us for an additional 12 months upon 180 days written notice prior to the end of the current term. Janssen also has the right to terminate the Janssen Agreement with or without cause after 30-days' notice, including if we are unable to agree to a new baseline for 2022. If Janssen were to exercise this right, we may be unable to recoup substantial investments we have made and intend to make in order to support the promotion of SIMPONI®. We have a limited history partnering with pharmaceutical companies for the promotion of therapeutics. Consequently, any predictions made about our future success or viability with respect to our promotion activities may not be as accurate as they could be if we had a history of successfully co-promoting therapeutics.

If we fail to successfully promote SIMPONI®, our ability to implement our integrated testing and therapeutics strategy and generate sufficient revenue to grow and sustain our business, and our business, financial condition and results of operations, will be materially adversely affected. This may also adversely affect our ability to secure additional therapeutic promotion opportunities.

We may be unable to manage our ongoing and future growth effectively, which could make it difficult to execute our business strategy.

In addition to the need to scale our testing capacity, our future growth plans will also impose significant added responsibilities on management, including the need to identify, recruit, train and integrate additional employees and the need to manage additional relationships with various partners, suppliers and other third parties. In particular, we have 53 representatives as of December 31, 2020 compared to 50 representatives as of December 31, 2019, and expect to continue to expand our salesforce in 2021, which we believe will help increase reach and frequency and support our integrated promotion of testing products and therapeutics. In addition, rapid and significant growth may strain our administrative and operational infrastructure and require us to expand our financial, development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. Our ability to manage our business and growth, as well as function as a public company, will require us to

continue to improve our operational, financial and management controls, reporting systems and procedures. The time and resources required to optimize these systems is uncertain, and failure to complete optimization in a timely and efficient manner could adversely affect our operations. If we are unable to manage our ongoing and future growth effectively, it may be difficult for us to execute our business strategy and our business could be harmed.

If we lose or are unable to secure partners for our integrated testing and therapeutics strategy, or if our partners do not apply adequate resources to their relationships with us or are unable to provide, on a timely basis, an adequate and reliable supply of the therapeutics that we promote, our potential for profitability may be adversely affected.

In addition to the Janssen Agreement, we plan to opportunistically evaluate, and may continue to enter into, additional agreements with pharmaceutical companies to integrate the promotion of our testing products with their therapeutics. We have also entered into, and may continue to enter into, other agreements that leverage our testing products and/or data generated from such tests. For example, we provide GSK our test result data to provide market insight into and help increase awareness of the benefits of an early and accurate diagnosis of SLE and monitoring disease activity.

The amount and timing of resources applied by our current or potential future partners are largely outside of our control. For example, we have limited control over, and rely on Janssen for, numerous activities that are critical to our ability to successfully promote SIMPONI®, such as pricing decisions, manufacture and supply of SIMPONI®, reimbursement support, marketing materials, the prosecution and enforcement of patents and other intellectual property rights related to SIMPONI® and public communications and presentations regarding SIMPONI®. We likewise have limited control of how our other partners use the information provided by our testing products.

If any of our current or future partners breaches or terminates our agreements, or fails to conduct the activities contemplated by our agreements in a timely manner, our success promoting the applicable therapeutics, testing products or information provided thereby could be diminished or blocked completely. It is possible that partners will change their strategic focus, pursue alternative technologies or develop alternative products, either on their own or in collaboration with others. For example, under the Janssen Agreement, Janssen is not prohibited from developing or commercializing products that are competitive with SIMPONI®. If Janssen commercializes any competing products, it may provide lower levels of support to SIMPONI® or may terminate our agreement entirely. The effectiveness of our partners, if any, in marketing the applicable therapeutics will also affect our revenue and earnings. In addition, if our other partners encounter problems with our testing products or information provided by our testing products that they rely on as part of their efforts, our reputation and that of our testing products could be damaged, and it could impair our ability to enter into future agreements to promote therapeutics.

We rely on Janssen to provide, on a timely basis, an adequate and reliable supply of SIMPONI®. Any delay or interruption of supply or Janssen's failure to comply with regulatory or other requirements could limit its ability to make, or cause it to cease sales, of SIMPONI®. Any manufacturing defect or error discovered after SIMPONI® has been produced and distributed could result in even more significant consequences, including costly recall procedures. In addition, the importation of pharmaceutical products into the United States is subject to regulation by the FDA, and the FDA can refuse to allow an imported product into the United States if it appears that the product fails to comply with applicable laws or regulations. Moreover, Janssen and its third-party manufacturers and suppliers may experience difficulties related to their overall business and financial stability. For example, in December 2019, a novel strain of coronavirus, COVID-19, has resulted in business closures and a limit on travel, as well as creating uncertainty in the broader economy and financial markets. Any disruption, including the extent to which COVID-19 has an effect on Janssen, may impact our ability to readily obtain supply and other requirements under our agreement with Janssen. To the extent Janssen faces manufacturing difficulties or is unable to provide an adequate and reliable supply of SIMPONI® on a timely basis, our reputation could be harmed and our business could suffer.

We do not have the capability and do not intend to discover or develop therapeutics on our own. Therefore, the success of our integrated testing and therapeutics strategy depends in part on our ability to acquire additional rights to promote therapeutics from new or existing partners. Other companies, many of which have substantially greater financial, marketing and sales resources than we do, also compete with us for the acquisition of rights to therapeutics. In addition, under the Janssen Agreement, we are prohibited from selling or promoting certain types of products that are used to treat the same indications that SIMPONI® is used to treat. We may not be able to successfully negotiate any additional agreements to promote therapeutics and, if established, these relationships may not be successful. For example, potential partners, particularly those that are actively marketing their own therapeutics, may be unwilling to license commercialization rights to us or otherwise enter into terms that allow us to meaningfully participate in sales growth for their products, which could limit the potential availability and value to us of additional agreements to promote therapeutics. The inability to enter into agreements for additional therapeutics

could limit the overall growth of our business and adversely affect our business, financial condition and results of operations. Disputes could also arise between us and our existing or future partners, as to a variety of matters, including financial and intellectual property matters or other obligations under our agreements. These disputes would be both expensive and time-consuming and may result in delays in the success of therapeutics or could damage our relationship with a partner.

We may experience limits on our revenue if rheumatologists decide not to order our testing products or our promoted therapeutics or if we are otherwise unable to create or maintain demand for our testing products and promoted therapeutics.

If we are unable to create or maintain demand for either our testing products or promoted therapeutics in sufficient volume, we may not generate sufficient revenue to become profitable. To generate increased demand, we will need to continue to educate rheumatologists about the benefits of our testing products through publications in peer-reviewed medical journals, presentations at medical conferences and other similar means. For example, in the fourth quarter of 2020, we were featured in six scientific presentations at the 2020 American College of Rheumatology's (ACR) Virtual Annual Conference, ACR Convergence 2020. We will also need to generate demand for both our testing products and promoted therapeutics through one-on-one education by our salesforce. We also plan to focus on educating patients about the benefits of these testing products and therapeutics, which we believe will be necessary to generate further demand. In addition, our inability to obtain and maintain coverage and adequate reimbursement from third-party payors may limit adoption by rheumatologists, as well as third-party payors exerting pressure on rheumatologists and healthcare providers to order in-network testing products which could adversely affect our revenue. With respect to SIMPONI® in particular, if we are unable to generate sales above certain thresholds agreed to with Janssen, we will not generate meaningful revenue under the Amended Janssen Agreement.

Rheumatologists may rely on guidelines issued by industry groups regarding the diagnosis, prognosis, treatment and monitoring of autoimmune and autoimmune-related diseases, and the monitoring of the effectiveness of therapeutic drugs used to treat such diseases before utilizing any diagnostic test or monitoring solution.

Our commercial success depends upon attaining and maintaining significant market acceptance of our testing products and promoted therapeutics among rheumatologists, patients, third-party payors and others in the medical community.

Our success depends on our ability to continue to develop and market testing products and promote therapeutics that are recognized and accepted as safe, effective, reliable and cost effective, and any testing product or promoted therapeutic that we offer may not gain or maintain market acceptance among rheumatologists, third-party payors, patients and the medical community. Market acceptance of our testing products and promoted therapeutics depends on a number of factors, including:

- the perceived accuracy of our test results by rheumatologists and patients;
- the potential and perceived advantages of our testing products and promoted therapeutics over alternative products and therapeutics;
- the demonstration in clinical studies of the performance and clinical validity of our testing products, the results of which studies may not replicate the positive results from earlier studies;
- the demonstration of clinical efficacy and safety of our promoted therapeutics compared to other more-established products;
- the introduction of new tests or therapeutics products that compete with our testing products or our promoted therapeutics or the introduction of generic versions of our promoted therapeutics;
- the product cost in relation to alternative products;
- the prevalence and severity of any adverse effects from our promoted therapeutics;
- the willingness of the target patient population to try new therapies and of rheumatologists to prescribe these therapies;
- any restrictions on the use of our promoted therapeutics, if approved, together with other medications;
- publicity concerning our testing products and promoted therapeutics or competing products and treatments;
- the availability of coverage and adequate reimbursement by third-party payors, including government authorities;
- relative convenience and ease of administration; and
- the effectiveness of our sales and marketing efforts.

In addition, if we or our partners had to withdraw a product from the market, it could harm our business and could impact market acceptance of our other testing products or promoted therapeutics. Further, our AVISE® CTD consists of various biomarkers, any of which could independently encounter issues with manufacturing, supply or overall quality. If any of the biomarkers in our AVISE® CTD test were to encounter any issues, we may experience an impact in the overall success of AVISE® CTD as a whole, including a reduction in average selling price or overall revenue, until such time as it can be remedied. Moreover, if our testing products and promoted therapeutics do not achieve an adequate level of acceptance by rheumatologists, hospitals, third-party payors or patients, we may not generate sufficient revenue from that testing product or therapeutic and may not become or remain profitable. Our efforts to educate the medical community and third-party payors regarding the benefits of our testing products and promoted therapeutics may require significant resources and may never be successful.

The sizes of the markets for our testing products and promoted therapeutics have not been established with precision, and may be smaller than we estimate.

Our estimates of the annual total addressable markets for our current and potential future testing products and promoted therapeutics are based on a number of internal and third-party estimates. These include, without limitation, the number of patients with autoimmune and autoimmune-related diseases and the assumed prices at which we can sell testing products and our partners can sell therapeutics in markets that have not been established. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. As a result, our estimates of the annual total addressable market for our current and potential future testing products and promoted therapeutics may prove to be incorrect. If the actual number of patients who would benefit from our testing products and promoted therapeutics, the price at which we and our partners can sell future testing products, or the annual total addressable market for our testing products and promoted therapeutics is smaller than we have estimated, it may impair our sales growth and have an adverse impact on our business.

We may expend our limited resources to pursue a particular testing product or promoted therapeutic and fail to capitalize on other testing products or promoted therapeutics that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on specific testing products and promoted therapeutics. As a result, we may forego or delay pursuit of opportunities with others that could have had greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. In addition, our spending on current and future research and development programs for testing products may not yield any commercially viable testing products. If we do not accurately evaluate the commercial potential or target market for a potential testing product or promoted therapeutic, we may forego other similar arrangements which would have been more advantageous for us to pursue.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide.

Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to:

- our ability to successfully market and sell our AVISE® testing products and continue to promote SIMPONI®;
- the extent to which our current testing and future testing products, if any, are eligible for coverage and reimbursement from third-party payors;
- public health crises such as the COVID-19 pandemic;
- the timing and cost of, and level of investment in, research, development, regulatory approval and commercialization activities relating to our testing products, which may change from time to time, and our ability to successfully commercialize new testing products;
- the cost of supplies, equipment and materials used for our testing products and laboratory operations, which may vary depending on the quantity of production and the terms of our agreements with third-party suppliers and manufacturers;
- expenditures that we may incur to acquire, develop or commercialize additional testing products and technologies;
- the level of demand for our testing products and promoted therapeutics, which may vary significantly;
- the receipt, timing and mix of revenue for our testing products and promoted therapeutics;

- future accounting pronouncements or changes in our accounting policies;
- the rate and extent to which payors make an overpayment determination and require us to return all or some portion of payments which we received in a prior period; and
- the timing and success or failure of competing products, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, it could have a material adverse effect on our business, financial condition and results or operations.

We rely on sole suppliers for some of the reagents, equipment and other materials used in our testing products, and we may not be able to find replacements or transition to alternative suppliers.

We rely on sole suppliers for critical supply of reagents, equipment and other materials that we use to perform the tests that comprise our testing products. We also purchase components used in our testing product transportation kits from sole-source suppliers. Some of these items are unique to these suppliers and vendors. While we have developed alternate sourcing strategies for many of these materials and vendors, we cannot be certain whether these strategies will be effective or the alternative sources will be available when we need them. We are not a major customer of some of our suppliers, and these suppliers may therefore give other customers' needs higher priority than ours. If our suppliers can no longer provide us with the materials we need to perform the tests that comprise our testing products, including as a result of the COVID-19 pandemic, if the materials do not meet our quality specifications, or if we cannot obtain acceptable substitute materials, an interruption in test processing could occur and, in certain circumstances, we may be required to amend or cancel test results we have issued. For example, in November 2019, we identified a potential quality issue with reagents for Anti-CarP, a biomarker that can be ordered with our AVISE® CTD test, that was resolved in September 2020. However, if we are unable to remedy future potential quality issues with unique reagent suppliers, or otherwise find a supplier for future biomarkers with issues, we may experience difficulties obtaining market acceptance for our products. Moreover, any issues with quality may result in a change from time to time of the composition of our tests, including our AVISE® CTD test, which could impact the average selling price and revenues received from sales of such test.

In addition, if we should encounter delays or difficulties in securing the quality and quantity of equipment we require for our testing products, we may need to reconfigure our test processes, which could result in an interruption in sales. Any such interruption may significantly affect our future revenue and harm our customer relations and reputation. In addition, in order to mitigate these risks, we may need to maintain inventories of these supplies at higher levels than would be the case if multiple sources of supply were available.

If we are unable to support demand for our current testing products or any of our future testing products or solutions, our business could suffer.

If demand for our testing products or any of our future testing products or solutions grows, we will need to continue to scale our testing capacity and processing technology, expand customer service, billing and systems processes and enhance our internal quality assurance program. We may also need additional certified laboratory scientists and other scientific and technical personnel to process higher volumes of our testing products. We cannot assure you that any increases in scale, related improvements and quality assurance will be successfully implemented or that appropriate personnel will be available. We will also need to purchase additional equipment, some of which can take several months or more to procure, setup and validate, and increase our software and computing capacity to meet increased demand. Failure to implement necessary procedures, transition to new processes, hire the necessary personnel, obtain any necessary additional equipment and increase software and computing capacity could result in higher costs of processing tests or inability to meet demand. There can be no assurance that we will be able to perform our testing on a timely basis at a level consistent with demand, or that our efforts to scale our operations, expand our personnel, equipment, software and computing capacities, or implement process enhancements will be successfully implemented and will not negatively affect the quality of test results. In addition, there can be no assurance that we will have adequate space in our laboratory facility to accommodate such required expansion. We are also currently collaborating with third parties in an effort to implement multiplex technology in our laboratory. We may experience difficulties securing a partner for this technology and integrating such technology into our existing laboratory operations, which could affect our ability to meet demand for our testing

products. If we encounter difficulty meeting market demand or quality standards, our reputation could be harmed and our future prospects and our business could suffer.

If third-party payors do not provide coverage and adequate reimbursement for our testing products, or they breach, rescind or modify their contracts or reimbursement policies or delay payments for our testing products or promoted therapeutics, or if we or our partners are unable to successfully negotiate payor contracts, our commercial success could be compromised.

Successful commercialization of our testing products depends, in large part, on the availability of coverage and adequate reimbursement from third-party payors, including government payors, such as Medicare and Medicaid and private insurers. For the testing products that we develop and commercialize as well as the therapeutics we promote, each third-party payor decides whether to cover the product, the amount it will reimburse for a covered product and the specific conditions for reimbursement.

Reimbursement by third-party payors may depend on a number of factors, including the payor's determination that tests using our technologies are:

- not experimental or investigational;
- medically necessary;
- demonstrated lead to improved patient outcomes;
- appropriate for the specific patient;
- cost-saving or cost-effective;
- supported by peer-reviewed medical journals; and
- included in clinical guidelines.

If we are unable to provide third-party payors with sufficient evidence of the clinical utility and validity of our test, they may not provide coverage, or may provide limited coverage, which will adversely affect our revenue and our ability to succeed. In addition, clinicians may be less likely to order a test unless third-party payors pay a substantial portion of the test price. Therefore, coverage determinations and reimbursement levels and conditions are critical to commercial success, and if we are not able to secure positive coverage determinations and reimbursement levels, our business will be materially adversely affected. Moreover, the COVID-19 pandemic may cause a delay in coverage decisions from Medicare and third-party payors, and have delayed ongoing and planned clinical trials involving our testing products, the occurrence of which may have a material adverse effect on our business.

Third-party payors and other entities also conduct technology assessments of new medical tests and devices and provide and/or sell the results of their assessments to other parties. These assessments may be used by third-party payors and health care providers as grounds to deny coverage for or refuse to use a test or procedure. In addition, third-party payors, have increased their efforts to control the cost, utilization and delivery of healthcare services. These measures have resulted in reduced payment rates and decreased utilization for the diagnostics industry.

Effective April 25, 2012, Palmetto GBA, the Medicare molecular diagnostic services program, or MolDx Program, contractor, assigned the AVISE® MTX assay a unique identifier and determined that the test meets the applicable Medicare coverage criteria to support dose optimization and therapeutic decision making for patients diagnosed with RA on methotrexate. Our current Medicare Administrative Contractor, Noridian Healthcare Solutions, LLC, or Noridian, has adopted this coverage policy. Other third-party payors make their own decisions as to whether to establish a policy to reimburse our testing products, however, and because approvals must be sought on a payor by payor basis, establishing broad coverage is a time-consuming and costly process. There are many third-party payors who have not yet established a coverage policy applicable to our testing products. In addition, several Blue Cross Blue Shield plans and Aetna issued non-coverage policies with respect to AVISE® Lupus, determining that AVISE® Lupus does not meet the medical criteria for coverage and is considered investigational and/or experimental.

While our testing products are reimbursed by a number of third-party payors, we do not currently have contracts with significant private payors. We have in the past, and will likely in the future, experience delays and temporary interruptions in the receipt of payments from third-party payors due to changes in their internal processes, documentation requirements and other issues, which could cause our revenue to fluctuate from period to period.

If we are not successful in reversing existing non-coverage policies, or if other third-party payors issue negative coverage policies, these policies could have a material adverse effect on our business and operations. Even if many third-party payors currently reimburse for our testing products, such payors may withdraw coverage at any time, review and adjust the rate of reimbursement, require co-payments from patients or stop paying for our testing products altogether, any of which would reduce our revenue.

Billing for our testing products is complex, and we must dedicate substantial time and resources to the billing process to be paid for our testing products.

Billing for our testing products is complex, time consuming and expensive. Depending on the billing arrangement and applicable law, we bill various third-party payors, including Medicare and private insurance companies, as well as patients, all of which have different billing requirements. We generally bill third-party payors for our testing products and pursue reimbursement on a case-by-case basis where pricing contracts are not in place. We may also face increased risk in our collection efforts, including long collection cycles and potential delays in claims processing, which could adversely affect our business, results of operations and financial condition.

Several factors contribute to the complexity of the billing process, including:

- differences between the list price for our testing products and the reimbursement rates of third-party payors;
- compliance with complex federal and state regulations related to billing Medicare;
- disputes among third-party payors as to which party is responsible for payment;
- differences in coverage among third-party payors;
- the effect of patient deductibles, co-payments or co-insurance;
- differences in information and billing requirements among third-party payors;
- changes to billing codes used for our testing products;
- risk of government audits related to billing;
- incorrect or missing billing information; and
- the resources required to manage the billing and claims appeals process.

We use standard industry billing codes, known as CPT codes, to bill for our testing products. If these codes were to change, there is a risk of an error being made in the claim adjudication process. Such errors can occur with claims submission, third-party transmission or in the processing of the claim by the payor. Claim adjudication errors may result in a delay in payment processing or a reduction in the amount of the payment received.

As we introduce new testing products, we will need to add new codes to our billing process as well as our financial reporting systems. Failure or delays in effecting these changes in external billing and internal systems and processes could negatively affect our collection rates, revenue and cost of collecting.

Our billing activities require us to implement compliance procedures and oversight, train and monitor our employees, and undertake internal audits to evaluate compliance with applicable laws and regulations as well as internal compliance policies and procedures. When payors deny our claims, in order to obtain reimbursement for services that we provide, we may challenge coverage and payment denials. Payors also conduct external audits to evaluate payments, which add further complexity to the billing process. If the payor makes an overpayment determination, there is a risk that we may be required to return all or some portion of prior payments we have received. Additionally, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, collectively the Affordable Care Act, or ACA, established a requirement for 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.

Additionally, from time to time, third-party payors change processes that may affect timely payment. These changes may result in uneven cash flow or impact the timing of revenue recognized with these payors. With respect to payments received from governmental programs, factors such as a prolonged government shutdown could cause significant regulatory delays or could result in attempts to reduce payments made to us by federal government healthcare programs. In addition, third-party payors may refuse to ultimately make payment if their processes and requirements have not been met on a timely basis. These billing complexities, and the related uncertainty in obtaining payment for our testing products could negatively affect our revenue and cash flow, our ability to achieve profitability, and the consistency and comparability of our results of operations.

In 2020, Noridian posted the calendar year 2021 Medicare Physician Fee Schedule, or MPFS, and Clinical Laboratory Fee Schedule, or CLFS, which establishes the reimbursement rates to be paid by Medicare for our jurisdiction for services performed on or after January 1, 2021. We have estimated that the implementation of these reimbursement rates will not result in a reduction in anticipated reimbursements from Medicare for our AVISE® CTD testing product compared to levels experienced in 2020. On March 27, 2020, the CARES Act included the temporary suspension of Medicare sequestration of 2% during the period beginning on May 1, 2020 and ending on December 31, 2020. The Consolidated Appropriations Act of 2021, signed into law on December 27, 2020, extends the suspension period to March 31, 2021. Revenue from Medicare comprised 20% and 25% of our revenue for the

years ended December 31, 2020 and 2019, respectively. Revenue from the sale of our AVISE® CTD testing products comprised 70% and 82% of our revenue for the years ended December 31, 2020 and 2019, respectively.

We also rely on a third-party provider to provide revenue cycle management software systems for certain processing and collection functions. In the past, we have experienced delays in claims processing as a result of our third-party provider making changes to its invoicing system, as well as not submitting claims to payors within the timeframe required. If claims for our testing products are not submitted to payors on a timely basis, or if we are required to switch to a different systems provider, it could have an adverse effect on our revenue and our business.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

At times, we share our proprietary technology and confidential information, including trade secrets, with third parties that conduct studies and other services on our behalf. We seek to protect our proprietary technology, in part, by entering into confidentiality agreements, consulting agreements or other similar agreements with our advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are intentionally or inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets and despite our efforts to protect our trade secrets, a competitor's discovery of our proprietary technology and confidential information or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business, financial condition, results of operations and prospects.

Significant safety or efficacy issues could arise for our promoted therapeutics, which could have an adverse effect on our revenue and financial condition.

Pharmaceutical products receive regulatory approval based on data obtained in controlled clinical trials of limited duration. Following regulatory approval, these products will be used over longer periods of time in many patients. Investigators may also conduct additional, and perhaps more extensive, studies. If new safety or efficacy issues are reported or if new scientific information becomes available (including results of post-marketing Phase 4 trials), or if governments change standards regarding safety, efficacy or labeling, our partners may be required to amend the conditions of use for a therapeutic. For example, a partner may voluntarily provide or be required to provide updated information on a therapeutics' label or narrow its approved indication, either of which could reduce the therapeutics' market acceptance. If safety or efficacy issues with a partner's therapeutic arise, sales of the therapeutic could be halted by the partner or by regulatory authorities. Safety or efficacy issues affecting suppliers' or competitors' products also may reduce the market acceptance of one of our partner's therapeutics.

New data about a partner's therapeutics, or products similar to a partner's therapeutics, could negatively impact demand for such therapeutics due to real or perceived safety issues or uncertainty regarding efficacy and, in some cases, could result in product withdrawal. Furthermore, new data and information, including information about therapeutic misuse, may lead government agencies, professional societies, practice management groups or organizations involved with various diseases to publish guidelines or recommendations related to the use of such therapeutics or the use of related therapies or place restrictions on sales. Such guidelines or recommendations may lead to lower sales of the applicable therapeutics and reduce our revenue or otherwise adversely affect our business, prospects, results of operations or financial condition.

If we are unable to maintain or expand our sales and marketing force to adequately address our customers' and current or future partners' needs, our business may be adversely affected.

We sell our testing products through our own specialized salesforce and have increased our salesforce in order to achieve the optimal reach and frequency and support our strategy of integrating the promotion of testing products and therapeutics. Our testing products compete in a concentrated specialty market, that of autoimmune and autoimmune-related diseases, and utilizing a specialized salesforce is integral to our integrated testing and therapeutics strategy. As such, we believe it is necessary to maintain a salesforce that includes sales representatives with specific technical backgrounds and industry expertise. For example, we have a salesforce of 53 representatives as of December 31, 2020, and expect to continue to expand our salesforce in 2021. Additional agreements for the promotion of therapeutics may require us to further expand our specialized salesforce. Training of additional sales representatives can be costly and time consuming, particularly given the level of experience and sophistication we seek in our salesforce. In addition, until recently, not all of our sales representatives have promoted therapeutics, including SIMPONI®, as part of our organization, and they will need to complete additional

training in order to effectively promote SIMPONI® and any other therapeutics that we promote through additional agreements. If we are unable to effectively retain, train and integrate additional sales representatives, it may adversely affect our ability to effectively market and sell our testing products. In addition, competition for highly specialized sales personnel is intense, and we may not be able to attract and retain personnel or be able to maintain an efficient and effective sales and marketing force.

Our future sales will depend in large part on our ability to maintain an effective salesforce. If we are unsuccessful in this regard, it could negatively impact our revenue growth and potential profitability.

If we are unable to compete successfully, we may be unable to increase or sustain our revenue or achieve profitability.

Our principal competition for our testing products is traditional methods used by healthcare providers to test patients with CTD-like symptoms. Such traditional methods include testing for a broad range of diagnostic, immunology and chemistry biomarkers, such as anti-nuclear antibodies, or ANA, and anti-double-stranded DNA, or anti-dsDNA, and serum complement biomarkers, such as C3 and C4. We also face competition from commercial laboratories, such as Laboratory Corporation of America Holdings, Quest Diagnostics Incorporated, ARUP Laboratories, Inc. and the Mayo Clinic, all of which have existing infrastructures to support the commercialization of diagnostic services. Large, multispecialty group medical clinics, health systems and academic medical university-based clinics may provide in-house clinical laboratories offering autoimmune and autoimmune-related disease testing services. Additionally, we compete against regional clinical laboratories providing testing in the autoimmune and autoimmune-related disease field, including Rheumatology Diagnostics Laboratories, Inc. (acquired by Laboratory Corporation of America in June 2020). Other potential competitors include companies that might develop diagnostic or disease or drug monitoring products, such as Myriad Genetics, Inc., Progentec Diagnostics Inc., Scipher Medicine Corporation, Genalyte Inc., Oncimmune plc, DxTerity Diagnostics Inc., and Immunovia AB. In the future, we may also face competition from companies developing new products or technologies.

Direct competition for the promotion of SIMPONI® includes all other companies with anti-TNF biologics and the marketing companies supporting their distribution and promotion. These products include HUMIRA® from Abbvie Inc., ENBREL® from Amgen Inc., CIMZIA® from UCB, INFLECTRA® from Pfizer, (biosimilar REMICADE®) and RENFLEXIS® from Merck & Co. (biosimilar REMICADE®). Additionally, we are restricted from promoting any other biologic or Janus kinase inhibitor, or JAK inhibitor, used for treatment of indications covered by the Janssen Agreement without Janssen's consent. Additional competitors include companies with other biologic drugs indicated for RA that have significant sales or sales potential. Specifically, these include ORENCIA® from Bristol-Myers Squibb Company, ACTEMRA® from Roche, RITUXAN® from Roche, XELJANZ® from Pfizer, KEVZARA® from Sanofi S.A., RINVOQ™ from Abbvie Inc. and OLUMIANT® from Eli Lilly and Company. There are also several late-stage RA drug and biosimilar development programs and several additional RA products that have minimal sales to date or that are indicated for other rheumatic indications competitive to SIMPONI® such as psoriatic arthritis and ankylosing spondylitis.

We believe the principal competitive factors in our target market include: quality and strength of clinical and analytical validation data; confidence in diagnostic results; safety and efficacy with respect to promoted therapeutics; sales and marketing capabilities; the extent of reimbursement; inclusion in clinical guidelines; cost-effectiveness; and ease of use.

Many of our potential competitors have widespread brand recognition and substantially greater financial, technical and research and development resources and selling and marketing capabilities than we do. Others may develop products with prices lower than ours that could be viewed by rheumatologists and payors as functionally equivalent to our solution or offer solutions at prices designed to promote market penetration, which could force us to lower the list price of our products and affect our ability to achieve profitability. If we are unable to change clinical practice in a meaningful way or compete successfully against current and future competitors, we may be unable to increase market acceptance and sales of our products, which could prevent us from increasing our revenue or achieving profitability and could cause the market price of our common stock to decline.

To compete successfully we must be able to demonstrate, among other things, that our testing products are accurate and cost effective and that we are effective in promoting therapeutics.

Developing new testing products involves a lengthy and complex process, and we may not be able to commercialize on a timely basis, or at all, other testing products we are developing.

We will continue to devote considerable resources to the research and development of our planned future testing products and enhancements to our current testing products. We may not be able to develop testing products with the clinical utility necessary to be useful and commercially successful. There are certain products for which a

commercial launch would trigger additional payment obligations to licensors of the technology. In these cases, if the economic projections of the product do not outweigh the additional obligations, we may not launch these products. In order to develop and commercialize testing products, we need to:

- expend significant funds to conduct substantial research and development;
- conduct successful validation studies;
- develop and scale our laboratory processes to accommodate different tests;
- achieve and maintain required regulatory certifications;
- develop and scale our infrastructure to be able to analyze increasingly large amounts of data; and
- build the commercial infrastructure to market and sell new testing products.

Our testing product development process involves a high degree of risk and may take several years. Our testing product development efforts may fail for many reasons, including:

- failure to identify additional biomarkers to incorporate into our testing products;
- failure or sub-optimal performance of the testing product at the research or development stage;
- difficulty in accessing archival patient blood specimens, especially specimens with known clinical results; or
- failure of clinical validation studies to support the effectiveness of the test.

Typically, few research and development projects result in commercial products, and success in early clinical studies often is not replicated in later studies. At any point, we may abandon development of a testing product candidate or we may be required to expend considerable resources repeating clinical studies, which would adversely affect the timing for generating potential revenue from a new testing product and our ability to invest in other products in our pipeline. In addition, as we develop testing products, we will have to make significant investments in product development, marketing and selling resources. If a clinical validation study fails to demonstrate the prospectively defined endpoints of the study, we might choose to abandon the development of the testing product or product feature that was the subject of the clinical study, which could harm our business. Additionally, competitors may develop and commercialize competing products or technologies faster than us or at a lower cost.

Developing new testing products and enhancements to our existing technologies is expensive and time consuming, and there is no assurance that such activities will result in significant new marketable testing products, enhancements to our current technologies, design improvements, cost savings, revenue or other expected benefits. If we spend significant resources on research and development and are unable to generate an adequate return on our investment or divert resources away from other, more attractive growth opportunities, our business and results of operations may be materially and adversely affected.

If we cannot enter into new clinical study collaborations, our product development and subsequent commercialization could be delayed.

In the past, we have entered into clinical study collaborations, and our success in the future depends in part on our ability to enter into additional collaborations with highly regarded institutions. This can be difficult due to internal and external constraints placed on these organizations. Some organizations may limit the number of collaborations they have with any one company so as to not be perceived as biased or conflicted. Organizations may also have insufficient administrative and related infrastructure to enable collaborations with many companies at once, which can extend the time it takes to develop, negotiate and implement a collaboration. Additionally, organizations often insist on retaining the rights to publish the clinical data resulting from the collaboration. The publication of clinical data in peer-reviewed medical journals is a crucial step in commercializing and obtaining reimbursement for testing products such as our testing products, and our inability to control when and if results are published may delay or limit our ability to derive sufficient revenue from any solution.

We may acquire businesses or assets, form joint ventures or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.

As part of our business strategy, we may pursue acquisitions of complementary businesses or assets, as well as technology licensing arrangements and other strategic transactions or collaborations with third parties. We also may pursue strategic alliances that leverage our core technology and industry experience to expand our offerings or distribution, make investments in other companies or acquire ownership rights to therapeutics that are synergistic with our testing products. To date, other than our acquisition of the medical diagnostics division of Cypress Bioscience, Inc. in 2010, we have not acquired other companies or therapeutics and, except with respect to certain collaboration agreements executed in connection with our integrated testing and therapeutics strategy, we have

limited experience with respect to the formation of strategic alliances and joint ventures. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions by us also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could harm our operating results. Integration of an acquired company, business or assets also may require management resources that otherwise would be available for ongoing development of our existing business. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance, joint venture or investment.

To finance any acquisitions or investments, we may choose to issue shares of our stock as consideration, which would dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may not be able to acquire other companies for stock. Alternatively, it may be necessary for us to raise additional funds for these activities through public or private financings or through the issuance of debt. Additional funds may not be available on terms that are favorable to us, or at all, and any debt financing may involve covenants limiting or restricting our ability to take certain actions.

Also, the anticipated benefit of any strategic alliance, joint venture or acquisition may not materialize or such strategic alliance, joint venture or acquisition may be prohibited. In addition, our loan agreement restricts our ability to pursue certain mergers, acquisitions, amalgamations or consolidations that we may believe to be in our best interest. Additionally, future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write-offs of goodwill, any of which could harm our financial condition. We cannot predict the number, timing or size of future joint ventures or acquisitions, or the effect that any such transactions might have on our operating results.

The diagnostics and therapeutics industries are subject to rapidly changing technology, which could make our testing products, promoted therapeutics and other testing products we develop obsolete.

Our industry is characterized by rapid technological changes, frequent new product introductions and enhancements and evolving industry standards. These advances require us to continuously develop our technology and work to develop new solutions to keep pace with evolving standards of care. Our testing products could become obsolete unless we continually innovate and expand our testing product offerings to include new clinical applications. If we are unable to develop new testing products or to demonstrate the applicability of our testing products for other diseases, our sales could decline and our competitive position could be harmed. In addition, if our promoted therapeutics become obsolete and we are unable to expand such agreements or find new partners, our sales could decline and our competitive position could be harmed. For example, with respect to SIMPONI® and the treatment of RA, active psoriatic arthritis, or active ankylosing spondylitis, there are many novel therapeutic approaches in development and we expect that the competition in this market will increase dramatically. If new therapeutics make SIMPONI® obsolete or diminish the degree to which rheumatologists prescribe it, our ability to generate revenue under the Janssen Agreement will be harmed.

Our failure to maintain relationships or build new relationships with key opinion leaders could materially adversely impact our business and prospects.

Key opinion leaders are able to influence clinical practice by publishing research and determining whether new tests should be integrated into clinical guidelines. We rely on key opinion leaders early in the development process to help ensure our clinical studies are designed and executed in a way that clearly demonstrates the benefits of our testing products to healthcare providers and payors. Our failure to maintain or build new relationships with such key opinion leaders could affect rheumatologist and patient perception of our testing products and result in a loss of existing and future customers and therefore materially adversely impact our business and prospects.

If we are sued for errors and omissions or professional liability, we could face substantial liabilities that exceed our resources.

