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, 2019

☐ **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, Suite C 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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of September 30, 2019, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $104.9 million, based on the closing price of the registrant's common stock on the Nasdaq Global Select Market of $15.49 per share. The registrant has elected to use September 30, 2019 as the calculation date, as of June 30, 2019 (the last business day of the registrant's most recently completed second fiscal quarter) the registrant was a privately-held concern.

Total shares of common stock outstanding as of the close of business on March 20, 2020 was 12,627,056.

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 2020 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, 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

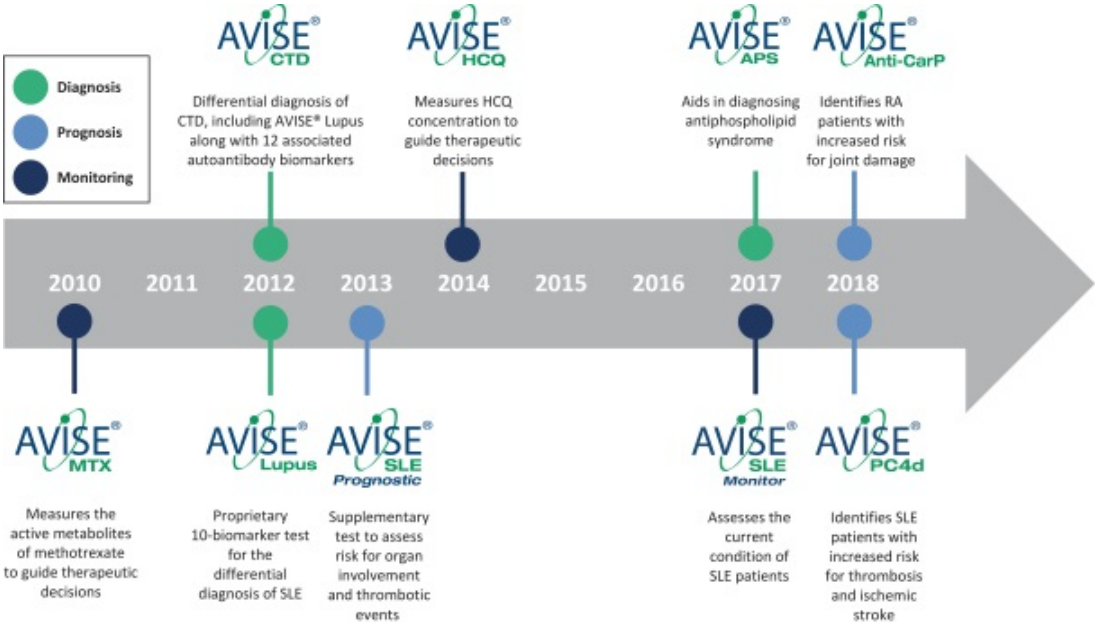
Exagen is dedicated to transforming the care continuum for patients suffering from debilitating and chronic autoimmune diseases by enabling timely differential diagnosis and optimizing therapeutic intervention. We have developed and are commercializing a portfolio of innovative testing products under 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 nine testing products under our AVISE® brand, which we are leveraging to establish partnerships with leading pharmaceutical companies. In December 2018, we entered into a co-promotion agreement with Janssen Biotech, Inc., or the Janssen agreement, to exclusively promote SIMPONI® (golimumab), a subcutaneous, once-per-month, anti-tumor necrosis factor, or anti-TNF, biologic prescribed in combination with methotrexate, in the United States for the treatment of adult patients with moderate to severe RA and for other indicated rheumatic diseases. Combined U.S. sales of SIMPONI® and SIMPONI ARIA®, an intravenous formulation, were approximately $1.2 billion in 2019, of which we estimate approximately 50% was from sales of SIMPONI®. We began direct promotion of SIMPONI® in January 2019 and expanded our salesforce from 31 representatives as of December 31, 2018 to 50 representatives as of December 31, 2019 to support these promotion efforts. 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. We therefore believe our strategy of integrating the promotion of testing products and therapeutics uniquely positions us to expand SIMPONI®'s U.S. market share. Our SIMPONI® promotion efforts contributed approximately $1.5 million in incremental revenue in 2019 with our quarterly tiered promotion fee based on the incremental increase in total prescribed units above a predetermined average baseline of approximately 29,000 prescribed units per quarter.

We believe our strategy of integrating the promotion of testing products and therapeutics differentiates us from other diagnostic and pharmaceutical companies, and provides our specialized salesforce greater access to rheumatologists. Our integrated testing and therapeutics strategy results in a unique opportunity to promote 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.

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 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.

Our RA-focused testing products include AVISE® MTX and AVISE® Anti-CarP. AVISE® MTX is a drug monitoring test designed to aid in the optimization of methotrexate therapy, the standard of care and first-line therapy for patients with RA. AVISE® MTX is based on our proprietary methotrexate polyglutamate, or MTXPG, technology that measures blood levels of MTXPGs, the active metabolite of methotrexate linked to disease control in RA patients. 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. 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® 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 market our AVISE® testing products using our specialized salesforce. Since the launch of AVISE® CTD in 2012 through December 31, 2019, we have delivered over 387,000 of these tests, representing a compound annual growth rate of 81%, with limited incremental investment in our commercial infrastructure. Over 105,000 AVISE® CTD tests were delivered in 2019, representing 26% growth over 2018, and the number of ordering healthcare providers in the fourth quarter of 2019 reached 1,707, representing 34% growth over the same period in 2018. In the fourth quarter of 2019, we reached 572 adopting healthcare providers, which we classify as those who had previously prescribed at least 11 diagnostic tests in the corresponding period, compared to 506 in the same period in 2018. A high percentage of adopting healthcare providers continue to order tests in subsequent quarters, including a retention rate of approximately 98% among adopting healthcare providers in the fourth quarter of 2019.

In addition, we continue to populate a growing proprietary database of over 384,000 de-identified patient test results. We believe the insight emerging from these results has the potential to unlock value for pharmaceutical and biotechnology companies in the 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 strategy of integrating the promotion of testing products and therapeutics differentiates us from other diagnostic and pharmaceutical companies, and provides our specialized salesforce greater access to rheumatologists. 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 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 who have a history using our portfolio of testing products.

In December 2018, we entered into the Janssen agreement for the promotion of SIMPONI® in order to advance our integrated testing and therapeutics strategy. To support the co-promotion of SIMPONI® to rheumatologists, we expanded our salesforce from 31 representatives as of December 31, 2018 to 50 representatives as of December 31, 2019 and expect to continue to expand our salesforce in 2020. We also have agreements with other leading pharmaceutical companies, including GlaxoSmithKline LLC, or GSK, and Horizon Pharma USA, Inc., or Horizon Therapeutics, that leverage our testing products and 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. Our agreement with Horizon Therapeutics entails utilizing our AVISE® MTX test to report on levels of MTXPG in patients undergoing methotrexate therapy in combination with its anti-gout product KRYSTEXXA® in an ongoing Phase 4 clinical trial. We plan to pursue additional partnerships with a focus on integrating therapeutics that are synergistic with our evolving portfolio of testing products.

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 and a few were previously involved with successfully building Prometheus Laboratories Inc., or Prometheus, which was focused on integrating diagnostics and therapeutics, prior to its acquisition by Nestlé Health Science S.A. in 2011.

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:

- ***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 payers 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.*** Our integrated testing and therapeutics strategy leverages our sales and marketing efforts, targeting rheumatologists for the commercialization of our testing products to promote therapeutics. This establishes a compelling synergy compared to traditional pharmaceutical sales resulting in greater access to rheumatologists and positions us to potentially create value for pharmaceutical partners. In January 2019, we began our exclusive promotion of SIMPONI® in the United States, leveraging our integrated testing and therapeutics strategy, for the treatment of adult patients with moderate to severe RA and for other indicated rheumatic diseases.
- ***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 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.

- ***Establish additional therapeutic partnerships.*** We believe our agreements with Janssen, and other leading pharmaceutical companies validate our unique value proposition to pharmaceutical companies seeking a competitive edge for 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 commercialization of therapeutics that are synergistic with our testing products.
- ***Achieve meaningful margin expansion.*** We believe growth from the promotion of therapeutics will meaningfully improve our margin profile and further support our goal of achieving profitability. We also expect an increase to our gross margins in the first quarter of 2020 following the expiration of a 10% annual royalty on our CB-CAPs technology. In addition, we believe we are well positioned to drive further margin expansion 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 payer 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.

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 drug targeting treatment of SLE in over 50 years, GSK's Benlysta®, was approved by the U.S. Food and Drug Administration, or the FDA. It is the only approved biologic for the treatment of SLE. Since its 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 nine 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 focus on leveraging our portfolio of testing products to promote therapeutics through our sales channel targeting the approximately 5,000 rheumatologists across the United States. 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. In January 2019, we began direct promotion of SIMPONI® with our specialized salesforce.

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 (21 as of December 31, 2019) 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.

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

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 is one of our newest offerings, which 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. 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.

AVISE® MTX

AVISE® MTX is a patented and validated blood test that precisely measures levels of MTXPG, the active form of methotrexate, in the patient's blood. 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. 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 payers, 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

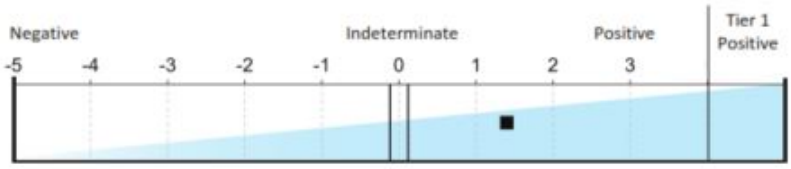
Order ID 200402
Provider Example Provider MD

Specimen
Collected 09/29/2019
Received 09/30/2019
Test Order
Created 09/30/2019
Reported 10/02/2019

Patient **Sample, Susan S**
Gender - DOB Female - 01/24/1974
Identifier Received
Exagen ID 300955

AVISE CTD Test Report

AVISE Lupus Result: **Positive - Index: 1.4**



Tier 1 Analytes	Value	Interpretation	Reference Range	Tier 1 Assessment
Anti-dsDNA IgG	20 IU/mL	Negative	<302 - Negative | ≥302 - Positive	Negative
Confirmation by Crithidia luciliae				
Anti-Smith IgG	1 U/mL	Negative	<5 - Negative | 5-10 - Equivocal | >10 - Positive	
CB-CAP: EC4d - Erythrocyte-bound C4d	25 Net MFI	POSITIVE	<15 - Negative | 15-75 - Positive | >75 - Strong Positive	
CB-CAP: BC4d - B-lymphocyte-bound C4d	100 Net MFI	POSITIVE	<61 - Negative | 61-200 - Positive | >200 - Strong Positive	

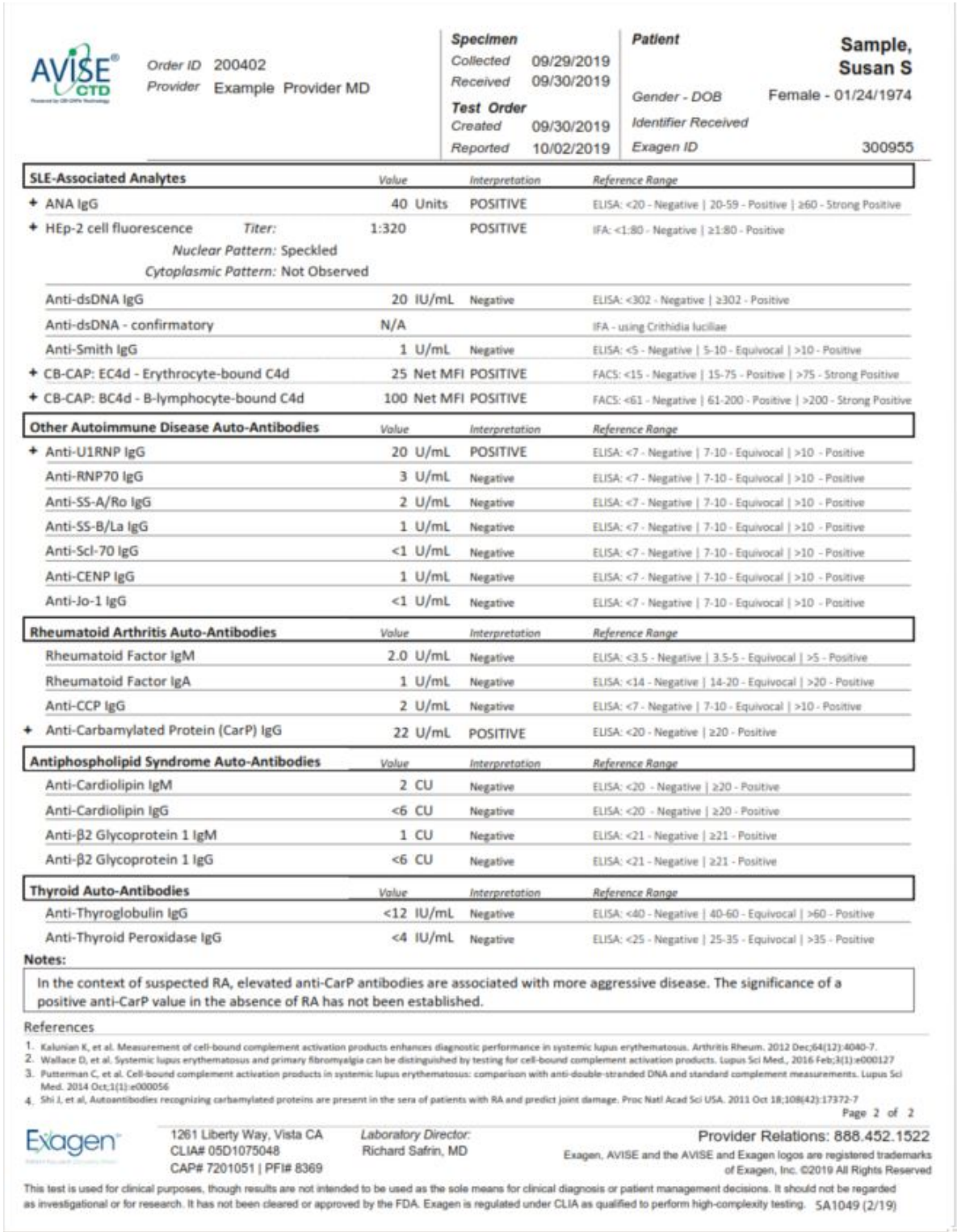
Note:
Criteria for Tier 1 Positive not met.

Tier 2 Analytes	Value	Interpretation	Reference Range	Tier 2 Assessment
ANA IgG	40 Units	POSITIVE	<20 - Negative | 20-59 - Positive | ≥60 - Strong Positive	Positive
CB-CAP: EC4d - Erythrocyte-bound C4d	25 Net MFI	POSITIVE	<15 - Negative | 15-75 - Positive | >75 - Strong Positive	
CB-CAP: BC4d - B-lymphocyte-bound C4d	100 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-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	2 U/mL	Negative	<7 - Negative | 7-10 - Equivocal | >10 - Positive	

Note:
This assessment is associated with an increased likelihood of SLE.

Test Method Description

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 200402
Provider Example Provider MD

Specimen
Collected 09/29/2019
Received 09/30/2019
Test Order
Created 09/30/2019
Reported 10/02/2019

Patient Sample, Susan S
Gender - DOB Female - 01/24/1974
Identifier Received
Exagen ID 300955

SLE-Associated Analytes	Value		Interpretation	Reference Range
+ ANA IgG	40	Units	POSITIVE	ELISA: <20 - Negative | 20-59 - Positive | ≥60 - Strong Positive
+ HEp-2 cell fluorescence Titer:	1:320		POSITIVE	IFA: <1:80 - Negative | ≥1:80 - Positive
Nuclear Pattern: Speckled				
Cytoplasmic Pattern: Not Observed				
Anti-dsDNA IgG	20	IU/mL	Negative	ELISA: <302 - Negative | ≥302 - Positive
Anti-dsDNA - confirmatory	N/A			IFA - using Crithidia luciliae
Anti-Smith IgG	1	U/mL	Negative	ELISA: <5 - Negative | 5-10 - Equivocal | >10 - Positive
+ CB-CAP: EC4d - Erythrocyte-bound C4d	25	Net MFI	POSITIVE	FACS: <15 - Negative | 15-75 - Positive | >75 - Strong Positive
+ CB-CAP: BC4d - B-lymphocyte-bound C4d	100	Net MFI	POSITIVE	FACS: <61 - Negative | 61-200 - Positive | >200 - Strong Positive

Other Autoimmune Disease Auto-Antibodies	Value		Interpretation	Reference Range
+ Anti-U1RNP IgG	20	U/mL	POSITIVE	ELISA: <7 - Negative | 7-10 - Equivocal | >10 - Positive
Anti-RNP70 IgG	3	U/mL	Negative	ELISA: <7 - Negative | 7-10 - Equivocal | >10 - Positive
Anti-SS-A/Ro IgG	2	U/mL	Negative	ELISA: <7 - Negative | 7-10 - Equivocal | >10 - 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-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	2.0	U/mL	Negative	ELISA: <3.5 - Negative | 3.5-5 - Equivocal | >5 - Positive
Rheumatoid Factor IgA	1	U/mL	Negative	ELISA: <14 - Negative | 14-20 - Equivocal | >20 - Positive
Anti-CCP IgG	2	U/mL	Negative	ELISA: <7 - Negative | 7-10 - Equivocal | >10 - Positive
+ Anti-Carbamylated Protein (CarP) IgG	22	U/mL	POSITIVE	ELISA: <20 - Negative | ≥20 - Positive

Antiphospholipid Syndrome Auto-Antibodies	Value		Interpretation	Reference Range
Anti-Cardiolipin IgM	2	CU	Negative	ELISA: <20 - Negative | ≥20 - Positive
Anti-Cardiolipin IgG	<6	CU	Negative	ELISA: <20 - Negative | ≥20 - Positive
Anti-β2 Glycoprotein 1 IgM	1	CU	Negative	ELISA: <21 - Negative | ≥21 - Positive
Anti-β2 Glycoprotein 1 IgG	<6	CU	Negative	ELISA: <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:

In the context of suspected RA, elevated anti-CarP antibodies are associated with more aggressive disease. The significance of a positive anti-CarP value in the absence of RA has not been established.

References

1. Kalunian K, et al. Measurement of cell-bound complement activation products enhances diagnostic performance in systemic lupus erythematosus. 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. Cell-bound complement activation products in systemic lupus erythematosus: comparison with anti-double-stranded DNA and standard complement measurements. Lupus Sci Med. 2014 Oct;1(1):e000056
4. Shi J, et al, Autoantibodies recognizing carbamylated proteins are present in the sera of patients with RA and predict joint damage. Proc Natl Acad Sci USA. 2011 Oct 18;108(42):17372-7

Exagen

1261 Liberty Way, Vista CA
CLIA# 05D1075048
CAP# 7201051 | PFI# 8369

Laboratory Director:
Richard Safrin, MD

Provider Relations: 888.452.1522

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. Combined U.S. sales of SIMPONI® and SIMPONI ARIA® were approximately $1.2 billion in 2019, of which we estimate approximately 50% was from sales of SIMPONI®.