The marketing, sale and use of our testing products could lead to liability claims if someone were to allege that any such testing product failed to perform as it was designed. We may also be subject to liability for errors in the results we provide to rheumatologists or for a misunderstanding of, or inappropriate reliance upon, the information we provide. We may also be subject to similar types of claims related to testing products we may develop in the future. Any errors or omissions or professional liability claim could result in substantial damages and be costly and time consuming for us to defend. Although we maintain professional liability insurance, we cannot assure you that our insurance would fully protect us from the financial impact of defending against these types of claims or any judgments, fines or settlement costs arising out of any such claims. Any errors or omissions 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 lawsuit could cause injury to our reputation or cause us to suspend sales of our testing products. Similarly, any product liability lawsuit affecting our partners could also cause injury to our reputation or cause the applicable partner to suspend sales of its therapeutics. We may also initiate a correction or removal for one of our testing products, issue a safety alert or undertake a field action or recall to reduce a risk to health posed by potential failure of our products to perform as designed, which could lead increase costs and lead to increased scrutiny by regulatory authorities and our customers regarding the quality and safety of our testing products and to negative publicity, including safety alerts, press releases or administrative or judicial actions. The occurrence of any of these events could have an adverse effect on our business and results of operations.

The loss of members of our senior management team or our inability to attract and retain highly skilled scientists, technicians and salespeople could adversely affect our business.

Our success depends largely on the skills, experience and performance of key members of our executive management team, including Fortunato Ron Rocca, our President and Chief Executive Officer, and others in key management positions. The efforts of each of these persons will be critical to us as we continue to develop our technologies and test processes and focus on our growth. If we were to lose one or more of these key employees, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategy.

In addition, our research and development programs and commercial laboratory operations depend on our ability to attract and retain highly skilled scientists, including licensed clinical laboratory scientists and biostatisticians. We may not be able to attract or retain qualified scientists and technicians in the future due to the intense competition for qualified personnel among life science businesses, particularly in Southern California. Because it is expected that there will be a shortage of clinical laboratory scientists in coming years, it may become more difficult to hire sufficient numbers of qualified personnel. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified scientific personnel. Additionally, our success depends on our ability to attract and retain qualified and highly-specialized salespeople. We may have difficulties locating, recruiting or retaining qualified salespeople, which could cause a delay or decline in the rate of adoption of our testing products and the sale of promoted therapeutics. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that could adversely affect our ability to support our research and development, clinical laboratory and sales efforts. All of our employees are at-will, which means that either we or the employee may terminate their employment at any time. Other than with respect to Mr. Rocca, we do not carry key man insurance for any of our employees.

If our sole laboratory facility becomes damaged or inoperable, we are required to vacate our existing facility or we are unable to expand our existing facility as needed, we will be unable to perform our testing services and our business will be harmed.

We currently derive all of our revenue from tests conducted at a single laboratory facility located in Vista, California. Vista is situated on or near earthquake fault lines. Our facility and equipment could be harmed or rendered inoperable by natural or man-made disasters, including earthquake, fire, flood, power loss, communications failure or terrorism, or public health crises such as the COVID-19 pandemic. In particular, we store all of our flow cytometers, the instrument we use to detect CB-CAPs on cells, at our Vista facility. If all of our flow cytometers were rendered inoperable simultaneously pursuant to a natural or man-made disaster, we would be unable to perform these key tests as we do in the ordinary course of our business. The inability to perform the tests contained in our testing products or to reduce the backlog of analyses that could develop if our facility is inoperable, for even a short period of time, including as a result of the COVID-19 pandemic, may result in the loss of customers or harm to our reputation, and we may be unable to regain those customers or repair our reputation in the future. Additionally, we store our bio-repository of specimens, which were collected in collaboration with leading academic institutions and help us to further validate our testing products, at our Vista facility. If these specimens were destroyed pursuant to a natural or man-made disaster or otherwise become unavailable, our ability to develop new testing products may be delayed. Furthermore, our facility and the equipment we use to perform our research and development work could be unavailable or costly and time-consuming to repair or replace. It would be difficult, time-consuming and expensive to rebuild our facility or license or transfer our proprietary technology to a third party, particularly in light of the licensure and accreditation requirements for a commercial laboratory like ours. Even in the unlikely event we are able to find a third party with such qualifications to enable us to conduct the tests contained in our testing products, we may be unable to negotiate commercially reasonable terms.

In order to rely on a third party to perform the tests contained in our testing products, we would need to engage another facility with established state licensure and Clinical Laboratory Improvement Amendments of 1988, or CLIA, accreditation under the scope of which tests could be performed following validation and other required procedures.

We cannot assure you that we would be able to find another CLIA-certified facility willing to comply with the required procedures, that any such facility would be willing to perform the tests contained in our testing products for us on commercially reasonable terms, or that it would be able to meet our quality standards.

In order to establish an additional clinical reference laboratory facility, we would have to spend considerable time and money securing adequate space, constructing the facility, recruiting and training employees, and establishing the additional operational and administrative infrastructure necessary to support a second facility. We may not be able, or it may take considerable time, to replicate our testing processes or results in a new facility. Additionally, any new clinical reference laboratory facility opened by us would be subject to certification under CLIA and licensing by several states, including California and New York, which could take a significant amount of time and result in delays in our ability to begin operations.

We believe we have the capacity to meet our projected needs for at least the next 12 months, although we may grow at a rate that is faster than we expect. Beyond this time frame, we may need to further expand our laboratory space. Any future expansion could disrupt laboratory operations, resulting in an inability to meet customer turnaround time expectations, and could be delayed, resulting in slower realization of laboratory efficiencies anticipated from the use of the expanded facilities. Adverse consequences resulting from a delay in the laboratory expansion could harm our relationships with our customers and our reputation, and could affect our ability to generate revenue.

We carry insurance for damage to our property and the disruption of our business, but this insurance may not cover all of the risks associated with damage or disruption to our business, provide coverage in amounts sufficient to cover our potential losses or continue to be available to us on acceptable terms, if at all.

Our testing process involves the use of sophisticated state-of-the-art equipment that requires precise calibration, and issues affecting such equipment may delay delivery or impact the quality of the test results to rheumatologists or otherwise adversely affect our operations.

As part of our process of determining CB-CAPs, which is part of our AVISE® Lupus product, we utilize a number of flow cytometers that require calibration and performance validation according to the requirements of the College of American Pathologists, or CAP, at specified time intervals. While we believe we have implemented appropriate controls and metrics in our laboratory to meet such requirements, we cannot provide any assurance that our instruments will not fall out of specification, in which case we would be required to re-calibrate them. Failure to timely re-calibrate our instruments could negatively impact the test results, which could result in liability and harm our reputation. Patient specimens degrade and become unusable generally within 48 hours of collection. Therefore, if we do not have other sufficient properly functioning flow cytometers due to failure to meet specifications or they otherwise become inoperable, our ability to process patient specimens in the required timeframe would be compromised and our business could be harmed.

Failure in our information technology, telephone or other systems could significantly disrupt our operations and adversely affect our business and financial condition.

Information technology and telephone systems are used extensively in virtually all aspects of our business, including laboratory testing, sales, billing, customer service, logistics and management of medical data. The success of our business depends on the ability to obtain, process, analyze, maintain and manage this data. Our management relies on our information systems because:

- patient specimens must be received, tracked and processed on a timely basis;
- test results must be reported on a timely basis;
- billings and collections for all customers must be managed efficiently and accurately;
- third-party ancillary billing services require proper tracking and reporting;
- pricing and other information related to our services is needed by our salesforce and other personnel in a timely manner to conduct business;
- patient-identifiable health information must be securely held and kept confidential;
- regulatory compliance requires proper tracking and reporting; and
- proper recordkeeping is required for operating our business, managing employee compensation and other personnel matters.

Our business, results of operations and financial condition may be adversely affected if, among other things:

- our information technology, telephone or other systems fail or are interrupted for any extended length of time;

- services relating to our information technology, telephone or other systems are not kept current;
- our information technology, telephone or other systems do not have the capacity to support expanded operations and increased levels of business;
- data is lost or unable to be restored or processed; or
- data is corrupted due to a breach of security.

Despite the precautionary measures we have taken to prevent breakdowns in our information technology, telephone and other systems, sustained or repeated system failures that interrupt our ability to process test orders, deliver test results or perform testing in a timely manner or that cause us to inadvertently disclose or lose patient information could adversely affect our business, results of operations and financial condition.

Security breaches, loss of data and other disruptions to us, our third-party service providers or our partners 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 our reputation.

In the ordinary course of our business, we and our partners, and our respective third-party service providers collect and store sensitive data, such as legally protected health information, including de-identified test reports, personally identifiable information about our patients, credit card information, intellectual property, and our proprietary business and financial information. We manage and maintain our applications and data utilizing a combination of on-site and vendor-owned systems. We face a number of risks related to our protection of, and our service providers' protection of, this critical information, including loss of access, unauthorized disclosure and unauthorized access, as well as risks associated with our ability to identify and audit such events. In addition, we have limited control over the storage of sensitive data by our third-party therapeutics partners as well as risks related to the transfer and sale of de-identified data files to such partners.

The secure processing, storage, maintenance and transmission of this critical information is vital to our operations and business strategy, and we devote significant resources to protecting such 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, may be vulnerable to attacks by hackers or viruses or otherwise breached due to employee error, malfeasance or other activities. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. Additionally, as a result of the COVID-19 pandemic, most of our employees are working remotely, which may increase the risk of security breaches, loss of data, and other disruptions as a consequence of more employees accessing sensitive and critical information from remote locations. Because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. While we do not believe that we have experienced any such attack or breach, if such an event were to occur, our networks would be compromised and the information we store on those networks could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, such as HIPAA, as amended by the HITECH Act, and their implementing regulations and regulatory penalties. Unauthorized access, loss or dissemination could also disrupt our operations, including our ability to process tests, provide test results, bill payors or patients, process claims and appeals, provide customer assistance services, conduct research and development activities, collect, process and prepare company financial information, provide information about our products and other patient and rheumatologist education and outreach efforts through our website and manage the administrative aspects of our business and could damage our reputation, any of which could adversely affect our business.

In addition, the interpretation and application of federal and state consumer, health-related and data protection laws in the United States are often uncertain, contradictory and 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. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices, systems and compliance procedures in a manner adverse to our business. Additionally, in connection with the ongoing COVID-19 pandemic, most of our employees are working remotely, which may increase the risk of security breaches, loss of data, and other disruptions as a consequence of more employees accessing sensitive and critical information from remote locations.

Performance issues, service interruptions or price increases by our shipping carrier could adversely affect our business, results of operations and financial condition, and harm our reputation and ability to provide testing services on a timely basis.

Expedited, reliable shipping is essential to our operations. We have been utilizing both United Parcel Service and Federal Express Corporation for reliable and secure point-to-point transport of patient specimens to our laboratory and enhanced tracking of these patient specimens. Should Federal Express, United Parcel Service, or any other carrier we may use in the future, encounter delivery performance issues such as loss, damage or destruction of a specimen, it may be difficult to replace our patient specimens in a timely manner and such occurrences may damage our reputation and lead to decreased utilization from rheumatologists for our testing services and increased cost and expense to our business. In addition, any significant increase in shipping time or disruption to delivery service, whether due to bad weather, natural disaster, public health epidemics or pandemics (including, for example, the COVID-19 pandemic), terrorist attacks or threats, or for other reasons, could adversely affect our ability to receive and process patient specimens on a timely basis.

If we, Federal Express, or United Parcel Service were to terminate our relationship, we would be required to find another party to provide expedited, reliable point-to-point transport of our patient specimens. There are only a few other providers of such nationwide transport services, and there can be no assurance that we will be able to enter into arrangements with such other providers on acceptable terms, if at all. Finding a new provider of transport services would be time-consuming and costly and result in delays in our ability to provide our testing services. Even if we were to enter into an arrangement with any such provider, there can be no assurance that they will provide the same level of quality in transport services currently provided to us by Federal Express and United Parcel Service. If any new provider does not provide, or if Federal Express or United Parcel Service does not continue to provide, the required quality and reliability of transport services at the same or similar costs, it could adversely affect our business, reputation, results of operations and financial condition.

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

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an “ownership change” (generally defined as a greater than 50 percentage-point change (by value) in its equity ownership by “5-percent shareholders,” as defined in the Code, over a rolling three-year period), the corporation’s ability to use its pre-change net operating loss, or NOL, carryforwards and other pre-change tax attributes to offset its post-change federal taxable income and taxes, as applicable, may be limited. We previously completed a study to assess whether an ownership change, as defined by Section 382 of the Code, had occurred from our formation through December 31, 2019. Based upon this study, we determined that ownership changes had occurred in 2003, 2008, 2012, 2017 and 2019, and that our ability to use a significant portion of our NOL carryforwards is subject to limitation under Section 382 of the Code as a result of a prior ownership change. If we undergo an ownership change as a result of subsequent shifts in our stock ownership, our ability to utilize our NOL carryforwards and other pre-change tax attributes could be further limited by Sections 382 and 383 of the Code. Similar provisions of state tax law may also apply. In addition, federal NOL carryforwards generated in periods after December 31, 2017, may be carried forward indefinitely but, in taxable years beginning after December 31, 2020, may only be used to offset 80% of our taxable income. As a result of the foregoing, if we earn net taxable income, our ability to use NOL carryforwards and other tax attributes to offset taxable income and taxes, as applicable, may be limited.

Recent U.S. tax legislation may materially adversely affect our financial condition, results of operations and cash flows.

Recently enacted U.S. tax legislation, known as the Tax Cuts and Jobs Act of 2017, has significantly changed the U.S. federal income taxation of U.S. corporations, including by reducing the U.S. corporate income tax rate and revising the rules governing NOLs. Many of these changes are effective immediately, without any transition periods or grandfathering for existing transactions. The legislation is unclear in many respects and could be subject to potential amendments and technical corrections, as well as interpretations and implementing regulations by the U.S. Treasury and U.S. Internal Revenue Service, any of which could lessen or increase certain adverse impacts of the legislation. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation, which often uses federal taxable income as a starting point for computing state and local tax liabilities. Based on our current evaluation of this legislation, the reduction of the U.S. corporate income tax rate required a provisional write-down of our deferred income tax assets (including the value of our NOL carryforwards and our tax credit carryforwards).

There may be other material adverse effects resulting from the legislation that we have not yet identified. While some of the changes made by the tax legislation may adversely affect us in one or more reporting periods and

prospectively, other changes may be beneficial on a going forward basis. We continue to work with our tax advisors to determine the full impact that the recent tax legislation as a whole will have on us. We urge our investors to consult with their legal and tax advisors with respect to such legislation and the potential tax consequences of investing in our common stock.

Our term loan contains restrictions that limit our flexibility in operating our business, and if we fail to comply with the covenants and other obligations under our loan agreement, the lenders may be able to accelerate amounts owed under the facility and may foreclose upon the assets securing our obligations.

In September 2017, we entered into the loan and security agreement with Innovatus Life Sciences Lending Fund I, LP, or Innovatus, which we subsequently amended in November 2019, or the Amended Loan Agreement. The Amended Loan Agreement is collateralized by substantially all of our personal property, including our intellectual property. The Amended Loan Agreement also subjects us to certain affirmative and negative covenants, including limitations on our ability to transfer or dispose of assets, merge with or acquire other companies, make investments, pay dividends, incur additional indebtedness and liens and conduct transactions with affiliates. We are also subject to certain covenants that require us to maintain a minimum liquidity of at least $2.0 million and achieve certain minimum amounts of annual revenue, as measured on a rolling twelve-month basis, and are required under certain conditions to make mandatory prepayments of outstanding principal. As a result of these covenants, we have certain limitations on the manner in which we can conduct our business, and we may be restricted from engaging in favorable business activities or financing future operations or capital needs until our current debt obligations are paid in full or we obtain the consent of Innovatus, which we may not be able to obtain. As of December 31, 2020, there was $25.0 million in principal outstanding under the term loan and an additional $1.8 million outstanding representing interest at 2.0% per annum payable in-kind by adding the amount to the outstanding principal balance of the term loans. Under the Amended Loan Agreement, we are required to repay any outstanding principal and capitalized interest in monthly installments over a two-year period commencing on December 1, 2022. Our revenues for the twelve-month period ended September 30, 2020 were lower than the specified targets in the Amended Loan Agreement, and as a result, we and Innovatus agreed on a new management plan and target to bring us back into compliance with the Amended Loan Agreement. At December 31, 2020, we were in compliance with all covenants of the Amended Loan Agreement. We cannot be certain that we will be able to generate sufficient cash flow or revenue to meet the financial covenants or pay the principal and accrued interest on our debt.

In addition, upon the occurrence of an event of default, Innovatus, among other things, can declare all indebtedness due and payable immediately, which would adversely impact our liquidity and reduce the availability of our cash flows to fund working capital needs, capital expenditures and other general corporate purposes. An event of default includes, but is not limited to, our failure to pay any amount due and payable under the Amended Loan Agreement, the occurrence of a material adverse change in our business as defined in the Amended Loan Agreement, our breach of any representation or warranty in the Amended Loan Agreement, our breach of any covenant in the Amended Loan Agreement (subject to a cure period in some cases), a change in control as defined in the Amended Loan Agreement, our default on any debt payments to a third party in an amount exceeding $500,000 or any voluntary or involuntary insolvency proceeding. If an event of default occurs and we are unable to repay amounts due under the Amended Loan Agreement, Innovatus could foreclose on substantially all of our personal property, including our intellectual property. We cannot be certain that future working capital, borrowings or equity financings will be available to repay or refinance our debt to Innovatus or any other debt we may incur in the future.

We may require substantial additional capital to finance our planned operations, which may not be available to us on acceptable terms or at all. Our failure to obtain additional financing when needed on acceptable terms, or at all, could force us to delay, limit, reduce or eliminate our product development programs, commercialization efforts or other operations.

We expect capital expenditures and operating expenses to increase over the next several years as we expand our infrastructure, commercial operations and research and development activities. We believe, based on our current plan, that our current cash and cash equivalents and anticipated future revenue, will be sufficient to meet our anticipated cash requirements for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our operating plans and other demands on our cash resources may change as a result of many factors currently unknown to us, including as a result of the COVID-19 pandemic, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other sources, such as strategic collaborations. If our available cash balances and anticipated future revenue are insufficient to satisfy our liquidity requirements, including because of lower demand for our testing products or promoted therapeutics or lower-than-expected rates of reimbursement from commercial third-party payors and government payors, or other risks described in this “Risk Factors” section, we may seek to raise additional capital through equity offerings, debt financings, collaborations or licensing arrangements. In the case of the incurrence of further indebtedness, the Amended Loan Agreement, subject to

certain customary exceptions, restricts our ability to incur additional indebtedness or encumber any of our property without the prior consent of Innovatus. Under the Amended Loan Agreement, we are required to make monthly interest payments at a rate equal to 8.5% (provided that 2.0% of the 8.5% is payable in-kind by adding the amount to the outstanding principal balance of the term loans). We may also consider raising additional capital in the future to expand our business, pursue strategic investments, take advantage of financing opportunities, or for other reasons. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. The timing and amounts of our future capital requirements are difficult to forecast and will depend on numerous factors, including: our ability to maintain and grow sales of our testing products, as well as the costs associated with conducting clinical studies to demonstrate the utility of our testing products and support reimbursement efforts; our ability to successfully promote therapeutics; fluctuations in working capital; the costs to expand our sales and marketing capabilities; the costs of developing our product pipeline, including the costs associated with conducting our ongoing and future validation studies; the additional costs we may incur as a result of operating as a public company and the extent to which we in-license, acquire or invest in complementary businesses or products.

Additional funding may not be available to us on acceptable terms, or at all. If we raise funds by issuing equity securities, dilution to our stockholders could result, and the market price of our common stock could decline. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock. The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights, and other operating restrictions that could adversely affect our ability to conduct our business. In addition, our Amended Loan Agreement restricts our ability to incur additional indebtedness or encumber any of our property without the prior consent of Innovatus, subject to certain exceptions. In the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms. These agreements may require that we relinquish or license to a third party on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves, or reserve certain opportunities for future potential arrangements when we might be able to achieve more favorable terms. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more research and development programs or selling and marketing initiatives. In addition, we may have to work with a partner on one or more of our testing products, promoted therapeutics or market development programs, which could lower the economic value of those programs to our company.

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

We currently market our in vitro diagnostic testing products in the United States as LDTs. LDTs are in vitro diagnostic tests that are intended for clinical use and are designed, manufactured, and used within a single laboratory. Although LDTs are classified as medical devices and the FDA has statutory authority to ensure that medical devices are safe and effective for their intended uses, the FDA has historically exercised enforcement discretion and has not enforced certain applicable FDA requirements, including premarket review, with respect to LDTs. Moreover, in August 2020, the U.S. Department of Health and Human Services, or HHS, announced that FDA will not require premarket review of LDTs absent notice-and-comment rulemaking.

Legislative and administrative proposals proposing to amend the 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, the FDA could modify its current approach to LDTs in a way that would subject our tests that we market as LDTs to the enforcement of additional regulatory requirements. In recent years, the FDA has stated its intention to modify its enforcement discretion policy with respect to LDTs. Specifically, on July 31, 2014, the FDA notified Congress of its intent to modify, in a risk-based manner, its policy of enforcement discretion with respect to LDTs. On October 3, 2014, the FDA issued two draft guidance documents 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),” or the Reporting Guidance. The FDA halted finalization of the guidance in November 2016 to allow for further public discussion on an appropriate oversight approach to LDTs and to give congressional authorizing committees the opportunity to develop a legislative solution, and FDA issued a discussion paper on possible approaches to LDT regulation in January 2017.

In addition, the FDA and Congress have, for over the past decade, considered a number of proposals to end the FDA's enforcement discretion policy for LDTs and subject LDTs to additional regulatory requirements. For example, Congress has recently been working on legislation to create an LDT and in vitro diagnostic regulatory framework for all in vitro clinical tests, or IVCTs, that would be separate and distinct from the existing medical device regulatory framework. In March 2020, members of the U.S. House of Representatives formally introduced the VALID Act (Verifying Accurate Leading-edge IVCT Development Act of 2020) in the House and an identical version of the bill was introduced in the U.S. Senate. If passed in its current form, the VALID Act would create a new category of medical products separate from medical devices called "in vitro clinical tests," or IVCTs, and bring all such products within the scope of FDA's oversight. As proposed, the bill grandfathers many existing tests from the proposed premarket approval, quality systems, and labeling requirements, but would require such tests to comply with other regulatory requirements (for example, registration and notification, adverse event reporting). The bill also provides for IVCTs introduced before the effective date (drafted to be approximately four years after the enactment date) to be transitional and remain on the market subject to certain conditions. It is unclear whether the VALID Act or any other legislative proposals would be passed by Congress or signed into law by the President. Depending on the approach adopted under any legislation, certain LDTs (likely those of higher risk) could become subject to some form of premarket review, potentially with a transition period for compliance and a grandfathering provision.

Even if the FDA does not modify its policy of enforcement discretion, whether due to changes in FDA policy or legislative action, the FDA may disagree that we are marketing our LDTs within the scope of its policy of enforcement discretion and may impose significant regulatory requirements, including the requirement for premarket review and clearance or approval. We may also be required to conduct clinical studies to support our currently marketed products or planned product launches.

If we are required to conduct such clinical trials, delays in the commencement or completion of clinical testing could significantly increase our test development costs and delay commercialization of any currently-marketed tests that we may be required to cease selling or the commercialization of any future tests that we may develop. Many of the factors that may cause or lead to a delay in the commencement or completion of clinical trials may also ultimately lead to delay or denial of regulatory clearance or approval. The commencement of clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites and the eligibility criteria for the clinical trial.

We may find it necessary to engage contract research organizations to perform data collection and analysis and other aspects of our clinical trials, which might increase the cost and complexity of our trials. We may also depend on clinical investigators, medical institutions and contract research organizations to perform the trials, and would control only certain aspects of their activities. Nevertheless, we would be responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on these third-parties would not relieve us of our regulatory responsibilities.

When conducting clinical trials, we and our third-party contractors are required to comply with good clinical practices, or GCPs, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the EEA, and comparable foreign regulatory authorities for products in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any third-party contractor fails to comply with applicable GCPs, the clinical data generated in clinical trials may be deemed unreliable and the FDA, Competent Authorities of the Member States of the EEA or comparable foreign regulatory authorities may require us to perform additional clinical trials before clearing or approving our marketing applications. A failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory clearance or approval process. In addition, if these parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality, completeness or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or for other reasons, our clinical trials may have to be extended, delayed or terminated. Many of these factors would be beyond our control. We may not be able to enter into replacement arrangements without undue delays or considerable expenditures. If there are delays in testing or clearances or approvals as a result of the failure to perform by third-parties, our research and development costs would increase, and we may not be able to obtain regulatory clearance or approval for our testing products. In addition, we may not be able to establish or maintain relationships with these parties on favorable terms, if at all. Each of these outcomes would harm our ability to market our testing products, or to achieve sustained profitability.

The FDA requires medical device manufacturers to comply with, among other things, current good manufacturing practices for medical devices, known as the Quality System Regulation, which requires manufacturers to follow elaborate design, testing, control, documentation and other quality assurance procedures during the manufacturing process; the medical device reporting regulation, which requires 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 it were to recur; labeling regulations, including the FDA's general prohibition against promoting products for unapproved or "off-label" uses; and the reports of corrections and removals regulation, which requires manufacturers to report to the FDA if a device correction or removal was initiated to reduce a risk to health posed by the device or to remedy a violation of the FDCA caused by the device which may present a risk to health.

Even if we were able to obtain FDA clearance or approval for one or more of our testing products, if required, a testing product may be subject to limitations on the indications for which it may be marketed or to other regulatory conditions. In addition, such clearance or approval may contain requirements for costly post-market testing and surveillance to monitor the safety or efficacy of the product.

The FDA has broad post-market enforcement powers, and if unanticipated problems with our testing products arise, or if we or our suppliers fail to comply with regulatory requirements following FDA clearance or approval, we may become subject to enforcement actions such as:

- adverse publicity, warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recalls, termination of distribution, administrative detention or seizures of our testing products;
- operating restrictions, partial suspension or total shutdown of production;
- customer notifications or repair, replacement or refunds;
- refusing our requests for 510(k) clearance or PMA approvals or foreign regulatory approvals of new testing products, new intended uses or modifications to existing testing products;
- withdrawals of current 510(k) clearances or PMAs or foreign regulatory approvals, resulting in prohibitions on sales of our testing products;
- FDA refusal to issue certificates to foreign governments needed to export testing products for sale in other countries; and
- criminal prosecution.

Any of these sanctions could also result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, results of operations and financial condition.

In addition, the FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approvals. For example, the results of the 2020 U.S. Presidential Election may impact our business and industry. Namely, the Trump administration took several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict whether or how these orders will be implemented, or whether they will be rescinded and replaced under the Biden administration. The policies and priorities of the new administration are unknown and could materially impact the regulations governing our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

Risks Related to Regulatory and Compliance Matters

Healthcare policy and payment changes may have a material adverse effect on our financial condition and results of operations.

Reimbursement to healthcare providers, such as specialized diagnostic service providers like us, is subject to continuing change in policies by third-party payors including governmental payors, such as Medicare and Medicaid, private insurers and other private payors, such as hospitals and private medical groups. Statutory and regulatory changes, retroactive rate adjustments and administrative rulings, and other policy changes may be implemented with little or no prior notice, all of which could materially decrease the range of services for which we are reimbursed or the reimbursement rates paid for our testing products.

On April 1, 2014, the Protecting Access to Medicare Act of 2014, or PAMA, was signed into law, which, among other things, implemented a new payment system for clinical laboratory tests reimbursed under the CLFS. Under the law, clinical laboratories must report laboratory test payment data for each Medicare-covered clinical diagnostic lab test that it furnishes. The reported data must include the payment rate and the volume of each test that was paid by each private third-party payor. Laboratories that fail to report the required payment information may be subject to

substantial civil monetary penalties. We bill Medicare for our testing products, and therefore we are subject to reporting requirements under PAMA.

The PAMA ruling issued on June 17, 2016 included data for reporting for the new PAMA process began in 2017, and in 2018, the Medicare payment rate for each clinical diagnostic lab test, with some exceptions, equaled the weighted median of the reported private third-party payor payment for the test, as calculated using data collected by applicable laboratories during the data collection period and reported to the Centers for Medicare and Medicaid Services, or CMS, during a specified data reporting period. At the beginning of 2020, these revisions to the CLFS have altered payment rates for clinical diagnostic lab tests under the CLFS, the estimated reduction in Medicare reimbursement rate for AVISE® CTD of 7.3% compared to levels experienced in 2019. Effective March 2020, as a result of our change in the composition of our AVISE® CTD test, the estimated reduction to the Medicare reimbursement rate for AVISE® CTD was 5.3% compared to levels experienced in 2019. We do not expect the revisions to the CLFS to impact Medicare reimbursement rate for AVISE® CTD in 2021 compared to levels experienced in 2020. On March 27, 2020, the CARES Act delayed the next reporting period until 2022 resulting in a 0% reduction for 2021, and the 15% reduction limits would apply in 2022-2024. We cannot be sure how revisions to the CLFS will affect reimbursement rates in the future.

Other laws make changes impacting clinical laboratories, many of which have already gone into effect. The ACA, enacted in March 2010, among other things, include provisions regarding the coordination and promotion of research on comparative clinical effectiveness of different technologies and procedures, initiatives to revise Medicare payment methodologies, such as bundling of payments across the continuum of care by providers and physicians, and initiatives to promote quality indicators in payment methodologies.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. 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 Tax Cuts and Jobs Act of 2017 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 U.S. Court of Appeals for the 5th Circuit upheld the District Court’s decision that the individual mandate was unconstitutional but remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing the case, although it remains unclear how the Supreme Court will rule. It is also unclear how other efforts, if any, to challenge, repeal or replace the ACA will impact the ACA or our business. Further, it is possible that additional governmental action be taken in response to the COVID-19 pandemic. We are monitoring the impact of the ACA in order to enable us to determine the trends and changes that may be necessitated by the legislation and that, in turn, may potentially impact our business over time.

Additionally, the Budget Control Act of 2011, among other things, resulted in aggregate reductions to Medicare payments to providers of 2% per fiscal year, beginning April 1, 2013, and due to additional legislative amendments to the statute, these reductions will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021, unless additional congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Some of our flow cytometry tests are reimbursed by the Medicare program under the MPFS. On April 16, 2015, President Obama signed the Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, which, among other actions, repealed the previous statutory formula by which CMS established annual updates to MPFS rates. MACRA created the Merit-Based Incentive Payment System which, beginning in 2019, more closely aligns physician payments with composite performance on performance metrics similar to three existing incentive programs (i.e., the Physician Quality Reporting System, the Value-based modifier program and the Electronic Health Record Meaningful Use program) and incentivizes physicians to enroll in alternative payment methods. At this time, we do not know whether these changes to the physician payment systems will have any impact on orders or payments for our testing products.

Medicare payments are significant to our business, not only because approximately 23% and 25% of the total payments we received from payors for the years ended December 31, 2020 and 2019, respectively, were derived from the Medicare program, but also because other payors often use the MPFS and CLFS amounts as a benchmark to develop their payment rates. We cannot predict whether Medicare and other third-party payor reimbursement rates that mirror Medicare’s will be sufficient to make our testing products commercially attractive.

In addition, some third-party payors have implemented, or are in the process of implementing, laboratory benefit management programs, often using third-party benefit managers to manage these programs. The stated goals of these programs are to help improve the quality of outpatient laboratory services, support evidence-based guidelines

for patient care and lower costs. The impact on laboratories, such as ours, of active laboratory benefit management by third parties is unclear, and we expect that it could have a negative impact on our revenue in the short term. It is possible that third-party payors will resist reimbursement for testing products that we offer in favor of less expensive tests, may require pre-approval for our testing products or may impose additional pricing pressure on and substantial administrative burden for reimbursement for our testing products.

Product pricing by companies is currently, and is expected to continue to be, under close scrutiny. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and patient programs, and reform government program reimbursement methodologies for products. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures.

We also cannot predict whether future healthcare initiatives will be implemented at the federal or state level or in countries outside of the United States in which we may do business in the future, or the effect any future legislation or regulation will have on us, including any initiatives implemented by the new Biden administration. Although we cannot predict the full effect of the recent legislative changes discussed above, cost reduction measures, the expansion in government's role in the U.S. healthcare industry and PAMA's changes to the reimbursement methodology under the CLFS, such changes individually or in the aggregate may result in decreased profits to us and/or lower reimbursement by third-party payors for our testing products, which may adversely affect our business, financial condition and results of operations.

Complying with numerous regulations pertaining to our business is an expensive and time-consuming process, and any failure to comply could result in substantial penalties.

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 mandate specific standards in the areas of personnel qualifications, administration, and participation in proficiency testing, patient test management, quality control, quality assurance and inspections. We have a current certificate of accreditation under CLIA to perform testing through our accreditation by CAP. To renew this certificate, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may make random inspections of our clinical reference laboratory.

Although we are required to hold a certificate of accreditation or compliance under CLIA that allows us to perform high complexity testing, we are not required to hold a certificate of accreditation through CAP. We could alternatively maintain a certificate of accreditation from another accrediting organization or a certificate of compliance through inspection by surveyors acting on behalf of the CLIA program. If our accreditation under CAP were to terminate, either voluntarily or involuntarily, we would need to convert our certification under CLIA to a certificate of compliance (or to a certificate of accreditation with another accreditation organization) in order to maintain our ability to perform clinical testing and to continue commercial operations. Whether we would be able to successfully maintain operations through either of these alternatives would depend upon the facts and circumstances surrounding termination of our CAP accreditation, such as whether any deficiencies were identified by CAP as the basis for termination and, if so, whether these were addressed to the satisfaction of the surveyors for the CLIA program (or another accrediting organization).

The failure to comply with CLIA requirements can result in enforcement actions, including the revocation, suspension, or limitation of our CLIA certificate of accreditation, as well as a directed plan of correction, state on-site monitoring, civil money penalties, civil injunctive suit and/or criminal penalties. We must maintain CLIA compliance and certification to be eligible to bill for tests provided to Medicare beneficiaries. If we were to be found out of compliance with CLIA program requirements and subjected to sanctions, our business and reputation could be harmed. Even if it were possible for us to bring our laboratory back into compliance, we could incur significant expenses and potentially lose revenue in doing so.

We are also required to maintain a license to conduct testing in California. California laws establish standards for day-to-day operation of our clinical reference laboratory, including the training and skills required of personnel and quality control. In addition, our clinical reference laboratory is licensed on a product-specific basis by New York as an out of state laboratory and our testing products, as LDTs, must be approved by the New York Department of Health, or NYDOH, on a product-by-product basis before they are offered in New York. We are also be subject to periodic inspection by the NYDOH and required to demonstrate ongoing compliance with NYDOH regulations and standards. To the extent NYDOH identified any non-compliance and we are unable to implement satisfactory corrective actions to remedy such non-compliance, the State of New York could withdraw approval for our testing

products. 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. Moreover, several other states require that we hold licenses to test specimens from patients in those states. Other states may have similar requirements or may adopt similar requirements in the future. Although we have obtained licenses from states where we believe we are required to be licensed, 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 currently have such requirements or will have such requirements in the future.

If we were to lose our CLIA accreditation or California license, whether as a result of a revocation, suspension or limitation, we would no longer be able to sell our testing products, which would limit our revenue and harm our business. If we were to lose our license or fail to obtain or maintain NYDOH approval for our laboratory developed tests in New York or if we were to lose our license in other states where we are required to hold licenses, we would not be able to test specimens from those states which would limit our revenue.

If we fail to comply with healthcare laws and regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

We and our partners, including those with whom we may enter into co-promotion or co-marketing arrangements, are also subject to healthcare fraud and abuse regulation by both the federal government and the states in which we or our partners conduct our business. These laws include, without limitation, state and federal anti-kickback, self-referral, fraud and abuse, false claims, and physician sunshine laws and regulations.

The Federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any good, facility, item or service, including laboratory services, reimbursable, in whole or in part, under Medicare, Medicaid or other federally financed healthcare programs. The term “remuneration” has been broadly interpreted to include anything of value. The Federal Anti-Kickback Statute has been interpreted to apply to arrangements between manufacturers on one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor, however, does not make the conduct per se illegal under the Federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Several courts have interpreted the statute’s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the Federal Anti-Kickback Statute has been violated. Further, 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 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 false claims laws.

On June 25, 2014, the Office of Inspector General of the Department of Health and Human Services, or the OIG, released a Special Fraud Alert, expressing concern regarding laboratory payments made to referring physicians and physician group practices for blood specimen collection, processing, and packaging. Specifically, the OIG expressed concern that such arrangements may implicate the Federal Anti-Kickback Statute when laboratories make payments to physicians for services that are already covered and reimbursed by Medicare, or are not commercially reasonable or exceed fair market value, all in order to induce physicians to order tests from such laboratory. Because the choice of laboratory and the decision to order laboratory tests is made or strongly influenced by the physician, with little or no input from patients, such payment may induce physicians to order more laboratory tests than are medically necessary, particularly when the payments are tied to, or take into account, the volume or value of business generated by the physician. We had entered into certain arrangements with physicians for services related to specimen collection, transporting and handling. Effective August 2015, we terminated all such agreements. To date, no regulatory authorities have contacted us regarding these arrangements. To the extent our prior arrangements are found to be inconsistent with applicable laws, we may be subject to significant penalties, including criminal penalties, and exclusion from participation in U.S. federal or state health care programs.

The Federal civil and criminal false claims law, including the False Claims Act, prohibit, among other things, any person from knowingly presenting or causing to be presented a false claim for payment to the federal government, or knowingly making or causing to be made a false statement to get a false or fraudulent claim paid by the federal government. A claim includes “any request or demand” for money or property presented to the U.S. government. In addition, private individuals have the ability to bring actions under these false claims laws in the name of the

government alleging false and fraudulent claims presented to or paid by the government (or other violations of the statutes) and to share in any amounts paid by the entity to the government in fines or settlement. Such suits, known as qui tam actions, have increased significantly in the healthcare industry in recent years. In addition, the federal civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. The majority of states also have statutes or regulations similar to the federal anti-kickback and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

We are also subject to the federal physician self-referral prohibitions, commonly known as the Stark Law, which prohibits, among other things, physicians who have a financial relationship, including an investment, ownership or compensation relationship with an entity, from referring Medicare patients for designated health services, which include clinical laboratory services, unless an exception applies. Similarly, entities may not bill Medicare or any other party for services furnished pursuant to a prohibited referral. In addition, the government may assert that a claim including items or services resulting from a violation of the Stark Law constitutes a false or fraudulent claim for purposes of the false claims laws. Many states have their own self-referral laws as well, which in some cases apply to all third-party payors, not just Medicare and Medicaid.

In addition, under the federal civil monetary penalties statute, a person is prohibited from offering or transferring to a Medicare or Medicaid beneficiary any remuneration, including waivers of co-payments and deductible amounts (or any part thereof), that the person 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. Moreover, in certain cases, providers who routinely waive copayments and deductibles for Medicare and Medicaid beneficiaries can also be held liable under the Federal Anti-Kickback Statute and civil False Claims Act. One of the statutory exceptions to the prohibition is non-routine, unadvertised waivers of copayments or deductible amounts based on individualized determinations of financial need or exhaustion of reasonable collection efforts. The OIG emphasizes, however, that this exception should only be used occasionally to address special financial needs of a particular patient. Although this prohibition applies only to federal healthcare program beneficiaries, the routine waivers of copayments and deductibles offered to patients covered by commercial payors may implicate applicable state laws related to, among other things, unlawful schemes to defraud, excessive fees for services, tortious interference with patient contracts and statutory or common law fraud. To the extent our patient assistance programs are found to be inconsistent with applicable laws, we may be required to restructure or discontinue such programs, or be subject to other significant penalties.

The ACA, among other things, also imposed new reporting requirements on manufacturers of certain devices, drugs and biologics for certain payments and transfers of value by them and in some cases their distributors to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other health care providers beginning in 2022, and teaching hospitals, as well as ownership and investment interests held by physicians (as defined by the statute) and their immediate family members. Manufacturers must submit reports by the 90th day of each calendar year. Because we manufacture our own LDTs solely for use by or within our own laboratory, we believe that we are exempt from these reporting requirements. We cannot assure you, however, that our 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, prospects, results of operations or financial condition.

It is possible that some of our business activities could be subject to challenge under one or more of such laws, including our promotion of SIMPONI®, which is subject to restriction of off-label use discussions. Such a challenge, regardless of the outcome, could have a material adverse effect on our business, business relationships, reputation, financial condition and results of operations. Although an effective compliance program can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with these laws may prove costly. If we or our operations, or any of the rheumatologists or entities with whom we do business are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to significant penalties, including administrative, civil and/or criminal penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in U.S. federal or state health care programs, such as Medicare and Medicaid in the U.S. and similar programs outside the U.S., a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could materially adversely affect our ability to operate our business and our financial results. To the extent that any of our testing products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-

marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

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

Failure to comply with HIPAA, the HITECH Act, their implementing regulations, and similar comparable state laws and regulations affecting the transmission, security and privacy of health information could result in significant penalties.

Numerous federal, state and foreign laws and regulations, including HIPAA and the HITECH Act, govern the collection, dissemination, disclosure, security, use and confidentiality of individually identifiable health informationhealth-related and other personal information. HIPAA and the HITECH Act require us to comply with standards for the use and disclosure of individually identifiable health information, or PHI, within our company and with third-parties. The privacy, security and breach notification rules promulgated under HIPAA, as amended by the HITECH Act, Standards for Privacy of Individually Identifiable Health Information, or Privacy Standards, and the Security Standards for the Protection of Electronic Protected Health Information, or Security Standards, under HIPAA establish a set of basic national privacy and security standards for the protection of individually identifiable health information 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. HIPAA requires covered entities, such as us, to develop and maintain policies and procedures with respect to individually identifiable health information that is used or disclosed, including the adoption of administrative, physical and technical safeguards to protect such information. HIPAA also requires us to provide individuals with certain rights with respect to their PHI. If we engage a business associate to help us carry out health care activities and functions, we must have a written business associate contract or other arrangement with the business associate that establishes specifically what the business associate has been engaged to do and requires the business associate to comply with the requirements of HIPAA. Further, in the event of a breach of unsecured PHI we must notify each individual whose PHI is breached as well as federal regulators and in some cases, must publicize the breach in local or national media.

Notably, whereas HIPAA previously directly regulated only these covered entities, the HITECH Act, which was signed into law as part of the stimulus package in February 2009, made certain of the Security Standards directly applicable to business associates. Further, the HITECH Act and the Final HIPAA Omnibus Rule that was promulgated in 2013, made additional parts of HIPAA directly applicable to business associates. As a result, both covered entities and business associates are now subject to significant civil and criminal penalties for failure to comply with the Privacy Standards and/or the Security Standards.

HIPAA and the HITECH Act also include standards for common healthcare electronic transactions and code sets, such as claims information, plan eligibility, payment information and the use of electronic signatures, and privacy and electronic security of individually identifiable health information. Covered entities, such as certain health care providers, are required to conform to such transaction set standards, known as the Standards for Electronic Transactions, pursuant to HIPAA.

In the conduct of our business, we process, maintain, and transmit sensitive data, including PHI. There can be no assurance that a breach of privacy or security will not occur. If there is a breach, we could be subject to various lawsuits, penalties, and damages and may be required to incur costs to mitigate the impact of the breach on affected individuals.

Penalties for failure to comply with a requirement of HIPAA vary significantly depending on the nature of violation and could include 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.

HIPAA requires covered entities to develop and maintain policies and procedures with respect to individually identifiable health information that is used or disclosed, including the adoption of administrative, physical and technical safeguards to protect such information. The HITECH Act expands the notification requirement for breaches of individually identifiable health information, restricts certain disclosures and sales of individually identifiable health information and provides a tiered system for civil monetary penalties for HIPAA violations. The Final HIPAA Omnibus Rule modifies the breach reporting standard in a manner that will likely make more data

security incidents qualify as reportable breaches. The HITECH Act also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney fees and costs associated with pursuing federal civil actions.

Additionally, certain states have adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. For example, the California Consumer Privacy Act, or the CCPA, which went into effect on January 1, 2020, gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. 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. Further, the CPRA recently passed in California, which will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

In Europe, the GDPR went into effect in May 2018 and imposes strict requirements for processing the personal data of individuals within the EEA. 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. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EU and the United States remains uncertain. For example, in 2016, the EU and United States agreed to a transfer framework for data transferred from the EU to the United States, called the Privacy Shield, but the Privacy Shield was invalidated in July 2020 by the Court of Justice of the European Union. Further, from January 1, 2021, companies have to comply with the GDPR and also the United Kingdom GDPR, or the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, i.e., fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, and it is unclear how United Kingdom data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the United Kingdom will be regulated in the long term. Currently there is a four to six-month grace period agreed in the EU and United Kingdom Trade and Cooperation Agreement, ending June 30, 2021 at the latest, whilst the parties discuss an adequacy decision. However, it is not clear whether (and when) an adequacy decision may be granted by the European Commission enabling data transfers from EU member states to the United Kingdom long term without additional measures. These changes may lead to additional costs and increase our overall risk exposure.

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, 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.

Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future growth may depend, in part, on our ability to develop and commercialize our testing products and promote therapeutics in foreign markets. We are not permitted to market or promote any of our testing products or promote therapeutics before we or our partners receive regulatory approval from applicable regulatory authorities in foreign markets, and we or they may never receive such regulatory approvals for any of our testing products or promoted therapeutics. To obtain separate regulatory approval in many other countries, parties must comply with numerous and varying regulatory requirements regarding safety and efficacy and governing, among other things, clinical trials, commercial sales, pricing and distribution of our testing products. If we or our partners obtain regulatory approval of our testing products and promoted therapeutics, and ultimately commercialize our testing

products or promoted therapeutics in foreign markets, we would be subject to additional risks and uncertainties, including:

- different regulatory requirements for approval of drugs in foreign countries;
- reduced protection for intellectual property rights;
- the existence of additional third-party patent rights of potential relevance to our business;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- foreign reimbursement, pricing and insurance regimes;
- workforce uncertainty in countries where labor unrest is common;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

Risks Related to our Intellectual Property

If we are unable to maintain intellectual property protection our competitive position could be harmed.

Our ability to protect our technologies such as CB-CAPs and methotrexate polyglutamates, or MTXPGs, affects our ability to compete and to achieve sustained profitability. We rely on a combination of U.S. and foreign patents and patent applications, copyrights, trademarks and trademark applications, and contractual restrictions to protect our intellectual property rights. We cannot be certain that the claims in our granted patents and pending patent applications covering our AVISE® testing products will be considered patentable or enforceable by the United States Patent and Trademark Office, or the USPTO, courts in the United States, or by patent offices and courts in foreign countries. If we fail to protect our intellectual property, third parties may be able to compete more effectively against us and we may incur substantial litigation costs in our attempts to recover or restrict use of our intellectual property.

We apply for patents covering our testing products and technologies and uses thereof, as we deem appropriate, however we may fail to apply for patents on important testing products and technologies in a timely fashion or at all, or we may fail to apply for patents in potentially relevant jurisdictions, or we may cease our prosecution and maintenance of patents in potentially relevant jurisdictions. Currently, we own or have an exclusive license to 13 issued U.S. patents, and certain corresponding foreign counterpart patents, relevant to our AVISE® testing products. We also own one issued U.S. patent, two pending U.S. patent applications, a pending PCT patent application, a pending U.S. provisional patent application, and certain corresponding foreign counterpart patents and patent applications relevant to our AVISE® testing products. While we intend to pursue additional patent applications, it is possible that our pending patent applications and any future applications may not result in issued patents. Even if such patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful opposition to our patents could deprive us of exclusive rights necessary for the further development of our AVISE® testing products. Furthermore, even if they are unchallenged, our patents may not adequately protect our intellectual property, provide exclusivity for our AVISE® testing products or prevent others from designing around our claims.

We might not have been the first to make the inventions covered by each of our pending patent applications and we might not have been the first to file patent applications for these inventions. To determine the priority of these inventions, we may have to participate in interference proceedings, derivation proceedings or other post-grant proceedings declared by the USPTO that could result in substantial cost to us. No assurance can be given that our patent applications will have priority over other patent applications. In addition, recent changes to the patent laws of the United States allow for various post-grant opposition proceedings that have not been extensively tested, and their outcome is therefore uncertain. Furthermore, if third parties bring these proceedings against our patents, we could experience significant costs and management distraction.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our AVISE® testing products and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. While we use commercially reasonable efforts to protect our trade secrets, our licensors,

employees, consultants, contractors and other advisors may unintentionally or willfully disclose such trade secret information to third parties and competitors. We attempt to protect our proprietary technology in large part by entering into confidentiality and non-disclosure agreements with our employees, consultants and other contractors. We cannot assure you, however, that these agreements will not be breached, that we will have adequate remedies for any breach or that competitors will not know of, or independently discover, our trade secrets. We cannot assure you that others will not independently develop substantially equivalent proprietary information or be issued patents that may prevent the sale of our testing products, technologies, services or know-how or require licensing and the payment of significant fees or royalties by us in order to produce our testing products, technologies or services. Further, we cannot be certain that the steps we have taken will prevent the misappropriation of our trade secrets and other confidential information.

Monitoring unauthorized disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate. If we were to enforce a claim that a third party had illegally obtained and was using our trade secrets, it would be expensive and time consuming, and the outcome would be unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets. If we are unable to prevent unauthorized material disclosure of our trade secrets and other confidential information to third parties, and in particular in jurisdictions where we have not filed for patent protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

Certain of our testing products utilize unpatented technology that is publicly available and can be used by our competitors.

Certain of our AVISE® testing products, such as AVISE® CTD, utilize both patented technology and publicly available technology that is not protected by patents or other intellectual property rights. We believe that using certain publicly available technology allows us to offer a better and more comprehensive testing product. However, the publicly available technology which we rely upon is also used in, and may continue to be used in, products which compete with our AVISE® testing products. Our competitors may independently develop competing diagnostic products and services that do not infringe our intellectual property.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our AVISE® testing products.

Our success is heavily dependent on intellectual property, particularly on obtaining and enforcing patents. Obtaining and enforcing patents in the diagnostics industry involves both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. The United States has enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. We may not develop additional proprietary products, methods and technologies that are patentable.

Some of our intellectual property has been discovered through government funded programs and thus may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights, and limit our ability to contract with non-U.S. manufacturers.

Some of the intellectual property rights we have acquired or licensed or may acquire or license in the future may have been generated through the use of U.S. government funding and may therefore be subject to certain federal regulations. For example, some of the research and development work related to our CB-CAPs technology was funded by government research grants. As a result, the U.S. government may have certain rights to intellectual property embodied in our testing products pursuant to the Bayh-Dole Act of 1980, or Bayh-Dole Act. These U.S. government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). The U.S. government also has the right

to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. industry may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. To the extent any of our future intellectual property is also generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our AVISE® testing products in all countries throughout the world would be prohibitively expensive. Moreover, we believe that obtaining foreign patents may be more difficult than obtaining domestic patents because of differences in patent laws and, accordingly, our patent position may be stronger in the United States than abroad. In addition, the laws of some foreign countries do not protect intellectual property rights in the same manner and to the same extent as laws in the United States. Various countries limit the subject matter that can be patented and limit the ability of a patent owner to enforce patents in the medical and other related fields. This may limit our ability to obtain or utilize those patents internationally. In order to manage our foreign patent costs and focus on the U.S. market, we made the decision to cease the prosecution and maintenance of certain of our foreign patents and patent applications related to our CB-CAPs technology, which is used in our AVISE® testing products. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection but enforcement of such patent protection is not as strong as that in the United States. These products may compete with our AVISE® testing products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

The patent protection and patent prosecution for some of our testing products may be dependent on third parties.

We or our licensors may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we or our licensors, whether current or future, fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our licensors are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

As a licensee of third parties, we rely on third parties to file and prosecute patent applications and maintain patents and otherwise protect the licensed intellectual property under some of our license agreements. We have not had and do not have primary control over these activities for certain of our patents or patent applications and other

intellectual property rights. We cannot be certain that such activities by third parties have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. Pursuant to the terms of the license agreements with some of our licensors, the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents and even if we are permitted to pursue such enforcement or defense, we will require the cooperation of our licensors. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it may permit other parties to compete with us. If any of our licensors or any of our future licensors or future collaborators fail to appropriately prosecute and maintain patent protection for patents covering any of our testing products, our ability to develop and commercialize those testing products may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products.

In addition, even where we have the right to control patent prosecution of patents and patent applications we have acquired or licensed from third parties, we may still be adversely affected or prejudiced by actions or inactions of our predecessors or licensors and their counsel that took place prior to us assuming control over patent prosecution.

Our technology acquired or licensed from various third parties may be subject to retained rights. Our predecessors or licensors often retain certain rights under their agreements with us, including the right to use the underlying technology for noncommercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our predecessors or licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

If we are limited in our ability to utilize acquired or licensed technologies, or if we lose our rights to critical in-licensed technology, we may be unable to successfully develop, out-license, market and sell our testing products, which could adversely affect our business. Our business strategy depends on the successful development of licensed and acquired technologies into commercial products. Therefore, any limitations on our ability to utilize these technologies may impair our ability to develop, out-license or market and sell our testing products.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We are a party to a number of license agreements under which we are granted intellectual property rights that are important to our business. For example, certain patent rights related to AVISE® Lupus are licensed from the University of Pittsburgh, certain patent rights related to AVISE® MTX are licensed from Prometheus. Our existing license agreements as related to our AVISE® testing products impose various regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations. If we fail to comply with our obligations under a license agreement, the license agreement may be terminated, in which event we would not be able to further develop or market certain AVISE® testing products. Additionally, we may not always have the first right to maintain, enforce or defend our licensed intellectual property rights and, although we would likely have the right to assume the maintenance, enforcement and defense of such intellectual property rights if our licensors do not, our ability to do so may be compromised by our licensors' acts or omissions.

Licensing of intellectual property rights is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property rights subject to a license agreement, including the scope of rights granted under the license agreement and other interpretation-related issues, and whether and the extent to which our technology and processes infringe on intellectual property rights of the licensor that are not subject to the licensing agreement. If disputes over intellectual property rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, our business, results of operations, financial condition and prospects may be adversely affected. We may enter into additional licenses in the future and if we fail to comply with obligations under those agreements, we could suffer adverse consequences.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent process. Periodic maintenance fees,

renewal fees, annuity fees and various other governmental fees on any issued patents and/or applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patents and/or applications. Our outside counsel has systems in place to monitor deadlines to pay these fees and to remind us of these fees, and our outside counsel employs an outside firm to pay these fees due to the USPTO and to foreign patent agencies based on our instructions. In the aggregate, these fees can be cost prohibitive for an early-stage company. Accordingly, we made a financially-driven decision to prioritize our payment of these fees and to allow certain of our applications to lapse, particularly with respect to our ex-U.S. rights licensed from the University of Pittsburgh related to our CB-CAPs technology. The permanent lapse of certain of these ex-U.S. rights may result in our patent position being stronger in the United States than abroad, such as in countries that are part of the European Patent Convention, and third parties may be able to compete more effectively against us in countries outside the United States, including in those countries that belong to the European Patent Convention. Additionally, while an inadvertent lapse may sometimes be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market earlier than should otherwise have been the case, which would have a material adverse effect on our business.

We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses.

Presently we have intellectual property rights, through licenses from third parties and under patents that we own, related to our AVISE® testing products. Because our programs may involve additional products that require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights. We may be unable to acquire or in-license proprietary rights that we identify as being necessary for our AVISE® testing products, and our partner may be unable to acquire any necessary rights for our promoted therapeutics. Even if we are able to obtain a license to such proprietary rights, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

The licensing and acquisition of third-party proprietary rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party proprietary rights that we may consider necessary or attractive in order to further develop our AVISE® testing products or our partners consider necessary or attractive in order to promote their therapeutic. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us, either on reasonable terms, or at all. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment, or at all. If we or our partner are unable to successfully obtain rights to required third-party intellectual property rights on commercially reasonable terms, our ability to further develop our AVISE® testing products and promote therapeutics, and our business, financial condition and prospects for growth could suffer.

Third-party claims alleging intellectual property infringement may prevent or delay our development efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patents and other intellectual property rights in the diagnostics industry, as well as administrative proceedings for challenging patents, including interference and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. The Leahy-Smith America Invents Act introduced new procedures including inter partes review and post grant review. The implementation of these procedures bring the possibility of third-party challenges to our patents and the outcome of such challenges could result in a loss or narrowing of our patent rights. In such an event, our competitors might be able to enter the market earlier than should otherwise have been the case, which would have a material adverse effect on our business. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our AVISE® testing products. As the diagnostics industry expands and more patents are issued, the risk increases that our activities related to our AVISE® testing products may give rise to claims of infringement of the patent rights of others.

We cannot assure you that any of our current or future AVISE® testing products will not infringe existing or future patents. Although we are not aware of any issued patents that will prevent us from marketing our AVISE® testing products, there may be third-party patents of which we are currently unaware with claims to materials or methods of

manufacture related to the use or manufacture of our AVISE® testing products. If a third party that owns such a patent asserts it successfully against one of our current or future AVISE® testing products, we may be unable to market our product, which could materially harm our business and because patent applications can take many years to issue and may be confidential for 18 months or more after filing, there may be currently pending third-party patent applications which may later result in issued patents that our AVISE® testing products or our technologies may infringe, or which such third parties claim are infringed by the use of our technologies.

Parties making claims against us for infringement or misappropriation of their intellectual property rights may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop one or more of our AVISE® testing products. Defense of these claims, regardless of their merit, would involve substantial expenses and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees if we are found to be willfully infringing a third party's patents, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or development of our AVISE® testing products. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop our AVISE® testing products, which could harm our business significantly. Even if we were able to obtain a license, the rights may be nonexclusive, which may give our competitors access to the same intellectual property.

In addition to infringement claims against us, if third parties have prepared and filed patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference proceedings in the USPTO to determine the priority of invention. Third parties may also attempt to initiate reexamination, post grant review or inter partes review of our patents in the USPTO. We may also become involved in similar proceedings in the patent offices in other jurisdictions regarding our intellectual property rights with respect to our AVISE® testing products and technology.

We may be involved in proceedings to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Third parties may infringe, misappropriate or otherwise violate our existing patents, patents that may issue to us in the future, or the patents of our licensors that are licensed to us. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

In addition, if we or one of our licensors initiated legal proceedings against a third party to enforce a patent covering one of our AVISE® testing products, the defendant could counterclaim that the patent covering such AVISE® testing product is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Such proceedings could result in an invalidation of our patents. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our AVISE® testing products. Such a loss of patent protection could have a material adverse impact on our business.

Litigation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our patents or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders. We are not aware of any third-party

infringement of our intellectual property rights that would have a materially adverse impact on our business. In addition, there can be no assurance that our licensors will be willing to bring and enforce claims to prevent third parties from infringing intellectual property that is licensed to us, particularly if the affected intellectual property is less important to the licensor's business than to ours. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

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

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other companies in our industry. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise improperly used or disclosed confidential information of these third parties or our employees' former employers. Further, we may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our AVISE® testing products. We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging our right to and use of confidential and proprietary information. If we fail in defending any such claims, in addition to paying monetary damages, we may lose our rights therein. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

Risks Related to Our Common Stock

Our stock price may be volatile, and you may not be able to sell shares of our common stock at or above the price you paid.

The public trading price for our common stock is affected by a number of factors, including:

- actual or anticipated variations in our and our competitors' financial condition and results of operations;
- announcements by us or our competitors of new products, strategic partnerships or capital commitments;
- changes in reimbursement by current or potential third-party payors;
- issuance of new securities analysts' reports or changed recommendations for our stock;
- actual or anticipated changes in regulatory oversight of our testing products;
- developments or disputes concerning our intellectual property or other proprietary rights;
- commencement of, or our involvement in, litigation;
- announced or completed acquisitions of businesses or technologies by us or our competitors;
- any major change in our management;
- changes in accounting principles;
- announcement or expectation of additional financing efforts;
- future sales of our common stock by our executive officers, directors and other stockholders; and
- general economic conditions and slow or negative growth of our markets, including as a result of the COVID-19 pandemic.

In addition, the stock market in general, and the market for stock of life sciences companies in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors, as well as general economic, political and market conditions such as recessions or interest rate changes, may seriously affect the market price of our common stock, regardless of our actual operating performance. As a result of this volatility, you may not realize any return on your investment in us and may lose some or all of your investment.

In addition, in the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources. Any adverse determination in any such litigation or any amounts paid to settle any such actual or threatened litigation could require that we make significant payments.

Future sales of shares by existing stockholders could cause our stock price 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 significantly reduce the trading price of our common stock and impair our ability to raise adequate capital through the sale of additional equity securities.

In addition, our directors and executive officers may establish programmed selling plans under Rule 10b5-1 of the Exchange Act for the purpose of effecting sales of our common stock. Any sales of securities by directors and executive officers, or the perception that those sales may occur, including the entry into such programmed selling plans, could have a material adverse effect on the trading price of our common stock.

In addition, the holders of 5,167,230 shares of common stock and holders of warrants to purchase 426,827 shares of common stock are entitled to rights with respect to registration of such shares under the Securities Act pursuant to an investors' rights agreement between such holders and us. If such holders, by exercising their registration rights, sell a large number of shares, they could adversely affect the market price for our common stock. If we file a registration statement for the purpose of selling additional shares to raise capital and are required to include shares held by these holders pursuant to the exercise of their registration rights, our ability to raise capital may be impaired.

Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could significantly reduce the value of our shares to a potential acquiror or delay or prevent changes in control or changes in our management without the consent of our board of directors. The provisions in our charter documents include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors, unless the board of directors grants such right to the stockholders, to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- the required approval of at least 66-2/3% of the shares entitled to vote to remove a director for cause, and the prohibition on removal of directors without cause;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- the ability of our board of directors to alter our amended and restated bylaws without obtaining stockholder approval;
- the required approval of at least 66-2/3% of the shares entitled to vote to adopt, amend or repeal our amended and restated bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- an exclusive forum provision providing that the Court of Chancery of the State of Delaware will be the exclusive forum for certain actions and proceedings;
- the requirement that a special meeting of stockholders may be called only by the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

We are also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

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

Our amended and restated certificate of incorporation provide that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation, or any action asserting a claim against us that is governed by the internal affairs doctrine; provided, that, this provision would not apply to suits brought to enforce a duty or liability created by Securities Act or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. To the extent that any such claims may be based upon federal law claims, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. By agreeing to this provision, however, the stockholders will not be deemed to have waived our compliance with the Federal Securities laws and rules and regulations thereunder. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. If a court were to find the choice of forum provisions in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

Our executive officers, directors and principal stockholders, if they choose to act together, have the ability to control or significantly influence all matters submitted to stockholders for approval.

As of December 31, 2020, our executive officers, directors and greater than 5% stockholders, in the aggregate, own approximately 74% of our outstanding capital stock. As a result, such persons, acting together, have the ability to control or significantly influence all matters submitted to our stockholders for approval, including the election and removal of directors and approval of any significant transaction, as well as our management and business affairs. This concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders.

We have never paid dividends on our capital stock, and we do not anticipate paying dividends in the foreseeable future. Your ability to achieve a return on your investment will depend on appreciation, if any, in the price of our common stock.

We have never declared or paid any cash dividends on our common stock and do not intend to pay any cash dividends in the foreseeable future. We currently intend to retain any future earnings to fund the growth of our business. In addition, our Amended Loan Agreement restricts our ability to pay cash dividends on our common stock and we may also enter into credit agreements or other borrowing arrangements in the future that will restrict our ability to declare or pay cash dividends on our common stock. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for the foreseeable future.

An active, liquid trading market for our common stock may not be maintained

Prior to our IPO, there had been no public market for our common stock. Our common stock only recently began trading on the Nasdaq Global Market, or Nasdaq, but we can provide no assurance that we will be able to develop and sustain an active trading market for our common stock. Even if an active trading market is developed, it may not be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses or technologies using our shares as consideration, which, in turn, could materially adversely affect our business.

General Risk Factors

Our failure to meet the continued listing requirements of the Nasdaq Global Market, or Nasdaq, could result in a delisting of our common stock.

If we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with Nasdaq's listing requirements.

If securities or industry analysts issue an adverse opinion regarding our stock or do not publish research or reports about our company, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that equity research analysts publish about us and our business. Currently, we have limited analyst coverage and we do not have any control over such analysts or the content and opinions included in their reports. Securities analysts may elect not to provide research coverage of our company, and such lack of research coverage may adversely affect the market price of our common stock. The price of our common stock could also decline if one or more equity research analysts downgrade our common stock or if those analysts issue other unfavorable commentary or cease publishing reports about us or our business. If one or more equity research analysts cease coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline.

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

We are an emerging growth company, as defined in the JOBS Act, and may remain an emerging growth company until the last day of the fiscal year following the fifth anniversary of the completion of our initial public offering, or IPO. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenue exceeds $1.07 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim condensed financial statements, with correspondingly reduced "Management's discussion and analysis of financial condition and results of operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; 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 whether investors will find our common stock less attractive if we 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 reduced or more volatile. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, therefore, we may not be subject to the same implementation timing for new or revised accounting standards as other public companies that are not emerging growth companies, which may make comparison of our financials 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 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 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.

We incur significant costs as a result of operating as a public company, and our management will be required to devote substantial time to compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses. We are subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, Sarbanes-Oxley, as well as rules subsequently adopted by the Securities and Exchange Commission, or the SEC, and Nasdaq to implement provisions of Sarbanes-Oxley, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the SEC has adopted additional rules and regulations in these areas, such as mandatory “say on pay” voting requirements that will apply to us when we cease to be an emerging growth company. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our testing products or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

Pursuant to Section 404 of Sarbanes-Oxley, our management will be required to report upon the effectiveness of our internal control over financial reporting beginning with the annual report for our fiscal year ending December 31, 2020. When we lose our status as an “emerging growth company” and reach an accelerated filer threshold, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we are in process of upgrading our information technology systems; implement additional financial and management controls, reporting systems and procedures; and hire additional accounting and finance staff. If we or, if required, our auditors are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begin its Section 404 reviews, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

If we use hazardous materials in a manner that causes contamination or injury, we could be liable for resulting damages.

We are subject to federal, state and local laws, rules and regulations governing the use, discharge, storage, handling and disposal of biological material, chemicals and waste. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, remediation costs and any related penalties or fines, and any liability could exceed our resources or any applicable insurance coverage we may have. The cost of compliance with these laws and regulations may become significant, and our failure to comply may result in substantial fines or other consequences, either of which could negatively affect our operating results.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. We rely on third-party manufacturers to produce our testing products. Our ability to obtain clinical supplies of our testing products could be disrupted if the operations of these suppliers were affected by a man-made or natural disaster or other business interruption. In addition, our corporate headquarters is located in Vista, California near major earthquake faults and fire zones, and the ultimate impact on us of being located near major earthquake faults and fire zones and being consolidated in a certain geographical area is unknown. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our testing products outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

Our corporate headquarters are located in Vista, California, where we lease approximately 27,000 square feet of office and laboratory space under a lease that expires in 2026, with an option to extend a portion of the lease for an additional five-year period.

We also lease an additional approximately 19,500 square feet office space in Vista, California, under a lease that is co-terminus with our other lease expiring in 2026, with an option to extend the lease for an additional five-year period. We believe that our current facilities are adequate for our current needs and that suitable additional alternative spaces will be available in the future on commercially reasonable terms, if required.

Item 3. Legal Proceedings

We are currently not a party to any material legal proceedings. From time to time, we may be involved in legal proceedings or subject to claims incident to the ordinary course of business. Regardless of the outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained.

Items 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 began trading on The Nasdaq Global Market on September 19, 2019 under the symbol "XGN." Prior to September 19, 2019, there was no public market for our common stock.

Holders of Record

As of March 12, 2021, there were approximately 47 stockholders of record of our common stock. This number was derived from our shareholder records and does not include beneficial owners of our common stock whose shares are held in "street" name with various dealers, clearing agencies, banks, brokers and other fiduciaries.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We intend to retain future earnings, if any, to finance the operation of our business and do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to dividend policy will be made at the discretion of our board of directors after considering our financial condition, results of operations, capital requirements, business prospects and other factors the board of directors deems relevant, and subject to the restrictions contained in any future financing instruments. In addition, our ability to pay cash dividends is currently prohibited by the terms of our Amended Loan Agreement.

Securities Authorized for Issuance under Equity Compensation Plans

See Part III, Item 12 of this Annual Report under the section titled "Security Ownership of Certain Beneficial Owners and Management" for information about our equity compensation plans which is incorporated by reference herein.

Performance Graph

Not applicable.

Recent Sales of Unregistered Securities

None.

Use of Proceeds

On September 18, 2019, the SEC declared effective our registration statement on Form S-1 (File No. 333-233446), as amended, filed in connection with our IPO. At the closing of the offering on September 23, 2019, we issued and sold 4,140,00 shares of our common stock at the initial public offering price to the public of $14.00 per share, which included the exercise in full of the underwriters' option to purchase additional shares. We received gross proceeds from the IPO of $58.0 million, before deducting underwriting discounts, commissions and other offering expenses, which resulted in net proceeds of approximately $50.4 million and offering-related transaction costs of approximately $7.5 million. Cowen and Company, LLC, Cantor Fitzgerald & Co. and William Blair & Company, L.L.C. acted as joint book-running managers for the offering. No offering expenses were paid or are payable, directly or indirectly, to our directors or officers, to persons owning 10% or more of any class of our equity securities or to any of our affiliates.

As of December 31, 2020, we have used approximately $16.8 million of the proceeds from our IPO primarily related to selling and marketing activities. There has been no material change in the planned use of such proceeds from that described in the final prospectus filed by us with the SEC on September 20, 2019.

Purchases of Equity Securities by the Issuer

None.

Item 6. Selected Financial Data

The following tables set forth our selected historical financial data as of, and for the periods ended on, the dates indicated. We have derived the selected statements of operations data for the years ended December 31, 2020 and 2019 and the balance sheet data as of December 31, 2020 and 2019 from our audited financial statements included elsewhere in this Annual Report on Form 10-K. We have derived the selected statements of operations data for the years ended December 31, 2018 and 2017 and the balance sheet data as of December 31, 2018 and 2017 from our audited financial statements not included in this Annual Report on Form 10-K. You should read this data together with our audited financial statements and the related notes included elsewhere in this Annual Report on Form 10-K and the section of this prospectus entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations." Our historical results for any prior period are not necessarily indicative of our future results.