We began direct promotion of SIMPONI® to rheumatologists with our specialized salesforce in January 2019 and expanded our salesforce from 31 representatives as of December 31, 2018 to 50 representatives as of December 31, 2019 and expect to continue to expand our salesforce in 2020. We believe our salesforce allows us to reach our target of the top 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 will receive a quarterly tiered promotion fee ranging from $750 to $1,250 per prescription based on incremental total prescribed units above a predetermined average baseline of approximately 29,000 prescribed units per quarter for an initial term of 18 months. We estimate the total U.S. addressable market for SIMPONI's ® approved indications, including RA, psoriatic arthritis and ankylosing spondylitis, to be approximately $28 billion. Based on this estimated market size, each incremental 1% of U.S. market share we are able to capture for SIMPONI® above the predetermined baseline of 29,000 prescribed units per quarter could result in incremental revenue to us of up to $84 million. We recognized co-promotional revenue of approximately $1.5 million during the year ended December 31, 2019 and expect to continue to recognize revenue as we perform co-promotional services based on the number of total prescribed units of SIMPONI® over the predetermined baseline. For more information regarding the Janssen agreement, 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 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. We plan to initiate proof of concept studies to develop alternatives to biopsy in the monitoring of transplant rejection and the differential diagnosis of fibromyalgia in the primary care physician setting. In addition, we are developing a panel of assays that we believe may have high prognostic value in patients with RA, Sjögren's, fibromyalgia and autoimmune thyroid, 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, 2019, our overall sales team consisted of approximately 60 members, including 50 sales representatives, six regional sales directors, one vice president, one senior vice president and two managed care professionals. In connection with the promotion of SIMPONI®, we expanded the number of sales representatives from 31 representatives as of December 31, 2018 to 50 representatives as of December 31, 2019, who are managed by a team of six regional sales directors. We expect to continue to expand our salesforce by up to approximately 25 additional representatives in 2020. Our increased salesforce allows for expansion into markets not previously covered by us. In addition, this salesforce expansion 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 our target of the top 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,* including safety and efficacy data for SIMPONI® 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 SIMPONI® and 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 payers, government payers and patients. Payment from commercial third-party payers differs depending on whether we have entered into a contract with the payer 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. Currently, we are reimbursed on an out-of-network basis, at various rates that can be higher or lower than participating providers. 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 payers, 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 payers' 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® MTX which helped us secure favorable coverage for that testing product from the MolDx Program, Noridian and various commercial Medicare Advantage plans. The two largest rheumatology super groups have included AVISE® MTX in their respective RA patient pathway guidelines for physician adoption of AVISE® MTX. In addition, UpToDate, a leading evidence-based clinical decision support resource for healthcare providers and payers, recommends the measurement of polyglutamate levels as done by AVISE® MTX. 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 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 payers to obtain maximum reimbursement. In parallel, a managed care team collaborates with our reimbursement specialists to ensure our payer 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 payers.

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).

In addition, we collaborated with leading health economic experts and clinicians to conduct a health economics study. The results of that health economics study were presented at the ACR conference in 2018, and demonstrated the cost savings to a payer associated with AVISE® Lupus over a one to four year time horizon. The above referenced studies are included in the AVISE® Lupus Dossier. We recently announced in March 2020 coverage and in-network contract with three California Medical Groups and anticipate additional coverage determinations and in-network contracting announcements in the second half of 2020.

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. 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. Other potential competitors include companies that might develop diagnostic or disease or drug monitoring products, such as Myriad Genetics, Inc., Progentec Diagnostics Inc., Kypha, LLC, Genalyte Inc., Oncimmune plc, DxTerity Diagnostics Inc., HealthTell, 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®). 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 payers 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. The predetermined average baseline for the initial term of 18 months is approximately 29,000 prescribed units per quarter, subject to adjustment under certain circumstances.

In September 2019 we exercised our option to extend the term of the Janssen agreement to December 31, 2021. 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 to, among other things, extend the term of the agreement through December 31, 2020.

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.

Master Services Agreement with Horizon Therapeutics

In August 2018, we entered into a master services agreement with Horizon Therapeutics, pursuant to which Horizon Therapeutics utilizes our AVISE® MTX test to report on levels of MTXPG in patients undergoing methotrexate therapy in combination with its anti-gout product KRYSTEXXA® in an ongoing Phase 4 clinical trial. Under the agreement, Horizon Therapeutics paid an initial one time set-up cost and now pays an incremental fee for each specimen processed. We provide, among other things, specimen collection kits, customized test requisition, pre-paid shipping, specimen storage and individual reports for each study subject. Either party can terminate the agreement for convenience upon 30 days' prior written notice to the other party. Absent early termination, the agreement will run through August 2020.

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 December 31, 2019, our portfolio primarily consisted of the following:

CB-CAPs

As of December 31, 2019, 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) and two pending patent application families 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.

Asset Purchase Agreement With Cellatope

In connection with the Cypress Purchase, we acquired an asset purchase agreement, dated February 2009 and amended December 2012 and again in January 2017, between Cypress and Cellatope Corporation, or Cellatope. Pursuant to the amended agreement, we obtained assets related to our AVISE® testing products. In connection with

one launch of our AVISE® SLE Monitor testing product, we paid an upfront payment of $100,000 and we are required to pay Cellatope a low-single digit royalty on net sales up to a maximum of $3.0 million.

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. These tests 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.

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 states 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 FDA further states its intention in the Framework Guidance to publish general LDT classification guidance within 18 months of date on which the Framework Guidance is finalized. The Reporting Guidance would further enable 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.

On January 13, 2017, the FDA released a document titled "Discussion Paper on Laboratory Developed Tests," or the Discussion Paper, which stated that the agency had declined to finalize the LDT guidances to allow for additional discussion on appropriate regulatory oversight. The FDA has not issued any proposed rules or guidance documents relating to LDTs since January 2017.

However, the FDA could ultimately modify its current approach to LDTs in a way that would subject our products marketed as LDTs to the enforcement of regulatory requirements. Moreover, legislative measures have recently been proposed in Congress that, if ultimately enacted, could provide the FDA with additional authority to require premarket review of and regulate LDTs.

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 Investigational Device Process

In the U.S., absent certain limited exceptions, human clinical trials intended to support medical device clearance or approval require an IDE application. Some types of studies deemed to present “non-significant risk” are deemed to have an approved IDE once certain requirements are addressed and IRB approval is obtained. If the device presents a “significant risk” to human health, as defined by the FDA, the sponsor must submit an IDE application to the FDA and obtain IDE approval prior to commencing the human clinical trials. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. Generally, clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the study protocol and informed consent are approved by appropriate IRBs at the clinical trial sites. Submission of an IDE will note necessarily result in the ability to commence clinical trials, and although the FDA’s approval of an IDE allows clinical testing to go forward for a specified number of subjects, it does not bind the FDA to accept the results of the trial as sufficient to prove the product’s safety and efficacy, even if the trial meets its intended success criteria.

All clinical trials must be conducted in accordance with the FDA’s IDE regulations that govern investigational device labeling, prohibit promotion and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. Clinical trials must further comply with the FDA’s good clinical practice regulations for IRB approval and for informed consent and other human subject protections. Required records and reports are subject to inspection by the FDA. The results of clinical testing may be unfavorable, or, even if the intended safety and efficacy success criteria are achieved, may not be considered sufficient for the FDA to grant marketing approval

or clearance of a product. The commencement or completion of any clinical trial may be delayed or halted, or be inadequate to support approval of a PMA application, for numerous reasons, including, but not limited to, the following:

- the FDA or other regulatory authorities do not approve a clinical trial protocol or a clinical trial, or place a clinical trial on hold;
- patients do not enroll in clinical trials at the rate expected;
- patients do not comply with trial protocols;
- patient follow-up is not at the rate expected;
- patients experience adverse events;
- patients die during a clinical trial, even though their death may not be related to the products that are evaluated during the trial;
- device malfunctions occur with unexpected frequency or potential adverse consequences;
- side effects or device malfunctions of similar products already in the market that change the FDA's view toward approval of new or similar PMAs or result in the imposition of new requirements or testing;
- institutional review boards and third-party clinical investigators may delay or reject the trial protocol;
- third-party clinical investigators decline to participate in a trial or do not perform a trial on the anticipated schedule or consistent with the clinical trial protocol, investigator agreement, investigational plan, good clinical practices, the IDE regulations or other FDA or IRB requirements;
- third-party investigators are disqualified by the FDA;
- we or third-party organizations do not perform data collection, monitoring and analysis in a timely or accurate manner or consistent with the clinical trial protocol or investigational or statistical plans, or otherwise fail to comply with the IDE regulations governing responsibilities, records and reports of sponsors of clinical investigations;
- third-party clinical investigators have significant financial interests related to us or our study such that the FDA deems the study results unreliable, or we or investigators fail to disclose such interests;
- regulatory inspections of our clinical trials or manufacturing facilities, which may, among other things, require us to undertake corrective action or suspend or terminate our clinical trials;
- changes in government regulations or administrative actions;
- the interim or final results of the clinical trial are inconclusive or unfavorable as to safety or efficacy; or
- the FDA concludes that our trial designs are unreliable or inadequate to demonstrate safety and efficacy.

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 forthcoming steps that the FDA intends 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. In May 2019, the FDA solicited public feedback on these proposals. The FDA requested public feedback on whether it should consider certain actions that might require new authority, such as whether to sunset certain older devices that were used as predicates under the 510(k) clearance pathway. These proposals have not yet been finalized or adopted, and the FDA may work with Congress to implement such proposals through legislation.

More recently, in September 2019, the FDA finalized 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 intends to develop and maintain a list device types appropriate for the “safety and performance based” pathway and will continue to develop product-specific guidance documents that identify the performance criteria for each such device type, as well as the testing methods recommended in the guidance documents, where feasible.

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. Overall, the FDA review of a PMA application generally takes between one and three years, but may take significantly longer. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

- the device may not be shown safe or effective to the FDA’s satisfaction;
- the data from pre-clinical studies and/or clinical trials may be found unreliable or insufficient to support approval;
- the manufacturing process or facilities may not meet applicable requirements; and

- changes in FDA approval policies or adoption of new regulations may require additional data.

If the FDA evaluation of a PMA is favorable, the FDA will issue either an approval letter, or an approvable letter, the latter of which usually contains a number of conditions that must be met in order to secure final approval of the PMA. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA approval letter authorizing commercial marketing of the device, subject to the conditions of approval and the limitations established in the approval letter. If the FDA's evaluation of a PMA application or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. The FDA also may determine that additional tests or clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and data 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.

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 payer 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 payers, 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 payer.

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 payers.

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 payers, 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

Health Insurance Portability and Accountability Act; California Consumer Privacy Act of 2018, or the CCPA

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 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, or the FTCA, 15 U.S.C § 45(a). The FTC expects a company’s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. The FTC’s guidance for appropriately securing consumers’ personal information is similar to what is required by the HIPAA security regulations.

In addition, certain state laws govern the privacy and security of health 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 has been characterized as the first “GDPR-like” privacy statute to be enacted in the United States because it mirrors a number of the key provisions of the European Union General Data Protection Regulation, or the GDPR, (discussed below). The CCPA 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 “protected health information” maintained by a covered entity or business associate, it may regulate or impact our processing of personal information depending on the context.

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 European Union enacted Regulation (EU) 2016/679 (General Data Protection Regulation, or GDPR), has been enacted in the European Union and 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. The GDPR provides that European Union 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. Additionally, following the United Kingdom's withdrawal from the European Union, we will have to comply with the GDPR and the United Kingdom GDPR, each regime having the ability to fine 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, for example around how data can lawfully be transferred between each jurisdiction, which exposes us to further compliance risk.

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 payer 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 payer 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 payer 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. PAMA's impact on Medicare reimbursement for AVISE® CTD in 2019 was a reduction of 10.1% and is expected to be a 7.3% reduction in 2020.

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 payers, 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. For example, the ACA requires each medical device manufacturer to pay a sales tax equal to 2.3% of the price for which such manufacturer sells its medical devices. The medical device tax has been suspended until December 31, 2019, but is scheduled to return beginning in 2020. It is unclear at this time when, or if, the provision of our LDTs will trigger the medical device tax if the FDA ends its policy of general enforcement discretion and regulates certain LDTs as medical devices, and it is possible that this tax will apply to some or all of our existing testing products or testing products we may develop in the future. The ACA also contains a number of other provisions, including 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. It is unclear how these decisions, subsequent appeals, or other efforts to challenge, repeal or replace the ACA will impact the ACA.

Additional state and federal health care reform measures may be adopted in the future, any of which could have a material adverse effect on the clinical laboratory industry.

Employees

As of December 31, 2019, we had 153 full-time employees, and 3 temporary employees. These included 31 in laboratory operations, seven in research and development, 63 in sales and marketing and 52 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.

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, 2019 and 2018 and

our total assets as of December 31, 2019 and 2018, 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, Suite C, 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.

Risks Related to Our Business and Strategy

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, 2019 and 2018, we incurred net losses of $12.0 and $8.0 million, respectively, and we expect to incur additional losses this year and in future years. As of December 31, 2019, we had an accumulated deficit of $164.6 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 promote SIMPONI®, to develop future testing products and to continue to execute our integrated testing and therapeutics strategy. 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. 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 effectively co-promote SIMPONI® will require us to be successful in a range of activities, including hiring, training and deploying additional sales representatives and creating demand for SIMPONI® through our commercial and sales activities as well as those of Janssen Biotech, Inc., or Janssen. Moreover, we may encounter difficulties in hiring effective sales representatives in furtherance of our promotion efforts for SIMPONI®, which could have a material impact on our ability to successfully generate co-promotion revenue. If we encounter difficulties promoting SIMPONI®, our ability to generate significant revenue under the Janssen Agreement will be harmed. Janssen also has the right to terminate the Janssen agreement with or without cause after 30-days' notice. 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.

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 expanded our salesforce from 31 representatives as of December 31, 2018 to 50 representatives as of December 31, 2019, and expect to continue to expand our salesforce in 2020, 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 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 our AVISE® MTX test data is used by Horizon Therapeutics to report on levels of MTXPG in patients undergoing methotrexate therapy in combination with its anti-gout product, KRYSTEXXA®, in an ongoing Phase 4 clinical trial.

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.

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

The recent outbreak of the coronavirus, COVID-19, which has been declared by the World Health Organization to be a pandemic has spread across the globe and is impacting worldwide economic activity. 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. While it is not possible at this time to estimate the impact that COVID-19 could have on our business, the continued spread of COVID-19 and the measures taken by the governments of countries affected could disrupt, among other things, the supply chain and the manufacture or shipment of testing products, our ability to process tests and deliver results, delay coverage decisions from Medicare and third party payors, and delay ongoing and planned clinical trials involving our tests. Additionally, we may experience a decrease or potential halt in shipments of our testing products as our suppliers may be required to focus their resources to manufacture testing kits in response to the COVID-19 outbreak, which could in turn result in decreased gross margins. 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. Additionally, the demand for our testing products, and the demand for therapeutics, may significantly decline or cease as COVID-19 continues to spread, including as a result of prioritization of hospital or clinical resources toward the outbreak or government imposed quarantines that impede patient movement or interrupt healthcare services or patients otherwise delaying or declining to seek treatment. 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. 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 outbreak 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 when needed. The extent to which the COVID-19 outbreak 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.

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 2019, we were featured in nine scientific presentations at the 2019 American College of Rheumatology's (ACR/ARHP) Annual Conference. 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 payers may limit adoption by rheumatologists. With respect to SIMPONI® in particular, if we are unable to generate sales above certain thresholds agreed to with Janssen, we will not receive any payments under the 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 payers 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 payers, 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 payers, 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 payers 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 payers 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 payers;
- public health crises such as the recent COVID-19 outbreak;
- 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 payers 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 outbreak, 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 in our AVISE® CTD test. As a result, if we are unable to remedy the quality issue discovered, or otherwise find a supplier for this biomarker, 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 payers 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 payer 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 payers, including government payers, 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 payer 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 payers may depend on a number of factors, including the payer’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 payers 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 payers 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 recent outbreak of COVID-19 may cause a delay in

coverage decisions from Medicare and third party payors, and delay ongoing and planned clinical trials involving our testing products, the occurrence of which may have a material adverse effect on our business.

Third-party payers 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 payers and health care providers as grounds to deny coverage for or refuse to use a test or procedure. In addition, third-party payers, 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's, or MolDx Program's, 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 payers 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 payer by payer basis, establishing broad coverage is a time-consuming and costly process. There are many third-party payers 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 payers, we do not currently have contracts with significant private payers. We have in the past, and will likely in the future, experience delays and temporary interruptions in the receipt of payments from third-party payers 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 payers issue negative coverage policies, these policies could have a material adverse effect on our business and operations. Even if many third-party payers currently reimburse for our testing products, such payers 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 payers, including Medicare and private insurance companies, as well as patients, all of which have different billing requirements. We generally bill third-party payers 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 payers;
- compliance with complex federal and state regulations related to billing Medicare;
- disputes among third-party payers as to which party is responsible for payment;
- differences in coverage among third-party payers;
- the effect of patient deductibles, co-payments or co-insurance;
- differences in information and billing requirements among third-party payers;
- 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 payer. 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 payers deny our claims, in order to obtain reimbursement for services that we provide, we may challenge coverage and payment denials. Payers also conduct external audits to evaluate payments, which add further complexity to the billing process. If the payer 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 payers 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 payers change processes that may affect timely payment. These changes may result in uneven cash flow or impact the timing of revenue recognized with these payers. 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 payers 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 2019, Noridian posted the calendar year 2020 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, 2020. We have estimated that the implementation of these reimbursement rates will result in an approximate 7.3% reduction in anticipated reimbursements from Medicare for our AVISE® CTD testing product from levels experienced in 2018. Revenue from Medicare comprised 25% and 30% of our revenue for the years ended December 31, 2019 and 2018, respectively. Revenue from the sale of our AVISE® CTD testing products comprised 82% of our revenue for the years ended December 31, 2019 and 2018.

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 payers within the timeframe required. If claims for our testing products are not submitted to payers 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 recently 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, to support the co-promotion of SIMPONI®, we expanded our salesforce from 31 representatives as of December 31, 2018 to 50 representatives as of December 31, 2019 and expect to continue to expand our salesforce in 2020. 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. Other potential competitors include companies that might develop diagnostic or disease or drug monitoring products, such as Myriad Genetics, Inc., Progentec Diagnostics Inc., Kypha, LLC, Genalyte Inc., Oncimmune plc, DxTerity Diagnostics Inc., HealthTell, 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®). 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 payers 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 payers. 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. We do not carry key man insurance for any of our employees.

Our recent management changes create uncertainties and could have a material adverse impact on our business, results of operations and financial condition.

In December 2019, Thierry Dervieux, Ph.D. resigned as our Chief Scientific Officer. Executive leadership transitions can be inherently difficult to manage and may cause disruption to our business. As a result of the recent changes in our management team, our existing management team has taken on additional responsibility, which has resulted in greater workload demands and could divert their attention away from certain key areas of our business. In addition, management transition inherently causes some loss of institutional knowledge, which can negatively affect strategy and execution, and our results of operations and financial condition could suffer as a result. The loss of services of one or more other members of senior management could have a material adverse effect on our business, operating results and financial condition.

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 outbreak. 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 outbreak, 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.

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.

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.

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.

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. While we have not 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 the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or 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 payers 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.

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. While we have recently begun working with United Parcel Service, we still rely extensively on a single carrier, 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, 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 outbreak), terrorist acts or threats, or for other reasons, could adversely affect our ability to receive and process patient specimens on a timely basis.

If we or Federal Express 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. If any new provider does not provide, or if Federal Express 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 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. Under recently enacted U.S. tax legislation, federal NOL carryforwards generated in periods after December 31, 2017, may be carried forward indefinitely but may only be used to offset 80% of our taxable income annually. We previously completed a study to assess whether an ownership change, as defined by Section 382 of the Code, had occurred from its 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. As a result, if we earn net taxable income, our ability to use such pre-change NOL carryforwards and other pre-change 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, and in November 2019, we entered into the first amendment, or the Loan Amendment, to our loan and security agreement, with Innovatus, which we collectively refer to as 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, 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. The Loan Amendment (i) decreased the interest rate on all borrowings to 8.5%, of which 2.0% is paid in-kind and capitalized to the principal amount of the outstanding term loan on a monthly basis under December 2022; after which interest accrues at an annual rate of 8.5%; (ii) extended the interest only period to December 2022 and the maturity date to November 19, 2024; (iii) revised the prepayment terms to (x) restrict prepayments for the initial year following the date of the Loan Amendment and (y) set the prepayment premium at 3% of the principal amount of any term loans prepaid prior to November 19, 2020, with such prepayment premium decreasing by 1% during each subsequent twelve-month period after November 2020; and (iv) replaced the interest-only milestones with a financial covenant requiring that we achieve a specified level of revenue, as measured on a rolling twelve-month basis, and commencing with the quarter ending December 31, 2019, subject to exceptions based on achievement of performance milestones and the ability to cure any default thereof with the issuance of equity securities or subordinated indebtedness. As of December 31, 2019, there was $25.0 million in principal outstanding under the term loan and an additional $1.2 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. 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 outbreak, 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 payers and government payers, 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.