	Years Ended December 31,			
(in thousands, except share and per share data)	**2020**	**2019**	**2018**	**2017**
Statements of Operations Data:				
Revenue	$ 41,975	$ 40,387	$ 32,440	$ 26,807
Operating expenses:				
Costs of revenue (excluding amortization of purchased technology)	16,559	18,808	15,379	14,137
Selling, general and administrative expenses	37,033	28,702	19,675	18,820
Research and development expenses	3,568	2,176	2,125	1,551
Amortization of intangible assets	—	—	141	186
Change in fair value of acquisition-related liabilities	—	—	—	(51)
Total operating expenses	57,160	49,686	37,320	34,643
Loss from operations	(15,185)	(9,299)	(4,880)	(7,836)
Interest expense	(2,565)	(3,491)	(2,868)	(2,948)
Loss on extinguishment of share purchase rights and 2013 Term Loan	—	—	—	(6,050)
Change in fair value of financial instruments	—	267	(318)	(9,391)
Other income, net	984	510	112	45
Loss before income taxes	(16,766)	(12,013)	(7,954)	(26,180)
Income tax benefit (expense)	79	(25)	(58)	549
Net loss	(16,687)	(12,038)	(8,012)	(25,631)
Accretion of redeemable convertible preferred stock	—	(4,640)	(9,318)	(5,353)
Deemed dividend recorded in connection with financing transactions	—	(13,601)	(1,152)	(1,790)
Net loss attributable to common stockholders	$ (16,687)	$ (30,279)	$ (18,482)	$ (32,774)
Net loss per share, basic and diluted	$ (1.32)	$ (8.46)	$ (293.34)	$ (520.18)
Weighted-average number of shares used to compute net loss per share, basic and diluted	12,632,780	3,578,771	63,005	63,005

(in thousands)	December 31, 2020	2019	2018	2017
Balance Sheet Data:				
Cash and cash equivalents	$ 57,448	$ 72,084	$ 13,164	$ 11,241
Working capital (1)	61,746	75,355	12,360	8,270
Total assets	78,375	88,310	28,887	20,390
Borrowings, non-current portion, net of discounts and debt issuance costs	26,659	25,854	24,617	18,809
Capital lease obligations, including current portion	884	874	360	108
Redeemable convertible preferred stock warrant liabilities	—	—	1,503	896
Redeemable convertible preferred stock	—	—	105,232	92,046
Total stockholders' equity (deficit)	41,839	55,659	(111,966)	(96,684)

(1) We define working capital as current assets less current liabilities. See our audited financial statements and the related notes included elsewhere in this Annual Report on Form 10-K for further details regarding our current assets and current liabilities.

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

You should read the following discussion of our financial condition and results of operations in conjunction with the financial statements and the notes thereto included elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business and financial performance, includes forward-looking statements that are based on current beliefs, plans and expectations and involve risks, uncertainties and assumptions. You should read the "Special note regarding forward-looking statements" and "Risk Factors" section of this Annual Report on Form 10-K for a discussion of important factors that could cause our actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are dedicated to transforming the care continuum for patients suffering from debilitating and chronic autoimmune diseases by enabling timely differential diagnosis and optimizing therapeutic intervention. We have developed and are commercializing a portfolio of innovative testing products under our AVISE® brand, several of which are based on our proprietary CB-CAPs technology. Our goal is to enable rheumatologists to improve care for patients through the differential diagnosis, prognosis and monitoring of complex autoimmune and autoimmune-related diseases, including SLE and RA. Our strategy includes leveraging our portfolio of testing products to market therapeutics through our sales channel, targeting the approximately 5,000 rheumatologists across the United States. Our business model of integrating testing products and therapeutics positions us to offer targeted solutions to rheumatologists and, ultimately, better serve patients.

We currently market 10 testing products under our AVISE® brand that allow for the differential diagnosis, prognosis and monitoring of complex autoimmune and autoimmune-related diseases. Our lead testing product, AVISE® CTD, enables differential diagnosis for patients presenting with symptoms indicative of a wide variety of CTDs and other related diseases with overlapping symptoms. We commercially launched AVISE® CTD in 2012 and revenue from this product comprised 70% and 82% of our revenue for the years ended December 31, 2020 and 2019, respectively. There is an unmet need for rheumatologists to add clarity in their CTD clinical evaluation, and we believe there is a significant opportunity for our tests that enable the differential diagnosis of these diseases, particularly for potentially life-threatening diseases such as SLE.

We are leveraging our portfolio of testing products to establish partnerships with leading pharmaceutical companies, academic research centers and patient advocacy organizations. In December 2018 we entered into the Janssen Agreement to exclusively promote SIMPONI® in order to advance our integrated testing and therapeutics strategy and we began direct promotion of SIMPONI® in January 2019. Our SIMPONI® promotion efforts contributed approximately $5.1 million and $1.5 million in revenue for the years ended December 31, 2020 and 2019, respectively, with our quarterly tiered promotion fee based on the incremental increase in total prescribed units above a predetermined average baseline. See "-Janssen Promotion Agreement" below for additional terms of the agreement. We also have agreements with GSK, Covance Inc. and Parexel, among others, that leverage our testing products and/or the information generated from such tests. We provide GSK, a leader in lupus therapeutics, our test result data to provide market insight into and help increase awareness of the benefits of early and accurate diagnosis of SLE and lupus nephritis, and monitoring disease activity. We partner with academic research centers and patient advocacy organizations, such as Brigham and Women's Hospital, Hospital for Special Surgery, and Duke University as well as the Lupus Foundation of America, to help improve the quality of life for people affected by autoimmune diseases through programs of research, education, support and advocacy. We plan to pursue additional strategic partnerships that are synergistic with our evolving portfolio of testing products.

We perform all of our AVISE® tests in our approximately 8,000 square foot clinical laboratory, which is certified by CLIA and accredited by CAP, and located in Vista, California. Our laboratory is certified for performance of high-complexity testing by CMS in accordance with CLIA. We are approved to offer our products in all 50 states. Our clinical laboratory reports all AVISE® testing product results within five business days. In the fourth quarter of 2020, we completed the build-out of approximately 2,000 additional square feet to our clinical laboratory.

We market our AVISE® testing products using our specialized salesforce. Unlike many diagnostic salesforces that are trained only to understand the comparative benefits of their tests, the specialized backgrounds of our salesforce coupled with our comprehensive training enables our sales representatives to interpret results from our de-identified patient test reports and provide unique insights in a highly tailored discussion with rheumatologists. Our integrated testing and therapeutics strategy results in a unique opportunity to promote and sell targeted therapies in patient focused sales calls with rheumatologists, including those with whom we have a longstanding relationship and history using our portfolio of testing products.

Reimbursement for our testing services comes from several sources, including commercial third-party payors, such as insurance companies and health maintenance organizations, government payors, such as Medicare, and patients. Reimbursement rates vary by product and payor. We continue to focus on expanding coverage among existing contracted rheumatologists and to achieve coverage with commercial payors, laboratory benefit managers and evidence review organizations.

Since inception we have devoted substantially all our efforts developing and marketing products for the diagnosis, prognosis and monitoring of autoimmune diseases. Although our revenue has increased sequentially year over year, we have never been profitable and, as of December 31, 2020 we had an accumulated deficit of $181.3 million. We incurred net losses of $16.7 million and $12.0 million for the years ended December 31, 2020 and 2019, respectively. We expect to continue to incur operating losses in the near term as our operating expenses will increase to support the growth of our business, as well as additional costs associated with being a public company. We have funded our operations primarily through equity and debt financings and revenue from sales of our products. Through the date of our initial public offering (IPO) in September 2019, our operations were financed primarily from sales of our common and redeemable convertible preferred stock and borrowings under various debt financings. In September 2019, we completed our IPO of 4,140,000 shares of our common stock at a price to the public of $14.00 per share, including the exercise in full by the underwriters of their option to purchase 540,000 additional shares of our common stock. Including the option exercise, the aggregate net proceeds to us from the offering was approximately $50.4 million, net of underwriting discounts, commissions and other offering expenses, for aggregate expenses of approximately $7.5 million. As of December 31, 2020, we had $57.4 million of cash and cash equivalents.

Impact of COVID-19

The current COVID-19 worldwide pandemic has presented substantial public health challenges and is affecting our employees, patients, physicians and other healthcare providers, communities and business operations, as well as the U.S. and global economies and financial markets. International and U.S. governmental authorities in impacted regions are taking actions in an effort to slow the spread of COVID-19, including issuing varying forms of "stay-at-home" orders, restricting business functions outside of one's home, restricting gatherings, restricting travel, and mandating social distancing and face coverings. Certain jurisdictions have begun re-opening only to return to restrictions due to increases in new COVID-19 cases. Even in areas where "stay-at-home" restrictions have been lifted and the number of COVID-19 cases have declined, many individuals remain cautious about resuming activities such as preventative-care medical visits. As a result of COVID-19 related limitations and reordering of priorities across the U.S. healthcare system, a reduction in patient flow occurred and our test volumes began to decrease in the second half of March 2020. We experienced an AVISE® CTD volume decrease of approximately 5% in the year ended December 31, 2020 as compared to 2019. By the end of the third quarter of 2020, the number of AVISE® CTD tests delivered substantially recovered to pre-COVID-19 AVISE® CTD tests reported in the first quarter of 2020, and in the fourth quarter of 2020, the number of AVISE® CTD delivered exceeded our pre-COVID-19 AVISE® CTD tests reported in the first quarter of 2020. For the three months ended December 31, 2020 as compared to the same period in 2019, we experienced a AVISE® CTD volume increase of approximately 5%. However, the continued spread of COVID-19 may adversely affect testing volumes in future periods, the extent of which is highly uncertain.

In addition, we believe there are several other important factors that have impacted, and that we expect will impact our operating performance and results of operations, including shutdowns of our facilities and operations as well as those of our suppliers and courier services, disruptions to the supply chain of material needed for our tests, our sales and commercialization activities and our ability to receive specimens and perform or deliver the results from our tests, delays in reimbursement and coverage decisions from Medicare and third-party payors and in interactions with regulatory authorities, as well as our inability to achieve volume-based pricing discounts with our key suppliers and absorb fixed laboratory expenses. For example, we have experienced delays in patient enrollment for ongoing and planned clinical studies involving our tests, which may delay or prevent launch of future test products. We have also experienced delays in procurement of our testing supplies due to the resurgence of varying forms of "stay-at-home" orders in the fourth quarter of 2020, which may continue into the future, and our partners, including Janssen,

may also experience a disruption in their ability to readily obtain supply. Our salesforce has been, and for an extended period of time may continue to be limited to their in-person interactions with healthcare providers, and therefore, also limited their ability to engage in various types of healthcare provider education activities. Healthcare providers and patients have canceled or delayed scheduling, and for an extended period of time may continue to cancel or delay scheduling, standard wellness visits and other non-emergency appointments and procedures, contributing to a decline in orders of our testing products. The portion of our workforce which has been working remotely in an effort to reduce the spread of COVID-19, may be infected from the virus or otherwise distracted. We may also face increased competition for laboratory employees due to the increased demand in the industry for such personnel. We may inaccurately estimate the duration or severity of the COVID-19 pandemic, which could cause us to misalign our staffing, spending, activities and precautionary measures with market current or future market conditions.

In response to the COVID-19 pandemic, we have curtailed non-essential travel and equipped most of our employees with the ability to work remotely with the exception of our clinical laboratory employees, and implemented measures to protect the health of our employees and to support the functionality of our clinical laboratory, such as providing personal protective equipment (including face masks or shields) and maintaining social distancing. In addition, in the second quarter of 2020, our salesforce recommenced certain field-based interactions and scaled marketing spend, although access to healthcare providers remains limited and the use of virtual sales tools has increased. From March 2020 through December 31, 2020, as a result of the COVID-19 pandemic, we terminated our temporary employees and 18 full-time employees, which included three employees at the vice president level. The full extent of which the COVID-19 pandemic will directly or indirectly continue to impact our business, results of operations and financial condition, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain it or treat COVID-19, as well as the economic impact on local, regional, national and international markets.

Factors Affecting Our Performance

In addition to the impact of COVID-19, we believe there are several important factors that have impacted, and that we expect will impact, our operating performance and results of operations, including:

- ***Continued Adoption of Our Testing Products.*** Since the launch of AVISE® CTD in 2012 and through December 31, 2020, we have delivered over 487,000 of these tests. For the year ended December 31, 2020, 100,450 AVISE® CTD tests were delivered, representing an approximate 5% decline over the same period in 2019. The number of ordering healthcare providers reached a record 2,500 for the year ended December 31, 2020, representing approximately 5% growth over the same period in 2019. In the fourth quarter of 2020, the number of ordering healthcare providers reached 1,690 compared to 1,707 in the same period in 2019, and we had a record 635 adopting healthcare providers (defined as those who previously prescribed at least 11 diagnostic tests in the corresponding period) compared to 572 in the same period in 2019. A high percentage of adopting healthcare providers continue to order tests in subsequent quarters, as approximately 99% of adopting healthcare providers from the third quarter of 2020 that order at least one diagnostic test in the fourth quarter of 2020. Revenue growth for our testing products will depend on our ability to continue to expand our base of ordering healthcare providers and increase our penetration with existing healthcare providers.
- ***Reimbursement for Our Testing Products***. Our revenue depends on achieving broad coverage and reimbursement for our tests from third-party payors, including both commercial and government payors such as Medicare. Payment from third-party payors differs depending on whether we have entered into a contract with the payors as a "participating provider" or do not have a contract and are considered a "non-participating provider." Payors will often reimburse non-participating providers, if at all, at a lower amount than participating providers. We have received a substantial portion of our revenue from a limited number of third-party commercial payors, most of which have not contracted with us to be a participating provider. Historically, we have experienced situations where commercial payors proactively reduced the amounts they were willing to reimburse for our tests, and in other situations, commercial payors have determined that the amounts they previously paid were too high and have sought to recover those perceived excess payments by deducting such amounts from payments otherwise being made. When we contract to serve as a participating provider, reimbursements are made pursuant to a negotiated fee schedule and are limited to only covered indications. If we are not able to obtain or maintain coverage and adequate reimbursement from third-party payors, we may not be able to effectively increase our testing volume and revenue as expected. Additionally, retrospective reimbursement adjustments can negatively impact our revenue and cause our financial results to fluctuate.

- ***Promotion of SIMPONI®***. We began promoting SIMPONI® in the United States under the Janssen Agreement in January 2019. Our SIMPONI® promotion efforts contributed approximately $5.1 million and $1.5 million in revenue for the years ended December 31, 2020 and 2019, respectively. We may continue to encounter difficulties in successfully promoting SIMPONI® and generating significant revenue under the Janssen Agreement. Our ability to effectively promote SIMPONI® will require us to be successful in a range of activities, including creating demand for SIMPONI® through our own sales activities as well as those of Janssen. In interest of supporting these efforts we plan to continue to evaluate the reach and frequency of our salesforce and the dedication of time and resources to supporting the co-promotion efforts of SIMPONI as compared to other aspects of our business. We expect to encounter difficulties being able to maintain meaningful co-promotion revenue based on sales over the predetermined baseline in 2021 and we may not be successful in materially increasing market share, potentially resulting in the recognition of the minimum promotion fee of $0.3 million in the first and second quarter of 2021, which would cause us to continue to rely on our existing testing products to drive revenue growth. Additionally, there is no minimum promotion fee for the second half of 2021.
- ***Development of Additional Testing Products.*** We rely on sales of our AVISE® CTD test to generate the significant majority of our revenue. We expect to continue to invest in research and development in order to develop additional testing products and expect these costs to increase. Our success in developing new testing products will be important in our efforts to grow our business by expanding the potential market for our testing products and diversifying our sources of revenue.
- ***Maintain Meaningful Margin***. We realized an increase to our gross margins beginning in the first quarter of 2020 following the expiration of a 10% annual royalty on our CB-CAPs technology. We believe we are well positioned to maintain meaningful margin through a continued focus on increasing operating leverage through the implementation of certain internal initiatives, such as conducting additional validation and reimbursement oriented clinical studies to facilitate payor coverage of our testing products, capitalizing on our growing reagent purchasing to negotiate improved volume-based pricing and automation in our clinical laboratory to reduce material and labor costs. However, our efforts to maintain a meaningful margin may be partially offset by our ability to generate meaningful co-promotion revenue in 2021.
- ***Timing of Our Research and Development Expenses***. Our spending on experiments and clinical studies may vary substantially from quarter to quarter. We also expend funds to secure clinical samples that can be used in discovery, product development, clinical validation, utility and outcome studies. The timing of these research and development activities is difficult to predict. If a substantial number of clinical samples are obtained in a given quarter or if a high-cost experiment is conducted in one quarter versus the next, the timing of these expenses will affect our financial results. We conduct clinical studies to validate our new testing products, as well as ongoing clinical and outcome studies to further expand the published evidence to support our commercialized AVISE® testing products. Spending on research and development for both experiments and studies may vary significantly by quarter depending on the timing of these various expenses.
- ***How We Recognize Revenue***. We record revenue on an accrual basis based on our estimate of the amount that will be ultimately realized for each test upon delivery based on a historical analysis of amounts collected by test and by payor. Changes to such estimates may increase or decrease revenue recognized in future periods.

While each of these areas present significant opportunities for us, they also pose significant risks and challenges that we must address. We discuss many of these risks, uncertainties and other factors in the section entitled "Risk Factors."

Janssen Promotion Agreement

In December 2018, we entered into the Janssen Agreement, under which we are responsible for the costs associated with our salesforce in promoting SIMPONI® in the United States. Janssen is responsible for all other costs associated with our promotion of SIMPONI® under the Janssen Agreement. In exchange for our sales and co-promotional services, we are entitled to a quarterly tiered promotion fee based on the incremental increase in total prescribed units of SIMPONI® for that quarter over a predetermined baseline. For the years ended December 31, 2020 and 2019, the tiered promotion fee ranged from $750 to $1,250 per prescription over a predetermined baseline. Due in part to COVID-19, in June 2020 we amended the Janssen Agreement, pursuant to which the predetermined average baseline for total prescribed units of SIMPONI® approximately 26,000 prescribed units per quarter, and subject to adjustment under certain circumstances. For each of the third and fourth quarters of 2020, we received a minimum promotion fee of $0.3 million and the fee was capped at 5% above the adjusted predetermined baseline. In December 2020, we further amended the Janssen Agreement, pursuant to which the predetermined average baseline for total prescribed units of SIMPONI® for the quarters ending December 31, 2020,

March 31, 2021 and June 30, 2021, was adjusted to approximately 28,750 prescribed units per quarter, subject to further adjustment under certain circumstances. For the first and second quarter of 2021, we will be entitled to an amended quarterly tiered promotion fee ranging from $500 to $1,000 per prescription based on the incremental increase in total prescribed units of SIMPONI® for that quarter over the predetermined baseline. Pursuant to the Amended Janssen Agreement, for each of the first and second quarters of 2021, we will receive a minimum promotion fee of $0.3 million and the fee will be capped at 10% above the adjusted predetermined baseline. We continued to receive a minimum promotion fee of $0.3 million and the fee was capped at 5% above the adjusted predetermined baseline for the quarter ended December 31, 2020. The quarterly tiered promotion fee for the remaining term of the Amended Janssen Agreement beginning with the quarter ended September 30, 2021 will revert to the terms set forth in the Janssen Agreement prior to the amendment, with no minimum promotion fee and no cap on predetermined baseline units. The Janssen Agreement expires on December 31, 2021, unless extended by us for an additional 12 months upon 180 days written notice prior to the end of the current term. If we elect to extend the term, the predetermined baseline for 2022 will be subject to future agreement by us and Janssen. Janssen may terminate the agreement at any time for any reason upon 30 days' notice to us, and we may terminate the agreement for any reason at the end of any calendar quarter upon 30 days' notice to Janssen. Either party may terminate the agreement in the event of the other party's default of any of its material obligations under the agreement if such default remains uncured for a specified period of time following receipt of written notice of such default.

We recognized approximately $5.1 million and $1.5 million in revenue for the year ended December 31, 2020 and 2019, respectively, for our promotional efforts under the Janssen Agreement.

Seasonality

Based on our experience to date, we expect some seasonal variations in our financial results due to a variety of factors, such as the year-end holiday period and other major holidays, vacation patterns of both patients and healthcare providers, including medical conferences, climate and weather conditions in our markets, seasonal conditions that may affect medical practices and provider activity, including for example influenza outbreaks that may reduce the percentage of patients that can be seen, and other factors relating to the timing of patient benefit changes, as well as patient deductibles and co-insurance limits.

Financial Overview

Revenue

To date, we have derived nearly all of our revenue from the sale of our testing products, most of which is attributable to our AVISE® CTD test. We primarily market our testing products to rheumatologists in the United States. The rheumatologists who order our testing products and to whom results are reported are generally not responsible for payment for these products. The parties that pay for these services, or payors, consist of healthcare insurers, government payors (primarily Medicare and Medicaid), client payors (i.e. hospitals, other laboratories, etc.), and patient self-pay. Our service is completed upon the delivery of test results to the prescribing rheumatologists which triggers billing for the service.

We recognize revenue in accordance with the provisions of ASC Topic 606, *Revenue from Contracts with Customers.* We record revenue on an accrual basis based on our estimate of the amount that will be ultimately realized for each test upon delivery based on a historical analysis of amounts collected by test and by payor. These assessments require significant judgment by management.

Our ability to increase our revenue will depend on our ability to further penetrate the market for our current and future testing products, and increase our reimbursement and collection rates for tests delivered, as well as our ability to continue to generate meaningful co-promotion revenue. We expect to encounter difficulties promoting SIMPONI® above the predetermined baseline potentially resulting in us receiving the minimum promotion fee of $0.3 million in the first and second quarter of 2021. Additionally, there is no minimum promotion fee for the second half of 2021. Our average reimbursement for AVISE® CTD decreased in 2020 as compared to 2019 due to the impacts of the PAMA rate reduction as well as changes to payor mix. However, PAMA is not expected to have an impact on our 2021 average reimbursement for AVISE® CTD as compared to 2020.

As discussed above, the number of AVISE® CTD tests delivered in the third quarter of 2020 substantially recovered to the pre-COVID-19 AVISE® CTD tests reported in the first quarter of 2020, and the number of AVISE® CTD tests delivered in the fourth quarter of 2020 exceeded pre-COVID-19 AVISE® CTD tests reported in the first quarter of

2020. However, the continued spread of COVID-19 may adversely affect testing volumes in future periods, the extent of which is highly uncertain.

Operating Expenses

Costs of Revenue

Costs of revenue represents the expenses associated with obtaining and testing patient specimens. The components of our costs of revenue include materials costs, direct labor, equipment and infrastructure expenses associated with testing specimens, shipping charges to transport specimens, blood specimen collections fees, royalties, depreciation and allocated overhead, including rent and utilities.

Each payor, commercial third-party, government, or individual, reimburses us at different amounts. These differences can be significant. As a result, our costs of revenue as a percentage of revenue may vary significantly from period to period due to the composition of payors for each month's billings.

Assuming future testing volumes are not negatively impacted by the spread of COVID-19, we expect that our costs of revenue will increase in absolute dollars as the number of tests we perform increases. However, we expect that the cost per test will decrease over time due to volume discounts on materials and shipping costs and other volume efficiencies we may gain as the number of tests we perform increases. As discussed above, the continued spread of COVID-19 may adversely affect testing volumes which may result in an increase in cost per test due to our inability to realize volume efficiencies.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist of personnel costs, including stock-based compensation expense, direct marketing expenses, accounting and legal expenses, consulting costs, and allocated overhead including rent, information technology, depreciation and utilities.

We expect that our selling, general and administrative expenses will increase in absolute dollars in 2021 as compared to 2020, as we continue to evaluate the reach and frequency of our sales and sales support functions, expected additions to headcount and increases for personnel costs, including stock-based compensation.

Research and Development Expenses

Research and development expenses include costs incurred to develop our technology, testing products and product candidates, collect clinical specimens and conduct clinical studies to develop and support our testing products and product candidates. These costs consist of personnel costs, including stock-based compensation expense, materials, laboratory supplies, consulting costs, costs associated with setting up and conducting clinical studies and allocated overhead including rent and utilities. We expense all research and development costs in the periods in which they are incurred.

We expect that our research and development expenses will increase in absolute dollars in 2021 as compared to 2020, as we continue to invest in research and development activities related to our existing testing products and product candidates, expected additions to headcount and increases for personnel costs, including stock-based compensation.

Interest Expense

Interest expense consists of cash and non-cash interest expense associated with our financing arrangements, including the borrowings under our Amended Loan Agreement with Innovatus.

We expect interest expense to remain consistent in 2021 as compared to 2020, and remain consistent thereafter until 2023.

Change in Fair Value of Financial Instruments

Prior to the completion of our IPO, we classified our outstanding warrants to purchase shares of our redeemable convertible preferred stock as liabilities on our balance sheets at their estimated fair value since the underlying redeemable convertible preferred stock was classified as temporary equity. At the end of each reporting period, changes in the estimated fair value during the period were recorded as a component of other income (expense).

In connection with the completion of our IPO in September 2019, all outstanding warrants to purchase shares of our redeemable convertible preferred stock either terminated or were converted into warrants to purchase shares of our common stock and accordingly, will no longer be subject to measurement.

Other Income, Net

Other income, net, consists primarily of interest income earned on our cash and cash equivalents and an amount received under the CARES Act.

Income Tax Benefit (Expense)

Income taxes include federal and state income taxes in the United States.

Results of Operations

Comparison of the Years Ended December 31, 2020 and 2019:

	Years Ended December 31,		
	2020	2019	Change
	(in thousands)		
Revenue	$ 41,975	$ 40,387	$ 1,588
Operating expenses:			
Costs of revenue	16,559	18,808	(2,249)
Selling, general and administrative expenses	37,033	28,702	8,331
Research and development expenses	3,568	2,176	1,392
Total operating expenses	57,160	49,686	7,474
Loss from operations	(15,185)	(9,299)	(5,886)
Interest expense	(2,565)	(3,491)	926
Change in fair value of financial instruments	—	267	(267)
Other income, net	984	510	474
Loss before income taxes	(16,766)	(12,013)	(4,753)
Income tax benefit (expense)	79	(25)	104
Net loss	$ (16,687)	$ (12,038)	$ (4,649)

Revenue

Revenue increased $1.6 million, or 3.9%, for the year ended December 31, 2020 compared to the year ended December 31, 2019, primarily due to an increase in revenue to approximately $5.1 million from the co-promotion of SIMPONI® for the year ended December 31, 2020 compared to approximately $1.5 million for the year ended December 31, 2019. The increase in revenue was partially offset by a decrease in the number of diagnostic tests delivered due in part to impacts of the COVID-19 pandemic, coupled with a decrease in average reimbursement per AVISE® CTD test. The number of AVISE® CTD tests, which accounted for 70% of revenue for the year ended December 31, 2020, decreased to 100,450 tests delivered in the year ended December 31, 2020 compared to 105,370 tests delivered in the same 2019 period. The number of AVISE® CTD tests increased to 28,601 for the three months ended December 31, 2020 compared to 27,133 tests delivered in the same 2019 period. The adoption of the AVISE® CTD test by rheumatologists for the year ended December 31, 2020 increased to 2,500 ordering healthcare providers as compared to 2,389 ordering healthcare providers in the same 2019 period. The number of ordering healthcare providers decreased to 1,690 for the three months ended December 31, 2020 compared to 1,707 in the same 2019 period.

Costs of Revenue

Costs of revenue decreased $2.2 million, or 12.0%, for the year ended December 31, 2020 compared to the year ended December 31, 2019. This decrease was primarily due to decreased direct costs such as materials and

supplies associated with the decrease in test volume and decreased royalty costs associated with the expiration of a royalty on our CB-CAPs technology for the year ended December 31, 2020 compared to the same 2019 period.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased $8.3 million, or 29.0%, for the year ended December 31, 2020 compared to the year ended December 31, 2019. This increase was primarily due to an increase of $5.6 million of employee related expenses, including stock-based compensation and recruitment expenses, increases related to insurance expenses of $1.0 million, legal fees of $0.7 million and audit and professional services of $0.7 million. The year ended December 31, 2020 included one-time restructuring charges of approximately $0.2 million.

Research and Development Expenses

Research and development expenses increased $1.4 million, or 64.0%, for the year ended December 31, 2020 compared to the year ended December 31, 2019. The increase was primarily due to an increase of $1.2 million of employee related expenses, including stock-based compensation and recruitment expenses, and an increase related to clinical study expenses of $0.2 million.

Interest Expense

Interest expense decreased $0.9 million, or 26.5%, for the year ended December 31, 2020 compared to the year ended December 31, 2019. This decrease was primarily due to the lower interest rate under our long-term borrowing arrangements for the year ended December 31, 2020 compared to the prior year period.

Change in Fair Value of Financial Instruments

The change in fair value of financial instruments decreased $0.3 million for the year ended December 31, 2020 compared to the year ended December 31, 2019. This decrease is due to the conversion of warrants to purchase preferred stock into warrants to purchase our common stock in connection with the completion of our IPO in September 2019. As a result, such warrants no longer require liability accounting which resulted in the recognition of income or expense.

Other Income, Net

Other income, net, increased $0.5 million for the year ended December 31, 2020 compared to the year ended December 31, 2019. This increase is primarily due to the $0.7 million received under the CARES Act due to lost revenues attributable to COVID-19 during the second quarter of 2020.

Income Tax Benefit (Expense)

Income tax benefit increased $0.1 million for the year ended December 31, 2020 compared to the year ended December 31, 2019 due to a change in tax law under the CARES Act.

Liquidity and Capital Resources

We have incurred net losses since our inception. For the years ended December 31, 2020 and 2019, we incurred a net loss of $16.7 million and $12.0 million, respectively, and we expect to incur additional losses and increased operating expenses in future periods. As of December 31, 2020, we had an accumulated deficit of $181.3 million. To date, we have generated only limited revenue, and we may never achieve revenue sufficient to offset our expenses.

Through the date of our IPO in September 2019, our operations were financed primarily from sales of our common and redeemable convertible preferred stock and borrowings under various debt financings. In September 2019, we completed our IPO of 4,140,000 shares of its common stock at a price to the public of $14.00 per share, including the exercise in full by the underwriters of their option to purchase 540,000 additional shares of our common stock. Including the option exercise, the aggregate net proceeds to us from the offering was approximately $50.4 million, net of underwriting discounts, commissions and other offering expenses, for aggregate expenses of approximately $7.5 million. As of December 31, 2020, we had $57.4 million of cash and cash equivalents. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Currently, our funds are held in cash and money market funds.

In September 2017, we entered into the loan and security agreement with Innovatus under which we immediately drew down $20.0 million. In December 2018, we borrowed an additional $5.0 million under the loan agreement. In November 2019, we amended the loan and security agreement with Innovatus, which we collectively refer to as the Amended Loan Agreement. Pursuant to the Amended Loan Agreement, the loan term is for five years with a final maturity date of November 2024. The Amended Loan Agreement accrues interest at an annual rate of 8.5%, of which 2.0%, during the first 36 months, will be treated as paid in-kind interest. Paid in-kind interest is added to the principal balance each period. After the initial 36 months of the loan, the entire 8.5% will be paid in cash at the end of each period. On or after the first anniversary of the Loan Amendment, but before the second anniversary of the Loan Amendment, we may, at our option, prepay the term loan borrowings by paying the lender a prepayment premium. Prepayment before the second anniversary of the Loan Amendment may only occur for specified reasons in the Amended Loan Agreement. The prepayment premium decreases by 1% during each subsequent twelve-month period after the first anniversary of the Loan Amendment.

Our obligations under the Amended Loan Agreement are secured by a security interest in substantially all of our assets, including our intellectual property. The Amended Loan Agreement contains customary conditions to borrowing, events of default, and covenants, including covenants requiring us to maintain certain levels of minimum liquidity of $2.0 million and achieve certain minimum amounts of revenue, and limiting our ability to dispose of assets, undergo a change in control, merge with or acquire other entities, incur debt, incur liens, pay dividends or other distributions to holders of our capital stock, repurchase stock and make investments, in each case subject to certain exceptions. The consequences of failing to achieve the performance covenant will be cured if, within sixty days of failing to achieve the performance covenant, we issue additional equity securities or subordinated debt with net proceeds sufficient to fund any cash flow deficiency generated from operations, as defined. Our revenues for the twelve-month period ended September 30, 2020 were lower than the specified targets, and as a result, we and Innovatus agreed to a new management plan and target to bring us back into compliance with the Loan Amendment. At December 31, 2020, we were in compliance with all covenants of the Amended Loan Agreement. In addition, upon the occurrence of an event of default, Innovatus, among other things, can declare all indebtedness due and payable immediately, which would adversely impact our liquidity and reduce the availability of our cash flows to fund working capital needs, capital expenditures and other general corporate purposes.

In connection with the execution of the loan and security agreement with Innovatus in November 2017, we issued the lender a seven-year warrant to purchase 15,384,615 shares of our Series F redeemable convertible preferred stock at an exercise price of $0.078 per share, and in December 2018, in connection with the additional $5.0 million borrowed under the loan and security agreement, we issued to the lender a seven-year warrant to purchase 3,846,154 shares of our Series F redeemable convertible preferred stock at an exercise price of $0.078 per share. In connection with the completion of our IPO in September 2019, the warrants were automatically converted into warrants exercisable for an aggregate of 104,722 shares of common stock at an exercise price of $14.32.

In April 2020, we received $0.7 million of funding under the CARES Act Provider Relief Fund, subject to our agreement to comply with the Department of Health & Human Services', or HHS, standard terms and conditions. The CARES Act Provider Relief Fund is a federal fund allocated for general distributions to Medicare facilities and providers impacted by the COVID-19 pandemic and is intended to support healthcare-related expenses or lost revenue attributable to COVID-19.

Funding Requirements

Our primary uses of cash are to fund our operations as we continue to grow our business. We expect to continue to incur operating losses in the near term as our operating expenses will be increased to support the growth of our business. We expect that our costs of revenue, selling, general and administrative expenses, and research and development expenses will continue to increase as we increase our test volume, expand our marketing efforts and increase our internal salesforce to drive increased adoption of and reimbursement for our AVISE® testing products, promote SIMPONI®, prepare to commercialize new testing products, continue our research and development efforts and further develop our product pipeline. We believe we have sufficient laboratory capacity to support increased test volume. We expect to make material additions for laboratory equipment and capital expenditures in the near term related to our laboratory facilities and expansion of research capabilities. 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.

We expect that our near- and longer-term liquidity requirements will continue to consist of working capital and general corporate expenses associated with the growth of our business, including payments we may be required to make upon the achievement of previously negotiated milestones associated with intellectual property we have

licensed, payments related to non-cancelable purchase obligations with one supplier for reagents, payments related to our principal and interest under our long term borrowing arrangements, payments for operating leases related to our office and laboratory space in Vista, California and payments for capital leases related to our laboratory equipment (see footnote 4 and footnote 5 in the audited financial statements included in this Annual Report on Form 10-K). Based on our current business plan, we believe that our existing cash and cash equivalents and our anticipated future revenue, will be sufficient to meet our anticipated cash requirements for at least the next 12 months from the date of this filing.

Our estimate of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including:

- the impact of the COVID-19 pandemic on our business, including challenges resulting from social distancing and stay-at-home orders through a reduction in testing volumes;
- our ability to maintain and grow sales of our AVISE® testing products, as well as the costs associated with conducting clinical studies to demonstrate the utility of our products and support reimbursement efforts;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for our testing products;
- fluctuations in working capital;
- the costs of developing our product pipeline, including the costs associated with conducting our ongoing and future validation studies;
- the additional costs we may incur as a result of operating as a public company;
- the costs associated with our promotion of SIMPONI®, including the expansion of our sales capabilities, and the extent and timing of generating revenue from such promotion; and
- the extent to which we establish additional partnerships or in-license, acquire or invest in complementary businesses or products.

Until such time, if ever, as we can generate revenue to support our costs structure, we expect to finance our operations through equity offerings, debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. If additional funding is required or desired, there can be no assurance that additional funds will be available to us on acceptable terms on a timely basis, if at all, or that we will generate sufficient cash from operations to adequately fund our operating needs or achieve or sustain profitability. If we are unable to raise additional capital or generate sufficient cash from operations to adequately fund our operations, we will need to delay, reduce or eliminate some or all of our research and development programs, product portfolio expansion plans or commercialization efforts. Doing so will likely have an unfavorable effect on our ability to execute on our business plan and could have a negative impact on our relationships with parties such as Janssen. If we cannot expand our operations or otherwise capitalize on our business opportunities because we lack sufficient capital, our business, financial condition, and results of operations could be adversely affected.

Cash Flows

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

	Years Ended December 31,	
(in thousands)	**2020**	**2019**
Net cash provided by (used in):		
Operating activities	$ (14,084)	$ (9,711)
Investing activities	(455)	(103)
Financing activities	(97)	68,734
(Decrease) increase in cash, cash equivalents and restricted cash	$ (14,636)	$ 58,920

Cash Flows from Operating Activities

Net cash used in operating activities for the year ended December 31, 2020 was $14.1 million and primarily resulted from our net loss of $16.7 million adjusted for non-cash charges of $3.9 million related to stock-based compensation, non-cash interest, depreciation, amortization and deferred income taxes and changes in our net operating assets of $1.3 million related to net increases in account receivables and prepaid expenses and other current assets, partially offset by net increases in accounts payables and accrued liabilities and other current liabilities.