The FDA has adopted a policy of enforcement discretion with respect to LDTs whereby the FDA does not actively enforce its regulatory requirements for such tests. However, the FDA has stated its intention to modify its enforcement discretion policy with respect to LDTs. If there are changes in FDA policy, or if the FDA disagrees that our marketed tests are LDTs or that we are marketing our tests outside the scope of the FDA’s current policy of enforcement discretion, our testing products may become subject to the FDA’s requirements for premarket review of medical devices, and we may be required to cease commercial sales of our testing products and conduct additional clinical testing prior to making submissions to the FDA to obtain premarket clearance or approval. 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.

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. 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 lose any marketing authorization that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

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 payers including governmental payers, such as Medicare and Medicaid, private insurers and other private payers, 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 payer. 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 final PAMA ruling was issued June 17, 2016. 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 payer 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. These revisions to the CLFS have altered payment rates for clinical diagnostic lab tests under the CLFS, with estimated reductions in Medicare reimbursement rates for AVISE® CTD of 7.3% and 10.1% in 2020 and 2019, respectively. 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, requires each medical device manufacturer to pay an excise tax in an amount equal to 2.3% of the price for which such manufacturer sells its medical devices that are listed with the FDA. Through a series of legislative amendments, the tax was suspended from 2016 through 2019. On December 20, 2019, the Further Consolidated Appropriations Act, 2020, was signed into law repealing the medical device excise tax as of January 1, 2020. 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. It is unclear how these decisions, subsequent appeals, or other efforts to challenge, repeal or replace the ACA will impact the ACA and our business.

Other significant measures contained in the ACA include, for example, 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. The ACA also includes significant new fraud and abuse measures, including required disclosures of financial arrangements with physician customers, lower thresholds for violations and increasing potential penalties for such violations. There have been judicial and Congressional challenges to certain aspects of the ACA, as well as efforts by the current presidential administration to repeal and replace the ACA, and we expect that there will be additional challenges and amendments to the ACA in the future. 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 2029 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 25% and 28% of the total payments we received from payers for the years ended December 31, 2019 and 2018, respectively, were derived from the Medicare program, but also because other payers often use the MPFS and CLFS amounts as a benchmark to develop their payment rates. We cannot predict whether Medicare and other third-party payer reimbursement rates that mirror Medicare's will be sufficient to make our testing products commercially attractive.

In addition, some third-party payers 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 payers 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. 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 payers 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 payer.

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. Many states have their own self-referral laws as well, which in some cases apply to all third-party payers, 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 payers 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.

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 and state laws and regulations, including HIPAA and the HITECH Act, govern the collection, dissemination, security, use and confidentiality of individually identifiable health information. HIPAA and the HITECH Act require us to comply with standards for the use and disclosure of individually identifiable health information within our company and with third parties. The 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. 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.

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.

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.

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, 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 payers;
- 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 outbreak.

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.

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.

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.

Prior to our initial public offering, or IPO, sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lock-up and other legal restrictions on resale discussed in the prospectus for the IPO lapse, the trading price of our common stock could decline.

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 8,418,257 shares of common stock and holders of warrants to purchase 436,581 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.

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.

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 and amended and restated bylaws 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 and amended and restated bylaws 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 our amended and restated bylaws, 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, 2019, our executive officers, directors and greater than 5% stockholders, in the aggregate, own approximately 61% 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 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.

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 60-month 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 20, 2020, there were approximately 71 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

From January 1, 2019 through December 31, 2019, we issued and sold the equity securities described below:

1. From January 2019 to May 2019, we issued an aggregate of 148,928,337 shares of our Series G redeemable convertible preferred stock at a purchase price of $0.078 per share, for aggregate consideration of approximately $11.6 million in cash.
2. In July 2019, we issued 233,446,519 shares of our Series H redeemable convertible preferred stock at a purchase price of $0.04712 per share, for aggregate consideration of approximately $11.0 million, and converted 148,928,337 shares of our Series G redeemable convertible preferred stock into 246,521,076 shares of our Series H redeemable convertible preferred stock.
3. From January 1, 2019 through September 23, 2019, we granted stock options to purchase an aggregate of 814,339 shares of our common stock at a weighted-average exercise price of $13.99 per share, to certain of our employees, consultants and directors in connection with services provided to us by such persons, none of which have been exercised, and 52,649 stock options have been cancelled. From January 1, 2019 through September 23, 2019, 50 options have been exercised for aggregate consideration of $92. From January 1, 2019 through September 23, 2019, 13,411 options have been cancelled.

No underwriters were involved in the foregoing issuances of securities. The securities described in paragraph (1) and (2) above were issued to investors in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(a)(2) under the Securities Act and Regulation D promulgated thereunder relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required. All holders of securities described above represented to us in connection with their

purchase or issuance that they were accredited investors and were acquiring the securities for their own account for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof and that they could bear the risks of the investment and could hold the securities for an indefinite period of time. The holders received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from such registration.

The stock options and the common stock issuable upon the exercise of such options as described in paragraph (3) above were issued pursuant to written compensatory plans or arrangements with our employees and directors, in reliance on the exemption from the registration requirements of the Securities Act provided by Rule 701 promulgated under the Securities Act or the exemption set forth in Section 4(a)(2) under the Securities Act and Regulation D promulgated thereunder relative to transactions by an issuer not involving any public offering. All recipients either received adequate information about us or had access, through employment or other relationships, to such information.

All of the foregoing securities are deemed restricted securities for purposes of the Securities Act. All of the foregoing securities included appropriate legends setting forth that the securities had not been registered and the applicable restrictions on transfer.

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, 2019, we have used approximately $2.1 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, 2019, 2018 and 2017 and the balance sheet data as of December 31, 2019, 2018 and 2017 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 year ended December 31, 2017 and the balance sheet data as of December 31, 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.

(in thousands, except share and per share data)	Years Ended December 31, 2019	2018	2017
Statements of Operations Data:			
Revenue	$ 40,387	$ 32,440	$ 26,807
Operating expenses:			
Costs of revenue (excluding amortization of purchased technology)	18,808	15,379	14,137
Selling, general and administrative expenses	28,702	19,675	18,820
Research and development expenses	2,176	2,125	1,551
Amortization of intangible assets	—	141	186
Change in fair value of acquisition-related liabilities	—	—	(51)
Total operating expenses	49,686	37,320	34,643
Loss from operations	(9,299)	(4,880)	(7,836)
Interest expense	(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	510	112	45
Loss before income taxes	(12,013)	(7,954)	(26,180)
Income tax expense (benefit)	25	58	(549)
Net loss	(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	$ (30,279)	$ (18,482)	$ (32,774)
Net loss per share, basic and diluted	$ (8.46)	$ (293.34)	$ (520.18)
Weighted-average number of shares used to compute net loss per share, basic and diluted	3,578,771	63,005	63,005

(in thousands)	December 31, 2019	2018	2017
Balance Sheet Data:			
Cash and cash equivalents	$ 72,084	$ 13,164	$ 11,241
Working capital (1)	75,355	12,360	8,270
Total assets	88,310	28,887	20,390
Borrowings, non-current portion, net of discounts and debt issuance costs	25,854	24,617	18,809
Capital lease obligations, including current portion	874	360	108
Redeemable convertible preferred stock warrant liabilities	—	1,503	896
Redeemable convertible preferred stock	—	105,232	92,046
Total stockholders' equity (deficit)	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 nine 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 82% of our revenue for each of the years ended December 31, 2019 and 2018. 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. In order to advance our integrated testing and therapeutics strategy, 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. We began direct promotion of SIMPONI® in January 2019 and in support of these promotion efforts we expanded our salesforce from 31 representatives as of December 31, 2018 to 50 representatives as of December 31, 2019. Our SIMPONI® promotion efforts contributed approximately $1.5 million in incremental revenue in 2019 with our quarterly tiered promotion fee based on the incremental increase in total prescribed units above a predetermined average baseline of approximately 29,000 prescribed units per quarter.

We also have additional agreements with other leading pharmaceutical companies, including GSK and Horizon Therapeutics, that leverage our testing products and the information generated from such tests. We plan to pursue additional strategic partnerships with a focus on the commercialization of therapeutics that are synergistic with our 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.

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 payers, such as insurance companies and health maintenance organizations, government payers, such as Medicare, and patients. Reimbursement rates vary by product and payer. We continue to focus on expanding coverage among existing contracted rheumatologists and to achieve coverage with commercial payers, 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, 2019 we had an accumulated deficit of $164.6 million. We incurred net losses of $12.0 million and $8.0 million for the years ended December 31, 2019 and 2018, 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, 2019, we had $72.1 million of cash and cash equivalents.

Factors Affecting Our Performance

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 its launch in 2012, we have grown the number of our AVISE® CTD tests delivered at a compound annual growth rate of 81%, with limited incremental investment in our commercial infrastructure. Over 105,000 AVISE® CTD tests were delivered in 2019, representing 26% growth over 2018, and the number of ordering healthcare providers reached 1,707 in the fourth quarter of 2019, representing 34% growth over the same quarter in 2018. In the fourth quarter of 2019, we reached 572 adopting healthcare providers, which we classify as those who had previously prescribed at least 11 diagnostic tests in the corresponding period, compared to 506 in the same period in 2018. More than 387,000 AVISE® CTD tests have been delivered since launch. 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 payers, including both commercial and government payers such as Medicare. Payment from third-party payers differs depending on whether we have entered into a contract with the payers as a "participating provider" or do not have a contract and are considered a "non-participating provider." Payers 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 payers, most of which have not contracted with us to be a participating provider. Historically, we have experienced situations where commercial payers proactively reduced the amounts they were willing to reimburse for our tests, and in other situations, commercial payers 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 payers, 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®***. In January 2019, we began promoting SIMPONI® in the United States under the Janssen agreement. Our SIMPONI® promotion efforts contributed approximately $1.5 million in incremental revenue in 2019 with our quarterly tiered promotion fee based on the incremental increase in

total prescribed units above a predetermined average baseline of approximately 29,000 prescribed units per quarter. We may encounter difficulties in successfully promoting SIMPONI® and generating significant revenue under the agreement. Our ability to effectively promote SIMPONI® will require us to be successful in a range of activities, including training and deploying additional sales representatives and creating demand for SIMPONI® through our own sales activities as well as those of Janssen. Based on our estimate of the total U.S. addressable market for SIMPONI®'s approved indications of $28 billion, each incremental 1% market share we are able to capture for SIMPONI® above the predetermined baseline under the Janssen Agreement could result in incremental revenue to us of up to $84 million. In interest of supporting these efforts we expect to continue to expand our salesforce in 2020. However, it may take longer to generate meaningful revenue than we currently expect and we may not be successful in materially increasing market share, which would cause us to continue to rely on our existing testing products to drive revenue growth.

- ***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.
- ***Margin Expansion***. We believe growth in our promotion of therapeutics will meaningfully improve our margin profile and further support our goal of achieving profitability. We also expect 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. In addition, we believe we are well positioned to drive further margin expansion 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 payer 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, these potential margin increases may be partially offset by expected decreases in Medicare reimbursement rates as a result of the Protecting Access to Medicare Act of 2014, or PAMA.
- ***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 payer. 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. In addition, the recent COVID-19 outbreak may have a material adverse effect on our business, financial condition and results of operations, including as a result of shutdowns of our facilities and operations as well as those of our suppliers and courier services, disrupt the supply chain of material needed for our tests, interrupt our ability to receive specimens, impair our ability to perform or deliver the results from our genomic tests, impede patient movement or interrupt healthcare services causing a decrease in test volumes, delay coverage decisions from Medicare and third party payors, and delay ongoing and planned clinical trials involving our tests. 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 a co-promotion agreement with Janssen, 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 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. The predetermined average baseline for the initial term of 18 months is approximately 29,000 prescribed units per quarter, subject to adjustment under certain circumstances. In September 2019, we

exercised our option to extend the term of the Janssen agreement to December 31, 2021. 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.

We recognized co-promotional revenue of approximately $1.5 million during the year ended December 31, 2019 and expect to continue to recognize revenue as we perform co-promotional services based on the number of total prescribed units of SIMPONI® over the predetermined baseline.

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 payers, consist of healthcare insurers, government payers (primarily Medicare and Medicaid), client payers (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 payer. 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 successfully promote SIMPONI®.

Operating Expenses

Costs of Revenue (Excluding Amortization of Purchased Technology)

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 payer, 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 payers for each month's billings.

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.

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 2020 as we expand our sales and sales support functions, including expansion activities related to our promotion of SIMPONI®, and incur expenses from operating as a public company for the entire year, including expenses related to compliance with the rules and regulations of the SEC and Nasdaq, additional insurance, investor relations activities and other administrative and professional services such as accounting, legal, regulatory and tax.

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 as we continue to invest in research and development activities related to our existing testing products and product candidates.

Amortization of Intangible Assets

Amortization of intangible assets represents the total amortization expense for our purchased technologies.

The intangible assets recorded as of December 31, 2017 became fully amortized in 2018; accordingly, we do not expect any future amortization expense related to these assets.

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 decrease in the near term due to lower interest rates.

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, 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.

Income Tax Expense

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

Results of Operations

Comparison of the Years Ended December 31, 2019 and 2018:

	Years Ended December 31,		
	2019	2018	Change
	(in thousands)		
Revenue	$ 40,387	$ 32,440	$ 7,947
Operating expenses:			
Costs of revenue (excluding amortization of purchased technology)	18,808	15,379	3,429
Selling, general and administrative expenses	28,702	19,675	9,027
Research and development expenses	2,176	2,125	51
Amortization of intangible assets	—	141	(141)
Total operating expenses	49,686	37,320	12,366
Loss from operations	(9,299)	(4,880)	(4,419)
Interest expense	(3,491)	(2,868)	(623)
Change in fair value of financial instruments	267	(318)	585
Other income, net	510	112	398
Loss before income taxes	(12,013)	(7,954)	(4,059)
Income tax expense	25	58	(33)
Net loss	$ (12,038)	$ (8,012)	$ (4,026)

Revenue

Revenue increased $7.9 million, or 24.5%, for the year ended December 31, 2019 compared to the year ended December 31, 2018, primarily due to an increase in the number of diagnostic tests delivered. The number of AVISE® CTD tests, which accounted for 82% of revenue for the years ended December 31, 2019 and 2018, increased to 105,370 tests delivered in the year ended December 31, 2019 compared to 83,405 tests delivered in the same 2018 period. The increase is primarily due to the increased adoption of the AVISE® CTD test by rheumatologists as the number of ordering healthcare providers increased to 1,707 for the fourth quarter of 2019 as compared to 1,278 healthcare providers in the same 2018 period.

In addition, we recognized approximately $1.5 million of revenue related to our SIMPONI® promotion efforts during the year ended December 31, 2019.

Costs of Revenue (excluding amortization of purchased technology)

Costs of revenue increased $3.4 million, or 22.3%, for the year ended December 31, 2019 compared to the year ended December 31, 2018. This increase was primarily due to increased direct costs such as materials and supplies, royalties, shipping and handling and labor associated with the increase in test volume in 2019 compared to 2018.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased $9.0 million, or 45.9%, for the year ended December 31, 2019 compared to the year ended December 31, 2018. This increase was primarily due to increased employee related expenses of $6.1 million as a result of increasing the size of our salesforce from 30 as of December 31, 2018 to 50 as of December 31, 2019. The remaining increase relates primarily to increased audit and professional services of $1.2 million, insurance expenses of $0.5 million and stock-based compensation expense of $0.4 million.

Research and Development Expenses

Research and development expenses remained relatively consistent for the year ended December 31, 2019 compared to the year ended December 31, 2018.

Amortization of Intangible Assets

Our purchased intangible assets were fully amortized at December 31, 2018, therefore there is no amortization expense recorded for the year ended December 31, 2019.

Interest Expense

Interest expense increased $0.6 million, or 21.7%, for the year ended December 31, 2019 compared to the year ended December 31, 2018. This increase was primarily due to higher principal amounts outstanding over the year ended December 31, 2019 compared to the prior year period, under our long-term borrowing arrangements.

Change in Fair Value of Financial Instruments

The change in fair value of financial instruments increased $0.6 million for the year ended December 31, 2019 compared to the year ended December 31, 2018. This increase resulted from changes in the valuation of our redeemable convertible preferred stock warrant liabilities.

Other Income, Net

Other income, net, increased $0.4 million for the year ended December 31, 2019 compared to the year ended December 31, 2018. This increase was due to the higher cash balance in our money market funds account during the year ended December 31, 2019 compared to the prior year period.

Income Tax Expense

Income tax expense remained relatively consistent for the year ended December 31, 2019 compared to the year ended December 31, 2018.

Liquidity and Capital Resources

We have incurred net losses since our inception. For the years ended December 31, 2019 and 2018, we incurred a net loss of $12.0 million and $8.0 million, respectively, and we expect to incur additional losses and increased operating expenses in future periods. As of December 31, 2019, we had an accumulated deficit of $164.6 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, 2019, we had $72.1 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, or the Loan Agreement, 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 executed the first amendment, or the Loan Amendment, to the Loan 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.

In connection with the execution of the Loan Agreement, 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 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.

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. Other than the addition of laboratory equipment, we expect that we will not need to make material capital expenditures in the near term related to our laboratory facilities. 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. 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.

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:

- 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;
- the impact of the recent COVID-19 outbreak on our business, including challenges resulting from social distancing and stay-at home orders through a reduction in testing volumes;
- fluctuations in working capital;
- 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;
- the costs of developing our product pipeline, including the costs associated with conducting our ongoing and future validation studies;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payers and adequate market share and revenue for our testing products;
- the additional costs we may incur as a result of operating as a public company; 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,	
	2019	2018
(in thousands)		
Net cash provided by (used in):		
Operating activities	$ (9,711)	$ (9,301)
Investing activities	(103)	(199)
Financing activities	68,734	11,423
Increase in cash, cash equivalents and restricted cash	$ 58,920	$ 1,923

Cash Flows from Operating Activities

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, partially offset by decreases in prepaid expenses and other current assets.

Net cash used in operating activities for the year ended December 31, 2018 was $9.3 million and primarily resulted from our net loss of $8.0 million adjusted for non-cash charges of $0.3 million for remeasurements of financial instruments and $1.8 million for depreciation, amortization and non-cash interest, partially offset by changes in our net operating assets consisting of $2.3 million increase in accounts receivable primarily due to the adoption of ASC 606 and $1.3 million related to net increases in prepaid expenses and other current assets, accounts payable, and accrued liabilities.

Cash Flows from Investing Activities

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

Net cash used in investing activities for the year ended December 31, 2018 was $0.2 million and was primarily due to net purchases of property and equipment.

Cash Flows from Financing Activities

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.

Net cash provided by financing activities for the year ended December 31, 2018 was $11.4 million and primarily resulted from $6.5 million of net proceeds received from the issuance of our redeemable convertible preferred stock and net proceeds of $5.0 million under our long-term borrowing arrangement with Innovatus.

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 payers (primarily Medicare and Medicaid), client payers (i.e. hospitals, other laboratories, etc.) and patient self-pays.

Payers 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 payers. 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 payer (i.e. each individual third party insurance, Medicare, client payers, patient self-pay, etc.) and per test basis.

Collection of our net revenues from payers 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. As of December 31, 2018, there were no performance obligations under the agreement and no consideration had been received.

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, 2019 and 2018.

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 $0.6 million and $0.1 million for the years ended December 31, 2019 and 2018, 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 10 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, 2019 and 2018.

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 Share Purchase Rights, 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.

Acquisition-Related Liabilities

In connection with the acquisition of the medical diagnostics division of Cypress in 2010, we initially agreed to pay an additional amount not to exceed $9.0 million in the event specified revenue, contractual and product launch milestones are achieved. This contingent liability required the use of inputs which were not observable in the market to assess its fair value at the end of each reporting period. For this liability, fair value was determined based on probabilities assigned to the milestones being achieved, revenue projections, and interest rates. Changes in fair value were recorded in the statement of operations and comprehensive loss. In February 2017, we amended two of the remaining agreements for which a contingent payment amount had been originally agreed to. One contingent payment amount remains outstanding.

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, however all tax years remain open for examination by federal tax authorities.

At December 31, 2019, our deferred tax assets are primarily comprised of federal and state tax net operating loss carryforwards. We 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. Therefore, our ability to utilize our net operating losses incurred prior to December 31, 2017 are limited. Our ability to utilize net operating loss carryforwards generated after December 31, 2017 will not expire under the Tax Cuts and Jobs Act of 2017.