Net cash used in operating activities for the year ended December 31, 2019 was $9.7 million and primarily resulted from our net loss of $12.0 million adjusted for non-cash charges of $2.2 million related to depreciation, amortization, stock-based compensation, non-cash interest and the revaluation of our preferred stock liabilities. The net cash used in operating activities was partially offset by changes in our net operating assets of $0.2 million related to net increases in accounts payable and accrued liabilities and other current liabilities, partially offset by decreases in prepaid expenses and other current assets.

Cash Flows from Investing Activities

Net cash used in investing activities for the year ended December 31, 2020 and 2019 was $0.5 million and $0.1 million, respectively, and was due to net purchases of property and equipment.

Cash Flows from Financing Activities

Net cash used in financing activities for the year ended December 31, 2020 was $0.1 million and primarily resulted from principal payments on capital lease obligations, as well as proceeds from the Paycheck Protection Program loan, which was subsequently repaid in May 2020, partially offset by proceeds from Employee Stock Purchase Plan purchases.

Net cash provided by financing activities for the year ended December 31, 2019 was $68.7 million and primarily resulted from the net proceeds received from our IPO of $50.4 million, as well as net proceeds received from the issuance of our redeemable convertible preferred stock of $18.4 million.

Critical Accounting Policies and Significant Management Estimates

Our management’s discussion and analysis of our financial condition and results of operations is based on our audited financial statements, which have been prepared in accordance with United States generally accepted accounting principles, or U.S. GAAP. The preparation of these audited financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the audited financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgement and estimates.

Revenue Recognition

To date, substantially all of our revenue has been derived from sales of our testing products. We primarily market our testing products to rheumatologists and their physician assistants in the United States. The healthcare professionals who order our services and to whom test results are reported are generally not responsible for payment for these services. The parties that pay for these services consist of healthcare insurers, government payors (primarily Medicare and Medicaid), client payors (i.e. hospitals, other laboratories, etc.) and patient self-pays.

Payors are billed at our list price. Net revenues recognized consist of amounts billed net of allowances for differences between amounts billed and the estimated consideration we expect to receive from such payors. We follow a standard process, which considers historical denial and collection experience, insurance reimbursement policies and other factors, to estimate allowances and implicit price concessions, recording adjustments in the current period as changes in estimates. Further adjustments to the allowances, based on actual receipts, is recorded upon settlement. The transaction price is estimated using an expected value method on a portfolio basis.

Our portfolios are grouped per payor (i.e. each individual third-party insurance, Medicare, client payors, patient self-pay, etc.) and per test basis.

Collection of our net revenues from payors is normally a function of providing complete and correct billing information to the healthcare insurers and generally occurs within 30 to 90 days of billing.

The process for estimating revenues and the ultimate collection of accounts receivable involves significant judgment and estimation by management.

In December 2018, we entered into the Janssen Agreement to co-promote SIMPONI® in the United States. Our obligations relating to sales and co-promotion services for SIMPONI® is a series of single performance obligations since Janssen simultaneously receives and consumes the benefits provided by our sales and co-promotional services. The method for measuring progress towards satisfying the performance obligations is based on prescribed units in excess of the contractual baseline at the contractual rate earned per unit since the agreement is cancelable.

Long-Lived Assets

Our long-lived assets are comprised principally of our property and equipment, finite lived intangible assets, and goodwill.

We amortize all finite lived intangible assets over their respective estimated useful lives. In considering whether intangible assets are impaired, we combine our intangible assets and other long-lived assets (excluding goodwill), into groupings, a determination which we principally make on the basis of whether the assets are specific to a particular test offered by us or technology we are developing. If we identify events or circumstances indicate that the associated carrying amount of assets within a group may not be recoverable, we will consider the assets in the group impaired if the carrying value of the group's assets and directly associated liabilities exceed the estimated cash flows expected to be generated over the estimated useful life of the assets in the group. Management's estimates of future cash flows are impacted by projected levels of tests and levels of reimbursement, as well as expectations related to the future cost structure of the entity.

Goodwill is not amortized but is tested for impairment at least annually or more frequently whenever a triggering event or change in circumstances occurs, at the reporting unit level. For our goodwill impairment analysis, we operate in a single reporting unit, and allocate all goodwill to this reporting unit. We are required to recognize an impairment charge if the carrying amount of the reporting unit exceeds its fair value. Management first assesses qualitative factors to determine whether it is more likely than not that the fair value of the reporting unit is less than the carrying amount as a basis for determining whether it is necessary to perform a quantitative assessment. If a quantitative assessment is deemed necessary, management uses all available information to make this fair value determination, including the present values of expected future cash flows using discount rates commensurate with the risks involved in the assets and observed market multiples of operating cash flows.

The judgments and estimates involved in identifying and quantifying the impairment of long-lived assets or goodwill involve inherent uncertainties, and the measurement of the fair value is dependent on the accuracy of the assumptions used in making the estimates and how those estimates compare to our future operating performance. No goodwill impairments were recorded during the years ended December 31, 2020 and 2019.

Following the completion of our IPO in September 2019, our stock price and associated market capitalization will also be considered in the determination of reporting unit fair value. A prolonged or significant decline in our share price could provide evidence of a need to record a material impairment to goodwill.

Stock-Based Compensation

We recognize compensation expense related to stock-based awards to employees and directors based on the estimated fair value of the awards on the date of grant over the requisite service period of the awards (usually the vesting period) on a straight-line basis. The grant date fair value, and the resulting stock-based compensation expense, is estimated using the Black-Scholes option pricing model. The grant date fair value of stock-based awards is expensed on a straight-line basis over the vesting period of the respective award.

We recorded stock-based compensation expense of approximately $2.7 million and $0.6 million for the years ended December 31, 2020 and 2019, respectively. We expect to continue to grant stock options and other equity-based awards in the future, and to the extent that we do, our stock-based compensation expense recognized in future periods will likely increase.

The Black-Scholes option pricing model requires the use of highly subjective and complex assumptions, which determine the fair value of stock-based awards. If we had made different assumptions, our stock-based compensation expense, net loss and net loss per share attributable to common stockholders could have been significantly different. See Notes 2 and 9 to our audited financial statements included elsewhere in this Annual Report on Form 10-K for information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options granted in the years ended December 31, 2020 and 2019.

Determination of the Fair Value of Our Common Stock

Prior to the completion of our IPO in September 2019, our board of directors, with the assistance of management, determined the fair value of our common stock on each grant date. All options to purchase shares of our common stock are intended to be granted with an exercise price per share no less than the fair value per share of our common stock underlying those options on the date of grant, based on the information known to us on the date of grant.

Following the closing of our initial public offering, our board of directors determines the fair value of our common stock based on its closing price as reported on the date of grant on the primary stock exchange on which our common stock is traded.

Estimated Fair Value of Redeemable Convertible Preferred Stock Warrants and Other Financial Instruments

Prior to the IPO, we entered into agreements with existing stockholders of our redeemable convertible preferred stock that contained future purchase obligations of redeemable convertible preferred stock at a fixed price. We evaluated these share purchase right agreements and assessed whether they meet the definition of a freestanding instrument and, if so, determined the fair value of the share purchase right liability and recorded it on the balance sheet. The share purchase right liability was revalued at each reporting period with changes in the fair value of the liability recorded as a component of other income (expense) in the statement of operations. The share purchase right liability was revalued at settlement and the resultant fair value was then reclassified to redeemable convertible preferred stock at that time. The estimated fair value of the share purchase right liability was determined using valuation models that consider the probability of achieving the requisite milestones, our cost of capital, the estimated time period the preferred stock right would be outstanding, consideration received for the convertible preferred stock, the number of shares to be issued to satisfy the preferred stock purchase right and at what price, and probability of the consummation of an initial public offering, as applicable.

We accounted for our redeemable convertible preferred stock warrant liabilities as freestanding instruments for shares that were puttable or redeemable. These warrants were classified as liabilities on our balance sheet and were recorded at their estimated fair values. At the end of each reporting period, changes in estimated fair value during the period were recorded as a component of other income (expense), net in the accompanying statement of operations. We continued to re-measure the fair value of the warrant liabilities until: (i) exercise; (ii) expiration of the related warrant; or (iii) conversion of the preferred stock underlying the security into common stock, which occurred in connection with the completion of our IPO in September 2019. We estimated the fair values of our warrant liabilities using an option pricing model based on inputs as of the valuation measurement dates, including the fair value of our redeemable convertible preferred stock, the estimated volatility of the price of our redeemable convertible preferred stock, the expected term of the warrants and the risk-free interest rates.

There were significant judgments and estimates inherent in the determination of the fair values of our preferred stock purchase right liabilities and redeemable convertible preferred stock warrant liabilities. If we had made different assumptions, the carrying value of these liabilities, net loss and net loss per share attributable to common stockholders could have been significantly different.

Income Taxes

We operate in, and are subject to tax authorities in, various tax jurisdictions in the United States. To date, we have not been audited by the Internal Revenue Service or any state income tax authority. All tax years remain open for examination by federal and state tax authorities.

At December 31, 2020, our deferred tax assets are primarily comprised of federal and state tax NOL carryforwards. We previously completed a study to assess whether an ownership change, as defined by Section 382 of the Code, had occurred from our formation through December 31, 2019. Based upon this study, we determined that ownership

changes had occurred in 2003, 2008, 2012, 2017 and 2019, and that our ability to use a significant portion of our NOL carryforwards is subject to limitation under Section 382 of the Code as a result of a prior ownership change. In addition, federal NOL carryforwards generated in periods after December 31, 2017, may be carried forward indefinitely but, in taxable years beginning after December 31, 2020, may only be used to offset 80% of our taxable income.

We are required to reduce our deferred tax assets by a valuation allowance if it is more likely than not that some or all of our deferred tax assets will not be realized. We must use judgment in assessing the potential need for a valuation allowance, which requires an evaluation of both negative and positive evidence. The weight given to the potential effect of negative and positive evidence should be commensurate with the extent to which it can be objectively verified. In determining the need for and amount of our valuation allowance, if any, we assess the likelihood that we will be able to recover our deferred tax assets using historical levels of income, estimates of future income and tax planning strategies. As a result of historical cumulative losses and uncertainties surrounding our ability to generate future taxable income and, based on all available evidence, we believe it is more likely than not that our recorded net deferred tax assets will not be realized. Accordingly, we have recorded a valuation allowance against all of our net deferred tax assets at December 31, 2020. We will continue to maintain a full valuation allowance on our deferred tax assets until there is sufficient evidence to support the reversal of all or some portion of this allowance.

The above listing is not intended to be a comprehensive list of all of our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by GAAP. There are also areas in which our management’s judgment in selecting any available alternative would not produce a materially different result. Please see our audited financial statements and notes thereto included elsewhere in this Annual Report on Form 10-K, which contain accounting policies and other disclosures required by GAAP.

Recent Accounting Pronouncements

See "Notes to the Financial Statements-Note 2-Recent Accounting Pronouncements" of our annual financial statements.

Off-Balance Sheet Arrangements

During the periods presented we did not have, nor do we currently have any off-balance sheet arrangements, as defined under the rules and regulations of the SEC.

JOBS Act Accounting Election

The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an "emerging growth company." The JOBS Act permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We have elected to use this extended transition period under the JOBS Act until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our audited financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We will remain an emerging growth company until the last day of our fiscal year following the fifth anniversary of the date of the first sale of our common equity securities pursuant to an effective registration statement under the Securities Act, which such fifth anniversary will occur in 2024. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, our annual gross revenues exceed $1.07 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 8. Financial Statements and Supplementary Data

The financial statements and supplemental data required by this item are set forth at the pages indicated in Part IV, Item 15(a)(1) of this Annual Report on Form 10-K.

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

None.

Item 9A. Controls and Procedures

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our chief executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, control may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated, as of the end of the period covered by this Annual Report on Form 10-K, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on that evaluation, our principal executive officer and principal financial officer have concluded that as of December 31, 2020, our disclosure controls and procedures were effective at the reasonable assurance level. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgement in evaluating the cost-benefit relationship of possible controls and procedures.

Attestation Report of the Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm due to an exemption provided by the JOBS Act for "emerging growth companies."

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting during the three months ended December 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Appointment of Chief Operating Officer

On March 13, 2021, our board of directors appointed of Mark Hazeltine, age 47, as our Chief Operating Officer, effective as of March 15, 2021. Mark Hazeltine has served in various positions of increasing responsibility since joining Exagen in March 2015, including general manager. Mr. Hazeltine received his Bachelor of Business Administration degree from the University of San Diego and Master of Business Administration degree from the Marshall School of Business at the University of Southern California. Additional information regarding Mr. Hazeltine's background, business and experience will appear in our Definitive Proxy Statement on Schedule 14A, to be filed with the SEC within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K, under the heading's "Executive Officers."

Pursuant to the terms of Mr. Hazeltine's offer letter, as amended effective as of March 15, 2021 in connection with his promotion, Mr. Hazeltine will receive an annual base salary of $375,950 and will be eligible to receive an annual incentive bonus at an initial target for calendar year 2021 of 45% of his annual base salary. The offer letter with Mr. Hazeltine provides for an indefinite term and for at-will employment. Mr. Hazeltine is also entitled to participate in all employee benefit plans, programs and arrangements maintained by the company and made available to employees generally.

There are no family relationships between Mr. Hazeltine and any of our directors or executive officers that are required to be disclosed pursuant to Item 401(d) of Regulation S-K. In addition, there are no transactions between us and Mr. Hazeltine, or any member of Mr. Hazeltine's immediate family, that are required to be disclosed pursuant to Item 404(a) of Regulation S-K.

Executive Change in Control Severance Plan

On March 15, 2021, the Compensation Committee of our board of directors adopted the Exagen Inc. Executive Change in Control Severance Plan, or the Severance Plan. The Severance Plan provides for the payment of cash severance and other benefits to our executives, including Fortunato Ron Rocca (President and Chief Executive Officer), Kamal Adawi (Chief Financial Officer and Corporate Secretary) and Mark Hazeltine (Chief Operating Officer), in the event of a qualifying termination of employment with us in connection with a change in control.

Under the Severance Plan, in the event of a termination of an executive’s employment by us without “cause” or by the executive for “good reason”, in either case, on or within twelve months following a “change in control”, the executive will be eligible to receive the following payments and benefits:

- a cash payment equal to 100% (or, for Mr. Rocca, 125%) of the sum of (i) the executive’s then-current annual base salary, plus (ii) the executive’s target cash performance bonus for the year in which the termination occurs, to be paid in a lump sum on the 30th day following the executive’s termination;
- a cash payment equal to the executive’s pro-rated cash performance bonus (based on actual performance) for the year in which the termination occurs;
- Company-subsidized COBRA premium payments for the executive and his or her covered dependents for up to 12 (or, for Mr. Rocca, 15) months; and
- full accelerated vesting of all outstanding equity awards of our company that vest solely based on the passage of time.

The executive’s right to receive the severance payments and benefits described above is subject to the executive’s delivery and, as applicable, non-revocation of a general release of claims in our favor and the executive’s continued compliance with any applicable restrictive covenants.

In addition, in the event that any payment under the Severance Plan, together with any other amounts paid to the executive by us, would subject the executive to an excise tax under Section 4999 of the Internal Revenue Code, such payments will be reduced to the extent that such reduction would produce a better net after-tax result for the executive.

The foregoing description of the Severance Plan is qualified in its entirety by reference to the full text of the Severance Plan, a copy of which is filed as Exhibit 10.46 to this Annual Report on Form 10-K and is incorporated herein by reference.

Part III.

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item is incorporated herein by reference to our Proxy Statement with respect to our 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics that applies to our officers, directors and employees, which is available on our website at www.exagen.com. The Code of Business Conduct and Ethics contains general guidelines for conducting the business of our company consistent with the highest standards of business ethics and is intended to qualify as a “code of ethics” within the meaning of Section 406 of the Sarbanes-Oxley Act of 2002 and Item 406 of Regulation S-K. In addition, we intend to promptly disclose (1) the nature of any amendment to our Code of Business Conduct and Ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions and (2) the nature of any waiver, including an implicit waiver, from a provision of our code of ethics that is granted to one of these specified officers, the name of such person who is granted the waiver and the date of the waiver on our website in the future.

Item 11. Executive Compensation

The information required by this item is incorporated herein by reference to our Proxy Statement with respect to our 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K.

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

The information required by this item is incorporated herein by reference to our Proxy Statement with respect to our 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K.

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

The information required by this item is incorporated herein by reference to our Proxy Statement with respect to our 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 14. Principal Accountant Fees and Services

The information required by this item is incorporated herein by reference to our Proxy Statement with respect to our 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K.

Part IV

Item 15. Exhibits and Financial Statement Schedules

Financial Statements and Financial Statement Schedules

(1) All financial statements

The financial statements of Exagen Inc., together with the report thereon of BDO USA, LLP, an independent registered public accounting firm, are included in this annual report on Form 10-K beginning on page 96.

(2) Financial statement schedules

All schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

(3) Exhibits

A list of exhibits is set form on the Exhibit Index immediately preceding the signature page of this Annual Report on Form 10-K and is incorporated herein by reference.

Item 16. Form 10-K Summary

None.

Exagen Inc.
Index to Financial Statements

Report of Independent Registered Public Accounting Firm

Stockholders and Board of Directors
Exagen Inc.
Vista, California

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Exagen Inc. ("the Company") as of December 31, 2020 and 2019, the related statements of operations, redeemable convertible preferred stock and stockholders' equity, and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2020 and 2019, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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 financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the 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 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2017.

San Diego, California

March 16, 2021

Exagen Inc.

Balance Sheets
(in thousands, except share and per share data)

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 57,448	$ 72,084
Accounts receivable, net	8,910	5,715
Prepaid expenses and other current assets	4,159	3,451
Total current assets	70,517	81,250
Property and equipment, net	2,102	1,380
Goodwill	5,506	5,506
Other assets	250	174
Total assets	$ 78,375	$ 88,310
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,014	$ 1,476
Accrued and other current liabilities	5,757	4,419
Total current liabilities	8,771	5,895
Borrowings-non-current portion, net of discounts and debt issuance costs	26,659	25,854
Deferred tax liabilities	158	264
Other non-current liabilities	948	638
Total liabilities	36,536	32,651
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized, no shares issued or outstanding at December 31, 2020 and December 31, 2019	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized at December 31, 2020 and December 31, 2019; 12,652,308 and 12,560,990 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	13	13
Additional paid-in capital	223,115	220,248
Accumulated deficit	(181,289)	(164,602)
Total stockholders' equity	41,839	55,659
Total liabilities and stockholders' equity	$ 78,375	$ 88,310

The accompanying notes are an integral part of these financial statements

Exagen Inc.

Statements of Operations
(in thousands, except share and per share data)

	Years Ended December 31,	
	2020	**2019**
Revenue	$ 41,975	$ 40,387
Operating expenses:		
Costs of revenue	16,559	18,808
Selling, general and administrative expenses	37,033	28,702
Research and development expenses	3,568	2,176
Total operating expenses	57,160	49,686
Loss from operations	(15,185)	(9,299)
Interest expense	(2,565)	(3,491)
Change in fair value of financial instruments	—	267
Other income, net	984	510
Loss before income taxes	(16,766)	(12,013)
Income tax benefit (expense)	79	(25)
Net loss	(16,687)	(12,038)
Accretion of redeemable convertible preferred stock	—	(4,640)
Deemed dividend recorded in connection with financing transactions	—	(13,601)
Net loss attributable to common stockholders (Note 2)	$ (16,687)	$ (30,279)
Net loss per share, basic and diluted (Note 2)	$ (1.32)	$ (8.46)
Weighted-average number of shares used to compute net loss per share, basic and diluted (Note 2)	12,632,780	3,578,771

The accompanying notes are an integral part of these financial statements

Exagen Inc.

Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity
(in thousands, except share and per share amounts)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
Balances at December 31, 2018	532,606,084	$ 105,232	63,005	$ —	$ 40,598	$ (152,564)	$ (111,966)
Accretion of redeemable convertible preferred stock	—	4,640	—	—	(4,640)	—	(4,640)
Exercise of stock options	—	—	1,548	—	4	—	4
Stock-based compensation	—	—	—	—	572	—	572
Issuance of Series G redeemable convertible preferred stock for aggregate proceeds of $0.078 per share, net of issuance costs of $124 (Note 7)	148,928,337	11,492	—	—	—	—	—
Issuance of Series H redeemable convertible preferred stock for aggregate proceeds of $0.047 per share, net of issuance costs of $318 (Note 7)	233,446,519	3,941	—	—	6,741	—	6,741
Deemed dividend recognized on beneficial conversion features of Series H redeemable convertible preferred stock (Note 7)	—	6,741	—	—	(6,741)	—	(6,741)
Deemed dividend from conversion of Series G to Series H redeemable convertible preferred stock (Note 7)	97,592,739	6,860	—	—	(6,860)		(6,860)
Conversion of preferred stock to common stock in connection with initial public offering (Note 7)	(1,012,573,679)	(138,906)	7,816,643	8	138,898	—	138,906
Issuance of common stock in initial public offering, net of underwriting discount, commissions and issuance costs (Note 8)	—	—	4,140,000	4	50,440	—	50,444
Net exercise of common and preferred stock warrants	—	—	539,794	1	510	—	511
Reclassification of redeemable convertible preferred stock warrant liabilities as equity	—	—	—	—	726	—	726
Net loss	—	—	—	—	—	(12,038)	(12,038)
Balances at December 31, 2019	—	—	12,560,990	13	220,248	(164,602)	55,659
Exercise of stock options	—	—	47,549	—	13	—	13
Issuance of stock under Employee Stock Purchase Plan	—	—	11,649	—	142	—	142
Stock-based compensation	—	—	—	—	2,694	—	2,694
Exercise of common stock warrants	—	—	32,120	—	18	—	18
Net loss	—	—	—	—	—	(16,687)	(16,687)
Balances at December 31, 2020	—	$ —	12,652,308	$ 13	$ 223,115	$ (181,289)	$ 41,839

The accompanying notes are an integral part of these financial statements

Exagen Inc.

Statements of Cash Flows
(in thousands)

	Years Ended December 31,	
	2020	2019
Cash flows from operating activities:		
Net loss	$ (16,687)	$ (12,038)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	546	591
Amortization of debt discount and debt issuance costs	274	691
Non-cash interest expense	531	546
Revaluation of warrant liabilities	—	(267)
Deferred income taxes	(106)	—
Loss on disposal of assets	—	20
Stock-based compensation	2,694	572
Changes in assets and liabilities:		
Accounts receivable, net	(3,195)	237
Prepaid expenses and other current assets	(708)	(1,255)
Other assets	(15)	(24)
Accounts payable	986	528
Accrued and other current liabilities	1,596	688
Net cash used in operating activities	(14,084)	(9,711)
Cash flows from investing activities:		
Purchases of property and equipment	(455)	(403)
Proceeds from sale of property and equipment	—	300
Net cash used in investing activities	(455)	(103)
Cash flows from financing activities:		
Proceeds from sale of common stock upon exercise of stock options	13	4
Proceeds from common stock issued under Employee Stock Purchase Plan	142	—
Proceeds from exercise of common stock warrants	18	—
Principal payment on capital lease obligations	(249)	(138)
Proceeds from Paycheck Protection Program loan	2,865	—
Repayment of Paycheck Protection Program loan	(2,865)	—
Proceeds from initial public offering, net of issuance costs and offering costs	—	50,444
Proceeds from issuance of Series G redeemable convertible preferred stock, net of issuance costs	—	7,742
Proceeds from issuance of Series H redeemable convertible preferred stock, net of issuance costs	—	10,682
Payments of deferred offering costs	(21)	—
Net cash (used in) provided by financing activities	(97)	68,734
Net change in cash, cash equivalents and restricted cash	(14,636)	58,920
Cash, cash equivalents and restricted cash, beginning of period	72,184	13,264
Cash, cash equivalents and restricted cash, end of period	$ 57,548	$ 72,184
Supplemental disclosure of cash flow information:		
Cash paid for interest expense	$ 1,758	$ 2,288
Supplemental disclosure of non-cash items:		
Accretion to redemption value of redeemable convertible preferred stock	$ —	$ 4,640
Equipment purchased under capital lease obligations	$ 260	$ 654
Costs incurred, but not paid, in connection with capital expenditures	$ 553	$ —
Conversion of redeemable convertible preferred stock	$ —	$ 138,906
Net exercise of common and preferred stock warrants	$ —	$ 511
Deferred offering costs included in accounts payable and accrued and other current liabilities	$ 40	$ —
Reclassification of redeemable convertible preferred stock warrant liabilities as equity	$ —	$ 726
Deemed dividend recognized for beneficial conversion features of Series H redeemable convertible preferred stock	$ —	$ 6,741
Deemed dividend from conversion of Series G to Series H redeemable convertible preferred stock	$ —	$ 6,860
Conversion of Series G to Series H redeemable convertible preferred stock	$ —	$ 11,875

The accompanying notes are an integral part of these financial statements

Note 1. Organization

Description of Business

The Company is dedicated to transforming the care continuum for patients suffering from debilitating and chronic autoimmune diseases by enabling timely differential diagnosis and optimizing therapeutic intervention.

Liquidity

The Company has incurred recurring losses and negative cash flows from operating activities since inception. The Company anticipates that it will continue to incur net losses into the foreseeable future. At December 31, 2020, the Company had cash and cash equivalents of $57.4 million and had an accumulated deficit of $181.3 million. Since inception, the Company has financed its operations primarily through private placements of preferred securities, the sale of common stock through its initial public offering (IPO) and debt financing arrangements. Based on the Company's current business plan, management believes that its existing capital resources will be sufficient to fund the Company's obligations for at least twelve months following the issuance of these financial statements.

To execute its business plans, the Company may need additional funding to support its continuing operations and pursue its growth strategy. Until such time as the Company can achieve significant cash flows from operations, if ever, it expects to finance its operations through the sale of its stock, debt financings or other strategic transactions. Although the Company has been successful in raising capital in the past, there is no assurance that it will be successful in obtaining such additional financing on terms acceptable to the Company, if at all. The terms of any financing may adversely affect the holdings or the rights of the Company's stockholders. If the Company is unable to obtain funding, the Company could be forced to delay, reduce or eliminate some or all of its programs, product portfolio expansion plans or commercialization efforts, which could have a material adverse effect on the Company's business, operating results and financial condition and the Company's ability to achieve its intended business objectives.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

The Company's financial statements are prepared in accordance with accounting principles generally accepted in the United States of America (GAAP). The preparation of the accompanying financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities as of the date of the financial statements, and the reported amounts of revenue and expenses during the reporting period. Actual results could materially differ from those estimates.

Significant estimates and assumptions made in the accompanying financial statements include, but are not limited to revenue recognition, the fair value of financial instruments measured at fair value, the recoverability of its long-lived assets (including goodwill), net deferred tax assets (and related valuation allowance), and for periods prior to the IPO, the fair value of the Company's common stock and redeemable convertible preferred stock. The Company evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could materially differ from those estimates.

Concentration of Credit Risk and Other Risk and Uncertainties

Financial instruments that potentially subject the Company to credit risk consist principally of cash, cash equivalents, and accounts receivable. Substantially all the Company's cash and cash equivalents are held at one financial institution that management believes is of high credit quality. Such deposits may, at times, exceed federally insured limits.

Significant payors and customers are those which represent more than 10% of the Company's total revenue or accounts receivable balance at each respective balance sheet date. For each significant payor and customers, revenue as a percentage of total revenue and accounts receivable as a percentage of total accounts receivable are as follows:

	Revenue	
	Years Ended December 31,	
	2020	2019
Medicare	20 %	25 %
Janssen (SIMPONI®)	12 %	*
Blue Shield	11 %	12 %
Medicare Advantage	11 %	11 %
United Healthcare	*	11 %

* Less than 10%.

	Accounts Receivable	
	December 31,	
	2020	2019
Janssen (SIMPONI®)	35 %	19 %
Blue Shield	11 %	15 %
United Healthcare	*	22 %

* Less than 10%.

For the years ended December 31, 2020 and 2019, approximately 70% and 82% of the Company's revenue was related to the AVISE® CTD test, respectively.

The Company is dependent on key suppliers for certain laboratory materials. For each of the years ended December 31, 2020 and 2019, approximately 97% of the Company's diagnostic testing supplies were purchased from two suppliers. An interruption in the supply of these materials would impact the Company's ability to perform testing services.

Disaggregation of Revenue

The following table includes the Company's revenues as disaggregated by payor and customer category (in thousands):

	Years Ended December 31,	
	2020	2019
Revenue:		
Healthcare insurers	$ 22,456	$ 23,984
Government	8,446	9,896
Client(1)	5,109	4,392
Other(2)	836	639
Janssen (SIMPONI®)	5,128	1,476
Total revenue	$ 41,975	$ 40,387

(1) Includes hospitals, other laboratories, etc.
(2) Includes patient self-pay that is immaterial.

Fair Value Measurements

The carrying value of the Company's cash and cash equivalents approximate fair value due to the short-term nature of these items. Based on the borrowing rates currently available to the Company for debt with similar terms and consideration of default and credit risk, the carrying value of the Company's long-term borrowings approximates its fair value, which is considered a Level 2 input.

Fair value is defined as the exchange price that would be received for an asset or an exit price paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.

The fair value hierarchy defines a three-level valuation hierarchy for disclosure of fair value measurements as follows:

Level 1 - Unadjusted quoted prices in active markets for identical assets or liabilities;

Level 2 - Inputs other than quoted prices included within Level I that are observable, unadjusted quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and

Level 3 - Unobservable inputs that are supported by little or no market activity for the related assets or liabilities.

The categorization of a financial instrument within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

Prior to the IPO, the Company's redeemable convertible preferred stock warrant liabilities were measured at fair value on a recurring basis and were classified as Level 3 liabilities. The Company recorded subsequent adjustments to reflect the increase or decrease in estimated fair value at each reporting date in current period earnings.

Cash, Cash Equivalents and Restricted Cash

The Company considers all highly-liquid investments purchased with a remaining maturity date upon acquisition of three months or less to be cash equivalents and are stated at cost, which approximates fair value.

In 2016, the Company entered into an arrangement with a financial institution with which it has an existing banking relationship whereby in exchange for the issuance of corporate credit cards, the Company agreed to obtain a $0.1 million certificate of deposit with this financial institution as collateral for the balances borrowed on these credit cards. The Company has classified the value of this certificate of deposit (including all interest earned thereon) within other assets in the accompanying balance sheets. The Company has the right to terminate the credit card program at any time. Upon termination of the credit card program and repayment of all outstanding balances owed, the Company may redeem the certificate of deposit (and all interest earned thereon).

Cash, cash equivalents and restricted cash presented in the accompanying statements of cash flows consist of the following (in thousands):

	December 31,	
	2020	2019
Cash and cash equivalents	$ 57,448	$ 72,084
Restricted cash	100	100
	$ 57,548	$ 72,184

Property and Equipment

Property and equipment are stated at cost, net of depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, generally between three and five years. Leasehold improvements are amortized on a straight-line basis over the lesser of the estimated useful life or the remaining term of the related lease. Maintenance and repairs are charged to expense as incurred, and improvements and betterments are capitalized. When assets are retired or otherwise disposed of, the cost and

accumulated depreciation are removed from the balance sheet and any resulting gain or loss is reflected in other income or expense in the statements of operations in the period realized.

Long-lived Assets

The Company's long-lived assets are comprised principally of its property and equipment, finite lived intangible assets, and goodwill.

If the Company identifies a change in the circumstances related to its long-lived assets, such as property and equipment and intangible assets (other than goodwill), that indicates the carrying value of any such asset may not be recoverable, the Company will perform an impairment analysis. A long-lived asset (other than goodwill) is deemed to be impaired when the undiscounted cash flows expected to be generated by the asset (or asset group) are less than the asset's carrying amount. Any required impairment loss would be measured as the amount by which the asset's carrying value exceeds its fair value, and would be recorded as a reduction in the carrying value of the related asset and a charge to operating expense.

Goodwill is reviewed for impairment annually (during the fourth quarter) or more frequently if indicators of impairment exist. As the Company operates in a single operating segment and reporting unit, the Company first assesses qualitative factors to determine whether it is more likely than not that the fair value of the reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform a quantitative assessment. If, after assessing qualitative factors, the Company determines it is not more likely than not that the fair value of a reporting unit is less than its carrying amount, then performing a quantitative assessment is unnecessary. If deemed necessary, a quantitative assessment compares 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 not considered impaired; otherwise, an impairment loss is recorded. There was no indication of impairment of goodwill for any periods presented.

Clinical Studies

From time to time, the Company engages in efforts to scientifically measure and document the application and efficacy of its various testing products. These arrangements typically require the Company to pay a fee to a third-party scientific investigator (usually a physician or research institution) for each subject enrolled in a clinical study, and the Company accrues expenses associated with these efforts as subjects are enrolled in each study. Expenses associated with clinical study activities are recorded in research and development expenses in the accompanying statement of operations.

Redeemable Convertible Preferred Stock

Prior to the completion of the IPO, the Company had multiple classes of redeemable convertible preferred stock, all of which were classified as temporary equity in the accompanying balance sheet as the redemption of the shares were outside of the Company's control. Redeemable convertible preferred stock which was redeemable on or after a certain date at the option of the holder was accreted to its redemption value from the date of issuance to the earliest redemption date.

In connection with the completion of the IPO in September 2019, all outstanding shares of redeemable convertible preferred stock were automatically converted into an aggregate of 7,816,643 shares of common stock, excluding warrant conversions.

Redeemable Convertible Preferred Stock Warrants

Prior to the completion of the IPO, the Company accounted for its redeemable convertible preferred stock warrants as liabilities based upon the characteristics and provisions of each instrument. The redeemable convertible preferred stock warrants were recorded at their fair value on the date of issuance and were revalued on each subsequent balance sheet date, with fair value changes recognized as increases or reductions in the statements of operations. Upon the completion of the IPO, all remaining outstanding warrants to purchase shares of redeemable convertible preferred stock were automatically converted into warrants to purchase shares of common stock. As such, the warrants no longer require liability accounting and the then fair value of the warrant liability was reclassified into stockholders' equity.

The Company performed the final remeasurement of the warrant liabilities as of the IPO closing date. See Note 7 for the amounts associated with the fair value measurements and Note 8 for further discussion on the remaining warrants.

Revenue Recognition

Substantially all of the Company's revenue has been derived from sales of its testing products and is primarily comprised of a high volume of relatively low-dollar transactions. The Company primarily markets its testing products to rheumatologists and their physician assistants in the United States. The healthcare professionals who order the Company's testing products and to whom test results are reported are generally not responsible for payment for these products. The parties that pay for these services (the Payors) consist of healthcare insurers, government payors (primarily Medicare and Medicaid), client payors (i.e., hospitals, other laboratories, etc.), and patient self-pay. The Company's service is a single performance obligation that is completed upon the delivery of test results to the prescribing physician which triggers revenue recognition.

Payors are billed at the Company's list price. Net revenues recognized consist of amounts billed net of allowances for differences between amounts billed and the estimated consideration the Company expects to receive from such payors. The process for estimating revenues and the ultimate collection of accounts receivable involves significant judgment and estimation. The Company follows a standard process, which considers historical denial and collection experience, insurance reimbursement policies and other factors, to estimate allowances and implicit price concessions, recording adjustments in the current period as changes in estimates occur. Further adjustments to the allowances, based on actual receipts, is recorded upon settlement. The transaction price is estimated using an expected value method on a portfolio basis. The Company's portfolios are grouped per payor (i.e. each individual third-party insurance, Medicare, client payors, patient self-pay, etc.) and per test basis.

Collection of the Company's net revenues from payors is normally a function of providing complete and correct billing information to the healthcare insurers and generally occurs within 30 to 90 days of billing. Contracts do not contain significant financing components based on the typical period of time between performance of services and collection of consideration.

Janssen Promotion Agreement

In December 2018, the Company entered into a co-promotion agreement (the Janssen Agreement) with Janssen Biotech, Inc. (Janssen) to co-promote SIMPONI® in the United States. The Company is responsible for the costs associated with its salesforce over the course of such co-promotion. Janssen is responsible for all other aspects of the commercialization of SIMPONI® under the Janssen Agreement. In exchange for the Company's sales and co-promotional services, the Company is entitled to a quarterly tiered promotion fee based on the incremental increase in total prescribed units of SIMPONI® for that quarter over a predetermined baseline. For the years ended December 31, 2020 and 2019, the tiered promotion fee ranged from $750 to $1,250 per prescription over a predetermined baseline. Due in part to COVID-19, in June 2020, the Janssen Agreement was amended (June Amended Janssen Agreement). In accordance with the June Amended Janssen Agreement, the predetermined average baseline for prescribed units for each remaining quarter in 2020 was adjusted and is subject to further adjustment, and for each of the third and fourth quarters of 2020, the Company received a minimum promotion fee of $0.3 million and the fee was capped at 5% above the adjusted predetermined baseline. In December 2020, the Janssen Agreement amended. The Janssen Agreement, as amended in June 2020 and December 2020 is collectively referred to as the Amended Janssen Agreement. In accordance with the Amended Janssen Agreement, the predetermined average baseline for prescribed units for the quarters ending December 31, 2020, March 31, 2021 and June 30, 2021, was adjusted to approximately 28,750 prescribed units per quarter, subject to adjustment under certain circumstances. For the first and second quarters of 2021, the Company will be entitled to an amended tiered promotion fee ranging from $500 to $1,000 per prescription based on the incremental increase in total prescribed units. Pursuant to the Amended Janssen Agreement, for the first and second quarters of 2021, the Company will receive a minimum promotion fee of $0.3 million and the fee will be capped at 10% above the adjusted predetermined baseline. The Company continued to receive a minimum promotion fee of $0.3 million and the fee was capped at 5% above the adjusted predetermined baseline for the quarter ended December 31, 2020. The quarterly tiered promotion fee for the remaining term of the Janssen Promotion Agreement beginning with the quarter ended September 30, 2021 will revert to the terms set forth in the Janssen Agreement prior to amendment, with no minimum promotion fee and no cap on predetermined baseline units. In addition, during the term of the Janssen Agreement, the Company is restricted from promoting any other biologic or Janus kinase inhibitor, or JAK inhibitor, used for treatment of indications covered by the agreement without first obtaining Janssen's written consent.

The Janssen Agreement expires on December 31, 2021, unless extended by the Company for an additional 12 months upon 180 days written notice prior to the end of the current term. If the Company elects to extend the term, the predetermined baseline for 2022 will be subject to future agreement by the Company and Janssen. Janssen may terminate the Amended Janssen Agreement at any time for any reason upon 30 days' notice to the Company, and the Company may terminate the Amended Janssen Agreement for any reason at the end of any calendar quarter upon 30 days' notice to Janssen. Either party may terminate the Amended Janssen Agreement in the event of the other party's default of any of its material obligations under the agreement if such default remains uncured for a specified period of time following receipt of written notice of such default.

The Company's obligations relating to sales and co-promotion services for SIMPONI® is a series of single performance obligations since Janssen simultaneously receives and consumes benefits provided by the Company's sales and co-promotional services. The method for measuring progress towards satisfying the performance obligations is based on prescribed units in excess of the contractual baseline at the contractual rate earned per unit since the agreement is cancelable. The Company recognized co-promotion revenue of approximately $5.1 million and $1.5 million during the years ended December 31, 2020 and 2019, respectively. The related expenses for marketing SIMPONI® are included in selling, general and administrative expenses and are expensed as incurred.

Research and Development

Costs associated with research and development activities are expensed as incurred and include, but are not limited to, personnel-related expenses, including stock-based compensation expense, materials, laboratory supplies, consulting costs, costs associated with setting up and conducting clinical studies and allocated overhead including rent and utilities.

Advertising and Marketing Costs

Costs associated with advertising and marketing activities are expensed as incurred. Total advertising and marketing costs were approximately $1.3 million and $1.6 million for the years ended December 31, 2020 and 2019, respectively, and are included in selling, general and administrative expenses in the accompanying statements of operations.

Shipping and Handling Costs

Costs incurred for shipping and handling are included in costs of revenue in the accompanying statements of operations and totaled approximately $1.4 million for each of the years ended December 31, 2020 and 2019.

Stock-Based Compensation

The Company recognizes compensation expense for all stock-based awards to employees and directors based on the grant-date estimated fair values over the requisite service period of the awards (usually the vesting period) on a straight-line basis. The fair value of stock options and purchases under the employee stock purchase plan (ESPP) rights is determined using the Black-Scholes-Merton (BSM) option pricing model, which requires management to make certain assumptions regarding a number of complex and subjective variables. Equity award forfeitures are recorded as they occur.

The BSM option pricing model incorporates various estimates, including the fair value of the Company's common stock, expected volatility, expected term and risk-free interest rates. The weighted-average expected term of options was calculated using the simplified method. This decision was based on the lack of relevant historical data due to the Company's limited historical experience. In addition, due to the Company's limited historical data, the estimated volatility incorporates the historical volatility over the expected term of the award of comparable companies whose share prices are publicly available. The risk-free interest rate for periods within the contractual term of the option is based on the U.S. Treasury yield in effect at the time of grant. The dividend yield was zero, as the Company has never declared or paid dividends and has no plans to do so in the foreseeable future.

Upon the effective date of the IPO, the Company began using the closing price of its common stock as the fair value of its common stock on the corresponding date. Prior to the completion of the IPO in September 2019, due to the absence of a public market for the Company's common stock, it was necessary to estimate the fair value of the common stock underlying the Company's stock-based awards when performing fair value calculations using the BSM option pricing model. The fair value of the common stock underlying the Company's stock-based awards was assessed on each grant date by the Company's board of directors (Board of Directors).

Comprehensive Loss

Comprehensive loss is defined as a change in equity of a business enterprise during a period, resulting from transactions from nonowner sources. There have been no items qualifying as other comprehensive loss and, therefore, for all periods presented, the Company's comprehensive loss was the same as its reported net loss.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company recognizes net deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future in excess of their net recorded amount, management would adjust the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Company records uncertain tax positions on the basis of a two-step process whereby (i) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (ii) for those tax positions that meet the more-likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50% likely to be realized upon ultimate settlement with the related tax authority. The Company recognizes interest and penalties related to unrecognized tax benefits within income tax expense. Any accrued interest and penalties are included within the related tax liability.

Net Loss Per Share

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period. Diluted 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 common stock equivalents outstanding for the period determined using the treasury-stock and if-converted methods. Potentially dilutive common stock equivalents are comprised of redeemable convertible preferred stock, warrants for the purchase of redeemable convertible preferred and common stock, options outstanding under the Company's stock option plans and shares of the Company's common stock pursuant to Employee Stock Purchase Plan. For the years ended December 31, 2020 and 2019, there is no difference in the number of shares used to calculate basic and diluted shares outstanding as the inclusion of the potentially dilutive securities would be antidilutive.

Potentially dilutive securities not included in the calculation of diluted net loss per share because to do so would be anti-dilutive are as follows (in common stock equivalent shares):

	Years Ended December 31,	
	2020	**2019**
Warrants to purchase common stock	426,827	461,273
Common stock options	1,975,761	1,375,542
Employee stock purchase plan	11,640	—
Total	2,414,228	1,836,815

Government Assistance Grant Income

Government assistance grants which are unconditional when received and intended to compensate for expenses incurred or replace lost revenue are recognized when those expenses are incurred or during the period that lost revenue is experienced, and are included in other income, net in the accompanying statements of operations.

Segment Reporting

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 in making decisions regarding resource allocation and assessing performance. The Company views its operations as, and manages its business in, one operating segment.

Recent Accounting Pronouncements Not Yet Adopted

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (FASB), or other standard setting bodies and adopted by the Company as of the specified effective date. Under the Jumpstart Our Business Startups Act of 2012 (JOBS Act), the Company meets the definition of an emerging growth company. The Company has elected to use the extended transition period for complying with new or revised accounting standards pursuant to Section 107(b) of the JOBS Act. Unless otherwise discussed, the impact of recently issued standards that are not yet effective will not have a material impact on the Company's financial position or results of operations upon adoption.

In February 2016, the FASB issued Accounting Standards Update (ASU) 2016-02, *Leases* (Topic 842). The new topic supersedes Topic 840, *Leases*, and increases transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and requires disclosures of key information about leasing arrangements. In July 2018, the FASB issued ASU 2018-10, *Codification Improvements to Topic 842*, which provides narrow amendments to clarify how to apply certain aspects of the new lease standard, and ASU 2018-11, *Leases: Targeted Improvements*, which was issued to provide relief to companies from restating comparative periods. Pursuant to this ASU, in the period of adoption the Company will not restate comparative periods presented in its financial statements. The effective date of this guidance for public companies is for reporting periods beginning after December 15, 2018. In June 2020, the FASB issued ASU 2020-05, which delays the adoption of ASU 2016-02 for non-public entities to fiscal years beginning after December 15, 2021, and interim periods beginning after December 15, 2022. As an emerging growth company as defined in the JOBS Act, the Company has elected to delay adoption of this ASU until January 1, 2022. Topic 842 mandates a modified retrospective transition method. The Company intends to adopt the new lease standard using a cumulative effect to accumulated deficit and will elect the package of practical expedients, which among other things will allow the Company to carry forward its historical lease classification. The Company is currently evaluating the impact of Topic 842 on its financial statements.

In December 2019, the FASB issued ASU 2019-12, *Simplifying the Accounting for Income Taxes*. The new guidance removes certain exceptions to the general principles of ASC 740 in order to simplify the complexities of its application. These changes include eliminations to the exceptions for intraperiod tax allocation, recognizing deferred tax liabilities related to outside basis differences, and year-to-date losses in interim periods, among others. The effective date of this guidance for public companies is for fiscal years, and interim period within those fiscal years, beginning after December 15, 2020. The Company does not anticipate the adoption will have a material impact on its financial statements.

Recently Adopted Accounting Standards

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement: Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement*, which adds and modifies certain disclosure requirements for fair value measurements. Under the new guidance, entities will no longer be required to disclose the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, or valuation processes for Level 3 fair value measurements. However, public companies will be required to disclose the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and related changes in unrealized gains and losses included in other comprehensive income. The narrative description of measurement uncertainty should be applied prospectively for only the most recent interim or annual period presented in the initial fiscal year of adoption. This update is effective for annual periods beginning after December 15, 2019, and interim periods within those periods, and early adoption is permitted. The Company adopted this guidance on January 1, 2020, and the adoption did not have a material impact on its financial statements.

Note 3. Other Financial Information

Prepaid Expenses and Other Current Assets

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

	December 31,	
	2020	2019
Diagnostic testing supplies	$ 1,203	$ 1,427
Prepaid product royalties	68	123
Prepaid maintenance and insurance contracts	2,229	1,768
Other prepaid and other current assets	659	133
Prepaid and other current assets	$ 4,159	$ 3,451

Property and Equipment

Property and equipment consist of the following (in thousands):

	December 31,	
	2020	2019
Furniture and fixtures	$ 64	$ 25
Laboratory equipment	2,679	2,228
Computer equipment and software	927	851
Leasehold improvements	1,072	424
Construction in progress	301	247
Total property and equipment	5,043	3,775
Less: accumulated depreciation and amortization	(2,941)	(2,395)
Property and equipment, net	$ 2,102	$ 1,380

Depreciation and amortization expense for the years ended December 31, 2020 and 2019, was approximately $0.5 million and $0.6 million, respectively. At December 31, 2020 and December 31, 2019, the gross book value of assets under capital lease was $1.2 million and $0.8 million, respectively, and is classified in "Laboratory equipment" in the table above.

Accrued and Other Current Liabilities

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

	December 31,	
	2020	2019
Accrued payroll and related expenses	$ 3,589	$ 2,362
Accrued interest	147	145
Accrued purchases of goods and services	311	319
Accrued royalties	221	727
Accrued clinical study activity	228	40
Capital lease obligations, current portion	308	238
Other accrued liabilities	953	588
Accrued and other current liabilities	$ 5,757	$ 4,419

Note 4. Borrowings

2017 Term Loan

In September 2017, the Company executed a term loan agreement (the 2017 Term Loan) with Innovatus Life Sciences Lending Fund I, LP (Innovatus) and borrowed $20.0 million, $17.8 million of which was immediately used to repay the Company's existing loan with Capital Royalty Partners II L.P. and its affiliates. On December 7, 2018, the Company borrowed an additional $5.0 million under the 2017 Term Loan. At December 31, 2020, no additional amounts remain available to borrow under the 2017 Term Loan.

In November 2019, the Company executed the First Amendment to the Loan and Security Agreement (the 2017 Loan Amendment). The interest rate on all borrowings under the Loan Amendment is 8.5%, of which 2.0% is paid in-kind in the form of additional term loans (PIK Loans) until December of 2022, after which interest accrues at an annual rate of 8.5%. The Company has estimated the effective interest rate of this loan to be approximately 10%. Accrued interest is due and payable monthly, unless the Company elects to pay paid-in-kind interest. The outstanding principal and accrued interest on the Loan Amendment will be repaid in twenty-four equal monthly installments commencing in December 2022. Upon repayment of the final installment under the Loan Amendment, the Company is required to pay an additional fee of $1.0 million. This obligation is being accreted into interest expense over the term of Loan Amendment using the effective interest method. For each of the years ended December 31, 2020 and 2019, the Company issued PIK Loans totaling $0.5 million.

The Loan Amendment requires a prepayment premium of 3% of the aggregate outstanding principal. The prepayment premium decreases by 1% during each subsequent twelve-month period after November 19, 2020.

The Loan Amendment is collateralized by a first priority security interest on substantially all of the Company's assets, including intellectual property. The affirmative covenants of the Loan Amendment require that the Company timely file taxes, maintain good standing and government compliance, maintain liability and other insurance, provide prompt notification of significant corporate events, and furnish audited financial statements within 150 days of fiscal year end without qualification as to the scope of the audit or as to going concern and without any other similar qualification.

The affirmative covenants require that the Company achieve a specified level of revenue, as measured quarterly on a rolling twelve-month basis, and commencing with the quarter ending December 31, 2019. The consequences of failing to achieve the performance covenant may be cured if, within sixty days of failing to achieve the performance covenant, the Company issues additional equity securities or subordinated debt with net proceeds sufficient to fund any cash flow deficiency generated from operations, as defined. The Company's revenues for the twelve-month ended September 30, 2020 were lower than the specified targets, as a result, the Company and Innovatus agreed on a new management plan and target to bring the Company back into compliance with the Loan Amendment. The Loan Amendment requires that the Company maintain certain levels of minimum liquidity. The Company is required to maintain an unrestricted cash balance of $2.0 million.

The negative covenants provide, among other things, that without the prior consent of Innovatus subject to certain exceptions, the Company may not dispose of certain assets, engage in certain business combinations or acquisitions, incur additional indebtedness or encumber any of the Company's property, pay dividends on the Company's capital stock or make prohibited investments. The Loan Amendment agreement provides that an event of default will occur if, among other triggers, (i) the Company defaults in the payment of any amount payable under the agreement when due, (ii) there occurs any circumstance(s) that could reasonably be expected to result in a material adverse effect on the Company's business, operations or condition, or on the Company's ability to perform its obligations under the agreement, (iii) the Company becomes insolvent, (iv) the Company undergoes a change in control or (v) the Company breaches any negative covenants or certain affirmative covenants in the agreement or, subject to a cure period, otherwise neglects to perform or observe any material item in the agreement.

At December 31, 2020, the Company was in compliance with all covenants of the Loan Amendment.

Upon an event of default in any of the Loan Amendment covenants, the repayment of the Loan Amendment may be accelerated and the applicable interest rate will be increased by 4.0% until the default is cured. Although repayment of the Loan Amendment can be accelerated under certain circumstances, the Company believes acceleration of this loan is not probable as of the date of these financial statements. Accordingly, the Company has reflected the amounts of the Loan Amendment due beyond twelve months of the balance sheet date as non-current.

Future Minimum Payments on the Outstanding Borrowings

As of December 31, 2020, future minimum aggregate payments, including interest, for outstanding borrowings under the Loan Amendment are as follows (in thousands):

Years Ending December 31,	
2021	$ 1,755
2022	2,996
2023	15,619
2024	14,280
Total	34,650
Less:	
Unamortized debt discount and issuance costs	(296)
Interest	(7,695)
Total borrowings, net of discounts and debt issuance costs	$ 26,659

Note 5. Commitments and Contingencies

Leases

As of December 31, 2020, the Company leases office and laboratory space in Vista, California, under leases that expire in January 2026, with an option to extend a portion of the lease for an additional 5-year period. In addition, the Company also leases additional office space in Vista, California, under a lease that expires in January 2026 with an option to extend the lease for an additional 5-year period. The Company's lease payments under each of these leases are subject to escalation clauses.

Minimum annual lease payments under non-cancelable lease arrangements at December 31, 2020 are as follows (in thousands):

Years Ending December 31,	Capital Leases	Operating Leases
2021	$ 344	$ 590
2022	318	613
2023	231	626
2024	58	640
2025	—	654
Thereafter	—	55
Total minimum lease payments	951	$ 3,178
Less: amount representing interest	(67)	
Present value of future minimum lease payments	884	
Less: current portion	(308)	
Long-term capital lease obligations	$ 576	

For the years ended December 31, 2020 and 2019, rent expense was $0.6 million and $0.5 million, respectively.

Acquisition-related liabilities

In connection with the acquisition of the medical diagnostics division of Cypress Bioscience, Inc. in 2010, the Company was required to pay certain amounts in the event that certain revenue milestones were achieved and upon the first commercial sale of a product associated with this acquisition. The acquisition also included amounts that may be due under several licensing agreements. All milestone payments other than one have been paid as of December 31, 2017. The remaining milestone obligation is for an additional $2.0 million payment due to Prometheus Laboratories, Inc. (Prometheus) for which the fair value was determined to be zero at December 31, 2020 and 2019.

In addition, the Company has ongoing royalty payment obligations on net sales of products which incorporate certain acquired technologies of 2.5%. Future royalties payable under these arrangements are limited to the lesser

of an aggregate of $1.2 million (including an upfront payment of $100,000) or the total royalties earned through January 1, 2024.

Licensing Agreements

The Company has licensed technology for use in its diagnostic tests. In addition to the milestone payments required by these agreements as described above, individual license agreements generally provide for ongoing royalty payments on net sales of products which incorporate licensed technology, as defined, ranging from 2.0% to 3.0%. Royalties are accrued when earned and recorded in costs of revenue in the accompanying statement of operations.

Supply Agreement

In September 2020, the Company entered into an amended supply agreement with one supplier for reagents which includes minimum annual purchase commitments of $4.1 million and $6.0 million for years ended December 31, 2021 and 2022, respectively, with a 15% annual increase thereafter through the year ended December 31, 2025.

Contingencies

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications; including subpoenas and other civil investigative demands, from governmental agencies, Medicare or Medicaid payors and managed care organizations reviewing billing practices or requesting comment on allegations of billing irregularities that are brought to their attention through billing audits or third parties. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future, but have not yet been made or of which of the Company believes to be immaterial. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated.

Litigation

From time to time, the Company may be subject to various legal proceedings that arise in the ordinary course of business activities.

Note 6. Fair Value Measurements

The following table sets forth the Company's financial instruments that were measured at fair value on a recurring basis within the fair value hierarchy (in thousands):

	December 31, 2020			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds	$ 34,507	$ 34,507	$ —	$ —

	December 31, 2019			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds	$ 70,760	$ 70,760	$ —	$ —

The fair value of the Company's money market funds is based on quoted market prices.

Note 7. Redeemable Convertible Preferred Stock

Series G Financing

In January 2019, the Company entered into an agreement with new and certain existing preferred stockholders to issue shares of Series G redeemable convertible preferred stock in multiple separate closings at a per share price of $0.078 in each closing. In conjunction with the issuance of the Series H redeemable convertible preferred stock,

each share of issued and outstanding Series G redeemable convertible preferred stock was converted into shares of Series H redeemable convertible preferred stock.

Series H Financing

In July 2019, the Company entered into an agreement with a new investor to issue shares of Series H redeemable convertible preferred stock at a per share price of $0.04712. The Company accounted for the difference between the effective conversion price of $0.04712 and the fair value of the underlying common stock at the commitment date as a beneficial conversion feature, which was immediately accreted as a deemed dividend. As a result, the Company recognized a beneficial conversion feature in the amount of $6.7 million in the third quarter of 2019, that was recorded as additional paid-in capital (in the absence of retained earnings) in the accompanying statement of redeemable convertible preferred stock and stockholders' equity. Additionally, the Company concluded that the conversion of shares of Series G into shares of Series H redeemable convertible preferred stock in connection with the issuance of Series H redeemable convertible preferred stock represented an extinguishment of the Series G shares. As a result, the Company recognized a deemed dividend for the extinguishment charge in the amount of $6.9 million in the third quarter of 2019, that was recorded as additional paid-in capital (in the absence of retained earnings) in the accompanying statement of redeemable convertible preferred stock and stockholders' equity.

Initial Public Offering

Upon completion of the Company's IPO in September 2019, an aggregate of 7,816,643 shares of common stock, excluding warrant conversion, were issued to the holders of the Company's Series A-3, Series B-3, Series C, Series D, Series E, Series F and Series H redeemable convertible preferred stockholders upon the automatic conversion of all shares of redeemable convertible preferred stock to common stock. As a result, no shares of redeemable convertible preferred stock remained outstanding at December 31, 2020 and 2019.

Note 8. Stockholders' Equity

Reverse Stock Split

On September 6, 2019, the Company effected a one-for-183.635 reverse stock split of its common stock (the Reverse Stock Split). The par value and the authorized shares of the common stock were not adjusted as a result of the Reverse Stock Split. All issued and outstanding common stock and the conversion ratio of the redeemable convertible preferred stock have been retroactively adjusted to reflect this Reverse Stock Split for all periods presented in the accompanying financial statements and notes to the financial statements.

Common Stock

On September 23, 2019, the Company closed its IPO of 4,140,000 shares of its common stock at a price to the public of $14.00 per share, including the exercise in full by the underwriters of their option to purchase 540,000 additional shares of the Company's common stock. Including the exercise of the option to purchase additional shares, the aggregate net proceeds to the Company from the offering was approximately $50.4 million, net of underwriting discounts, commissions and other offering expenses, for aggregate expenses of approximately $7.5 million. In addition, an aggregate of 7,816,643 shares of common stock, excluding warrant conversions, were issued to the holders of the Company's Series A-3, Series B-3, Series C, Series D, Series E, Series F and Series H redeemable convertible preferred stockholders upon the automatic conversion of all shares of redeemable convertible preferred stock to common stock.

Outstanding Warrants

The following equity classified warrants to purchase common stock were outstanding as of December 31, 2020:

	Shares	Exercise Price	Issuance date	Expiration date
Common stock warrants	252,798	$ 1.84	January 19, 2016	January 19, 2026
Common stock warrants	69,176	1.84	March 31, 2016	March 31, 2026
Common stock warrants	131	1.84	April 1, 2016	April 1, 2026
Common stock warrants	83,778	14.32	September 7, 2017	September 7, 2024
Common stock warrants	20,944	14.32	December 7, 2018	December 7, 2025
	426,827			

During the year ended December 31, 2020, warrants to purchase common stock were exercised resulting in the issuance of 32,120 shares of the Company's common stock and cash proceeds of an immaterial amount.

Note 9. Stock Option Plan

In September 2019, the Company's Board of Directors adopted, and the Company's stockholders approved, the 2019 Incentive Award Plan (the 2019 Plan). A total of (i) 2,011,832 shares of common stock plus (ii) shares subject to awards granted under the 2013 Plan on or before the effective date of the 2019 Plan became available for issuance under the 2019 Plan and was initially be reserved for issuance under the 2019 Plan. Under the 2019 Plan, the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units and other awards to individuals who are then employees, officers, non-employee directors or consultants of the Company or its subsidiaries. The options generally expire ten years after the date of grant and are exercisable to the extent vested. Vesting is established by the Board of Directors and is generally four years from the date of grant. The 2019 Plan contains an "evergreen provision" that allows annual increases in the number of shares available for issuance on the first day of each calendar year through January 1, 2029 in an amount equal to the lesser of: (i) 4% of the outstanding capital stock on each December 31st, or (ii) such lesser amount determined by the Board of Directors. As of December 31, 2020, 1,139,323 shares remained available for future awards. Under the evergreen provision, on January 1, 2021, an additional 506,092 shares became available for issuance under the 2019 Plan.

Activity under the Company's stock option plans is set forth below:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding, December 31, 2019	1,375,542	$ 8.33	9.16	$ 23,654
Granted	951,031	$ 16.02		
Exercised	(47,549)	$ 0.27		
Forfeited	(293,412)	$ 10.46		
Expired	(9,851)	$ 29.02		
Outstanding, December 31, 2020	1,975,761	$ 11.81	8.71	$ 6,750
Vested and expected to vest, December 31, 2020	1,975,761	$ 11.81	8.71	$ 6,750
Options exercisable, December 31, 2020	464,606	$ 6.75	8.01	$ 3,362

The weighted-average grant date fair value per share of employee options granted to employees during the years ended December 31, 2020 and 2019 was $7.55 and $7.79, respectively. The intrinsic value is calculated as the difference between the fair value of the Company's common stock and the exercise price of the stock options. The fair value of the Company's common stock is $13.20 and $25.40 per share at December 31, 2020 and 2019, respectively. The intrinsic value of options exercised for the years ended December 31, 2020 and 2019 was $1.0 million and an immaterial amount, respectively.

Stock-Based Compensation Expense

The fair value of employee stock options was estimated using the following assumptions to determine the fair value of stock options granted:

	Years Ended December 31,	
	2020	2019
Expected volatility	47%-53%	46%-59%
Risk-free interest rate	0.4%-1.7%	1.6%-2.6%
Dividend yield	—	—
Expected term (in years)	5.50-6.08	5.75-6.08

Employee Stock Purchase Plan

In September 2019, the Board of Directors adopted the Employee Stock Purchase Plan (the ESPP). The ESPP became effective on the day the ESPP was adopted by the Company's Board of Directors. The ESPP permits participants to purchase common stock through payroll deductions of up to 20% of their eligible compensation. A total of 120,000 shares of common stock was initially reserved for issuance under the ESPP. In addition, the number of shares of common stock available for issuance under the ESPP will be annually increased on the first day of each fiscal year during the term of the ESPP, beginning with the 2020 calendar year through January 1, 2029 in an amount equal to the lesser of (i) 1% of the outstanding capital stock on December 31st, or (ii) such lesser amount determined by the Board of Directors. Under the evergreen provision, on January 1, 2021, an additional 126,523 shares became available for issuances under the ESPP. Stock-based compensation expense for the ESPP was an immaterial amount for the year ended December 31, 2020.

The following assumptions were used to calculate the stock-based compensation for each stock purchase right granted under the ESPP:

	Years Ended December 31,
	2020
Expected volatility	58%-83%
Risk-free interest rate	0.1%-1.1%
Dividend yield	—
Expected term (in years)	0.5

Total non-cash stock-based compensation expense recorded related to options granted and stock purchase rights granted under the ESPP in the statement of operations is as follows (in thousands):

	Years Ended December 31,	
	2020	2019
Cost of revenue	$ 33	$ 9
Selling, general and administrative	2,419	445
Research and development	242	118
Total	$ 2,694	$ 572

As of December 31, 2020, total unrecognized compensation cost was $8.5 million, which is expected to be recognized over a remaining weighted-average vesting period of 2.8 years.

Common stock reserved for future issuance consists of the following at December 31, 2020:

Warrants to purchase common stock	426,827
Common stock option grants issued and outstanding	1,975,761
Common shares available for grant under the stock option plan	1,139,323
Common shares available for future issuance under ESPP	233,961
Total	3,775,872

Note 10. Income Taxes

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

	Years Ended December 31,	
	2020	2019
Current:		
Federal	$ —	$ —
State	27	5
Total current	27	5
Deferred:		
Federal	(117)	10
State	11	10
Total deferred	(106)	20
(Benefit) provision for income tax	$ (79)	$ 25

The effective tax rate of our provision for income taxes differs from the federal statutory rate as follows:

	Years Ended December 31,	
	2020	2019
Federal statutory tax rate	(21.0)%	(21.0)%
State income taxes, net of federal tax benefits	(3.9)%	(3.6)%
Change in fair value of preferred stock liabilities	— %	(0.5)%
Change in valuation allowance	22.6 %	(36.1)%
Limitation of net operating losses	— %	59.8 %
Other	1.8 %	1.6 %
Effective tax rate	(0.5)%	0.2 %

Significant components of the Company's deferred tax assets at December 31, 2020 and 2019 are shown below. A valuation allowance has been established as realization of the Company's deferred tax assets has not met the more likely-than-not threshold requirement. If the Company's judgment changes and it is determined that the Company will be able to realize these deferred tax assets, the tax benefits relating to any reversal of the valuation allowance on deferred tax assets will be accounted for as a reduction to income tax expense (in thousands).

	December 31,	
	2020	2019
Deferred tax assets:		
Net operating loss carryforwards	$ 17,733	$ 15,287
Research and development tax credits	629	419
Accruals, reserves and other	1,448	590
Interest expense	1,306	744
Basis differences in fixed and intangible assets	117	225
Total gross deferred tax assets	21,233	17,265
Less: Valuation allowance	(20,596)	(16,797)
Deferred tax assets, net	637	468
Deferred tax liabilities:		
Financing and acquisition-related liabilities	(336)	(336)
Indefinite lived assets	(459)	(396)
Deferred tax liabilities, net	(795)	(732)
Net deferred tax liabilities	$ (158)	$ (264)

Changes in the valuation allowance for deferred tax assets during the years ended December 31, 2020 and 2019, which related primarily to increases in net operating loss carryforwards, accrued revenue and accruals and reserves were as follows (in thousands):

	December 31,	
	2020	2019
Valuation allowance at the beginning of the year	$ 16,797	$ 21,138
Decreases recorded as benefits to income tax provision	—	(4,341)
Increases recorded to income tax provision	3,799	—
Valuation allowance at the end of the year	$ 20,596	$ 16,797

At December 31, 2020 and 2019, the Company had federal net operating loss carryforwards of approximately $70.6 million and $60.7 million, respectively. At December 31, 2020 and 2019, the Company had state net operating loss carryforwards of $48.9 million and $43.5 million, respectively. Approximately $43.5 million of the federal tax loss carryforwards will begin to expire in 2022, unless previously utilized. The federal net operating loss carryforwards generated in after December 31, 2017 of $27.1 million will carryforward indefinitely. The Company's state tax loss carryforwards will expire in 2032, unless previously utilized.

At December 31, 2019, the Company's deferred tax assets are primarily comprised of federal and state tax net operating loss carryforwards. The Company completed a formal study through the year ended December 31, 2019 and determined ownership changes within the meaning of Internal Revenue Code (IRC), Section 382 had occurred in 2003, 2008, 2012, 2017 and 2019. Based on the analysis, $61.8 million of the Company's tax attribute carryforwards through December 31, 2017 cannot be utilized under IRC Section 382. The Company's ability to utilize net operating loss carryforwards generated after December 31, 2017 will not expire under the Tax Cuts and Jobs Act of 2017. The Company adjusted tax attribute carry forwards and deferred tax assets accordingly. As the deferred tax assets associated with the tax attribute carry forwards were fully offset by a valuation allowance, a corresponding reduction in the Company's valuation allowance was also recorded, resulting in no income tax impact.

The Company is subject to taxation in the U.S. and in various state jurisdictions. The Company's tax years for 2002 and forward are subject to examination by the U.S. and state tax authorities due to the carryforward of unutilized net operating losses and research and development credits.

The Company recognizes interest and/or penalties related to income tax matters in its provision for income taxes. The Company does not have any accruals for, and did not recognize any, interest or penalties in these financial statements in any period presented.

Uncertain Tax Positions

At December 31, 2020 and 2019, the Company had no unrecognized tax benefits.

The Company does not believe that the balance of unrecognized tax benefits will materially change within the next twelve months.

Note 11. Related Parties

The closings of the Series G financing and the Series H financing described in Note 7 were issued to existing holders of the Company's redeemable convertible preferred stock, including certain members of our Board of Directors.

Note 12. 401(k) Plan

The Company sponsors an employee savings plan that qualifies as a deferred salary arrangement under Section 401(k) of the Code. Participating employees may defer up to the Internal Revenue Service annual contribution limit. Additionally, the Company may elect to make contributions into the savings plan at its sole discretion. For the years ended December 31, 2020 and 2019, the Company made contributions to the Plan at 3% of qualified employee compensation, which totaled approximately $0.5 million and $0.4 million, respectively.

Note 13. COVID-19

During 2020, due to the worldwide COVID-19 pandemic, the Company experienced a reduction in patient test volumes, delays in patient enrollment in ongoing and planned clinical studies, and delays in the procurement of its testing supplies. In response to the pandemic, the Company has curtailed non-essential employee travel, equipped employees with the ability to work remotely with the exception of clinical laboratory employees, and reduced marketing spend and employee headcount. The reduction in headcount resulted in a restructuring charge for termination benefits of $0.3 million which has been paid as of December 31, 2020. The full extent to which the COVID-19 pandemic will directly or indirectly continue to impact the Company's business, results of operations and financial condition, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain it or treat COVID-19, as well as the economic impact on local, regional and international markets.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) was enacted in response to the COVID-19 pandemic. The CARES Act, among other things, permits NOL carryovers and carrybacks to offset 100% of taxable income for taxable years beginning before 2021. Under the Tax Cuts and Jobs Act (TCJA), NOLs generated post TCJA were allowed to be carried forward indefinitely but were only allowed to offset 80% of taxable income. As a result of the CARES Act and the change to permit NOLs generated in taxable years 2018, 2019 and 2020 to offset 100% of taxable income, the Company released valuation allowance against its deferred tax assets in the amount of $0.1 million for the year ended December 31, 2020.

On December 27, 2020, the Consolidated Appropriations Act, 2021 was signed into law. It provides additional COVID-19 focused relief and extends certain provisions of the CARES Act. At this time, the Company does not believe that the Consolidated Appropriations Act, 2021 has a material impact on its financial statements.

In April 2020, the Company received $0.7 million of funding under the CARES Act Provider Relief Fund, subject to the Company's agreement to comply with the Department of Health & Human Services' (HHS) standard terms and conditions. The CARES Act Provider Relief Fund is a federal fund allocated for general distributions to Medicare facilities and providers impacted by the COVID-19 pandemic and is intended to support COVID-related expenses or lost revenue attributable to COVID-19. The funding received is considered a government grant which is recognized when there is reasonable assurance that the grant will be received and that conditions attached to the grant have

been met. For the year ended December 31, 2020, the Company recognized $0.7 million due to lost revenue attributable to COVID-19, which is reflected in other income, net, on its statements of operations.

On April 16, 2020, the Company entered into a promissory note with BOKF, NA dba Bank of Oklahoma, the lender, evidencing an unsecured loan pursuant to the U.S. Small Business Administration (SBA) Paycheck Protection Program (PPP) of the CARES Act of approximately $2.9 million (the PPP Loan). The Company applied for and received the PPP Loan pursuant to the then published PPP qualification and certification requirements. On April 23, 2020, the SBA, in consultation with the Department of Treasury, issued new guidance that created uncertainty regarding the qualification requirements for the PPP Loan (the New Guidance). In light of the New Guidance, on May 11, 2020, the Company paid off in full the principal and interest on the PPP Loan, resulting in the termination of the promissory note.