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, 2019. 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 prospectus, 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, 2019, 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.

Management's Report on Internal Control Over Financial Reporting

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting due to a transition period established by the rules of the SEC, which requires such assessment to be included beginning with a registrant's second Annual Report on Form 10-K.

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, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

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 2020 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 2020 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 2020 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 2020 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 2020 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 91.

(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, 2019 and 2018, the related statements of operations, stockholders’ equity (deficit), 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, 2019 and 2018, 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 25, 2020

Exagen Inc.

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

	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 72,084	$ 13,164
Accounts receivable, net	5,715	5,952
Prepaid expenses and other current assets	3,451	2,196
Total current assets	81,250	21,312
Property and equipment, net	1,380	1,566
Goodwill	5,506	5,506
Other assets	174	503
Total assets	$ 88,310	$ 28,887
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 1,476	$ 1,279
Accrued liabilities	4,419	3,923
Proceeds received prior to issuance of Series G redeemable convertible preferred stock	—	3,750
Total current liabilities	5,895	8,952
Borrowings-non-current portion, net of discounts and debt issuance costs	25,854	24,617
Redeemable convertible preferred stock warrant liabilities	—	1,503
Deferred tax liabilities	264	245
Other non-current liabilities	638	304
Total liabilities	32,651	35,621
Commitments and contingencies (Note 6)		
Redeemable convertible preferred stock, $0.001 par value; none and 750,300,000 shares authorized at December 31, 2019 and 2018, respectively; none and 532,606,084 shares issued and outstanding at December 31, 2019 and December 31, 2018, respectively; liquidation preference of $0 and $163,316 at December 31, 2019 and December 31, 2018, respectively	—	105,232
Stockholders' equity (deficit):		
Preferred stock, $0.001 par value; 10,000,000 shares authorized, no shares issued or outstanding at December 31, 2019; no shares authorized, issued or outstanding at December 31, 2018	—	—
Common stock, $0.001 par value; 200,000,000 and 1,470,000,000 shares authorized at December 31, 2019 and December 31, 2018, respectively; 12,560,990 and 63,005 shares issued and outstanding at December 31, 2019 and December 31, 2018, respectively	13	—
Additional paid-in capital	220,248	40,598
Accumulated deficit	(164,602)	(152,564)
Total stockholders' equity (deficit)	55,659	(111,966)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 88,310	$ 28,887

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,	
	2019	**2018**
Revenue	$ 40,387	$ 32,440
Operating expenses:		
Costs of revenue (excluding amortization of purchased technology)	18,808	15,379
Selling, general and administrative expenses	28,702	19,675
Research and development expenses	2,176	2,125
Amortization of intangible assets	—	141
Total operating expenses	49,686	37,320
Loss from operations	(9,299)	(4,880)
Interest expense	(3,491)	(2,868)
Change in fair value of financial instruments	267	(318)
Other income, net	510	112
Loss before income taxes	(12,013)	(7,954)
Income tax expense	25	58
Net loss	(12,038)	(8,012)
Accretion of redeemable convertible preferred stock	(4,640)	(9,318)
Deemed dividend recorded in connection with financing transactions	(13,601)	(1,152)
Net loss attributable to common stockholders (Note 2)	$ (30,279)	$ (18,482)
Net loss per share, basic and diluted (Note 2)	$ (8.46)	$ (293.34)
Weighted-average number of shares used to compute net loss per share, basic and diluted (Note 2)	3,578,771	63,005

The accompanying notes are an integral part of these financial statements

Exagen Inc.

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

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balances at December 31, 2017	497,691,757	$ 92,046	63,005	$ —	$ 50,954	$ (147,638)	$ (96,684)
Cumulative effect of changes in accounting principle related to revenue recognition	—	—	—	—	—	3,086	3,086
Accretion of redeemable convertible preferred stock	—	9,318	—	—	(9,318)	—	(9,318)
Stock-based compensation	—	—	—	—	114	—	114
Issuance of Series F redeemable convertible preferred stock for aggregate proceeds of $0.078 per share, net of issuance costs of $7, in the third tranche closing of the Series F financing	34,914,327	3,868	—	—	(1,152)	—	(1,152)
Net loss	—	—	—	—	—	(8,012)	(8,012)
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 8)	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 8)	233,446,519	3,941	—	—	6,741	—	6,741
Deemed dividend recognized on beneficial conversion features of Series H redeemable convertible preferred stock (Note 8)	—	6,741	—	—	(6,741)	—	(6,741)
Deemed dividend from conversion of Series G to Series H redeemable convertible preferred stock (Note 8)	97,592,739	6,860	—	—	(6,860)		(6,860)
Conversion of preferred stock to common stock in connection with initial public offering (Note 8)	(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 9)	—	—	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

The accompanying notes are an integral part of these financial statements

Exagen Inc.

Statements of Cash Flows
(in thousands)

	Years Ended December 31,	
	2019	2018
Cash flows from operating activities:		
Net loss	$ (12,038)	$ (8,012)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	591	731
Amortization of debt discount and debt issuance costs	691	587
Non-cash interest expense	546	515
Revaluation of warrant liabilities	(267)	318
Deferred income taxes	—	31
Loss on disposal of assets	20	6
Stock-based compensation	572	114
Changes in assets and liabilities:		
Accounts receivable, net	237	(2,262)
Prepaid expenses and other current assets	(1,255)	(781)
Other assets	(24)	(8)
Accounts payable	528	(824)
Accrued and other liabilities	688	284
Net cash used in operating activities	(9,711)	(9,301)
Cash flows from investing activities:		
Purchases of property and equipment	(403)	(199)
Proceeds from sale of property and equipment	300	—
Purchases of short-term investments	—	(2,000)
Maturities of short-term investments	—	2,000
Net cash used in investing activities	(103)	(199)
Cash flows from financing activities:		
Proceeds from sale of common stock upon exercise of stock options	4	—
Principal payment on capital lease obligations	(138)	(38)
Proceeds from issuance of 2017 Term Loan, net of issuance costs of $5	—	4,995
Proceeds from initial public offering, net of issuance costs and offering costs	50,444	—
Proceeds from the issuance of Series F redeemable convertible preferred stock, net of issuance costs	—	2,716
Proceeds from issuance of Series G redeemable convertible preferred stock, net of issuance costs	7,742	3,750
Proceeds from issuance of Series H redeemable convertible preferred stock, net of issuance costs	10,682	—
Net cash provided by financing activities	68,734	11,423
Increase in cash, cash equivalents and restricted cash	58,920	1,923
Cash, cash equivalents and restricted cash, beginning of period	13,264	11,341
Cash, cash equivalents and restricted cash, end of period	$ 72,184	$ 13,264
Supplemental disclosure of cash flow information:		
Cash paid for interest expense	$ 2,288	$ 1,730
Supplemental disclosure of non-cash items:		
Accretion to redemption value of redeemable convertible preferred stock	$ 4,640	$ 9,318
Equipment purchased under capital lease obligations	$ 654	$ 289
Fair value of warrant liabilities recorded as discount on debt	$ —	$ 289
Costs incurred, but not paid, in connection with capital expenditures	$ —	$ 331
Conversion of redeemable convertible preferred stock	$ 138,906	$ —
Net exercise of common and preferred stock warrants	$ 511	$ —
Issuance costs included in accounts payable and accrued liabilities	$ —	$ 355
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	$ —
Deemed dividend from issuance of Series F redeemable convertible preferred stock	$ —	$ 1,152
Adjustment upon adoption of Topic 606	$ —	$ 3,086

The accompanying notes are an integral part of these financial statements

Note 1. Organization

Description of Business

Exagen Inc. (the Company) was incorporated under the laws of the state of New Mexico in 2002, under the name Exagen Corporation. In 2003, Exagen Corporation changed its state of incorporation from New Mexico to Delaware by merging with and into Exagen Diagnostics, Inc., pursuant to which the Company changed its name to Exagen Diagnostics, Inc. In January 2019, the Company changed its name to Exagen Inc. 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.

Initial Public Offering

On September 23, 2019, the Company closed its initial public offering (the 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.

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.

Liquidity

The Company has suffered 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, 2019, the Company had cash and cash equivalents of $72.1 million and had an accumulated deficit of $164.6 million, respectively. Since inception, the Company has financed its operations primarily through private placements of preferred securities, the sale of common stock through its 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 payers 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 payer, 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,	
	2019	2018
Medicare	25 %	30 %
Blue Shield	12 %	14 %
United Healthcare	11 %	12 %
Medicare Advantage	11 %	10 %
Janssen (SIMPONI®)	*	*

* Less than 10%.

	Accounts Receivable	
	December 31,	
	2019	2018
Medicare	*	26 %
Blue Shield	15 %	16 %
United Healthcare	22 %	11 %
Medicare Advantage	*	11 %
Janssen (SIMPONI®)	19 %	*

* Less than 10%.

For the years ended December 31, 2019 and 2018, approximately 82% of the Company's revenue was related to the AVISE® CTD test.

The Company is dependent on key suppliers for certain laboratory materials. For the years ended December 31, 2019 and 2018, approximately 97% and 95%, respectively, of the Company's inventories 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 payer category (in thousands):

	Years Ended December 31,	
	2019	2018
Revenue:		
Healthcare insurers	$ 23,984	$ 21,070
Government	9,896	10,024
Client	4,392	608
Other(1)	639	738
Janssen (SIMPONI®)	1,476	—
Total revenue	$ 40,387	$ 32,440

(1) Includes patient self-pay that is immaterial.

Fair Value Measurements

The carrying value of the Company's cash and cash equivalents, other assets and accrued liabilities 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,	
	2019	2018
Cash and cash equivalents	$ 72,084	$ 13,164
Restricted cash	100	100
	$ 72,184	$ 13,264

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 5 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 Payers) consist of healthcare insurers, government payers (primarily Medicare and Medicaid), client payers (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.

Payers 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 payers. 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. 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 payer (i.e. each individual third-party insurance, Medicare, client payers, patient self-pay, etc.) and per test basis.

Collection of the Company's net revenues from payers 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.

The Company early adopted Accounting Standards Codification (ASC) Topic 606, *Revenue from Contracts with Customers* (Topic 606) as of January 1, 2018 using a cumulative-effect adjustment to the opening balance of accumulated deficit and accounts receivable of $3.1 million.

Janssen Promotion Agreement

In December 2018, the Company entered into a co-promotion agreement with Janssen (the Janssen agreement) 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 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. The promotion fee is determined on a sliding rate, ranging from the high hundreds of dollars to the low one thousands per prescribed unit of SIMPONI®, depending on the number of increased prescriptions, and varies per increased prescription. 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.

In September 2019, the Company exercised their option to extend the term of the Janssen agreement to December 31, 2021. Janssen can terminate the agreement at any time for any reason upon 30 days' notice to the Company, and the Company 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.

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 revenue of approximately $1.5 million during the year ended December 31, 2019. 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 $1.6 million and $1.4 million for the years ended December 31, 2019 and 2018, 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 and $1.2 million for the years ended December 31, 2019 and 2018, respectively.

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 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 and options outstanding under the Company's stock option plans. For the years ended December 31, 2019 and 2018, 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,	
	2019	2018
Redeemable convertible preferred stock	—	5,202,940
Warrants to purchase redeemable convertible preferred stock	—	224,493
Warrants to purchase common stock	461,273	934,789
Common stock options	1,375,542	661,180
Total	1,836,815	7,023,402

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

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. As an emerging growth company as defined in the JOBS Act, the Company has elected to delay adoption of this ASU until January 1, 2021. 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 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. 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 is currently evaluating the impact of ASU 2018-13 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,	
	2019	2018
Diagnostic testing supplies	$ 1,427	$ 1,174
Prepaid product royalties	123	176
Prepaid maintenance and insurance contracts	1,768	698
Other prepaid assets	133	148
Prepaid and other current assets	$ 3,451	$ 2,196

Property and Equipment

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

	December 31,	
	2019	2018
Furniture and fixtures	$ 25	$ 25
Laboratory equipment	2,228	1,855
Computer equipment and software	851	796
Leasehold improvements	424	399
Construction in progress	247	310
Total property and equipment	3,775	3,385
Less: accumulated depreciation and amortization	(2,395)	(1,819)
Property and equipment, net	$ 1,380	$ 1,566

Depreciation and amortization expense for the years ended December 31, 2019 and 2018, was approximately $0.6 million. At December 31, 2019 and December 31, 2018, the gross book value of assets under capital lease was $0.8 million and $0.4 million, respectively, and is classified in "Laboratory equipment" in the table above.

Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	December 31,	
	2019	2018
Accrued payroll and related expenses	$ 2,362	$ 2,111
Accrued deferred offering costs	—	355
Accrued interest	145	178
Accrued purchases of goods and services	319	243
Accrued royalties	727	602
Accrued clinical study activity	40	146
Capital lease obligations, current portion	238	81
Other accrued liabilities	588	207
Accrued liabilities	$ 4,419	$ 3,923

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, 2019, 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 (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, or 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 PIK 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 the years ended December 31, 2019 and 2018, the Company issued PIK Loans totaling $0.5 million.

If the Loan Amendment is prepaid after November 19, 2019, but before November 19, 2020, 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 will be waived 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. In addition, 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, 2019, 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.

In connection with the 2017 Term Loan, the Company paid issuance costs of $0.4 million to Innovatus and an additional $0.1 million to third parties. These fees were recorded as discounts to the carrying value of the 2017 Term Loan. The Company also issued Innovatus warrants (i) on the closing date of the 2017 Term Loan, to purchase 15,384,615 shares of Series F redeemable convertible preferred stock at an exercise price of $0.078 per share and (ii) on December 7, 2018, to purchase 3,846,154 shares of Series F redeemable convertible preferred stock at an exercise price of $0.078 per share (Note 5). These warrants are immediately exercisable and will expire if

unexercised seven years after their issuance. The fair value of the warrants on each of their dates of issuance, determined using BSM option pricing model, was recorded as a discount to long-term debt and an offsetting amount recognized as a liability. The resulting debt discount is being amortized to interest expense using the effective interest method over the term of the 2017 Term Loan. In connection with the completion of the IPO in September 2019, the Series F redeemable convertible preferred stock warrants automatically converted into warrants exercisable for an aggregate of 104,722 shares of common stock.

Future Minimum Payments on the Outstanding Borrowings

As of December 31, 2019, future minimum aggregate payments, including interest, for outstanding borrowings under the Loan Amendment are as follows (in thousands):

	Years Ending December 31,
2020	$ 1,725
2021	1,755
2022	2,996
2023	15,619
2024	14,280
Total	36,375
Less:	
Unamortized debt discount and issuance costs	(390)
Interest	(10,131)
Total borrowings, net of discounts and debt issuance costs	$ 25,854

Note 5. Warrants to Purchase Common or Preferred Stock

In connection with the completion of the Company's IPO in September 2019:

- The remaining outstanding Series F redeemable convertible preferred stock warrants automatically converted into warrants exercisable for an aggregate 104,722 shares of common stock.
- Warrants to purchase common stock for 569,184 shares of the Company's common stock were exercised via cashless exercise resulting in the issuance of 512,363 shares of common stock. Unexercised warrants to purchase common stock for 9,054 shares were terminated prior to the completion of the IPO.
- Warrants to purchase Series D and Series E redeemable convertible preferred stock for 119,771 shares of the Company's common stock were exercised via cashless exercise resulting in the issuance of 27,431 shares of common stock.

Outstanding Warrants

The following warrants to purchase common stock were outstanding as of December 31, 2019:

	Shares	Exercise Price	Issuance date	Expiration date
Common stock warrants	282,402	$ 1.84	January 19, 2016	January 19, 2026
Common stock warrants	74,018	1.84	March 31, 2016	March 31, 2026
Common stock warrants	131	1.84	April 1, 2016	April 1, 2026
Common stock warrants (1)	83,778	14.32	September 8, 2017	September 8, 2024
Common stock warrants (1)	20,944	14.32	December 7, 2018	December 7, 2025
	461,273			

(1) Prior to the conversion upon IPO, the remaining warrants were for the purchase of Series F redeemable convertible preferred stock.

The outstanding warrants to purchase shares of common stock are equity classified at December 31, 2019.

Note 6. Commitments and Contingencies

Leases

As of December 31, 2019, the Company leases an office and laboratory space in Vista, California, under a lease that expires in January 2021, with options to extend the lease for two additional 36-month periods. In addition, the Company also leases an office space in Vista, California, under a lease that expires in January 2021 with an option to extend the lease for an additional 24-month 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, 2019 are as follows (in thousands):

Years Ending December 31,	Capital Leases	Operating Leases
2020	$ 272	$ 411
2021	272	34
2022	246	—
2023	159	—
2024	—	—
Total minimum lease payments	949	$ 445
Less: amount representing interest	(75)	
Present value of future minimum lease payments	874	
Less: current portion	(238)	
Long-term capital lease obligations	$ 636	

For the years ended December 31, 2019 and 2018, rent expense was $0.5 million and $0.4 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, 2019 and December 31, 2018.

In addition, the Company has ongoing royalty payment obligations on net sales of products which incorporate certain acquired technologies ranging from 2.5% to 7.5%. Future royalties payable under these arrangements are limited to the lesser of an aggregate of $4.2 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 3.0% to 20.0%. Royalties are accrued when earned and recorded in costs of revenue in the accompanying statement of operations.

Supply Agreement

In January 2018, the Company entered into a supply agreement with one supplier for reagents which includes a minimum annual purchase commitment of $3.25 million for each of the three years covered by the agreement, which terminates in 2021.

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 payers 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. 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

The Company is not a party to any litigation and does not have contingent reserves established for any litigation liabilities. From time to time, the Company may be subject to various legal proceedings that arise in the ordinary course of business activities.

Note 7. 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, 2019			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds	$ 70,760	$ 70,760	$ —	$ —

	December 31, 2018			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds	$ 8,618	$ 8,618	$ —	$ —
Liabilities:				
Redeemable convertible preferred stock warrant liabilities	$ 1,503	$ —	$ —	$ 1,503

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

The following table includes a roll-forward of the financial instruments measured on a recurring basis and classified within Level 3 of the fair value hierarchy (in thousands):

	Liability Classified Warrants
Balances at December 31, 2017	$ 896
Issuance of warrants to purchase shares of Series F redeemable convertible preferred stock in connection with 2017 Term Loan (Note 4)	289
Remeasurement of financial instruments	318
Balances at December 31, 2018	1,503
Remeasurement of financial instruments	(267)
Net exercise of preferred stock warrants	(510)
Reclassification of liability classified warrants to stockholders' equity (deficit)	(726)
Balance at December 31, 2019	$ —

Changes in the fair value of the Company's liability classified warrants are recorded in the line item change in fair value of financial instruments in the accompanying statement of operations.

Note 8. Redeemable Convertible Preferred Stock

On January 2, 2019, the Company amended and restated its restated certificate of incorporation to, among other things, increase its authorized shares of convertible preferred stock from 750,300,000 to 955,500,000 shares, of which 205,200,000 shares are designated as Series G convertible preferred stock and set forth the rights, preferences and privileges of the Series G convertible preferred stock.

On July 11, 2019, the Company amended and restated its restated certificate of incorporation to among other things, increase its authorized shares of convertible preferred stock from 955,500,000 to 1,038,667,059 shares, of which 479,967,595 shares are designated as Series H redeemable convertible preferred stock and set forth the rights, preferences and privileges of the Series H redeemable convertible preferred stock.

Upon completion of the Company's IPO in September 2019, 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. As a result, no shares of redeemable convertible preferred stock remain outstanding at December 31, 2019.

Series F Financing

In December 2017, the Company's Board of Directors authorized a third tranche closing of the issuance to existing preferred stockholders in connection with the Company's Series F financing, which was completed between December 2017 and January 2018. In December 2017, a group of existing investors of the Company purchased 54,246,756 shares of Series F redeemable convertible preferred stock at a per share price of $0.078 for aggregate gross proceeds of approximately $4.2 million. In early January 2018, a group of existing stockholders of the Company purchased an additional 34,914,327 shares of Series F redeemable convertible preferred stock at a per share price of $0.078 for aggregate gross proceeds of approximately $2.7 million.

The Company concluded that the third tranche closing of the Series F preferred stock purchase agreement contained a single freestanding financial instrument, shares of Series F redeemable convertible preferred stock, and the Company determined there were no embedded features requiring bifurcation in the shares of Series F redeemable convertible preferred stock issued in the third tranche closing. The Company accounted for the difference between the estimated fair value and the $0.078 per share purchase price of shares of Series F redeemable convertible preferred stock issued in the third tranche closing as a deemed dividend since all investors in the third closing are existing preferred stockholders of the Company, and the Company did not identify any elements to the transaction which it believes were compensatory in nature. As a result, the Company recognized a deemed dividend in the amount of $1.2 million in the first quarter of 2018, 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’ deficit.

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 per share price of $0.078 in each closing. Shares of Series G redeemable convertible preferred stock were issuable under the Series G preferred stock purchase agreement until the earlier of March 31, 2019 or the issuance of all authorized shares of Series G redeemable convertible preferred stock, as specified in the Company's amended and restated certificate of incorporation.

In January 2019 and March 2019, the Company sold 88,030,905 and 9,615,384 shares, respectively, of Series G redeemable convertible preferred stock for aggregate gross proceeds of approximately $7.6 million to new and existing investors, of which $3.75 million of gross proceeds were received as of December 31, 2018 and are included in the accompanying December 31, 2018 balance sheet.

In May 2019, the Company sold an additional 51,282,048 shares of Series G redeemable convertible preferred stock for aggregate gross proceeds of approximately $4.0 million to existing investors.

In addition, in May 2019, the Series G preferred stock purchase agreement was amended to include the right of the Company to require certain holders of Series G redeemable convertible preferred stock to purchase an additional 32,051,280 shares of Series G redeemable convertible preferred stock at $0.078 per share, for total aggregate proceeds of $2.5 million, at any time after July 31, 2019 and prior to May 31, 2020. This right terminated in connection with the issuance of the Series H redeemable convertible stock in July 2019.

The Company concluded that the closings of the Series G preferred stock purchase agreement in January and March 2019, contained a single freestanding financial instrument, shares of Series G redeemable convertible preferred stock, and the Company determined there were no embedded features requiring bifurcation in the shares of Series G redeemable convertible preferred stock issued. The Company concluded the closing in May 2019 contained two freestanding financial instruments, shares of Series G redeemable convertible preferred stock and the Company call right, and the Company concluded there were no embedded features requiring bifurcation in the shares of Series G redeemable convertible preferred stock issued. The Company call right was deemed to have nominal value since it was with insiders with knowledge of the imminent closing of Series H redeemable convertible 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. Pursuant to the terms of the agreement, the new investor purchased 233,446,519 shares of Series H redeemable convertible preferred stock for gross proceeds of approximately $11.0 million. In connection with the Series H financing, the Company converted all of the 148,928,337 outstanding shares of the Company's Series G redeemable convertible preferred stock into 246,521,076 shares of Series H redeemable convertible preferred stock on a dollar-for-dollar basis.

The Company concluded that the closing of the Series H preferred stock purchase agreement contained a single freestanding financial instrument, shares of Series H redeemable convertible preferred stock, and the Company determined there were no embedded features requiring bifurcation in the shares of Series H redeemable convertible preferred stock issued at closing. 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 (deficit). 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 (deficit).

Note 9. Stockholders' Equity (Deficit)

Common Stock

Common stockholders are entitled to dividends as and when declared by the Board of Directors, subject to the rights of holders of all classes of stock outstanding having priority rights as to dividends. There have been no dividends declared to date. The holder of each share of common stock is entitled to one vote.

On January 2, 2019, the Company amended and restated its restated certificate of incorporation to, among other things, increase its authorized shares of common stock from 1,470,000,000 to 1,675,200,000 shares.

On July 11, 2019, the Company amended and restated its restated certificate of incorporation to, among other things, increase its authorized shares of common stock from 1,675,200,000 to 1,970,000,000 shares.

The Company filed its amended and restated certificate of incorporation on September 23, 2019, authorizing 200,000,000 shares of common stock and 10,000,000 shares of preferred 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.

Note 10. Stock Option Plan

In December 2012, the Company's Board of Directors adopted the 2013 Stock Option Plan (the Plan). Pursuant to the Plan, employees, consultants, and directors may be granted either incentive stock options or non-qualified stock options to purchase shares of the Company's common stock. In July 2019, the number of shares reserved for issuance under the Plan was increased from 669,806 to 1,663,681 shares.

In September 2019, the Company's Board of Directors adopted, and the Company's stockholders approved, the 2019 Incentive Award Plan (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. 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 will initially be reserved for issuance under the 2019 Plan. 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, 2019, 1,283,996 shares remained available for future awards. Under the evergreen provision, on January 1, 2020, an additional 502,440 shares became available for issuance under the 2019 Plan.

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.

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, 2018	661,180	$ 1.22	9.52	$ 6,198
Granted	816,356	$ 13.99		
Exercised	(1,548)	$ 2.41		
Forfeited	(99,967)	$ 7.50		
Expired	(479)	$ 42.08		
Outstanding, December 31, 2019	1,375,542	$ 8.33	9.16	$ 23,654
Vested and expected to vest, December 31, 2019	1,375,542	$ 8.33	9.16	$ 23,654
Options exercisable, December 31, 2019	203,344	$ 3.49	7.85	$ 4,625

The weighted-average grant date fair value per share of employee options granted to employees during the years ended December 31, 2019 and 2018 was $7.79 and $0.17, 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 $25.40 and $9.92 per share at December 31, 2019 and 2018, respectively. The intrinsic value of options exercised for the years ended December 31, 2019 and 2018 was an immaterial amount and zero, 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,	
	2019	2018
Expected volatility	46%-59%	70%
Risk-free interest rate	1.6%-2.6%	1.4% - 2.6%
Dividend yield	—	—
Expected term (in years)	5.75-6.08	6.08

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

	Years Ended December 31,	
	2019	2018
Cost of revenue	$ 9	$ 12
Selling, general and administrative	445	93
Research and development	118	9
Total	$ 572	$ 114

As of December 31, 2019, total unrecognized compensation cost was $5.6 million, which is expected to be recognized over a remaining weighted-average vesting period of 3.3 years.

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, 2020, an additional 125,610 shares became available for issuances under the ESPP. There has been no stock-based compensation expense incurred related to the ESPP for the year ended December 31, 2019.

Common stock reserved for future issuance consists of the following at December 31, 2019:

Warrants to purchase common stock	461,273
Common stock option grants issued and outstanding	1,375,542
Common shares available for grant under the stock option plan	1,283,996
Common shares available for future issuance under ESPP	120,000
Total	3,240,811

Note 11. Income Taxes

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

	Years Ended December 31,	
	2019	2018
Current:		
Federal	$ —	$ —
State	5	27
Total current	5	27
Deferred:		
Federal	10	10
State	10	21
Total deferred	20	31
Provision for income tax	$ 25	$ 58

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

	Years Ended December 31,	
	2019	2018
Federal statutory tax rate	(21.0)%	(21.0)%
State income taxes, net of federal tax benefits	(3.6)%	(3.9)%
Change in fair value of preferred stock liabilities	(0.5)%	0.8 %
Change in valuation allowance	(36.1)%	23.2 %
Limitation of net operating losses	59.8 %	— %
Other	1.6 %	1.6 %
Effective tax rate	0.2 %	0.7 %

Significant components of the Company's deferred tax assets at December 31, 2019 and 2018 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,	
	2019	2018
Deferred tax assets:		
Net operating loss carryforwards	$ 15,287	$ 18,937
Research and development tax credits	419	313
Accruals, reserves and other	590	1,394
Interest expense	744	691
Basis differences in fixed and intangible assets	225	230
Total gross deferred tax assets	17,265	21,565
Less: Valuation allowance	(16,797)	(21,138)
Deferred tax assets, net	468	427
Deferred tax liabilities:		
Financing and acquisition-related liabilities	(336)	(338)
Indefinite lived assets	(396)	(334)
Deferred tax liabilities, net	(732)	(672)
Net deferred tax liabilities	$ (264)	$ (245)

Changes in the valuation allowance for deferred tax assets during the years ended December 31, 2019 and 2018, which related primarily to increases in net operating loss carryforwards, accrued revenue and accruals and reserves were as follows (in thousands):

	December 31,	
	2019	2018
Valuation allowance at the beginning of the year	$ 21,138	$ 19,929
Decreases recorded as benefits to income tax provision	(4,341)	—
Increases recorded to income tax provision	—	1,209
Valuation allowance at the end of the year	$ 16,797	$ 21,138

At December 31, 2019 and 2018, the Company had federal net operating loss carryforwards of approximately $60.7 million and $80.8 million, respectively. At December 31, 2019 and 2018, the Company had state net operating loss carryforwards of $43.5 million and $30.6 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 $17.2 million will carryforward indefinitely and be available to offset up to 80% of future taxable income each year. 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, 2019 and 2018, 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 12. Related Parties

The Company entered into a consulting services agreement, as amended, with a member of the Company's Board of Directors under which this board member provides certain scientific consulting services to the Company. Under this agreement, as amended in June 2018, this board member is compensated at a bi-weekly rate of $5,000 (plus reimbursement for certain administrative and travel related expenses) and received options to purchase 544 shares of common stock in November 2017, the commencement date of the agreement. Total amounts paid to this board member under this agreement for the years ended December 31, 2019 and 2018, were $130,000 and $126,000, respectively, which was recorded in research and development expenses in the accompanying statements of operations. The Company accounted for the grant of options as an award to a non-employee and measures compensation cost for this award based on the value of the award at the date the consulting services are complete. The options granted to this board member were granted at an exercise price of $0.367 (the estimated fair value of share of common stock on the grant date using an OPM model), and vests over a three-year term expected to coincide with the period the board member is expected to provide consulting services to the Company. The estimated fair value of the awards and related compensation cost recognized during the years ended December 31, 2019 and 2018 was immaterial. All compensation cost related to these awards is recorded in research and development expenses in the accompanying statements of operations. Effective July 12, 2019, this consultant no longer serves on the Company's Board of Directors.

In September 2011, the Company entered into a license agreement with the Company's former Chief Scientific Officer, and a related company, De Novo Diagnostics, Inc. The license agreement, covering novel methods for monitoring low-dose methotrexate therapy, relates to technology developed by the Company's former Chief Scientific Officer prior to joining the Company. The technology has yet to be used by the Company. Under the agreement, the Company's Chief Scientific Officer will be eligible to receive up to $0.6 million upon the achievement of certain sales milestones and an ongoing royalty of 5% on sales.

The third tranche closing of the Series F financing, the closings of the Series G financing and the Series H financing described in Note 8 were issued to existing holders of the Company's redeemable convertible preferred stock, including certain members of our Board of Directors.

Note 13. 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, 2019 and 2018, the Company made contributions to the Plan at 3% of qualified employee compensation, which totaled approximately $0.4 million.

Note 14. Subsequent Events

Subsequent to December 31, 2019, stock options for 290,000 shares of the Company's common stock were granted to Company employees.

In March 2020, the Company entered into a new lease agreement related to expanded office and laboratory space in the building attached to the Company's existing headquarters. The initial term of the lease agreement is five years and nine months, expiring in January 2026. The lease agreement provides for monthly base rent of $12,724

beginning in May 2020, which amount shall increase 3% annually beginning in February 2022. The lease agreement does not include any right or option to extend the term after its expiration.

In March 2020, the Company entered into a lease extension on our existing office space located adjacent to the Company's headquarters. The lease extension extends the term from February 2021, until its new expiration in January 2026. The lease extension provides that the base monthly rent for the leased space shall be $19,000, for the 12-month period beginning in February 2021, which amount shall increase $600 on a monthly basis each additional 12-month period until its expiration. In addition, the lease extension added an option for the Company to extend the term of the lease for one five year period, commencing when the prior term expires.

In addition, in March 2020, the Company entered into a lease amendment relating to its headquarters. The lease amendment extends to the term of the lease from April 2020, until its new expiration in January 2026. The lease amendment provides that the base monthly rent for the leased space shall be $16,308.57, for the 10-month period beginning in April 2020, which amount shall increase to $17,325 in February 2021, and shall increase 3% annually thereafter. In addition, the lease amendment added an option for the Company to extend the term of the lease for one five year period, commencing when the prior term expires.

In March 2020 the World Health Organization declared the outbreak of a novel coronavirus (COVID-19) as a pandemic. As a result, the Company is taking the steps to protect the health, safety and well-being of its employees, Associates, and communities by equipping various staff members to work remotely for an uncertain period of time. The Company has started to experience challenges resulting from social distancing and stay-at home orders through a reduction in testing volumes. The Company cannot reasonably estimate the length or severity of this pandemic, which may result in a material adverse impact on its balance sheets, results of operations and cash flows in 2020.

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	Form of Common Stock Purchase Warrant issued to investors by the Registrant in connection with private placement financings.	S-1/A	333-233446	4.4	9/9/2019	
4.4	Form of Preferred Stock Purchase Warrant issued to Capital Royalty Partners and related advisors by the Registrant in connection with the Term Loan Agreement, by and between Capital Royalty Partners II L.P., Capital Royalty Partners II - Parallel Fund "A" L.P., Parallel Investment Opportunities Partners II L.P. and the Registrant.	S-1/A	333-233446	4.5	9/9/2019	
4.5	Form of Warrant to Purchase Shares of Preferred Stock issued to investors by the Registrant in October 2015.	S-1/A	333-233446	4.6	9/9/2019	
4.6	Amendment to Convertible Promissory Notes and Warrants, dated January 19, 2016.	S-1/A	333-233446	4.7	9/9/2019	
4.7	Form of Common Stock Purchase Warrant to purchase common stock issued to investors by the Registrant in 2016.	S-1/A	333-233446	4.8	9/9/2019	
4.8	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#	Exagen Inc. 2019 Employee Stock Purchase Plan.	S-1/A	333-233446	10.5	9/9/2019	
10.6†	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	
10.7†	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	

10.8	Asset Purchase Agreement, dated February 9, 2009, by and between the Registrant (as successor in interest to Cypress Bioscience, Inc.) and Cellatope Corporation.	S-1/A	333-233446	10.8	9/9/2019
10.9	Amendment No. One to Asset Purchase Agreement, dated December 14, 2012, by and between the Registrant and Cellatope Corporation.	S-1/A	333-233446	10.9	9/9/2019
10.10	Amendment No. Two to Asset Purchase Agreement, dated January 11, 2017, by and between the Registrant and Cellatope Corporation.	S-1/A	333-233446	10.10	9/9/2019
10.11†	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
10.12†	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
10.13	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
10.14†	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
10.15	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
10.16	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
10.17†	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
10.18†	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
10.19†	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
10.20†	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
10.21	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
10.22†	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
10.23†	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

10.24†	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	
10.25	Standard Industrial/Commercial Multi-Tenant Lease, dated January 13, 2012, by and between RGS Properties and the Registrant.	S-1/A	333-233446	10.25	9/9/2019	
10.26	First Amendment to Standard Industrial/Commercial Multi-Tenant Lease, dated December 1, 2013, by and between RGS Properties and the Registrant.	S-1/A	333-233446	10.26	9/9/2019	
10.27	Second Amendment to Standard Industrial/Commercial Multi-Tenant Lease, dated April 29, 2016, by and between RGS Properties and the Registrant.					X
10.28	Third Amendment to Standard Industrial/Commercial Multi-Tenant Lease, dated June 16, 2017, by and between RGS Properties and the Registrant.					X
10.29	Fourth Amendment to Standard Industrial/Commercial Multi-Tenant Lease, dated March 16, 2020, by and between RGS Properties and the Registrant.					X
10.30	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	
10.31	First Amendment to Standard Industrial/Commercial Single-Tenant Lease, dated August 2, 2017, by and between Geiger Court, LLC and the Registrant.					X
10.32	Extension of Lease to Standard Industrial/Commercial Single-Tenant Lease, dated March 12, 2020, by and between Liberty Vista and the Registrant.					X
10.33	Standard Industrial/Commercial Multi-Tenant Lease, dated March 17, 2020 by and between RGS Properties and the Registrant.					X
10.34	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	
10.35	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	
10.36	First Amendment to Loan and Security Agreement with Innovatus Life Sciences Lending I, LP dated November 19, 2019.					X
10.37#	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	
10.38	Form of Indemnification Agreement for Directors and Officers.	S-1/A	333-233446	10.35	9/9/2019	
10.39#	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	
10.40#	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	
10.41#	Offer Letter dated February 21, 2020, by and between Debra Zack, MD Ph.D. and the Registrant.					X
10.42#	Non-Employee Director Compensation Program.	S-1/A	333-233446	10.38	9/9/2019	

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 25, 2020

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 25, 2020
/s/ Kamal Adawi Kamal Adawi	Chief Financial Officer and Corporate Secretary (Principal Financial and Accounting Officer)	March 25, 2020
/s/ Brian Birk Brian Birk	Chairman of the Board of Directors	March 25, 2020
/s/ Chet Burrell Chet Burrell	Director	March 25, 2020
/s/ Jeff Elliott Jeff Elliott	Director	March 25, 2020
/s/ Tina S. Nova, Ph.D. Tina S. Nova, Ph.D.	Director	March 25, 2020
/s/ Ebetuel Pallares, Ph.D. Ebetuel Pallares, Ph.D.	Director	March 25, 2020
/s/ Bruce C. Robertson, Ph.D. Bruce C. Robertson, Ph.D.	Director	March 25, 2020
/s/ James L.L. Tullis James L.L. Tullis	Director	March 25, 2020

Exhibit 10.27

SECOND ADDENDUM TO STANDARD INDUSTRIAL/COMMERCIAL MULTI-TENANT LEASE – NET DATED JANUARY 13, 2012 BY AND BETWEEN RGS PROPERTIES, AS LESSOR AND EXAGEN DIAGNOSTICS, INC. AS LESSEE, FOR THE PREMISES LOCATED AT 1261 LIBERTY WAY, SUITE B AND C, CALIFORNIA.

Lessor and Lessee mutually agree to amend the lease as follows:

Paragraph 1.3 (Term):
The Lease Term will be extended to the new Expiration Date of January 31, 2018

Paragraph 50 (Rent Schedule):
Base Rent shall be as follows:

Dates	Base Rent
February 1, 2017 - January 31, 2018	$12,705.44 per month

All other terms and conditions of the existing Lease shall remain in full force and effect.

This addendum shall automatically expire if not executed by Lessee on or before Wednesday, April 13, 2016.

LESSOR:
RGS Properties

By: /s/ Greg Smith

By: /s/ Scott Smith

Date: 4/29/2016

LESSEE:
Exagen Diagnostics, Inc.

By: /s/ Ron Rocca

Title: CEO

Date: 4/29/2016

Exhibit 10.28

THIRD ADDENDUM TO STANDARD INDUSTRIAL/COMMERCIAL MULTI-TENANT LEASE – NET DATED JANUARY 13, 2012 BY AND BETWEEN RGS PROPERTIES, AS LESSOR AND EXAGEN DIAGNOSTICS, INC. AS LESSEE, FOR THE PREMISES LOCATED AT 1261 LIBERTY WAY, SUITE B AND C, CALIFORNIA.

Lessor and Lessee mutually agree to amend the lease as follows:

Paragraph 1.3 (Term):
The Lease Term will be extended to the new Expiration Date of January 31, 2021

Paragraph 50 (Rent Schedule):
Base Rent shall be as follows:

Dates	**Base Rent**
February 1, 2018 - January 31, 2019	$13,086.60 per month
February 1, 2019 - January 31, 2020	$13,479.20 per month
February 1, 2020 - January 31, 2021	$13,883.57 per month

HVAC repairs and maintenance:

Attached to this Addendum is Exhibit B1: HVAC Report by Gilmore Refrigeration, Inc. Within sixty (60) days of Lessee's execution of this addendum, Lessor, at Lessor's expense, shall complete the following items noted in Exhibit B1:

a. Complete the recommended repairs and any needed service on units 10 & 12.
b. Unit #13: Replace condenser motor, correction of the ducting so that recirculation ducting is installed and the supply and return is tied.
c. Unit #14: Replacement of condenser motor and servicing.
d. Unit #15: Replace pol contactor necessary to deliver power to the unit. Any additional repairs to Unit #15 shall be the responsibility of Lessee.

Lessee will be responsible for any other work or modifications to HVAC systems as determined by Lessee. Upon execution of this Addendum, Lessee shall be responsible for contracting direct with an HVAC vendor for maintenance and repairs and have full control over the HVAC systems.