Index to Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed/Furnished Herewith
		Form	File No.	Exhibit	Exhibit Filing Date	
3.1	Form of Amended and Restated Certificate of Incorporation.	8-K	001-39049	3.1	9/23/2019	
3.2	Form of Amended Restated Bylaws.	8-K	001-39049	3.2	9/23/2019	
4.1	Specimen stock certificate evidencing the shares of common stock.	S-1/A	333-233446	4.1	9/9/2019	
4.2	Amended and Restated Investors' Rights Agreement, dated July 12, 2019, by and among the Registrant and certain of its stockholders.	S-1/A	333-233446	4.2	9/9/2019	
4.3	Amendment to Convertible Promissory Notes and Warrants, dated January 19, 2016.	S-1/A	333-233446	4.7	9/9/2019	
4.4	Form of Warrant to Purchase Stock issued to Innovatus Life Sciences Lending Fund I, LP in connection with the Registrant's 2018 loan agreement.	S-1/A	333-233446	4.9	9/9/2019	
10.1#	Exagen Corporation 2002 Stock Option Plan, as amended, and form of option agreement thereunder.	S-1/A	333-233446	10.1	9/9/2019	
10.2#	Exagen Diagnostics, Inc. 2013 Stock Option Plan, as amended, and form of option agreement thereunder.	S-1/A	333-233446	10.2	9/9/2019	
10.3#	Exagen Inc. 2019 Incentive Award Plan.	S-1/A	333-233446	10.3	9/9/2019	
10.4#	Form of Option Agreement under Exagen Inc. 2019 Incentive Award Plan.	S-1/A	333-233446	10.4	9/9/2019	
10.5#	Form of Restricted Stock Unit Agreement under Exagen Inc. 2019 Incentive Award Plan.					X
10.6#	Exagen Inc. 2019 Employee Stock Purchase Plan.	S-1/A	333-233446	10.5	9/9/2019	
10.7†	License Agreement, dated September 13, 2007, by and between Prometheus Laboratories Inc. and the Registrant (as successor in interest to Proprius, Inc.).	S-1/A	333-233446	10.6	9/9/2019	
10.8†	First Amendment to License Agreement, dated October 23, 2013, by and between Prometheus Laboratories Inc. and the Registrant (as successor in interest to Cypress Bioscience, Inc.).	S-1/A	333-233446	10.7	9/9/2019	
10.9†	Asset Purchase Agreement, dated October 8, 2010, by and between Cypress Bioscience, Inc., Proprius, Inc. and the Registrant.	S-1/A	333-233446	10.11	9/9/2019	
10.10†	Amendment No. One to Asset Purchase Agreement, dated March 10, 2011, by and between Cypress Bioscience, Inc., Proprius, Inc. and the Registrant.	S-1/A	333-233446	10.12	9/9/2019	
10.11	Amendment No. Two to Asset Purchase Agreement, dated August 21, 2012, by and between Royalty Pharma Collection Trust, Proprius, Inc. and the Registrant.	S-1/A	333-233446	10.13	9/9/2019	
10.12†	Amendment No. Three to Asset Purchase Agreement, dated February 6, 2013, by and between Royalty Pharma Collection Trust, Proprius, Inc. and the Registrant.	S-1/A	333-233446	10.14	9/9/2019	
10.13	Amendment No. Four to Asset Purchase Agreement, dated October 8, 2013, by and between Royalty Pharma Collection Trust, Proprius, Inc. and the Registrant.	S-1/A	333-233446	10.15	9/9/2019	

10.14	Amendment No. Five to Asset Purchase Agreement, dated January 26, 2016, by and between Royalty Pharma Collection Trust, Proprius, Inc. and the Registrant.	S-1/A	333-233446	10.16	9/9/2019	
10.15†	Amendment No. Six to Asset Purchase Agreement, dated February 16, 2017, by and between Royalty Pharma Collection Trust, Proprius, Inc. and the Registrant.	S-1/A	333-233446	10.17	9/9/2019	
10.16†	Amended and Restated Exclusive License Agreement, dated August 2, 2011, by and between the University of Pittsburgh—Of the Commonwealth System of Higher Education and the Registrant.	S-1/A	333-233446	10.18	9/9/2019	
10.17†	First Amendment to Amended and Restated Exclusive License Agreement, dated May 17, 2012, by and between the University of Pittsburgh—Of the Commonwealth System of Higher Education and the Registrant.	S-1/A	333-233446	10.19	9/9/2019	
10.18†	Second Amendment to Amended and Restated Exclusive License Agreement, dated September 30, 2013, by and between the University of Pittsburgh—Of the Commonwealth System of Higher Education and the Registrant.	S-1/A	333-233446	10.20	9/9/2019	
10.19	Third Amendment to Amended and Restated Exclusive License Agreement, dated June 24, 2016, by and between the University of Pittsburgh—Of the Commonwealth System of Higher Education and the Registrant.	S-1/A	333-233446	10.21	9/9/2019	
10.20†	Exclusive License Agreement, dated September 30, 2013, by and between the University of Pittsburgh—Of the Commonwealth System of Higher Education and the Registrant.	S-1/A	333-233446	10.22	9/9/2019	
10.21†	Exclusive License Agreement, dated September 5, 2011, by and between Thierry Dervieux, Ph.D. and the Registrant.	S-1/A	333-233446	10.23	9/9/2019	
10.22†	Co-Promotion Agreement, dated December 10, 2018, by and between Janssen Biotech, Inc. and the Registrant.	S-1/A	333-233446	10.24	9/9/2019	
10.23†	Amendment #1 to Co-Promotion Agreement, dated January 1, 2019, by and between Janssen Biotech, Inc. and the Registrant.	10-Q	001-39049	10.1	7/28/2020	
10.24†	Amendment #2 to Co-Promotion Agreement, dated June 18, 2020, by and between Janssen Biotech, Inc. and the Registrant.	10-Q	001-39049	10.2	7/28/2020	
10.25†	Amendment #3 to Co-Promotion Agreement, dated December 23, 2020, by and between Janssen Biotech, Inc. and the Registrant.					X
10.26	Standard Industrial/Commercial Multi-Tenant Lease, dated January 13, 2012, by and between RGS Properties and the Registrant.	10-Q	001-39049	10.1	7/28/2020	
10.27	First Amendment to Standard Industrial/Commercial Multi-Tenant Lease, dated December 1, 2013, by and between RGS Properties and the Registrant.	10-Q	001-39049	10.2	7/28/2020	
10.28	Second Amendment to Standard Industrial/Commercial Multi-Tenant Lease, dated April 29, 2016, by and between RGS Properties and the Registrant.	10-K	001-39049	10.27	3/25/2020	
10.29	Third Amendment to Standard Industrial/Commercial Multi-Tenant Lease, dated June 16, 2017, by and between RGS Properties and the Registrant.	10-K	001-39049	10.28	3/25/2020	

10.30	Fourth Amendment to Standard Industrial/Commercial Multi-Tenant Lease, dated March 16, 2020, by and between RGS Properties and the Registrant.	10-K	001-39049	10.29	3/25/2020	
10.31	Standard Industrial/Commercial Single-Tenant Lease, dated September 4, 2014, by and between Geiger Court, LLC and the Registrant.	S-1/A	333-233446	10.31	9/9/2019	
10.32	First Amendment to Standard Industrial/Commercial Single-Tenant Lease, dated August 2, 2017, by and between Geiger Court, LLC and the Registrant.	10-K	001-39049	10.31	3/25/2020	
10.33	Extension of Lease to Standard Industrial/Commercial Single-Tenant Lease, dated March 12, 2020, by and between Liberty Vista and the Registrant.	10-K	001-39049	10.32	3/25/2020	
10.34	First Amendment to Standard Industrial/Commercial Single-Tenant Lease, dated January 6, 2021, by and between Liberty Vista and the Registrant.					X
10.35	Standard Industrial/Commercial Multi-Tenant Lease, dated March 17, 2020 by and between RGS Properties and the Registrant.	10-K	001-39049	10.33	3/25/2020	
10.36	Master Lease Agreement, dated February 1, 2018, by and between Celtic Commercial Finance, a division of MB Equipment Finance, LLC and the Registrant.	S-1/A	333-233446	10.32	9/9/2019	
10.37	Loan and Security Agreement, dated September 7, 2017, by and between Innovatus Life Sciences Lending Fund I, LP and the Registrant.	S-1/A	333-233446	10.33	9/9/2019	
10.38	First Amendment to Loan and Security Agreement with Innovatus Life Sciences Lending I, LP dated November 19, 2019.	10-K	001-39049	10.36	3/25/2020	
10.39	Acknowledgement Letter to Loan and Security Agreement, by and between Innovatus Life Sciences Lending Fund I, LP and the Registrant.	10-Q	001-39049	10.1	11/10/2020	
10.40#	Offer Letter, dated October 12, 2010, by and between Thierry Dervieux, Ph.D. and the Registrant, as amended on September 9, 2011 and September 6, 2019.	S-1/A	333-233446	10.34	9/9/2019	
10.41	Form of Indemnification Agreement for Directors and Officers.	S-1/A	333-233446	10.35	9/9/2019	
10.42#	Offer Letter, dated October 7, 2011, by and between Fortunato Ron Rocca and the Registrant, as amended on September 4, 2019.	S-1/A	333-233446	10.36	9/9/2019	
10.43#	Offer Letter, dated May 16, 2017, by and between Kamal Adawi and the Registrant, as amended on September 4, 2019.	S-1/A	333-233446	10.37	9/9/2019	
10.44#	Offer Letter dated February 21, 2020, by and between Debra Zack, MD Ph.D. and the Registrant.	10-K	001-39049	10.41	3/25/2020	
10.45#	Non-Employee Director Compensation Program.	S-1/A	333-233446	10.38	9/9/2019	
10.46#	Executive Change in Control Severance Plan.					X
23.1	Consent of Independent Registered Public Accounting Firm					X
24.1	Power of Attorney (included on signature page).					X
31.1	Certificate of Principal Executive Officer, pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certificate of Principal Financial Officer, pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X

32.1*	Certifications Pursuant to U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Public Company Accounting Reform and Investor Protection Act of 2002.	X
101.SCH	XBRL Taxonomy Extension Schema Document.	X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.	X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.	X
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document.	X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.	X

***** This certification is deemed not filed for purpose of section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

\# Indicates management contract or compensatory plan.

† Portions of this exhibit (indicated by asterisks) have been omitted for confidentiality purposes.

Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

EXAGEN INC.

Date: March 16, 2021

by: /s/ Fortunato Ron Rocca
Fortunato Ron Rocca
President and Chief Executive Officer
(Principal Executive Officer)

Power of Attorney

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Fortunato Ron Rocca and Kamal Adawi as his or her true and lawful attorneys-in-fact, and each of them, with full power of substitution, for him or her in any and all capacities, to sign any amendments to this Annual Report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact, and either of them, or his or their substitute or substitutes may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Fortunato Ron Rocca Fortunato Ron Rocca	President, Chief Executive Officer and Director (Principal Executive Officer)	March 16, 2021
/s/ Kamal Adawi Kamal Adawi	Chief Financial Officer and Corporate Secretary (Principal Financial and Accounting Officer)	March 16, 2021
/s/ Brian Birk Brian Birk	Chairman of the Board of Directors	March 16, 2021
/s/ Jeff Elliott Jeff Elliott	Director	March 16, 2021
/s/ Wendy S. Johnson Wendy S. Johnson	Director	March 16, 2021
/s/ Tina S. Nova, Ph.D. Tina S. Nova, Ph.D.	Director	March 16, 2021
/s/ Ebetuel Pallares, Ph.D. Ebetuel Pallares, Ph.D.	Director	March 16, 2021
/s/ Bruce C. Robertson, Ph.D. Bruce C. Robertson, Ph.D.	Director	March 16, 2021
/s/ James L.L. Tullis James L.L. Tullis	Director	March 16, 2021

Exhibit 10.5

EXAGEN INC.

2019 INCENTIVE AWARD PLAN

RESTRICTED STOCK Unit Grant Notice

Exagen Inc., a Delaware corporation (the "***Company***"), has granted to the participant listed below ("***Participant***") the Restricted Stock Units (the "***RSUs***") described in this Restricted Stock Unit Grant Notice (this "***Grant Notice***"), subject to the terms and conditions of the Exagen Inc. 2019 Incentive Award Plan (as amended from time to time, the "***Plan***") and the Restricted Stock Unit Agreement attached hereto as **Exhibit A** (the "***Agreement***"), both of which are incorporated into this Grant Notice by reference. Capitalized terms not specifically defined in this Grant Notice or the Agreement have the meanings given to them in the Plan.

Participant:	[To be specified]
Grant Date:	[To be specified]
Number of RSUs:	[To be specified]
Vesting Commencement Date:	[To be specified]
Vesting Schedule:	[To be specified]

By accepting (whether in writing, electronically or otherwise) the RSUs, Participant agrees to be bound by the terms of this Grant Notice, the Plan and the Agreement. Participant has reviewed the Plan, this Grant Notice and the Agreement in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Grant Notice and fully understands all provisions of the Plan, this Grant Notice and the Agreement. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator upon any questions arising under the Plan, this Grant Notice or the Agreement.

EXAGEN INC.		**PARTICIPANT**
By:	_____	_____
Name:	_____	[Participant Name]
Title:	_____	

RESTRICTED STOCK UNIT AGREEMENT

Capitalized terms not specifically defined in this Restricted Stock Unit Agreement (this "***Agreement***") have the meanings specified in the Grant Notice or, if not defined in the Grant Notice, in the Plan.

ARTICLE I.
GENERAL

1.1 Award of RSUs. The Company has granted the RSUs to Participant effective as of the Grant Date set forth in the Grant Notice (the "***Grant Date***"). Each RSU represents the right to receive one Share as set forth in this Agreement. Participant will have no right to the distribution of any Shares until the time (if ever) the RSUs have vested.

1.2 Incorporation of Terms of Plan. The RSUs are subject to the terms and conditions set forth in this Agreement and the Plan, which is incorporated herein by reference. In the event of any inconsistency between the Plan and this Agreement, the terms of the Plan will control.

1.3 Unsecured Promise. The RSUs will at all times prior to settlement represent an unsecured Company obligation payable only from the Company's general assets.

ARTICLE II.
VESTING; FORFEITURE AND SETTLEMENT

2.1 Vesting; Forfeiture. The RSUs will vest according to the vesting schedule in the Grant Notice except that any fraction of an RSU that would otherwise be vested will be accumulated and will vest only when a whole RSU has accumulated. In the event of Participant's Termination of Service for any reason, all unvested RSUs will immediately and automatically be cancelled and forfeited, except as otherwise determined by the Administrator or provided in a binding written agreement between Participant and the Company.

2.2 Settlement.

a) The RSUs will be paid in Shares as soon as administratively practicable after the vesting of the applicable RSU, but in no event later than March 15 of the year following the year in which the RSU's vesting date occurs.

b) Notwithstanding the foregoing, the Company may delay any payment under this Agreement that the Company reasonably determines would violate Applicable Law until the earliest date the Company reasonably determines the making of the payment will not cause such a violation (in accordance with Treasury Regulation Section 1.409A-2(b)(7)(ii)); provided the Company reasonably believes the delay will not result in the imposition of excise taxes under Section 409A.

ARTICLE III.
TAXATION AND TAX WITHHOLDING

3.1 Representation. Participant represents to the Company that Participant has reviewed with Participant's own tax advisors the tax consequences of this award of RSUs (the "***Award***") and the transactions contemplated by the Grant Notice and this Agreement. Participant is relying solely on such advisors and not on any statements or representations of the Company or any of its agents.

3.2 Tax Withholding.

a) Subject to Section 3.2(b), payment of the withholding tax obligations with respect to the Award may be by any of the following, or a combination thereof, as determined by [the Company in its sole discretion / Participant or the Administrator][1]:

i) Cash or check;

ii) In whole or in part by delivery of Shares, including Shares delivered by attestation and Shares retained from the Award creating the tax obligation, valued at their Fair Market Value on the date of delivery; or

iii) In whole or in part by the Company withholding of Shares otherwise vesting or issuable under this Award in satisfaction of any applicable withholding tax obligations.

b) Unless [the Company / Participant or the Administrator] otherwise determines, and subject to Section 9.10 of the Plan, payment of the withholding tax obligations with respect to the Award shall be by [delivery (including electronically or telephonically to the extent permitted by the Company) of an irrevocable and unconditional undertaking by a broker acceptable to the Company to deliver promptly to the Company sufficient funds to satisfy the applicable tax withholding obligations] / [delivery (including electronically or telephonically to the extent permitted by the Company) by Participant to the Company of a copy of irrevocable and unconditional instructions to a broker acceptable to the Company that Participant has placed a market sell order with such broker with respect to Shares then-issuable upon settlement of the Award, and that the broker has been directed to deliver promptly to the Company funds sufficient to satisfy the applicable tax withholding obligations; provided, that payment of such proceeds is then made to the Company at such time as may be required by the Administrator][2].

c) Subject to Section 9.5 of the Plan, the applicable tax withholding obligation will be determined based on Participant's Applicable Withholding Rate. Participant's "***Applicable Withholding Rate***" shall mean (i) if Participant is subject to Section 16 of the Exchange Act, the greater of (A) the minimum applicable statutory tax withholding rate or (B) with Participant's consent, the maximum individual tax withholding rate permitted under the rules of the applicable taxing authority for tax withholding attributable to the underlying transaction, or (ii) if Participant is not subject to Section 16 of the Exchange Act, the minimum applicable statutory tax withholding rate or such other higher rate approved by the Company; *provided*, *however*, that (i) in no event shall Participant's Applicable Withholding Rate exceed the maximum individual statutory tax rate in the applicable jurisdiction at the time of such withholding (or such other rate as may be required to avoid the liability classification of the applicable award under generally accepted accounting principles in the United States of America); and (ii) the number of Shares tendered or withheld, if applicable, shall be rounded up to the nearest whole Share sufficient to cover the applicable tax withholding obligation, to the extent rounding up to the nearest whole Share does not result in the liability classification of the RSUs under generally accepted accounting principles.

d) Participant acknowledges that Participant is ultimately liable and responsible for all taxes owed in connection with the RSUs, regardless of any action the Company or any Subsidiary takes with respect to any tax withholding obligations that arise in connection with the RSUs. Neither the Company nor any Subsidiary makes any representation or undertaking regarding the treatment of any tax withholding in connection with the awarding, vesting or payment of the RSUs or the subsequent sale of Shares. The Company and its

[1] NTD: "Participant or the Administrator" for Section 16 individuals. "The Company" for non-Section 16 individuals.

[2] NTD: Use second bracketed language for Section 16 individuals.

Subsidiaries do not commit and are under no obligation to structure the RSUs to reduce or eliminate Participant's tax liability.

ARTICLE IV.
OTHER PROVISIONS

4.1 Adjustments. Participant acknowledges that the RSUs and the Shares subject to the RSUs are subject to adjustment, modification and termination in certain events as provided in this Agreement and the Plan.

4.2 Clawback. The Award and the Shares issuable hereunder shall be subject to any clawback or recoupment policy in effect on the Grant Date or as may be adopted or maintained by the Company following the Grant Date, including the Dodd-Frank Wall Street Reform and Consumer Protection Act and any rules or regulations promulgated thereunder.

4.3 Notices. Any notice to be given under the terms of this Agreement to the Company must be in writing and addressed to the Company in care of the Company's General Counsel at the Company's principal office or the General Counsel's then-current email address or facsimile number. Any notice to be given under the terms of this Agreement to Participant must be in writing and addressed to Participant (or, if Participant is then deceased, to the Designated Beneficiary) at Participant's last known mailing address, email address or facsimile number in the Company's personnel files. By a notice given pursuant to this Section, either party may designate a different address for notices to be given to that party. Any notice will be deemed duly given when actually received, when sent by email, when sent by certified mail (return receipt requested) and deposited with postage prepaid in a post office or branch post office regularly maintained by the United States Postal Service, when delivered by a nationally recognized express shipping company or upon receipt of a facsimile transmission confirmation.

4.4 Titles. Titles are provided herein for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.

4.5 Conformity to Securities Laws. Participant acknowledges that the Plan, the Grant Notice and this Agreement are intended to conform to the extent necessary with all Applicable Laws and, to the extent Applicable Laws permit, will be deemed amended as necessary to conform to Applicable Laws.

4.6 Successors and Assigns. The Company may assign any of its rights under this Agreement to a single or multiple assignees, and this Agreement will inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer set forth in this Agreement or the Plan, this Agreement will be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.

4.7 Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan or this Agreement, if Participant is subject to Section 16 of the Exchange Act, the Plan, the Grant Notice, this Agreement and the RSUs will be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3) that are requirements for the application of such exemptive rule. To the extent Applicable Laws permit, this Agreement will be deemed amended as necessary to conform to such applicable exemptive rule.

4.8 Entire Agreement; Amendment. The Plan, the Grant Notice and this Agreement (including any exhibit hereto) constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Participant with respect to the subject matter hereof. To the extent permitted by the Plan, this Agreement may be wholly or partially amended or otherwise modified,

suspended or terminated at any time or from time to time by the Administrator or the Board; provided, however, that except as may otherwise be provided by the Plan, no amendment, modification, suspension or termination of this Agreement shall materially and adversely affect the RSUs without the prior written consent of Participant.

4.9 Agreement Severable. In the event that any provision of the Grant Notice or this Agreement is held illegal or invalid, the provision will be severable from, and the illegality or invalidity of the provision will not be construed to have any effect on, the remaining provisions of the Grant Notice or this Agreement.

4.10 Limitation on Participant's Rights. Participation in the Plan confers no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and may not be construed as creating a trust. Neither the Plan nor any underlying program, in and of itself, has any assets. Participant will have only the rights of a general unsecured creditor of the Company with respect to amounts credited and benefits payable, if any, with respect to the RSUs, and rights no greater than the right to receive cash or the Shares as a general unsecured creditor with respect to the RSUs, as and when settled pursuant to the terms of this Agreement.

4.11 Not a Contract of Employment. Nothing in the Plan, the Grant Notice or this Agreement confers upon Participant any right to continue in the employ or service of the Company or any Subsidiary or interferes with or restricts in any way the rights of the Company and its Subsidiaries, which rights are hereby expressly reserved, to discharge or terminate the services of Participant at any time for any reason whatsoever, with or without cause, except to the extent expressly provided otherwise in a written agreement between the Company or a Subsidiary and Participant.

4.12 Counterparts. The Grant Notice may be executed in one or more counterparts, including by way of any electronic signature, subject to Applicable Law, each of which will be deemed an original and all of which together will constitute one instrument.

*** * * * ***

Exhibit 10.25

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE EXAGEN INC. HAS DETERMINED THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO EXAGEN INC. IF PUBLICLY DISCLOSED.

AMENDMENT #3 TO CO-PROMOTION AGREEMENT

As contemplated in the Co-Promotion Agreement between Exagen and Janssen signed December 10, 2018, please find attached the final Baseline TRxU for October through December (4th Quarter) of 2020, which has been agreed upon by the Janssen and Exagen Teams. This Baseline TRxU include CVS/Anthem data for the zip codes covered by Exagen sale representatives.

The below table will replace Section 2.2.2 Adjusted Baseline TRxU figures for Quarter ending December 31st, 2020 on page 2 and Section 2.12 Adjusted Baseline TRxU 4Q20, Maximum Payment and Actual Payout for 4Q20 on page 4 in the Amendment # 2 of Co-Promotion Agreement Contract No. C2020012644 and further amended via notice dated October 29th, 2020 Contract No. C2020023283.

	Q4 2020
Baseline	[***]
Max Payout	[***]

The parties have agreed that the following sections of the Agreement are hereby amended as follows effective as the date of this notice:

2.3.4. The terms of the Promotion Fee shall be adjusted for the quarters ending March 31, 2021 and June 30, 2021 as follows:

2.3.4.1 The Promotion Fee shall be based on a unit value for each quarter over Baseline TRxU, allocated as follows:

For the Quantities	Promotion Fee per unit
[***]	[***]
[***]	[***]
[***]	[***]

2.3.4.2 Unit quantities below Baseline TRxU in a quarter will be counted as zero for purposes of calculating Quantities for Promotion Fee per unit.

2.3.4.3 Janssen will pay Exagen a Minimum Promotion Fee of $300,000 for each of the quarters ending March 31, 2021 and June 30, 2021

2.3.4.4 In addition, the Promotion Fee will be capped at an amount reflecting the payment due in the event that Exagen's TRxU exceeds 10% above the Baseline TRxU for the quarters ending March 31, 2021 and June 30, 2021.

For example:
[***]

2.3.5 For the remaining quarters of the Contract Term Extension (July 1, 2021 – December 31, 2021) and any additional Third Term, the Promotion Fee payment terms shall revert to the terms set forth in the Co-Promotion Agreement, with no Minimum Promotion Fee and no Cap (Section 2.3.3).

*** Certain Confidential Information Omitted

In accordance with Amendment #2 dated June 18th, 2020 to the Agreement, please find the Second Term Baseline TRxU for the First Half of 2021:

Quarter ending	**Baseline TRxU**
March 31, 2021	[***]
June 30, 2021	[***]

Please indicate your acceptance by signing the space provided below and returning to Janssen.

JANSSEN BIOTECH, INC.
By: /s/ Howard Reid
Name: Howard Reid
Title: Director of Marketing
Date: Dec 23, 2020

Accepted and agreed
As of the date set forth above:
By: /s/ Mark Hazeltine
Name: Mark Hazeltine
Title: General Manager
Date: Dec 23, 2020

*** Certain Confidential Information Omitted

Exhibit 10.34

FIRST AMENDMENT OF LEASE

This First Amendment of Lease is made on December 30, 2020, between Liberty Vista, a California limited partnership, ("Lessor"), whose address is 1000 Pioneer Way, El Cajon, CA 92020, and Exagen Diagnostics, Inc., ("Lessee"), with reference to 1221 Liberty Way, San Diego, CA 92083 who agree as follows:

1. **Recitals.** This First Amendment of Lease is made with reference to the following facts and objectives:

    a. Lessor and Lessee entered into a written Lease dated August 15, 2014, as extended February 1, 2018, and as extended February 25, 2020 ("the Lease") in which Lessor leased to Lessee, and Lessee leased from Lessor, premises located in the City of Vista, County of San Diego, California, commonly known as 1221 Liberty Way, Vista, CA 92083, consisting of approximately 19,504 square feet ("Premises").

    b. The term of the Lease expires on January 31, 2026.

    c. The parties desire to amend the Base Rent Schedule to include amortization of the additional tenant improvement allowance.

2. **Tenant Improvement Allowance.** Lessee used its "Additional Allowance" of Fifty Thousand Dollars ($50,000.00) and was reimbursed for the same by Lessor. Pursuant the terms of the Lease the $50,000 additional allowance shall be amortized at 7% annual interest over the remaining term and paid monthly by Lessee as additional Base Rent (as shown in the Base Monthly Rent Schedule below).

3. **Base Monthly Rent Schedule.**

Term	Base Rent	Additional Base Rent *(Amortized TIA)*	Total Base Rent
February 1, 2021 through January 31, 2022	$ 19,000.00	$ 990.00	$ 19,990.00
February 1, 2022 through January 31, 2023	$ 19,600.00	$ 990.00	$ 20,590.00
February 1, 2023 through January 31, 2024	$ 20,200.00	$ 990.00	$ 21,190.00
February 1, 2024 through January 31, 2025	$ 20,800.00	$ 990.00	$ 21,790.00
February 1, 2025 through January 31, 2026	$ 21,400.00	$ 990.00	$ 22,390.00

4. **Effectiveness of Lease.** Except as set forth in this First Amendment of Lease, all the provisions of the Lease shall remain unchanged and in full force and effect.

LESSOR:
Liberty Vista
A California Limited Partnership
By: Hamann Property Management, Inc.
Authorized Agent

By: /s/ Brendan Thiessen
Brendan Thiessen - Asset Manager
Date: 1/6/2021

LESSEE:
Exagen Diagnostics, Inc.

By: /s/ Fortunato Ron Rocca
Fortunato Ron Rocca, President & CEO
Date: 1/6/2021

Exhibit 10.46

EXAGEN INC.
EXECUTIVE CHANGE IN CONTROL SEVERANCE PLAN

Exagen Inc., a Delaware corporation (the "Company"), has adopted this Exagen Inc. Executive Change in Control Severance Plan, including the attached Exhibits (the "Plan"), for the benefit of Participants (as defined below) on the terms and conditions hereinafter stated. The Plan, as set forth herein, is intended to provide severance protections to a select group of management or highly compensated employees (within the meaning of ERISA (as defined below)) in connection with qualifying terminations of employment.

1. **Defined Terms**. Capitalized terms used but not otherwise defined herein shall have the meanings indicated below:

1.1 "Actual Incentive Compensation" means the Participant's cash performance bonus, if any, for the year in which the Date of Termination occurs, based on actual performance during the year in which the Date of Termination occurs.

1.2 "Base Compensation" means the Participant's annual base salary rate in effect immediately prior to a CIC Termination, disregarding any reduction which gives rise to Good Reason.

1.3 "Board" means the Board of Directors of the Company.

1.4 "Cash Salary Severance" means the portion of a Participant's Cash Severance that is based on the Participant's Base Compensation determined in accordance with Exhibit A attached hereto.

1.5 "Cash Severance" means the Cash Salary Severance and, if applicable, the Incentive Compensation Severance, determined in accordance with Exhibit A attached hereto.

1.6 "Cause" means the occurrence of any one or more of the following events that the Board has determined, in good faith, has occurred: (i) the Participant's failure to substantially perform the Participant's duties (other than a failure resulting from the Participant's disability), including the Participant's failure to follow any lawful directive from the Board or the Participant's immediate supervisor; (ii) the Participant's violation of any code or standard of behavior generally applicable to Employees or executives of the Company; (iii) engaging in conduct that may reasonably result in reputational, economic or financial injury to the Company or its affiliates; (iv) the Participant's commission of, indictment for or plea of nolo contendere to a felony, any crime involving fraud or embezzlement under federal, state or local laws or a crime involving moral turpitude; (v) the Participant's failure to devote substantially all of the Participant's working time to the business of the Company and its affiliates; (vi) the Participant's unlawful use (including being under the influence) or possession of illegal drugs on the premises of the Company or any of its affiliates or while performing the Participant's duties and responsibilities for the Company or any of its affiliates; (vii) the Participant's commission of an act of fraud, willful misconduct or gross negligence with respect to the Company or its affiliates, or the Participant's material breach of fiduciary duty against the Company or any of its affiliates; (viii) the Participant's engaging in misconduct in connection with the performance of any of the Participant's duties, including by embezzlement or theft from the Company or its affiliates, misappropriating funds

from the Company or its affiliates or securing or attempting to secure personally any profit in connection with any transaction entered into on behalf of the Company or its affiliates; or (ix) the Participant's active disloyalty to the Company or its affiliates, including willfully aiding a competitor or improperly disclosing confidential information.

1.7 "Change in Control" shall have the meaning set forth in the Company's 2019 Incentive Award Plan.

1.8 "CIC Protection Period" means the 12 month period beginning on a Change in Control and ending on and including the one-year anniversary of the date of a Change in Control.

1.9 "CIC Termination" means a Qualifying Termination which occurs during the CIC Protection Period.

1.10 "Claimant" shall have the meaning set forth in Section 11.1 hereof.

1.11 "COBRA" means the Consolidated Omnibus Budget Reconciliation Act of 1985.

1.12 "COBRA Period" means the number of months during which the Participant is entitled to COBRA Premium Payments, determined in accordance with Exhibit A or Exhibit B attached hereto, as applicable.

1.13 "COBRA Premium Payment" shall have the meaning set forth in Section 4.2(b) hereof.

1.14 "Code" means the Internal Revenue Code of 1986, as amended from time to time, or any successor thereto.

1.15 "Committee" means the Compensation Committee of the Board, or such other committee as may be appointed by the Board to administer the Plan.

1.16 "Date of Termination" means the effective date of the termination of the Participant's employment.

1.17 "Employee" means an individual who is an employee (within the meaning of Code Section 3401(c)) of the Company or any of its subsidiaries.

1.18 "Equity Award" means a Company equity award that vests solely based on the passage of time.

1.19 "ERISA" means the Employee Retirement Income Security Act of 1974, as amended, and the regulations promulgated thereunder.

1.20 "Excise Tax" shall have the meaning set forth in Section 7.1 hereof.

1.21 "Good Reason" means the occurrence of any one or more of the following events without the Participant's prior written consent, unless the Company fully corrects the circumstances constituting Good Reason (provided such circumstances are capable of correction) as provided below:

(a) a change in the Participant's position with the Company which materially diminishes such Participant's duties, responsibilities, or authority;

(b) a material diminution of the Participant's Base Compensation and/or Target Incentive Compensation; or

(c) a relocation of the Participant's principal place of employment by more than twenty (20) miles.

Notwithstanding the foregoing, the Participant will not be deemed to have resigned for Good Reason unless (1) the Participant provides the Company with written notice setting forth in reasonable detail the facts and circumstances claimed by the Participant to constitute Good Reason within 90 days after the date of the occurrence of any event that the Participant knows or should reasonably have known to constitute Good Reason, (2) the Company fails to cure such acts or omissions within 30 days following its receipt of such notice, and (3) the effective date of the Participant's termination for Good Reason occurs no later than 60 days after the expiration of the Company's cure period.

1.22 "Incentive Compensation Severance" means the portion of a Participant's Cash Severance that is based on the Participant's Actual Incentive Compensation or Target Incentive Compensation, as applicable, as determined in accordance with Exhibit A attached hereto.

1.23 "Independent Advisors" shall have the meaning set forth in Section 7.2 hereof.

1.24 "Participant" means each Employee who is selected by the Administrator to participate in the Plan and is provided with (and, if applicable, countersigns) a Participation Notice in accordance with Section 13.2 hereof, other than any Employee who, at the time of his or her termination of employment, is covered by a plan or agreement with the Company or a subsidiary that provides for cash severance or termination benefits that explicitly supersedes and/or replaces the payments and benefits provided under this Plan. For the avoidance of doubt, retention bonus payments, change in control bonus payments and other similar payments shall not constitute "cash severance" for purposes of this definition.

1.25 "Participation Notice" shall have the meaning set forth in Section 13.2 hereof.

1.26 "Qualifying Termination" means a termination of the Participant's employment with the Company or a subsidiary, as applicable, by the Company or a subsidiary, as applicable, without Cause, or by the Participant for Good Reason. A Qualifying Termination shall not include a termination due to the Participant's death or disability.

1.27 "Release" shall have the meaning set forth in Section 4.3 hereof.

1.28 "Severance Benefits" means the severance payments and benefits to which a Participant may become entitled pursuant to Section 4 of the Plan and Exhibit A attached hereto.

1.29 "Target Incentive Compensation" means the Participant's target cash performance bonus, if any, for the year in which the Date of Termination occurs.

1.30 "Total Payments" shall have the meaning set forth in Section 7.1 hereof.

2. **Effectiveness of the Plan; Notification**. The Plan shall become effective on March 15, 2021. The Administrator shall, pursuant to a Participation Notice, notify each Participant that such Participant has been selected to participate in the Plan.

3. **Administration**. Subject to Section 13.4 hereof, the Plan shall be interpreted, administered and operated by the Committee (the "Administrator"), which shall have complete authority, subject to the express provisions of the Plan, to interpret the Plan, to prescribe, amend and rescind rules and regulations relating to the Plan, and to make all other determinations necessary or advisable for the administration of the Plan. The Administrator may delegate any of its duties hereunder to a subcommittee, or to such person or persons from time to time as it may designate other than to any Participant in the Plan, and the Administrator may delegate (other than to any Participant in the Plan) its duty to provide a Participation Notice to a Participant in the Plan. All decisions, interpretations and other actions of the Administrator (including with respect to whether a CIC Termination has occurred) shall be final, conclusive and binding on all parties who have an interest in the Plan.

4. **Severance Benefits**.

4.1 Eligibility. Each Employee who qualifies as a Participant and who experiences a CIC Termination is eligible to receive Severance Benefits under the Plan.