Roof and Skylights:

Lessor will repair all roof leaks and replace skylights as needed. Lessor warrants the integrity of the roof through the term of the lease extension and will repair all roof leaks within sixty (60) days following Lessee's execution of the lease extension.

Option to Extend:

Lessee shall have one (1), three (3) year option to extend per the attached exhibit (paragraph 61b).

All other terms and conditions of the existing Lease shall remain in full force and effect.

LESSOR:	**LESSEE:**
RGS Properties	**Exagen Diagnostics, Inc.**
By: /s/ Greg Smith	By: /s/ Ron Rocca
By:	Title: CEO
Date: 6/16/2017	Date: 5/9/2017

Exhibit 10.29

FOURTH ADDENDUM TO STANDARD INDUSTRIAL/COMMERCIAL MULTI-TENANT LEASE – NET DATED JANUARY 13, 2012 BY AND BETWEEN RGS PROPERTIES, AS LESSOR AND EXAGEN DIAGNOSTICS, INC., AS LESSEE, FOR THE PREMISES LOCATED AT 1261 LIBERTY WAY, SUITES B AND C, CALIFORNIA.

Lessor and Lessee mutually agree to amend the lease as follows:

Paragraph 1.3 (Term):
The Lease Term will be extended to the new Expiration Date of January 31, 2026.

Paragraph 50 (Rent Schedule):
Base Rent shall be as follows:

Dates	**Base Rent**
April 1, 2020 – January 31, 2021	$16,308.57 per month
February 1, 2021 – January 31, 2022	$17,325.00 per month
February 1, 2022 – January 31, 2023	$17,844.75 per month
February 1, 2023 – January 31, 2024	$18,380.09 per month
February 1, 2024 – January 31, 2025	$18,931.49 per month
February 1, 2025 – January 31, 2026	$19,499.44 per month

HVAC repairs and maintenance:

Attached to this addendum is Exhibit A which outlines the HVAC units at 1261 Liberty Way Suite B & C. The HVAC units numbered 4, 9 and 10 are nearing the end of their useful life. If they are deemed be beyond repair and no longer operable, then the Lessor shall be responsible to replace these three units as needed during the term of this lease renewal.

Tenant Improvement Allowance:

Lessor shall provide a $216,000.00 Tenant Improvements allowance to the Lessee to refurbish the Suite per a mutual approved space plan and shall follow the provisions outlined in the lease in regards to any improvements in the building. The Tenant Improvement allowance shall be used solely for improvements to the building.

Restoration:

Lessee shall not be responsible for any restorations to the Premises or expansion space at the expiration of the lease term so long as the improvements were approved by the Lessor.

Option to Extend:

Lessee shall have one (1), sixty (60) month option to extend at fair market value (FMV) upon nine (9) months prior written notice to Lessor per the attached option to extend addendum.

Parking:

At Lessor’s sole cost, they shall provide 18 additional parking spaces from Suite A. The remainder of parking spaces are designated and may be marked for Pixel Imaging to use until they vacate the building. Parking will be enforced if Exagen employees park in Pixel Imaging designated spaces.

Contingency:

This lease is contingent on Pixel Imaging, the current tenant in Suite A, signing their lease termination.

All other terms and conditions of the existing Lease shall remain in full force and effect.

This addendum shall automatically expire if not executed by Lessee on or before Friday March 6, 2020.

AGREED AND ACCEPTED:

LESSOR:	**LESSEE:**
RGS Properties	**Exagen Diagnostics, Inc.**
By: /s/ Scott Smith	By: /s/ Ron Rocca
By: /s/ Greg Smith	Title: CEO
Date: 3/16/2020	Date: 3/6/2020

Exhibit A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Exagen Diagnostics
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7261 Liberty Way
11
Pixel Imaging Media
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E5
14B
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E6
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E7

OPTION(S) TO EXTEND
STANDARD LEASE ADDENDUM

Dated: February 27, 2020
By and Between
Lessor: RGS Properties
Lessee: Exagen Diagnostics, Inc
Property Address: 1261 Liberty Way, Ste B&C, Vista, CA 92081

(street address, city, state, zip) Paragraph: 1

A. OPTION(S) TO EXTEND:
Lessor hereby grants to Lessee the option to extend the term of this Lease for One (1) additional Sixty (60) month period(s) commencing when the prior term expires upon each and all of the following terms and conditions:

(i) In order to exercise an option to extend, Lessee must give written notice of such election to Lessor and Lessor must receive the same at least nine months but not more than twelve months prior to the date that the option period would commence, time being of the essence. If proper notification of the exercise of an option is not given and/or received, such option shall automatically expire. Options (if there are more than one) may only be exercised consecutively.

(ii) The provisions of paragraph 39, including those relating to Lessee's Default set forth in paragraph 39.4 of this Lease, are conditions of this Option.

(iii) Except for the provisions of this Lease granting an option or options to extend the term, all of the terms and conditions of this Lease except where specifically modified by this option shall apply.

(iv) This Option is personal to the original Lessee, and cannot be assigned or exercised by anyone other than said original Lessee and only while the original Lessee is in full possession of the Premises and without the intention of thereafter assigning or subletting.

(v) The monthly rent for each month of the option period shall be calculated as follows, using the method(s) indicated below: (Check Method(s) to be Used and Fill in Appropriately)

☒ **II. Market Rental Value Adjustment(s) (MRV)**
a. On (Fill in MRV Adjustment Date(s)) February 1, 2026 the Base Rent shall be adjusted to the "Market Rental Value" of the property as follows:

1) Four months prior to each Market Rental Value Adjustment Date described above, the Parties shall attempt to agree upon what the new MRV will be on the adjustment date. If agreement cannot be reached, within thirty days, then:

(a) Lessor and Lessee shall immediately appoint a mutually acceptable appraiser or broker to establish the new MRV within the next 30 days. Any associated costs will be split equally between the Parties, or

(b) Both Lessor and Lessee shall each immediately make a reasonable determination of the MRV and submit such determination, in writing, to arbitration in accordance with the following provisions:

(i) Within 15 days thereafter, Lessor and Lessee shall each select an independent third party ☐ appraiser or ☐ broker ("Consultant" check one) of their choice to act as an arbitrator (Note: the parties may not select either of the Brokers that was involved in negotiating the Lease). The two arbitrators so appointed shall immediately select a third mutually acceptable Consultant to act as a third arbitrator.

(ii) The 3 arbitrators shall within 30 days of the appointment of the third arbitrator reach a decision as to what the actual MRV for the Premises is, and whether Lessor's or Lessee's submitted MRV is the closest thereto. The decision of a majority of the arbitrators shall be binding on the Parties. The submitted MRV which is determined to be the closest to the actual MRV shall thereafter be used by the Parties.

(iii) If either of the Parties fails to appoint an arbitrator within the specified 15 days, the arbitrator timely appointed by one of them shall reach a decision on his or her own, and said decision shall be binding on the Parties.

(iv) The entire cost of such arbitration shall be paid by the party whose submitted MRV is not selected, ie. the one that is NOT the closest to the actual MRV.

2) When determining MRV, the Lessor, Lessee and Consultants shall consider the terms of comparable market transactions which shall include, but not limited to, rent, rental adjustments, abated rent, lease term and financial condition of tenants.

3) Notwithstanding the foregoing, the new Base Rent shall not be less than the rent payable for the month immediately preceding the rent adjustment.

b. Upon the establishment of each New Market Rental Value:

1) the new MRV will become the new "Base Rent" for the purpose of calculating any further Adjustments, and

2) the first month of each Market Rental Value term shall become the new "Base Month" for the purpose of calculating any further Adjustments.

☐ **IV. Initial Term Adjustments**

The formula used to calculate adjustments to the Base Rate during the original Term of the Lease shall continue to be used during the extended term.

B. NOTICE:

Unless specified otherwise herein, notice of any rental adjustments, other than Fixed Rental Adjustments, shall be made as specified in paragraph 23 of the Lease.

C. BROKER'S FEE:

The Brokers shall be paid a Brokerage Fee for each adjustment specified above in accordance with paragraph 15 of the Lease or if applicable, paragraph 9 of the Sublease.

Exhibit 10.31

FIRST ADDENDUM TO STANDARD INDUSTRIAL/COMMERCIAL SINGLE-TENANT LEASE – NET DATED AUGUST 15, 2014 BY AND BETWEEN GEIGER COURT, LLC, AS LESSOR AND EXAGEN DIAGNOSTICS, INC. AS LESSEE, FOR THE PREMISES LOCATED AT 1221 LIBERTY WAY, VISTA, CALIFORNIA.

Lessor and Lessee mutually agree to amend the lease as follows:

Paragraph 1.3 (Term):
The Lease Term will be extended to the new Expiration Date of January 31, 2021

Paragraph 50 (Rent Schedule):
Base Rent shall be as follows:

Dates	**Base Rent**
February 1, 2018 - January 31, 2019	$19,308.96 per month
February 1, 2019 - January 31, 2020	$19,888.23 per month
February 1, 2020 - January 31, 2021	$20,484.88 per month

Paragraph 58 (Existing Furniture):

Replace “Lessee may use furniture for $0.01/SF per month during the Lease Term” with “Lessee may use furniture for no charge during the Lease Term”.

Building Improvements:

Landlord will replace outdated thermostats in building with new advanced thermostats. Landlord will replace manual rocker light switches in offices, conference rooms, copy room and break room with motion sensing automatic on and off switches. Tenant will coordinate the installation of these improvements remit direct costs to Landlord for reimbursement.

1. Landlord to pay initial $2,500. Tenant to pay next $2,500. Cost to be split 50/50 over $5,000.
2. Landlord cost capped at no higher than $5,000.
3. All work to be completed prior to end of 2017.

Lessee will be responsible for any other work or modifications to HVAC systems as determined by Lessee. Upon execution of this Addendum, Lessee shall be responsible for contracting direct with an HVAC vendor for maintenance and repairs and have full control over the HVAC systems.

All other terms and conditions of the existing Lease shall remain in full force and effect.

LESSOR:	**LESSEE:**
Geiger Court, LLC	**Exagen Diagnostics, Inc.**
By: /s/ Hal Tilbury	By: /s/ Ron Rocca
By:	Title: CEO
Date: 8/2/2017	Date: 8/2/2017

Exhibit 10.32

EXTENSION OF LEASE

This Extension of Lease is made on February 25, 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 Extension 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 ("the Lease") in which Lessor leased to Lessee, and Lessee leased from Lessor, premises located in the City of San Diego, County of San Diego, California, commonly known as 1221 Liberty Way, San Diego, CA 92083, consisting of approximately 19,504 square feet ("Premises").

    b. The term of the Lease expires on January 31, 2021.

    c. The parties desire to extend the term of the Lease for an additional period of five (5) years beginning February 1, 2021.

2. **Extension of Term.** The term of the Lease shall be extended for an additional period of five (5) years from and after February 1, 2021, so that the term of the Lease shall extend to and include January 31, 2026.

3. **Base Monthly Rent.** Base monthly rent for the extended term shall be as follows:

February 1, 2021 through January 31, 2022	$19,000.00 Payable Monthly
February 1, 2022 through January 31, 2023	$19,600.00 Payable Monthly
February 1, 2023 through January 31, 2024	$20,200.00 Payable Monthly
February 1, 2024 through January 31, 2025	$20,800.00 Payable Monthly
February 1, 2025 through January 31, 2026	$21,400.00 Payable Monthly

4. **Rent Abatement.** Base Monthly Rent shall be 50% abated commencing the first full month after execution of this extension and continuing for a total of ten (10) months thereafter. Rent Abatement is contingent upon this Extension being executed by Lessee no later than March 6, 2020 at 4pm PST. If the Extension is executed after this time the abated rent shall be nine (9) months and decline at a rate of one (1) month of rent abatement for each one (1) week delay in executing the Extension.

5. **Signage.** Lessee will be permitted to install reasonable and appropriate signage, subject to applicable laws and regulations and Lessors prior written consent.

6. **Condition of Premise.** The property will be delivered in its "as-is" condition upon lease extension execution.

7. **Tenant Improvement Allowance.** Lessor hereby grants to Lessee a tenant improvement allowance of Seventy-Five Thousand Dollars ($75,000.00) (the "Allowance"). If the Tenant Improvement costs exceeds the Allowance, Lessee agrees to pay for such excess using its funds or the Lessor provided "Additional Allowance" of up to Fifty Thousand Dollars ($50,000.00). Any portion of the Additional Allowance used by Lessee shall be amortized over the remaining term of the lease at 7% annual increase and paid monthly as additional Base Rent. The Allowance and Additional Allowance (collectively the "Allowances") are to be used for the payment of the cost of preparing all plans and specifications, the payment of plan check, permit and fees relating to construction of the tenant improvements, and construction of the tenant improvements. Lessor shall not charge a construction management or supervision fee for its oversight of the Tenant Improvements. The cost of the Tenant Improvements shall be charged against the Allowances. In no event will the Allowances be used to pay for Lessee's furniture, artifacts, equipment, telephone systems or any other items of personal property or Lessee. All tenant improvements must be approved by Lessor and permitted with the local governing authority prior to construction. Any unused portion of the Allowances as of January 31, 2021 will not be refunded to Lessee or be available to Lessee as a credit against any obligations of Lessee under the Lease. Lessor shall reimburse Lessee for approved expenses upon receipt of copies of paid invoices and appropriate lien releases from outside contractors.

    Lessee inherited improvements from the previous tenant and has continued to make capital improvements to the Premises; therefore, Lessee shall not be responsible for any restoration of improvements completed prior to this extension agreement.

8. **ADA Compliance.** Lessor warrants that to the best of its knowledge the exterior improvements meet applicable ADA requirements. If the exterior improvements do not comply with said warranty, Lessor shall, except as otherwise provided in the Lease, promptly after receipt of written notice from Lessee setting forth with specificity the nature and extent of such non compliance, rectify the same at Lessor's expense. If Lessee does not give Lessor written notice of

non-compliance with this warranty by January 31, 2021, correction of that non-compliance shall be the obligation of the Lessee at Lessee's sole cost and expense.

9. **Lessor's Work.** Lessor shall be responsible for delivering all exterior building lights in good operating condition and removing the four (4) dead trees at the entrance of the building (subject to Lessors review of specific trees) within 60 days of a fully executed lease Extension.

10. **Maintenance and Operating Costs and Obligations.** Lessor will arrange for the management of the property and arrange and supervise the maintenance of the landscaping, parking lot, roof, HVAC equipment. building exterior. Lessee will reimburse Landlord for the appropriate costs and appropriate reserves.

11. **Governmental Regulations.** Lessor will be responsible for any binding governmental order pertaining to the property that is not related to Lessee's use, occupancy or alteration of the property. Lessee will be responsible for any governmental order pertaining to the property that is related to its use, occupancy or alteration of the property.

12. **Option.** Lessor hereby grants to Lessee the option to extend the term of this Lease for one (1) five (5) year period at Fair Market Value, commencing when the prior term expires. In order to exercise an option to extend, Lessee must give written notice of such election to Lessor at least nine (9) months prior to the date that the option period would commence. The Base Rent during the first year of the option period shall be at the then prevailing fare market rate, but not less than the Base Rent in effect immediately prior to the commencement of the extended term. Thereafter, on each anniversary of the commencement of the extended term, the Base Rent will increase by 3%.

13. **Utilities.** Lessee will be responsible for all utilities serving the property.

14. **FF&E.** Lessee has the right, at its sole cost and expense, to repair, replace, or dispose of all existing furniture in the building. Lessor shall have no further rights to said furniture.

15. **Security Deposit:** Lessee's Security Deposit shall be $22,000.00. Lessor currently holds a Security Deposit of $40,412.00 and will return to Lessee $18,412.00 within 30 days of executing this Extension.

16. **Lessor Ownership Assignment.** The Lessor of the premises was assigned from Oak Properties, a California general partnership to: Liberty Vista, a California limited partnership.

17. **Effectiveness of Lease.** Except as set forth in this Extension 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

Date: 3/12/2020

LESSEE:
Exagen Diagnostics, Inc.

By: /s/ Fortunato Ron Rocca
Fortunato Ron Rocca, President & CEO

Date: 3/06/2020

Exhibit 10.33

STANDARD INDUSTRIAL/COMMERCIAL MULTI-TENANT LEASE-NET

1. Basic Provisions ("Basic Provisions").

1.1 **Parties.** This Lease ("**Lease**"), dated for reference purposes only February 27, 2020 , is made by and between RGS Properties ("**Lessor**") and Exagen Diagnostics, Inc ("**Lessee**"), (collectively the "**Parties**", or individually a "**Party**").

1.2(a) **Premises:** That certain real property, including all improvements therein or to be provided by Lessor under the terms of this Lease, commonly known as (street address, unit/suite, city, state): 1261 Liberty Way, Ste A, Vista, CA 92081 ("**Premises**"). The Premises are located in the County of San Diego , and are generally described as (describe briefly the nature of the Premises and the "Project"): approximately 13,254 SF of a larger industrial building . In addition to Lessee's rights to use and occupy the Premises as hereinafter specified, Lessee shall have nonexclusive rights to any utility raceways of the building containing the Premises ("**Building**") and to the Common Areas (as defined in Paragraph 2.7 below), but shall not have any rights to the roof, or exterior walls of the Building or to any other buildings in the Project. The Premises, the Building, the Common Areas, the land upon which they are located, along with all other buildings and improvements thereon, are herein collectively referred to as the "**Project**." (See also Paragraph 2)

1.2(b) **Parking:** Twenty-six (26) unreserved vehicle parking spaces. (See also Paragraph 2.6)

1.3 **Term:** Five (5) years and Nine (9) months ("**Original Term**") commencing May 1, 2020 ("**Commencement Date**") and ending January 31, 2026 ("**Expiration Date**"). (See also Paragraph 3)

1.4 **Early Possession:** If the Premises are available Lessee may have nonexclusive possession of the Premises commencing NA ("**Early Possession Date**"). (See also Paragraphs 3.2 and 3.3)

1.5 **Base Rent:** $12,724.00 per month ("**Base Rent**"), payable on the First (1st) day of each month commencing May 1, 2020 . (See also Paragraph 4)

☑ If this box is checked, there are provisions in this Lease for the Base Rent to be adjusted. See Paragraph 54 .

1.6 **Lessee's Share of Common Area Operating Expenses:** Forty-seven point nine percent (47.9 %) ("**Lessee's Share**"). In the event that the size of the Premises and/or the Project are modified during the term of this Lease, Lessor shall recalculate Lessee's Share to reflect such modification.

1.7 **Base Rent and Other Monies Paid Upon Execution:**

(a) **Base Rent:** $12,724.00 for the period July 1 - 31, 2020 .

(b) **Common Area Operating Expenses:** $4,234.80 for the period May 1 - 31, 2020 .

(c) **Security Deposit:** $14,321.00 ("**Security Deposit**"). (See also Paragraph 5)

(e) **Total Due Upon Execution of this Lease:** $31,279.80 .

1.8 **Agreed Use**: General office and warehouse storage for a diagnostic company . (See also Paragraph 6)

1.9 **Insuring Party.** Lessor is the "**Insuring Party**". (See also Paragraph 8)

1.10 **Real Estate Brokers.** (See also Paragraph 15 and 25)

(a) **Representation**: Each Party acknowledges receiving a Disclosure Regarding Real Estate Agency Relationship, confirms and consents to the following agency relationships in this Lease with the following real estate brokers ("**Broker(s)**") and/or their agents ("Agent(s)"):

Lessor's Brokerage Firm Lee & Associates Commercial Real Estate Services, Inc - NSDC License No. 01096996 Is the broker of (check one): ☑ the Lessor; or ☐ both the Lessee and Lessor (dual agent).

Lessor's Agent Peter Merz & Daniel Knoke License No. 01269042 | 01215373 is (check one): ☑ the Lessor's Agent (salesperson or broker associate); or ☐ both the Lessee's Agent and the Lessor's Agent (dual agent).

Lessee's Brokerage Firm CBRE License No. 00409987 Is the broker of (check one): ☑ the Lessee; or ☐ both the Lessee and Lessor (dual agent).

Lessee's Agent Andrew Ewald & Blake Wilson License No. 01308891 | 02001878 is (check one): ☑ the Lessee's Agent (salesperson or broker associate); or ☐ both the Lessee's Agent and the Lessor's Agent (dual agent).

(b) **Payment to Brokers.** Upon execution and delivery of this Lease by both Parties, Lessor shall pay to the Brokers the brokerage fee agreed to in a separate written agreement (or if there is no such agreement, the sum of 3 % of the total Base Rent) for the brokerage services rendered by the Brokers.

1.11 **Guarantor.** The obligations of the Lessee under this Lease are to be guaranteed by NA ("**Guarantor**"). (See also Paragraph 37)

1.12 **Attachments.** Attached hereto are the following, all of which constitute a part of this Lease:

☑ an Addendum consisting of Paragraphs 50 through 53 ;

☑ a site plan depicting the Premises; **Exhibit A**

☐ a site plan depicting the Project;

☐ a current set of the Rules and Regulations for the Project;

☐ a current set of the Rules and Regulations adopted by the owners' association;

☐ a Work Letter;

☑ other (specify): Rent Adjustments, Agency Disclosure .

2. Premises.

2.1 **Letting**. Lessor hereby leases to Lessee, and Lessee hereby leases from Lessor, the Premises, for the term, at the rental, and upon all of the terms, covenants and conditions set forth in this Lease. While the approximate square footage of the Premises may have been used in the marketing of the Premises for purposes of comparison, the Base Rent stated herein is NOT tied to square footage and is not subject to adjustment should the actual size be determined to be different. **NOTE: Lessee is advised to verify the actual size prior to executing this Lease.**

2.2 **Condition**. Lessor shall deliver that portion of the Premises contained within the Building ("**Unit**") to Lessee broom clean and free of debris on the Commencement Date or the Early Possession Date, whichever first occurs ("**Start Date**"), and, so long as the required service contracts described in Paragraph 7.1(b) below are obtained by Lessee and in effect within thirty days following the Start Date, warrants that the existing electrical, plumbing, fire sprinkler, lighting, heating, ventilating and air conditioning systems ("**HVAC**"), loading doors, sump pumps, if any, and all other such elements in the Unit, other than those constructed by Lessee, shall be in good operating condition on said date, that the structural elements of the roof, bearing walls and foundation of the Unit shall be free of material defects, and that the Unit does not contain hazardous levels of any mold or fungi defined as toxic under applicable state or federal law. If a noncompliance with such warranty exists as of the Start Date, or if one of such systems or elements should malfunction or fail within the appropriate warranty period, Lessor shall, as Lessor's sole obligation with respect to such matter, except as otherwise provided in this Lease, promptly after receipt of written notice from Lessee setting forth with specificity the nature and extent of such noncompliance, malfunction or failure, rectify same at Lessor's expense. The warranty periods shall be as follows: (i) 6 months as to the HVAC systems, and (ii) 30 days as to the remaining systems and other elements of the Unit. If Lessee does not give Lessor the required notice within the appropriate warranty period, correction of any such noncompliance, malfunction or failure shall be the obligation of Lessee at Lessee's sole cost and expense (except for the repairs to the fire sprinkler systems, roof, foundations, and/or bearing walls see Paragraph 7). Lessor also warrants, that unless otherwise specified in writing, Lessor is unaware of (i) any recorded Notices of Default affecting the Premise; (ii) any delinquent amounts due under any loan secured by the Premises; and (iii) any bankruptcy proceeding affecting the Premises.

2.3 **Compliance**. Lessor warrants that to the best of its knowledge the improvements on the Premises comply with the building codes, applicable laws,

covenants or restrictions of record, regulations, and ordinances ("**Applicable Requirements**") that were in effect at the time that each improvement, or portion thereof, was constructed. Said warranty does not apply to the use to which Lessee will put the Premises, modifications which may be required by the Americans with Disabilities Act or any similar laws as a result of Lessee's use (see Paragraph 49), or to any Alterations or Utility Installations (as defined in Paragraph 7.3(a)) made or to be made by Lessee. **NOTE: Lessee is responsible for determining whether or not the Applicable Requirements, and especially the zoning are appropriate for Lessee's intended use, and acknowledges that past uses of the Premises may no longer be allowed.** If the Premises do not comply with said warranty, Lessor shall, except as otherwise provided, promptly after receipt of written notice from Lessee setting forth with specificity the nature and extent of such noncompliance, rectify the same at Lessor's expense. If Lessee does not give Lessor written notice of a noncompliance with this warranty within 6 months following the Start Date, correction of that noncompliance shall be the obligation of Lessee at Lessee's sole cost and expense. If the Applicable Requirements are hereafter changed so as to require during the term of this Lease the construction of an addition to or an alteration of the Unit, Premises and/or Building, the remediation of any Hazardous Substance, or the reinforcement or other physical modification of the Unit, Premises and/or Building ("**Capital Expenditure**"), Lessor and Lessee shall allocate the cost of such work as follows:

(a) Subject to Paragraph 2.3(c) below, if such Capital Expenditures are required as a result of the specific and unique use of the Premises by Lessee as compared with uses by tenants in general, Lessee shall be fully responsible for the cost thereof, provided, however, that if such Capital Expenditure is required during the last 2 years of this Lease and the cost thereof exceeds 6 months' Base Rent, Lessee may instead terminate this Lease unless Lessor notifies Lessee, in writing, within 10 days after receipt of Lessee's termination notice that Lessor has elected to pay the difference between the actual cost thereof and the amount equal to 6 months' Base Rent. If Lessee elects termination, Lessee shall immediately cease the use of the Premises which requires such Capital Expenditure and deliver to Lessor written notice specifying a termination date at least 90 days thereafter. Such termination date shall, however, in no event be earlier than the last day that Lessee could legally utilize the Premises without commencing such Capital Expenditure.

(b) If such Capital Expenditure is not the result of the specific and unique use of the Premises by Lessee (such as, governmentally mandated seismic modifications), then Lessor shall pay for such Capital Expenditure and Lessee shall only be obligated to pay, each month during the remainder of the term of this Lease or any extension thereof, on the date that on which the Base Rent is due, an amount equal to 1/144th of the portion of such costs reasonably attributable to the Premises. Lessee shall pay Interest on the balance but may prepay its obligation at any time. If, however, such Capital Expenditure is required during the last 2 years of this Lease or if Lessor reasonably determines that it is not economically feasible to pay its share thereof, Lessor shall have the option to terminate this Lease upon 90 days prior written notice to Lessee unless Lessee notifies Lessor, in writing, within 10 days after receipt of Lessor's termination notice that Lessee will pay for such Capital Expenditure. If Lessor does not elect to terminate, and fails to tender its share of any such Capital Expenditure, Lessee may advance such funds and deduct same, with Interest, from Rent until Lessor's share of such costs have been fully paid. If Lessee is unable to finance Lessor's share, or if the balance of the Rent due and payable for the remainder of this Lease is not sufficient to fully reimburse Lessee on an offset basis, Lessee shall have the right to terminate this Lease upon 30 days written notice to Lessor.

(c) Notwithstanding the above, the provisions concerning Capital Expenditures are intended to apply only to non-voluntary, unexpected, and new Applicable Requirements. If the Capital Expenditures are instead triggered by Lessee as a result of an actual or proposed change in use, change in intensity of use, or modification to the Premises then, and in that event, Lessee shall either: (i) immediately cease such changed use or intensity of use and/or take such other steps as may be necessary to eliminate the requirement for such Capital Expenditure, or (ii) complete such Capital Expenditure at its own expense. Lessee shall not have any right to terminate this Lease.

2.4 **Acknowledgements**. Lessee acknowledges that: (a) it has been given an opportunity to inspect and measure the Premises, (b) it has been advised by Lessor and/or Brokers to satisfy itself with respect to the size and condition of the Premises (including but not limited to the electrical, HVAC and fire sprinkler systems, security, environmental aspects, and compliance with Applicable Requirements and the Americans with Disabilities Act), and their suitability for Lessee's intended use, (c) Lessee has made such investigation as it deems necessary with reference to such matters and assumes all responsibility therefor as the same relate to its occupancy of the Premises, (d) it is not relying on any representation as to the size of the Premises made by Brokers or Lessor, (e) the square footage of the Premises was not material to Lessee's decision to lease the Premises and pay the Rent stated herein, and (f) neither Lessor, Lessor's agents, nor Brokers have made any oral or written representations or warranties with respect to said matters other than as set forth in this Lease. In addition, Lessor acknowledges that: (i) Brokers have made no representations, promises or warranties concerning Lessee's ability to honor the Lease or suitability to occupy the Premises, and (ii) it is Lessor's sole responsibility to investigate the financial capability and/or suitability of all proposed tenants.

2.5 **Lessee as Prior Owner/Occupant**. The warranties made by Lessor in Paragraph 2 shall be of no force or effect if immediately prior to the Start Date Lessee was the owner or occupant of the Premises. In such event, Lessee shall be responsible for any necessary corrective work.

2.6 **Vehicle Parking**. Lessee shall be entitled to use the number of Parking Spaces specified in Paragraph 1.2(b) on those portions of the Common Areas designated from time to time by Lessor for parking. Lessee shall not use more parking spaces than said number. Said parking spaces shall be used for parking by vehicles no larger than full-size passenger automobiles or pickup trucks, herein called "**Permitted Size Vehicles**." Lessor may regulate the loading and unloading of vehicles by adopting Rules and Regulations as provided in Paragraph 2.9. No vehicles other than Permitted Size Vehicles may be parked in the Common Area without the prior written permission of Lessor. In addition:

(a) Lessee shall not permit or allow any vehicles that belong to or are controlled by Lessee or Lessee's employees, suppliers, shippers, customers, contractors or invitees to be loaded, unloaded, or parked in areas other than those designated by Lessor for such activities. (b) Lessee shall not service or store any vehicles in the Common Areas.

(c) If Lessee permits or allows any of the prohibited activities described in this Paragraph 2.6, then Lessor shall have the right, without notice, in addition to such other rights and remedies that it may have, to remove or tow away the vehicle involved and charge the cost to Lessee, which cost shall be immediately payable upon demand by Lessor.

2.7 **Common Areas - Definition**. The term "**Common Areas**" is defined as all areas and facilities outside the Premises and within the exterior boundary line of the Project and interior utility raceways and installations within the Unit that are provided and designated by the Lessor from time to time for the general nonexclusive use of Lessor, Lessee and other tenants of the Project and their respective employees, suppliers, shippers, customers, contractors and invitees, including parking areas, loading and unloading areas, trash areas, roofs, roadways, walkways, driveways and landscaped areas.

2.8 **Common Areas - Lessee's Rights**. Lessor grants to Lessee, for the benefit of Lessee and its employees, suppliers, shippers, contractors, customers and invitees, during the term of this Lease, the nonexclusive right to use, in common with others entitled to such use, the Common Areas as they exist from time to time, subject to any rights, powers, and privileges reserved by Lessor under the terms hereof or under the terms of any rules and regulations or restrictions governing the use of the Project. Under no circumstances shall the right herein granted to use the Common Areas be deemed to include the right to store any property, temporarily or permanently, in the Common Areas. Any such storage shall be permitted only by the prior written consent of Lessor or Lessor's designated agent, which consent may be revoked at any time. In the event that any unauthorized storage shall occur, then Lessor shall have the right, without notice, in addition to such other rights and remedies that it may have, to remove the property and charge the cost to Lessee, which cost shall be immediately payable upon demand by Lessor.

2.9 **Common Areas - Rules and Regulations**. Lessor or such other person(s) as Lessor may appoint shall have the exclusive control and management of the Common Areas and shall have the right, from time to time, to establish, modify, amend and enforce reasonable rules and regulations ("**Rules and Regulations**") for the management, safety, care, and cleanliness of the grounds, the parking and unloading of vehicles and the preservation of good order, as well as for the convenience of other occupants or tenants of the Building and the Project and their invitees. Lessee agrees to abide by and conform to all such Rules and Regulations, and shall use its best efforts to cause its employees, suppliers, shippers, customers, contractors and invitees to so abide and conform. Lessor shall not be responsible to Lessee for the noncompliance with said Rules and Regulations by other tenants of the Project.

2.10 **Common Areas - Changes**. Lessor shall have the right, in Lessor's sole discretion, from time to time:

(a) To make changes to the Common Areas, including, without limitation, changes in the location, size, shape and number of driveways, entrances, parking spaces, parking areas, loading and unloading areas, ingress, egress, direction of traffic, landscaped areas, walkways and utility raceways;

(b) To close temporarily any of the Common Areas for maintenance purposes so long as reasonable access to the Premises remains available; (c) To designate other land outside the boundaries of the Project to be a part of the Common Areas;

(d) To add additional buildings and improvements to the Common Areas;

(e) To use the Common Areas while engaged in making additional improvements, repairs or alterations to the Project, or any portion thereof; and

(f) To do and perform such other acts and make such other changes in, to or with respect to the Common Areas and Project as Lessor may, in the exercise of sound business judgment, deem to be appropriate.

3. Term.

3.1 **Term**. The Commencement Date, Expiration Date and Original Term of this Lease are as specified in Paragraph 1.3.

3.2 **Early Possession**. Any provision herein granting Lessee Early Possession of the Premises is subject to and conditioned upon the Premises being available for such possession prior to the Commencement Date. Any grant of Early Possession only conveys a nonexclusive right to occupy the Premises. If Lessee totally or partially occupies the Premises prior to the Commencement Date, the obligation to pay Base Rent shall be abated for the period of such Early Possession. All other terms of this Lease (including but not limited to the obligations to pay Lessee's Share of Common Area Operating Expenses, Real Property Taxes and insurance premiums and to maintain the Premises) shall be in effect during such period. Any such Early Possession shall not affect the Expiration Date.

3.3 **Delay In Possession**. Lessor agrees to use its best commercially reasonable efforts to deliver possession of the Premises to Lessee by the Commencement

Date. If, despite said efforts, Lessor is unable to deliver possession by such date, Lessor shall not be subject to any liability therefor, nor shall such failure affect the validity of this Lease or change the Expiration Date. Lessee shall not, however, be obligated to pay Rent or perform its other obligations until Lessor delivers possession of the Premises and any period of rent abatement that Lessee would otherwise have enjoyed shall run from the date of delivery of possession and continue for a period equal to what Lessee would otherwise have enjoyed under the terms hereof, but minus any days of delay caused by the acts or omissions of Lessee. If possession is not delivered within 60 days after the Commencement Date, as the same may be extended under the terms of any Work Letter executed by Parties, Lessee may, at its option, by notice in writing within 10 days after the end of such 60 day period, cancel this Lease, in which event the Parties shall be discharged from all obligations hereunder. If such written notice is not received by Lessor within said 10 day period, Lessee's right to cancel shall terminate. If possession of the Premises is not delivered within 120 days after the Commencement Date, this Lease shall terminate unless other agreements are reached between Lessor and Lessee, in writing.

3.4 **Lessee Compliance**. Lessor shall not be required to tender possession of the Premises to Lessee until Lessee complies with its obligation to provide evidence of insurance (Paragraph 8.5). Pending delivery of such evidence, Lessee shall be required to perform all of its obligations under this Lease from and after the Start Date, including the payment of Rent, notwithstanding Lessor's election to withhold possession pending receipt of such evidence of insurance. Further, if Lessee is required to perform any other conditions prior to or concurrent with the Start Date, the Start Date shall occur but Lessor may elect to withhold possession until such conditions are satisfied.

4. Rent.

4.1. **Rent Defined**. All monetary obligations of Lessee to Lessor under the terms of this Lease (except for the Security Deposit) are deemed to be rent ("**Rent**").

4.2 **Common Area Operating Expenses**. Lessee shall pay to Lessor during the term hereof, in addition to the Base Rent, Lessee's Share (as specified in Paragraph 1.6) of all Common Area Operating Expenses, as hereinafter defined, during each calendar year of the term of this Lease, in accordance with the following provisions:

(a) "**Common Area Operating Expenses**" are defined, for purposes of this Lease, as all costs relating to the ownership and operation of the Project, including, but not limited to, the following:

(i) The operation, repair and maintenance, in neat, clean, good order and condition , and if necessary the replacement, of the following:

(aa) The Common Areas and Common Area improvements, including parking areas, loading and unloading areas, trash areas, roadways, parkways, walkways, driveways, landscaped areas, bumpers, irrigation systems, Common Area lighting facilities, fences and gates, elevators, roofs, exterior walls of the buildings, building systems and roof drainage systems.

(bb) Exterior signs and any tenant directories. (cc) Any fire sprinkler systems.

(dd) All other areas and improvements that are within the exterior boundaries of the Project but outside of the Premises and/or any other space occupied by a tenant.

(ii) The cost of water, gas, electricity and telephone to service the Common Areas and any utilities not separately metered.

(iii) The cost of trash disposal, pest control services, property management, security services, owners' association dues and fees, the cost to repaint the exterior of any structures and the cost of any environmental inspections.

(iv) Reserves set aside for maintenance, repair and/or replacement of Common Area improvements and equipment.

(v) Real Property Taxes (as defined in Paragraph 10).

(vi) The cost of the premiums for the insurance maintained by Lessor pursuant to Paragraph 8. (vii) Any deductible portion of an insured loss concerning the Building or the Common Areas.

(viii) Auditors', accountants' and attorneys' fees and costs related to the operation, maintenance, repair and replacement of the Project.

(ix) The cost of any capital improvement to the Building or the Project not covered under the provisions of Paragraph 2.3 provided; however, that Lessor shall allocate the cost of any such capital improvement over a 12 year period and Lessee shall not be required to pay more than Lessee's Share of 1/144th of the cost of such capital improvement in any given month. Lessee shall pay Interest on the unamortized balance but may prepay its obligation at any time.

(x) The cost of any other services to be provided by Lessor that are stated elsewhere in this Lease to be a Common Area Operating Expense.

(b) Any Common Area Operating Expenses and Real Property Taxes that are specifically attributable to the Unit, the Building or to any other building in the Project or to the operation, repair and maintenance thereof, shall be allocated entirely to such Unit, Building, or other building. However, any Common Area Operating Expenses and Real Property Taxes that are not specifically attributable to the Building or to any other building or to the operation, repair and maintenance thereof, shall be equitably allocated by Lessor to all buildings in the Project.

(c) The inclusion of the improvements, facilities and services set forth in Subparagraph 4.2(a) shall not be deemed to impose an obligation upon Lessor to either have said improvements or facilities or to provide those services unless the Project already has the same, Lessor already provides the services, or Lessor has agreed elsewhere in this Lease to provide the same or some of them.

(d) Lessee's Share of Common Area Operating Expenses is payable monthly on the same day as the Base Rent is due hereunder. The amount of such payments shall be based on Lessor's estimate of the annual Common Area Operating Expenses. Within 60 days after written request (but not more than once each year) Lessor shall deliver to Lessee a reasonably detailed statement showing Lessee's Share of the actual Common Area Operating Expenses for the preceding year. If Lessee's payments during such year exceed Lessee's Share, Lessor shall credit the amount of such over-payment against Lessee's future payments. If Lessee's payments during such year were less than Lessee's Share, Lessee shall pay to Lessor the amount of the deficiency within 10 days after delivery by Lessor to Lessee of the statement.

(e) Common Area Operating Expenses shall not include any expenses paid by any tenant directly to third parties, or as to which Lessor is otherwise reimbursed by any third party, other tenant, or insurance proceeds.

4.3 **Payment**. Lessee shall cause payment of Rent to be received by Lessor in lawful money of the United States, without offset or deduction (except as specifically permitted in this Lease), on or before the day on which it is due. All monetary amounts shall be rounded to the nearest whole dollar. In the event that any invoice prepared by Lessor is inaccurate such inaccuracy shall not constitute a waiver and Lessee shall be obligated to pay the amount set forth in this Lease. Rent for any period during the term hereof which is for less than one full calendar month shall be prorated based upon the actual number of days of said month. Payment of Rent shall be made to Lessor at its address stated herein or to such other persons or place as Lessor may from time to time designate in writing. Acceptance of a payment which is less than the amount then due shall not be a waiver of Lessor's rights to the balance of such Rent, regardless of Lessor's endorsement of any check so stating. In the event that any check, draft, or other instrument of payment given by Lessee to Lessor is dishonored for any reason, Lessee agrees to pay to Lessor the sum of $25 in addition to any Late Charge and Lessor, at its option, may require all future Rent be paid by cashier's check. Payments will be applied first to accrued late charges and attorney's fees, second to accrued interest, then to Base Rent and Common Area Operating Expenses, and any remaining amount to any other outstanding charges or costs.