4.2 CIC Termination Payment. In the event that a Participant experiences a CIC Termination, then, subject to the Participant's execution and, to the extent applicable, non-revocation of a Release in accordance with Section 4.3 hereof, and subject to any additional requirements specified in the Plan, the Company shall pay or provide to the Participant the following Severance Benefits:

(a) Cash Severance Payment. The Company shall pay to the Participant an amount equal to the Cash Severance determined in accordance with Exhibit A attached hereto. Subject to Section 6.2 hereof, the Cash Severance (as set forth on Exhibit A) shall be paid in a lump sum on the 30th day following the Date of Termination.

(b) COBRA. Subject to the requirements of the Code, if the Participant properly elects healthcare continuation coverage under the Company's group health plans pursuant to COBRA, to the extent that the Participant is eligible to do so, then the Company shall directly pay or, at its election, reimburse the Participant for the COBRA premiums for the Participant and the Participant's covered dependents (in an amount determined based on the same benefit levels as would have applied if the Participant's employment had not been terminated based on the Participant's elections in effect on the Date of Termination) until the earlier of the end of the month during which the Participant's COBRA Period, determined in accordance with Exhibit A attached hereto, ends or the date the Participant becomes eligible for healthcare coverage under a subsequent employer's health plan (the "COBRA Premium Payment"). Notwithstanding the foregoing, (i) if any plan pursuant to which such benefits are provided is not, or ceases prior to the expiration of the period of continuation coverage to be, exempt from the application of Code Section 409A under Treasury Regulation Section 1.409A-1(a)(5), or (ii) the Company is otherwise unable to continue to cover the Participant under its group health plans without penalty under applicable law (including without limitation, Section 2716 of the Public Health Service

Act), then, in either case, an amount equal to each remaining Company reimbursement shall thereafter be paid to the Participant in substantially equal monthly installments over the COBRA Period (or the remaining portion thereof).

(c) Equity Award Treatment. Each outstanding Equity Award held by the Participant as of his or her Date of Termination shall become fully vested and, to the extent applicable, exercisable.

4.3 Release. Notwithstanding anything herein to the contrary, no Participant shall be eligible or entitled to receive or retain any Severance Benefits under the Plan unless he or she executes a general release of claims substantially in the form attached hereto as Exhibit B (the "Release") within 21 days (or 45 days if necessary to comply with applicable law) after the Date of Termination and, if he or she is entitled to a seven day post-signing revocation period under applicable law, does not revoke such Release during such seven day period.

5. **Limitations**. Notwithstanding any provision of the Plan to the contrary, if a Participant's status as an Employee is terminated for any reason other than due to a CIC Termination, the Participant shall not be entitled to receive any Severance Benefits under the Plan, and the Company shall not have any obligation to such Participant under the Plan.

6. **Section 409A**.

6.1 General. To the extent applicable, the Plan shall be interpreted and applied consistent and in accordance with Code Section 409A and Department of Treasury regulations and other interpretive guidance issued thereunder. Notwithstanding any provision of the Plan to the contrary, to the extent that the Administrator determines that any payments or benefits under the Plan may not be either compliant with or exempt from Code Section 409A and related Department of Treasury guidance, the Administrator may in its sole discretion adopt such amendments to the Plan or take such other actions that the Administrator determines are necessary or appropriate to (a) exempt the compensation and benefits payable under the Plan from Code Section 409A and/or preserve the intended tax treatment of such compensation and benefits, or (b) comply with the requirements of Code Section 409A and related Department of Treasury guidance; *provided*, *however*, that this Section 6.1 shall not create any obligation on the part of the Administrator to adopt any such amendment or take any other action, nor shall the Company have any liability for failing to do so.

6.2 Potential Six-Month Delay. Notwithstanding anything to the contrary in the Plan, no amounts shall be paid to any Participant under the Plan during the six-month period following such Participant's "separation from service" (within the meaning of Code Section 409A(a)(2)(A)(i) and Treasury Regulation Section 1.409A-1(h)) to the extent that the Administrator determines that paying such amounts at the time or times indicated in the Plan would result in a prohibited distribution under Code Section 409A(a)(2)(B)(i). If the payment of any such amounts is delayed as a result of the previous sentence, then on the first business day following the end of such six-month period (or such earlier date upon which such amount can be paid under Code Section 409A without resulting in a prohibited distribution, including as a result of the Participant's death), the Participant shall receive payment of a lump-sum amount equal to the cumulative amount that would have otherwise been payable to the Participant during such six-month period without interest thereon.

6.3 Separation from Service. A termination of employment shall not be deemed to have occurred for purposes of any provision of the Plan providing for the payment of any amounts or benefits that constitute "nonqualified deferred compensation" under Code Section 409A upon or following a termination of employment unless such termination is also a "separation from service" within the meaning of Code Section 409A and, for purposes of any such provision of the Plan, references to a "termination," "termination of employment" or like terms shall mean "separation from service".

6.4 Reimbursements. To the extent that any payments or reimbursements provided to a Participant under the Plan are deemed to constitute compensation to the Participant to which Treasury Regulation Section 1.409A-3(i)(1)(iv) would apply, such amounts shall be paid or reimbursed reasonably promptly, but not later than December 31st of the year following the year in which the expense was incurred. The amount of any such payments eligible for reimbursement in one year shall not affect the payments or expenses that are eligible for payment or reimbursement in any other taxable year, and the Participant's right to such payments or reimbursement of any such expenses shall not be subject to liquidation or exchange for any other benefit.

6.5 Installments. For purposes of applying the provisions of Code Section 409A to the Plan, each separately identified amount to which a Participant is entitled under the Plan shall be treated as a separate payment. In addition, to the extent permissible under Code Section 409A, the right to receive any installment payments under the Plan shall be treated as a right to receive a series of separate payments and, accordingly, each such installment payment shall at all times be considered a separate and distinct payment as permitted under Treasury Regulation Section 1.409A-2(b)(2)(iii). Whenever a payment under the Plan specifies a payment period with reference to a number of days, the actual date of payment within the specified period shall be within the sole discretion of the Company.

7. **Limitation on Payments**.

7.1 Best Pay Cap. Notwithstanding any other provision of the Plan, in the event that any payment or benefit received or to be received by a Participant (including any payment or benefit received in connection with a termination of the Participant's employment, whether pursuant to the terms of the Plan or any other plan, arrangement or agreement) (all such payments and benefits, including the Severance Benefits, being hereinafter referred to as the "Total Payments") would be subject (in whole or part), to the excise tax imposed under Code Section 4999 (the "Excise Tax"), then, after taking into account any reduction in the Total Payments provided by reason of Code Section 280G in such other plan, arrangement or agreement, the Cash Severance benefits under the Plan shall first be reduced, and any noncash severance payments hereunder shall thereafter be reduced, to the extent necessary so that no portion of the Total Payments is subject to the Excise Tax but only if (a) the net amount of such Total Payments, as so reduced (and after subtracting the net amount of federal, state and local income taxes on such reduced Total Payments and after taking into account the phase out of itemized deductions and personal exemptions attributable to such reduced Total Payments) is greater than or equal to (b) the net amount of such Total Payments without such reduction (but after subtracting the net amount of federal, state and local income taxes on such Total Payments and the amount of Excise Tax to which the Participant would be subject in respect of such unreduced Total Payments and after taking into account the phase out of itemized deductions and personal exemptions attributable to such unreduced Total Payments).

7.2 Certain Exclusions. For purposes of determining whether and the extent to which the Total Payments will be subject to the Excise Tax, (a) no portion of the Total Payments, the receipt or retention of which the Participant has waived at such time and in such manner so as not to constitute a "payment" within the meaning of Code Section 280G(b), will be taken into account; (b) no portion of the Total Payments will be taken into account which, in the written opinion of an independent, nationally recognized accounting firm (the "Independent Advisors") selected by the Company, does not constitute a "parachute payment" within the meaning of Code Section 280G(b)(2) (including by reason of Code Section 280G(b)(4)(A)) and, in calculating the Excise Tax, no portion of such Total Payments will be taken into account which, in the opinion of Independent Advisors, constitutes reasonable compensation for services actually rendered, within the meaning of Code Section 280G(b)(4)(B), in excess of the "base amount" (as defined in Code Section 280G(b)(3)) allocable to such reasonable compensation; and (c) the value of any non-cash benefit or any deferred payment or benefit included in the Total Payments shall be determined by the Independent Advisors in accordance with the principles of Code Sections 280G(d)(3) and (4).

8. **No Mitigation**. No Participant shall be required to seek other employment or attempt in any way to reduce or mitigate any Severance Benefits payable under the Plan and the amount of any such Severance Benefits shall not be reduced by any other compensation paid or provided to any Participant following such Participant's termination of service.

9. **Successors**.

9.1 Company Successors. The Plan shall inure to the benefit of and shall be binding upon the Company and its successors and assigns. Any successor (whether direct or indirect and whether by purchase, lease, merger, consolidation, liquidation or otherwise) to all or substantially all of the Company's business and/or assets shall assume and agree to perform the obligations of the Company under the Plan.

9.2 Participant Successors. The Plan shall inure to the benefit of and be enforceable by each Participant's personal or legal representatives, executors, administrators, successors, heirs, distributees, devisees, legatees or other beneficiaries. If a Participant dies while any amount remains payable to such Participant hereunder, all such amounts shall be paid in accordance with the terms of the Plan to the executors, personal representatives or administrators of such Participant's estate.

10. **Notices**. All communications relating to matters arising under the Plan shall be in writing and shall be deemed to have been duly given when hand delivered, faxed, emailed or mailed by reputable overnight carrier or United States certified mail, return receipt requested, addressed, if to a Participant, to the address or email address on file with the Company or to such other address or email address as the Participant may have furnished to the other in writing in accordance herewith and, if to the Company, to such address as may be specified from time to time by the Administrator, except that notice of change of address shall be effective only upon actual receipt.

11. **Claims Procedure; Arbitration**.

11.1 Claims. Generally, Participants are not required to present a formal claim in order to receive benefits under the Plan. If, however, any person (the "Claimant") believes that benefits are being denied improperly, that the Plan is not being operated properly, that fiduciaries of the Plan have breached

their duties, or that the Claimant's legal rights are being violated with respect to the Plan, the Claimant must file a formal claim, in writing, with the Administrator. This requirement applies to all claims that any Claimant has with respect to the Plan, including claims against fiduciaries and former fiduciaries, except to the extent the Administrator determines, in its sole discretion that it does not have the power to grant all relief reasonably being sought by the Claimant. A formal claim must be filed within 90 days after the date the Claimant first knew or should have known of the facts on which the claim is based, unless the Administrator consents otherwise in writing. The Administrator shall provide a Claimant, on request, with a copy of the claims procedures established under Section 11.2 hereof.

11.2 Claims Procedure. The Administrator has adopted procedures for considering claims (which are set forth in Exhibit C attached hereto), which it may amend or modify from time to time, as it sees fit. These procedures shall comply with all applicable legal requirements. These procedures may provide that final and binding arbitration shall be the ultimate means of contesting a denied claim (even if the Administrator or its delegates have failed to follow the prescribed procedures with respect to the claim). The right to receive benefits under the Plan is contingent on a Claimant using the prescribed claims and arbitration procedures to resolve any claim.

12. **Covenants.**

12.1 Restrictive Covenants. A Participant's right to receive and/or retain the Severance Benefits payable under this Plan is conditioned upon and subject to the Participant's continued compliance with any restrictive covenants (e.g., confidentiality, non-solicitation, non-competition, non-disparagement) contained in any other written agreement between the Participant and the Company, as in effect on the date of the Participant's CIC Termination, as well as the restrictive covenants set forth on Annex A attached hereto.

12.2 Return of Property. A Participant's right to receive and/or retain the Severance Benefits payable under the Plan is conditioned upon the Participant's return to the Company of all Company documents (and all copies thereof) and other Company property (in each case, whether physical, electronic or otherwise) in the Participant's possession or control.

13. **Miscellaneous.**

13.1 Entire Plan; Relation to Other Agreements. The Plan, together with any Participation Notice issued in connection with the Plan, contains the entire understanding of the parties relating to the subject matter hereof and supersedes any prior agreement, arrangement and understanding between any Participant, on the one hand, and the Company and/or any subsidiary, on the other hand, with respect to the subject matter hereof. Severance payable under the Plan is not intended to duplicate any other severance benefits payable to a Participant by the Company. By participating in the Plan and accepting the Severance Benefits hereunder, the Participant acknowledges and agrees that any prior agreement, arrangement and understanding between any Participant, on the one hand, and the Company and/or any subsidiary, on the other hand, with respect to the subject matter hereof is hereby revoked and ineffective with respect to the Participant (including with respect to any severance arrangement contained in an effective employment agreement or employment letter agreement by and between the Participant and the Company (and/or any subsidiary)), but only to the extent such prior agreement, arrangement or understanding provides for severance during the CIC Protection Period. For clarity, to the extent such agreement, arrangement or understanding provides severance protection to the Participant outside of the

CIC Protection Period, such agreement is not superseded by this Plan and any Participation Notice issued in connection with the Plan.

13.2 Participation Notices. The Administrator shall have the authority, in its sole discretion, to select Employees to participate in the Plan and to provide written notice to any such Employee that he or she is a Participant in, and eligible to receive Severance Benefits under, the Plan (a "Participation Notice") at or any time prior to his or her termination of employment.

13.3 No Right to Continued Service. Nothing contained in the Plan shall (a) confer upon any Participant any right to continue as an employee of the Company or any subsidiary, (b) constitute any contract of employment or agreement to continue employment for any particular period, or (c) interfere in any way with the right of the Company to terminate a service relationship with any Participant, with or without Cause.

13.4 Termination and Amendment of Plan. Prior to the consummation of a Change in Control, the Plan may be amended or terminated by the Administrator at any time and from time to time, in its sole discretion. From and after the consummation of a Change in Control, the Plan may not be amended, modified, suspended or terminated except with the express written consent of each Participant who would be adversely affected by any such amendment, modification, suspension or termination.

13.5 Survival. Section 7 (Limitation on Payments), Section 11 (Claims Procedure; Arbitration) and Section 12 (Covenants) hereof shall survive the termination or expiration of the Plan and shall continue in effect.

13.6 Severance Benefit Obligations. Notwithstanding anything contained herein, Severance Benefits paid or provided under the Plan may be paid or provided by the Company or any subsidiary employer, as applicable.

13.7 Withholding. The Company shall have the authority and the right to deduct and withhold an amount sufficient to satisfy federal, state, local and foreign taxes required by law to be withheld with respect to any Severance Benefits payable under the Plan.

13.8 Benefits Not Assignable. Except as otherwise provided herein or by law, no right or interest of any Participant under the Plan shall be assignable or transferable, in whole or in part, either directly or by operation of law or otherwise, including without limitation by execution, levy, garnishment, attachment, pledge or in any manner; no attempted assignment or transfer thereof shall be effective; and no right or interest of any Participant under the Plan shall be liable for, or subject to, any obligation or liability of such Participant. When a payment is due under the Plan to a Participant who is unable to care for his or her affairs, payment may be made directly to his or her legal guardian or personal representative.

13.9 Applicable Law. The Plan is intended to be an unfunded "top hat" pension plan within the meaning of U.S. Department of Labor Regulation Section 2520.104-23 and shall be interpreted, administered, and enforced as such in accordance with ERISA. To the extent that state law is applicable, the statutes and common law of the State of Delaware, excluding any that mandate the use of another jurisdiction's laws, will apply.

13.10 Validity. The invalidity or unenforceability of any provision of the Plan shall not affect the validity or enforceability of any other provision of the Plan, which shall remain in full force and effect.

13.11 Captions. The captions contained in the Plan are for convenience only and shall have no bearing on the meaning, construction or interpretation of the Plan's provisions.

13.12 Expenses. The expenses of administering the Plan shall be borne by the Company or its successor, as applicable.

13.13 Unfunded Plan. The Plan shall be maintained in a manner to be considered "unfunded" for purposes of ERISA. The Company shall be required to make payments only as benefits become due and payable. No person shall have any right, other than the right of an unsecured general creditor against the Company, with respect to the benefits payable hereunder, or which may be payable hereunder, to any Participant, surviving spouse or beneficiary hereunder. If the Company, acting in its sole discretion, establishes a reserve or other fund associated with the Plan, no person shall have any right to or interest in any specific amount or asset of such reserve or fund by reason of amounts which may be payable to such person under the Plan, nor shall such person have any right to receive any payment under the Plan except as and to the extent expressly provided in the Plan. The assets in any such reserve or fund shall be part of the general assets of the Company, subject to the control of the Company.

* * * * *

Annex A

RESTRICTIVE COVENANTS

(a) The Participant shall hold in a fiduciary capacity for the benefit of the Company all secret or confidential information, knowledge or data relating to the Company and its subsidiaries and affiliates, which shall have been obtained by the Participant in connection with the Participant's employment by the Company and which shall not be or become public knowledge (other than by acts by the Participant or representatives of the Participant in violation of this Annex or Plan). After termination of the Participant's employment with the Company, the Participant shall not, without the prior written consent of the Company or as may otherwise be required by law or legal process, communicate or divulge any such information, knowledge or data, to anyone other than the Company and those designated by it; provided, however, that if the Participant receives actual notice that the Participant is or may be required by law or legal process to communicate or divulge any such information, knowledge or data, the Participant shall promptly so notify the Company.

(b) While employed by the Company, the Participant shall not be engaged in any other business activity that would be competitive with the business of the Company and its subsidiaries or affiliates. In addition, while employed by the Company and, for a period of 12 months after the Date of Termination, the Participant shall not directly or indirectly solicit, induce, or encourage any employee or consultant of the Company and/or its subsidiaries and affiliates to terminate their employment or other relationship with the Company and its subsidiaries and affiliates or to cease to render services to the Company and/or its subsidiaries and affiliates and the Participant shall not initiate discussion with any such person for any such purpose or authorize or knowingly cooperate with the taking of any such actions by any other individual or entity except, in each case, to the extent the foregoing occurs as a result of general advertisements or other solicitations not specifically targeted to such employees and consultants. During the Participant's employment with the Company and thereafter, the Participant shall not use any trade secret of the Company or its subsidiaries or affiliates to solicit, induce, or encourage any customer, client, vendor, or other party doing business with any member of the Company and its subsidiaries and affiliates to terminate its relationship therewith or transfer its business from any member of the Company and its subsidiaries and affiliates and the Participant shall not initiate discussion with any such person for any such purpose or authorize or knowingly cooperate with the taking of any such actions by any other individual or entity.

(c) Subject to Section (d) of this Annex, during the Participant's service with the Company and thereafter, excepting any litigation between the parties, the Participant agrees not to publish or disseminate, directly or indirectly, any statements, whether written or oral, that are or could be harmful to or reflect negatively on any of the Company or any of its subsidiaries or affiliates, or that are otherwise disparaging of any policies, procedures, practices, decision-making, conduct, professionalism or compliance with standards of the Company, its affiliates or any of their past or present officers, directors, employees, advisors or agents

(d) Notwithstanding anything in this Annex or the Plan to the contrary, nothing contained in this Annex or the Plan shall prohibit either party (or either party's attorney(s)) from (i) filing a charge with, reporting possible violations of federal law or regulation to, participating in any investigation by, or cooperating with the U.S. Securities and Exchange Commission, the

Financial Industry Regulatory Authority, the Equal Employment Opportunity Commission, the National Labor Relations Board, the Occupational Safety and Health Administration, the U.S. Commodity Futures Trading Commission, the U.S. Department of Justice or any other securities regulatory agency, self-regulatory authority or federal, state or local regulatory authority (collectively, "Government Agencies"), or making other disclosures that are protected under the whistleblower provisions of applicable law or regulation, (ii) communicating directly with, cooperating with, or providing information (including trade secrets) in confidence to any Government Agencies for the purpose of reporting or investigating a suspected violation of law, or from providing such information to such party's attorney(s) or in a sealed complaint or other document filed in a lawsuit or other governmental proceeding, and/or (iii) receiving an award for information provided to any Government Agency. Pursuant to 18 USC Section 1833(b), the Participant will not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that is made: (x) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney, and solely for the purpose of reporting or investigating a suspected violation of law; or (y) in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. Further, nothing in this Annex or the Plan is intended to or shall preclude either party from providing truthful testimony in response to a valid subpoena, court order, regulatory request or other judicial, administrative or legal process or otherwise as required by law. If the Participant is required to provide testimony, then unless otherwise directed or requested by a Government Agency or law enforcement, the Participant shall notify the Company as soon as reasonably practicable after receiving any such request of the anticipated testimony.

Exhibit A

Calculation of Change in control Severance Amounts

Tier	Cash Salary Severance	Incentive Compensation Severance	COBRA Period
1	125% Base Compensation plus Target Incentive Compensation	Pro-rata Actual Incentive Compensation (pro-rated based on the number of days worked during the year in which the Date of Termination occurs, divided by the total number of days in such year)*	15 months
2	100% Base Compensation plus Target Incentive Compensation		12 months

* Payable on the date on which annual bonuses are generally paid (but no later than March 15 of the year following year in which the Date of Termination occurs).

EXHIBIT B

FORM OF RELEASE

1. Release. For valuable consideration, including the payments or benefits under Section 4 of the Exagen Inc. Executive Change in Control Severance Plan (the "***Severance Plan***"), the receipt and adequacy of which are hereby acknowledged, the undersigned does hereby release and forever discharge the "***Releasees***" hereunder, consisting of Exagen Inc., a Delaware corporation (the "***Company***"), and the Company's partners, subsidiaries, associates, affiliates, successors, heirs, assigns, agents, directors, officers, employees, representatives, lawyers, insurers, and all persons acting by, through, under or in concert with them, or any of them, of and from any and all manner of action or actions, cause or causes of action, in law or in equity, suits, debts, liens, contracts, agreements, promises, liability, claims, demands, damages, losses, costs, attorneys' fees or expenses, of any nature whatsoever, known or unknown, fixed or contingent (hereinafter called "***Claims***"), which the undersigned now has or may hereafter have against the Releasees, or any of them, by reason of any matter, cause, or thing whatsoever from the beginning of time to the date hereof. The Claims released herein include, without limiting the generality of the foregoing, any Claims in any way arising out of, based upon, or related to the employment or termination of employment of the undersigned by the Releasees, or any of them; any alleged breach of any express or implied contract of employment; any alleged torts or other alleged legal restrictions on Releasees' right to terminate the employment of the undersigned; and any alleged violation of any federal, state or local statute or ordinance including, without limitation, Title VII of the Civil Rights Act of 1964, the Age Discrimination In Employment Act, the Americans With Disabilities Act.

2. Claims Not Released. Notwithstanding the foregoing, this general release (the "***Release***") shall not operate to release any rights or claims of the undersigned (i) to payments or benefits under Section 4 of the Severance Plan, with respect to the payments and benefits provided in exchange for this Release, (ii) to payments or benefits under any equity award agreement between the undersigned and the Company, (iii) to accrued or vested benefits the undersigned may have, if any, as of the date hereof under any applicable plan, policy, practice, program, contract or agreement with the Company, (iv) to any Claims, including claims for indemnification and/or advancement of expenses arising under any indemnification agreement between the undersigned and the Company or under the bylaws, certificate of incorporation or other similar governing document of the Company, (v) to any Claims which cannot be waived by an employee under applicable law or (vi) with respect to the undersigned's right to communicate directly with, cooperate with, or provide information to, any federal, state or local government regulator.

3. Unknown Claims.

THE UNDERSIGNED ACKNOWLEDGES THAT THE UNDERSIGNED HAS BEEN ADVISED BY LEGAL COUNSEL AND IS FAMILIAR WITH THE PROVISIONS OF CALIFORNIA CIVIL CODE SECTION 1542, WHICH PROVIDES AS FOLLOWS:

> "A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS THAT THE CREDITOR OR RELEASING PARTY DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE AND THAT, IF KNOWN BY HIM OR HER, WOULD HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR OR RELEASED PARTY."

THE UNDERSIGNED, BEING AWARE OF SAID CODE SECTION, HEREBY EXPRESSLY WAIVES ANY RIGHTS THE UNDERSIGNED MAY HAVE THEREUNDER, AS WELL AS UNDER ANY OTHER STATUTES OR COMMON LAW PRINCIPLES OF SIMILAR EFFECT.

4. Exceptions. Notwithstanding anything in this Release to the contrary, nothing contained in this Release shall prohibit the undersigned from (i) filing a charge with, reporting possible violations of federal law or regulation to, participating in any investigation by, or cooperating with any governmental agency or entity or making other disclosures that are protected under the whistleblower provisions of applicable law or regulation and/or (ii) communicating directly with, cooperating with, or providing information (including trade secrets) in confidence to, any federal, state or local government regulator (including, but not limited to, the U.S. Securities and Exchange Commission, the U.S. Commodity Futures Trading Commission, or the U.S. Department of Justice) for the purpose of reporting or investigating a suspected violation of law, or from providing such information to the undersigned's attorney or in a sealed complaint or other document filed in a lawsuit or other governmental proceeding. Pursuant to 18 USC Section 1833(b), the undersigned will not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that is made: (x) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney, and solely for the purpose of reporting or investigating a suspected violation of law; or (y) in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal.

5. Representations. The undersigned represents and warrants that there has been no assignment or other transfer of any interest in any Claim which the undersigned may have against Releasees, or any of them, and the undersigned agrees to indemnify and hold Releasees, and each of them, harmless from any liability, Claims, demands, damages, costs, expenses and attorneys' fees incurred by Releasees, or any of them, as the result of any such assignment or transfer or any rights or Claims under any such assignment or transfer. It is the intention of the parties that this indemnity does not require payment as a condition precedent to recovery by the Releasees against the undersigned under this indemnity.

6. No Action. The undersigned agrees that if the undersigned hereafter commences any suit arising out of, based upon, or relating to any of the Claims released hereunder or in any manner asserts against Releasees, or any of them, any of the Claims released hereunder, then the undersigned agrees to pay to Releasees, and each of them, in addition to any other damages caused to Releasees thereby, all attorneys' fees incurred by Releasees in defending or otherwise responding to said suit or Claim.

7. No Admission. The undersigned further understands and agrees that neither the payment of any sum of money nor the execution of this Release shall constitute or be construed as an admission of any liability whatsoever by the Releasees, or any of them, who have consistently taken the position that they have no liability whatsoever to the undersigned.

8. OWBPA. The undersigned agrees and acknowledges that this Release constitutes a knowing and voluntary waiver and release of all Claims the undersigned has or may have against the Company and/or any of the Releasees as set forth herein, including, but not limited to, all Claims arising under the Older Worker's Benefit Protection Act and the Age Discrimination in Employment Act. In accordance with the Older Worker's Benefit Protection Act, the undersigned is hereby advised as follows:

(i) the undersigned has read the terms of this Release, and understands its terms and effects, including the fact that the undersigned agreed to release and forever discharge the Company and each of the Releasees, from any Claims released in this Release;

(ii) the undersigned understands that, by entering into this Release, the undersigned does not waive any Claims that may arise after the date of the undersigned's execution of this Release, including without limitation any rights or claims that the undersigned may have to secure enforcement of the terms and conditions of this Release;

(iii) the undersigned has signed this Release voluntarily and knowingly in exchange for the consideration described in this Release, which the undersigned acknowledges is adequate and satisfactory to the undersigned and which the undersigned acknowledges is in addition to any other benefits to which the undersigned is otherwise entitled;

(iv) the Company advises the undersigned to consult with an attorney prior to executing this Release;

(v) the undersigned has been given at least [21][1] days in which to review and consider this Release. To the extent that the undersigned chooses to sign this Release prior to the expiration of such period, the undersigned acknowledges that the undersigned has done so voluntarily, had sufficient time to consider the Release, to consult with counsel and that the undersigned does not desire additional time and hereby waives the remainder of the [21]-day period; and

(vi) the undersigned may revoke this Release within seven days from the date the undersigned signs this Release and this Release will become effective upon the expiration of that revocation period if the undersigned has not revoked this Release during such seven-day period. If the undersigned revokes this Release during such seven-day period, this Release will be null and void and of no force or effect on either the Company or the undersigned and the undersigned will not be entitled to any of the payments or benefits which are expressly conditioned upon the execution and non-revocation of this Release. Any revocation must be in writing and sent to [*name*], via electronic mail at [*email address*], on or before [5:00 p.m. Pacific time] on the seventh day after this Release is executed by the undersigned.

9. Governing Law. This Release is deemed made and entered into in the State of California, and in all respects shall be interpreted, enforced and governed under the internal laws of the State of California, to the extent not preempted by federal law.

IN WITNESS WHEREOF, the undersigned has executed this Release this ____ day of _____, ____.

_____

[_____]

[1] NTD: Use 45 days in a group termination, and include information regarding terminated positions.

EXHIBIT C

Detailed Claims Procedures

Section 1.1. Claim Procedure. Claims for benefits under the Plan shall be administered in accordance with Section 503 of ERISA and the Department of Labor Regulations thereunder. The Administrator shall have the right to delegate its duties under this Exhibit and all references to the Administrator shall be a reference to any such delegate, as well. The Administrator shall make all determinations as to the rights of any Participant, beneficiary, alternate payee or other person who makes a claim for benefits under the Plan (each, a "Claimant"). A Claimant may authorize a representative to act on his or her behalf with respect to any claim under the Plan. A Claimant who asserts a right to any benefit under the Plan he or she has not received, in whole or in part, must file a written claim with the Administrator. All written claims shall be submitted to [____].

(a) Regular Claims Procedure. The claims procedure in this subsection (a) shall apply to all claims for Plan benefits.

(1) Timing of Denial. If the Administrator denies a claim in whole or in part (an "adverse benefit determination"), then the Administrator will provide notice of the decision to the Claimant within a reasonable period of time, not to exceed 90 days after the Administrator receives the claim, unless the Administrator determines that an extension of time for processing is required. In the event that the Administrator determines that such an extension is required, written notice of the extension will be furnished to the Claimant before the end of the initial 90 day review period. The extension will not exceed a period of 90 days from the end of the initial 90 day period, and the extension notice will indicate the special circumstances requiring such extension of time and the date by which the Administrator expects to render the benefit decision.

(2) Denial Notice. The Administrator shall provide every Claimant who is denied a claim for benefits with a written or electronic notice of its decision. The notice will set forth, in a manner to be understood by the Claimant:

(i) the specific reason or reasons for the adverse benefit determination;

(ii) reference to the specific Plan provisions on which the determination is based;

(iii) a description of any additional material or information necessary for the Claimant to perfect the claim and an explanation as to why such information is necessary; and

(iv) an explanation of the Plan's appeal procedure and the time limits applicable to such procedures, including a statement of the Claimant's right to bring an action under Section 502(a) of ERISA after receiving a final adverse benefit determination upon appeal.

(3) Appeal of Denial. The Claimant may appeal an initial adverse benefit determination by submitting a written appeal to the Administrator within 60 days of receiving notice of the denial of the claim. The Claimant:

(i) may submit written comments, documents, records and other information relating to the claim for benefits;

(ii) will be provided, upon request and without charge, reasonable access to and copies of all documents, records and other information relevant to the Claimant's claim for benefits; and

(iii) will receive a review that takes into account all comments, documents, records and other information submitted by the Claimant relating to the appeal, without regard to whether such information was submitted or considered in the initial benefit determination.

(4) Decision on Appeal. The Administrator will conduct a full and fair review of the claim and the initial adverse benefit determination. The Administrator holds regularly scheduled meetings at least quarterly. The Administrator shall make a benefit determination no later than the date of the regularly scheduled meeting that immediately follows the Plan's receipt of an appeal request, unless the appeal request is filed within 30 days preceding the date of such meeting. In such case, a benefit determination may be made by no later than the date of the second regularly scheduled meeting following the Plan's receipt of the appeal request. If special circumstances require a further extension of time for processing, a benefit determination shall be rendered no later than the third regularly scheduled meeting of the Administrator following the Plan's receipt of the appeal request. If such an extension of time for review is required, the Administrator shall provide the Claimant with written notice of the extension, describing the special circumstances and the date as of which the benefit determination will be made, prior to the commencement of the extension. The Administrator generally cannot extend the review period any further unless the Claimant voluntarily agrees to a longer extension. The Administrator shall notify the Claimant of the benefit determination as soon as possible but not later than five days after it has been made.

(5) Notice of Determination on Appeal. The Administrator shall provide the Claimant with written or electronic notification of its benefit determination on review. In the case of an adverse benefit determination, the notice shall set forth, in a manner intended to be understood by the Claimant:

(i) the specific reason or reasons for the adverse benefit determination;

(ii) reference to the specific Plan provisions on which the adverse benefit determination is based;

(iii) a statement that the Claimant is entitled to receive, upon request and without charge, reasonable access to, and copies of, all documents, records and other information relevant to the claim for benefits;

(iv) a statement describing any voluntary appeal procedures offered by the Plan and the Claimant's right to obtain the information about such procedures; and

(v) a statement of the Claimant's right to bring an action under Section 502(a) of ERISA.

(b) Exhaustion; Judicial Proceedings. No action at law or in equity shall be brought to recover benefits under the Plan until the claim and appeal rights described in the Plan have been exercised and the Plan benefits requested in such appeal have been denied in whole or in part. If any judicial proceeding is undertaken to appeal the denial of a claim or bring any other action under ERISA other than a breach of fiduciary claim, the evidence presented may be strictly limited to the evidence timely presented to the Administrator. Any such judicial proceeding must be filed by the earlier of: (a) one year after the Administrator's final decision regarding the claim appeal or (b) one year after the Participant or other Claimant commenced payment of the Plan benefits at issue in the judicial proceeding. The jurisdiction and venue for any judicial proceedings arising under or relating to the Plan will be exclusively in the courts in California, including the federal courts located there should federal jurisdiction exist. This paragraph (c) shall not be construed to prohibit the enforcement of any arbitration agreements.

(c) Administrator's Decision is Binding. Benefits under the Plan shall be paid only if the Administrator decides in its sole discretion that a Claimant is entitled to them. In determining claims for benefits, the Administrator has the authority to interpret the Plan, to resolve ambiguities, to make factual determinations, and to resolve questions relating to eligibility for and amount of benefits. Subject to applicable law, any decision made in accordance with the above claims procedures is final and binding on all parties and shall be given the maximum possible deference allowed by law. A misstatement or other mistake of fact shall be corrected when it becomes known and the Administrator shall make such adjustment on account thereof as it considers equitable and practicable.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

Exagen Inc.
Vista, California

We hereby consent to the incorporation by reference in the Registration Statement Form S-3 (No. 333-250015) and Form S-8 (No. 333-233878) of Exagen Inc. of our report dated March 16, 2021, relating to the financial statements, which appears in this Form 10-K.

/s/ BDO USA, LLP

San Diego, California
March 16, 2021

Exhibit 31.1

EXAGEN INC.

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Fortunato Ron Rocca, certify that:

1. I have reviewed this Annual Report on Form 10-K of Exagen 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) [paragraph omitted in accordance with Exchange Act Rule 13a-14(a)];

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

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 16, 2021

/s/ Fortunato Ron Rocca
Fortunato Ron Rocca
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

EXAGEN INC.

CERTIFICATION OF CHIEF FINANCIAL OFFICER

PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Kamal Adawi, certify that:

1. I have reviewed this Annual Report on Form 10-K of Exagen 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) [paragraph omitted in accordance with Exchange Act Rule 13a-14(a)];

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

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 16, 2021

/s/ Kamal Adawi
Kamal Adawi
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Exagen Inc. (the "Company") hereby certifies, to such officer's knowledge, that:

1. The accompanying annual report on Form 10-K of the Company for the fiscal year ended December 31, 2020 (the "Report") fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented therein.

Dated: March 16, 2021

/s/ Fortunato Ron Rocca
Fortunato Ron Rocca
President and Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION OF CHIEF FINANCIAL OFFICER

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Exagen Inc. (the "Company") hereby certifies, to such officer's knowledge, that:

1. The accompanying annual report on Form 10-K of the Company for the fiscal year ended December 31, 2020 (the "Report") fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented therein.

Dated: March 16, 2021

/s/ Kamal Adawi
Kamal Adawi
Chief Financial Officer (Principal Financial and Accounting Officer)