5. Security Deposit. Lessee shall deposit with Lessor upon execution hereof the Security Deposit as security for Lessee's faithful performance of its obligations under this Lease. If Lessee fails to pay Rent, or otherwise Defaults under this Lease, Lessor may use, apply or retain all or any portion of said Security Deposit for the payment of any amount already due Lessor, for Rents which will be due in the future, and/ or to reimburse or compensate Lessor for any liability, expense, loss or damage which Lessor may suffer or incur by reason thereof. If Lessor uses or applies all or any portion of the Security Deposit, Lessee shall within 10 days after written request therefor deposit monies with Lessor sufficient to restore said Security Deposit to the full amount required by this Lease. If the Base Rent increases during the term of this Lease, Lessee shall, upon written request from Lessor, deposit additional monies with Lessor so that the total amount of the Security Deposit shall at all times bear the same proportion to the increased Base Rent as the initial Security Deposit bore to the initial Base Rent. Should the Agreed Use be amended to accommodate a material change in the business of Lessee or to accommodate a sublessee or assignee, Lessor shall have the right to increase the Security Deposit to the extent necessary, in Lessor's reasonable judgment, to account for any increased wear and tear that the Premises may suffer as a result thereof. If a change in control of Lessee occurs during this Lease and following such change the financial condition of Lessee is, in Lessor's reasonable judgment, significantly reduced, Lessee shall deposit such additional monies with Lessor as shall be sufficient to cause the Security Deposit to be at a commercially reasonable level based on such change in financial condition. Lessor shall not be required to keep the Security Deposit separate from its general accounts. Within 90 days after the expiration or termination of this Lease, Lessor shall return that portion of the Security Deposit not used or applied by Lessor. Lessor shall upon written request provide Lessee with an accounting showing how that portion of the Security Deposit that was not returned was applied. No part of the Security Deposit shall be considered to be held in trust, to bear interest or to be prepayment for any monies to be paid by Lessee under this Lease. THE SECURITY DEPOSIT SHALL NOT BE USED BY LESSEE IN LIEU OF PAYMENT OF THE LAST MONTH'S RENT.

6. Use.

6.1 **Use**. Lessee shall use and occupy the Premises only for the Agreed Use, or any other legal use which is reasonably comparable thereto, and for no other purpose. Lessee shall not use or permit the use of the Premises in a manner that is unlawful, creates damage, waste or a nuisance, or that disturbs occupants of or causes damage to neighboring premises or properties. Other than guide, signal and seeing eye dogs, Lessee shall not keep or allow in the Premises any pets, animals, birds, fish, or reptiles. Lessor shall not unreasonably withhold or delay its consent to any written request for a modification of the Agreed Use, so long as the same will not impair the structural integrity of the Building or the mechanical or electrical systems therein, and/or is not significantly more burdensome to the Project. If Lessor

elects to withhold consent, Lessor shall within 7 days after such request give written notification of same, which notice shall include an explanation of Lessor's objections to the change in the Agreed Use.

6.2 **Hazardous Substances**.

(a) **Reportable Uses Require Consent**. The term "**Hazardous Substance**" as used in this Lease shall mean any product, substance, or waste whose presence, use, manufacture, disposal, transportation, or release, either by itself or in combination with other materials expected to be on the Premises, is either: (i) potentially injurious to the public health, safety or welfare, the environment or the Premises, (ii) regulated or monitored by any governmental authority, or (iii) a basis for potential liability of Lessor to any governmental agency or third party under any applicable statute or common law theory. Hazardous Substances shall include, but not be limited to, hydrocarbons, petroleum, gasoline, and/or crude oil or any products, byproducts or fractions thereof. Lessee shall not engage in any activity in or on the Premises which constitutes a Reportable Use of Hazardous Substances without the express prior written consent of Lessor and timely compliance (at Lessee's expense) with all Applicable Requirements. "**Reportable Use**" shall mean (i) the installation or use of any above or below ground storage tank, (ii) the generation, possession, storage, use, transportation, or disposal of a Hazardous Substance that requires a permit from, or with respect to which a report, notice, registration or business plan is required to be filed with, any governmental authority, and/or (iii) the presence at the Premises of a Hazardous Substance with respect to which any Applicable Requirements requires that a notice be given to persons entering or occupying the Premises or neighboring properties. Notwithstanding the foregoing, Lessee may use any ordinary and customary materials reasonably required to be used in the normal course of the Agreed Use, ordinary office supplies (copier toner, liquid paper, glue, etc.) and common household cleaning materials, so long as such use is in compliance with all Applicable Requirements, is not a Reportable Use, and does not expose the Premises or neighboring property to any meaningful risk of contamination or damage or expose Lessor to any liability therefor. In addition, Lessor may condition its consent to any Reportable Use upon receiving such additional assurances as Lessor reasonably deems necessary to protect itself, the public, the Premises and/or the environment against damage, contamination, injury and/or liability, including, but not limited to, the installation (and removal on or before Lease expiration or termination) of protective modifications (such as concrete encasements) and/or increasing the Security Deposit.

(b) **Duty to Inform Lessor**. If Lessee knows, or has reasonable cause to believe, that a Hazardous Substance has come to be located in, on, under or about the Premises, other than as previously consented to by Lessor, Lessee shall immediately give written notice of such fact to Lessor, and provide Lessor with a copy of any report, notice, claim or other documentation which it has concerning the presence of such Hazardous Substance.

(c) **Lessee Remediation**. Lessee shall not cause or permit any Hazardous Substance to be spilled or released in, on, under, or about the Premises (including through the plumbing or sanitary sewer system) and shall promptly, at Lessee's expense, comply with all Applicable Requirements and take all investigatory and/or remedial action reasonably recommended, whether or not formally ordered or required, for the cleanup of any contamination of, and for the maintenance, security and/or monitoring of the Premises or neighboring properties, that was caused or materially contributed to by Lessee, or pertaining to or involving any Hazardous Substance brought onto the Premises during the term of this Lease, by or for Lessee, or any third party.

(d) **Lessee Indemnification**. Lessee shall indemnify, defend and hold Lessor, its agents, employees, lenders and ground lessor, if any, harmless from and against any and all loss of rents and/or damages, liabilities, judgments, claims, expenses, penalties, and attorneys' and consultants' fees arising out of or involving any Hazardous Substance brought onto the Premises by or for Lessee, or any third party (provided, however, that Lessee shall have no liability under this Lease with respect to underground migration of any Hazardous Substance under the Premises from areas outside of the Project not caused or contributed to by Lessee). Lessee's obligations shall include, but not be limited to, the effects of any contamination or injury to person, property or the environment created or suffered by Lessee, and the cost of investigation, removal, remediation, restoration and/or abatement, and shall survive the expiration or termination of this Lease. No termination, cancellation or release agreement entered into by Lessor and Lessee shall release Lessee from its obligations under this Lease with respect to Hazardous Substances, unless specifically so agreed by Lessor in writing at the time of such agreement.

(e) **Lessor Indemnification**. Except as otherwise provided in paragraph 8.7, Lessor and its successors and assigns shall indemnify, defend, reimburse and hold Lessee, its employees and lenders, harmless from and against any and all environmental damages, including the cost of remediation, which are suffered as a direct result of Hazardous Substances on the Premises prior to Lessee taking possession or which are caused by the gross negligence or willful misconduct of Lessor, its agents or employees. Lessor's obligations, as and when required by the Applicable Requirements, shall include, but not be limited to, the cost of investigation, removal, remediation, restoration and/or abatement, and shall survive the expiration or termination of this Lease.

(f) **Investigations and Remediations**. Lessor shall retain the responsibility and pay for any investigations or remediation measures required by governmental entities having jurisdiction with respect to the existence of Hazardous Substances on the Premises prior to the Lessee taking possession, unless such remediation measure is required as a result of Lessee's use (including "Alterations", as defined in paragraph 7.3(a) below) of the Premises, in which event Lessee shall be responsible for such payment. Lessee shall cooperate fully in any such activities at the request of Lessor, including allowing Lessor and Lessor's agents to have reasonable access to the Premises at reasonable times in order to carry out Lessor's investigative and remedial responsibilities.

(g) **Lessor Termination Option**. If a Hazardous Substance Condition (see Paragraph 9.1(e)) occurs during the term of this Lease, unless Lessee is legally responsible therefor (in which case Lessee shall make the investigation and remediation thereof required by the Applicable Requirements and this Lease shall continue in full force and effect, but subject to Lessor's rights under Paragraph 6.2(d) and Paragraph 13), Lessor may, at Lessor's option, either (i) investigate and remediate such Hazardous Substance Condition, if required, as soon as reasonably possible at Lessor's expense, in which event this Lease shall continue in full force and effect, or (ii) if the estimated cost to remediate such condition exceeds 12 times the then monthly Base Rent or $100,000, whichever is greater, give written notice to Lessee, within 30 days after receipt by Lessor of knowledge of the occurrence of such Hazardous Substance Condition, of Lessor's desire to terminate this Lease as of the date 60 days following the date of such notice. In the event Lessor elects to give a termination notice, Lessee may, within 10 days thereafter, give written notice to Lessor of Lessee's commitment to pay the amount by which the cost of the remediation of such Hazardous Substance Condition exceeds an amount equal to 12 times the then monthly Base Rent or $100,000, whichever is greater. Lessee shall provide Lessor with said funds or satisfactory assurance thereof within 30 days following such commitment. In such event, this Lease shall continue in full force and effect, and Lessor shall proceed to make such remediation as soon as reasonably possible after the required funds are available. If Lessee does not give such notice and provide the required funds or assurance thereof within the time provided, this Lease shall terminate as of the date specified in Lessor's notice of termination.

6.3 **Lessee's Compliance with Applicable Requirements**. Except as otherwise provided in this Lease, Lessee shall, at Lessee's sole expense, fully, diligently and in a timely manner, materially comply with all Applicable Requirements, the requirements of any applicable fire insurance underwriter or rating bureau, and the recommendations of Lessor's engineers and/or consultants which relate in any manner to the Premises, without regard to whether said Applicable Requirements are now in effect or become effective after the Start Date. Lessee shall, within 10 days after receipt of Lessor's written request, provide Lessor with copies of all permits and other documents, and other information evidencing Lessee's compliance with any Applicable Requirements specified by Lessor, and shall immediately upon receipt, notify Lessor in writing (with copies of any documents involved) of any threatened or actual claim, notice, citation, warning, complaint or report pertaining to or involving the failure of Lessee or the Premises to comply with any Applicable Requirements. Likewise, Lessee shall immediately give written notice to Lessor of: (i) any water damage to the Premises and any suspected seepage, pooling, dampness or other condition conducive to the production of mold; or (ii) any mustiness or other odors that might indicate the presence of mold in the Premises.

6.4 **Inspection; Compliance**. Lessor and Lessor's "**Lender**" (as defined in Paragraph 30) and consultants authorized by Lessor shall have the right to enter into Premises at any time, in the case of an emergency, and otherwise at reasonable times after reasonable notice, for the purpose of inspecting and/or testing the condition of the Premises and/or for verifying compliance by Lessee with this Lease. The cost of any such inspections shall be paid by Lessor, unless a violation of Applicable Requirements, or a Hazardous Substance Condition (see Paragraph 9.1) is found to exist or be imminent, or the inspection is requested or ordered by a governmental authority. In such case, Lessee shall upon request reimburse Lessor for the cost of such inspection, so long as such inspection is reasonably related to the violation or contamination. In addition, Lessee shall provide copies of all relevant material safety data sheets (**MSDS**) to Lessor within 10 days of the receipt of written request therefor. Lessee acknowledges that any failure on its part to allow such inspections or testing will expose Lessor to risks and potentially cause Lessor to incur costs not contemplated by this Lease, the extent of which will be extremely difficult to ascertain. Accordingly, should the Lessee fail to allow such inspections and/or testing in a timely fashion the Base Rent shall be automatically increased, without any requirement for notice to Lessee, by an amount equal to 10% of the then existing Base Rent or $100, whichever is greater for the remainder to the Lease. The Parties agree that such increase in Base Rent represents fair and reasonable compensation for the additional risk/costs that Lessor will incur by reason of Lessee's failure to allow such inspection and/or testing. Such increase in Base Rent shall in no event constitute a waiver of Lessee's Default or Breach with respect to such failure nor prevent the exercise of any of the other rights and remedies granted hereunder.

7. Maintenance; Repairs; Utility Installations; Trade Fixtures and Alterations.

7.1 **Lessee's Obligations**.

(a) **In General**. Subject to the provisions of Paragraph 2.2 (Condition), 2.3 (Compliance), 6.3 (Lessee's Compliance with Applicable Requirements), 7.2 (Lessor's Obligations), 9 (Damage or Destruction), and 14 (Condemnation), Lessee shall, at Lessee's sole expense, keep the Premises, Utility Installations (intended for Lessee's exclusive use, no matter where located), and Alterations in good order, condition and repair (whether or not the portion of the Premises requiring repairs, or the means of repairing the same, are reasonably or readily accessible to Lessee, and whether or not the need for such repairs occurs as a result of Lessee's use, any prior use, the elements or the age of such portion of the Premises), including, but not limited to, all equipment or facilities, such as plumbing, HVAC equipment, electrical, lighting facilities, boilers, pressure vessels, fixtures, interior walls, interior surfaces of exterior walls, ceilings, floors, windows, doors, plate glass, and skylights but excluding any items which are the responsibility of Lessor pursuant to Paragraph 7.2. Lessee, in keeping the Premises in good order, condition and repair, shall exercise and perform good maintenance practices, specifically including the procurement and maintenance of the service contracts required by Paragraph 7.1(b)

below. Lessee's obligations shall include restorations, replacements or renewals when necessary to keep the Premises and all improvements thereon or a part thereof in good order, condition and state of repair.

(b) **Service Contracts**. Lessee shall, at Lessee's sole expense, procure and maintain contracts, with copies to Lessor, in customary form and substance for, and with contractors specializing and experienced in the maintenance of the following equipment and improvements, if any, if and when installed on the Premises: (i) HVAC equipment, (ii) boiler and pressure vessels, and (iii) clarifiers. However, Lessor reserves the right, upon notice to Lessee, to procure and maintain any or all of such service contracts, and Lessee shall reimburse Lessor, upon demand, for the cost thereof.

(c) **Failure to Perform**. If Lessee fails to perform Lessee's obligations under this Paragraph 7.1, Lessor may enter upon the Premises after 10 days' prior written notice to Lessee (except in the case of an emergency, in which case no notice shall be required), perform such obligations on Lessee's behalf, and put the Premises in good order, condition and repair, and Lessee shall promptly pay to Lessor a sum equal to 115% of the cost thereof.

(d) **Replacement**. Subject to Lessee's indemnification of Lessor as set forth in Paragraph 8.7 below, and without relieving Lessee of liability resulting from Lessee's failure to exercise and perform good maintenance practices, if an item described in Paragraph 7.1(b) cannot be repaired other than at a cost which is in excess of 50% of the cost of replacing such item, then such item shall be replaced by Lessor, and the cost thereof shall be prorated between the Parties and Lessee shall only be obligated to pay, each month during the remainder of the term of this Lease, on the date on which Base Rent is due, an amount equal to the product of multiplying the cost of such replacement by a fraction, the numerator of which is one, and the denominator of which is 144 (ie. 1/144th of the cost per month). Lessee shall pay Interest on the unamortized balance but may prepay its obligation at any Time.

7.2 **Lessor's Obligations**. Subject to the provisions of Paragraphs 2.2 (Condition), 2.3 (Compliance), 4.2 (Common Area Operating Expenses), 6 (Use), 7.1 (Lessee's Obligations), 9 (Damage or Destruction) and 14 (Condemnation), Lessor, subject to reimbursement pursuant to Paragraph 4.2, shall keep in good order, condition and repair the foundations, exterior walls, structural condition of interior bearing walls, exterior roof, fire sprinkler system, Common Area fire alarm and/or smoke detection systems, fire hydrants, parking lots, walkways, parkways, driveways, landscaping, fences, signs and utility systems serving the Common Areas and all parts thereof, as well as providing the services for which there is a Common Area Operating Expense pursuant to Paragraph 4.2. Lessor shall not be obligated to paint the exterior or interior surfaces of exterior walls nor shall Lessor be obligated to maintain, repair or replace windows, doors or plate glass of the Premises.

7.3 **Utility Installations; Trade Fixtures; Alterations**.

(a) **Definitions**. The term "**Utility Installations**" refers to all floor and window coverings, air and/or vacuum lines, power panels, electrical distribution, security and fire protection systems, communication cabling, lighting fixtures, HVAC equipment, plumbing, and fencing in or on the Premises. The term "**Trade Fixtures**" shall mean Lessee's machinery and equipment that can be removed without doing material damage to the Premises. The term "Alterations" shall mean any modification of the improvements, other than Utility Installations or Trade Fixtures, whether by addition or deletion. "**Lessee Owned Alterations and/or Utility Installations**" are defined as Alterations and/or Utility Installations made by Lessee that are not yet owned by Lessor pursuant to Paragraph 7.4(a).

(b) **Consent**. Lessee shall not make any Alterations or Utility Installations to the Premises without Lessor's prior written consent. Lessee may, however, make nonstructural Alterations or Utility Installations to the interior of the Premises (excluding the roof) without such consent but upon notice to Lessor, as long as they are not visible from the outside, do not involve puncturing, relocating or removing the roof or any existing walls, will not affect the electrical, plumbing, HVAC, and/or life safety systems, do not trigger the requirement for additional modifications and/or improvements to the Premises resulting from Applicable Requirements, such as compliance with Title 24, and/or life safety systems, and the cumulative cost thereof during this Lease as extended does not exceed a sum equal to 3 month's Base Rent in the aggregate or a sum equal to one month's Base Rent in any one year. Notwithstanding the foregoing, Lessee shall not make or permit any roof penetrations and/or install anything on the roof without the prior written approval of Lessor. Lessor may, as a precondition to granting such approval, require Lessee to utilize a contractor chosen and/or approved by Lessor. Any Alterations or Utility Installations that Lessee shall desire to make and which require the consent of the Lessor shall be presented to Lessor in written form with detailed plans. Consent shall be deemed conditioned upon Lessee's: (i) acquiring all applicable governmental permits, (ii) furnishing Lessor with copies of both the permits and the plans and specifications prior to commencement of the work, and (iii) compliance with all conditions of said permits and other Applicable Requirements in a prompt and expeditious manner. Any Alterations or Utility Installations shall be performed in a workmanlike manner with good and sufficient materials. Lessee shall promptly upon completion furnish Lessor with as-built plans and specifications. For work which costs an amount in excess of one month's Base Rent, Lessor may condition its consent upon Lessee providing a lien and completion bond in an amount equal to 150% of the estimated cost of such Alteration or Utility Installation and/or upon Lessee's posting an additional Security Deposit with Lessor.

(c) **Liens; Bonds**. Lessee shall pay, when due, all claims for labor or materials furnished or alleged to have been furnished to or for Lessee at or for use on the Premises, which claims are or may be secured by any mechanic's or materialmen's lien against the Premises or any interest therein. Lessee shall give Lessor not less than 10 days' notice prior to the commencement of any work in, on or about the Premises, and Lessor shall have the right to post notices of non-responsibility. If Lessee shall contest the validity of any such lien, claim or demand, then Lessee shall, at its sole expense defend and protect itself, Lessor and the Premises against the same and shall pay and satisfy any such adverse judgment that may be rendered thereon before the enforcement thereof. If Lessor shall require, Lessee shall furnish a surety bond in an amount equal to 150% of the amount of such contested lien, claim or demand, indemnifying Lessor against liability for the same. If Lessor elects to participate in any such action, Lessee shall pay Lessor's attorneys' fees and costs.

7.4 **Ownership; Removal; Surrender; and Restoration**.

(a) **Ownership**. Subject to Lessor's right to require removal or elect ownership as hereinafter provided, all Alterations and Utility Installations made by Lessee shall be the property of Lessee, but considered a part of the Premises. Lessor may, at any time, elect in writing to be the owner of all or any specified part of the Lessee Owned Alterations and Utility Installations. Unless otherwise instructed per paragraph 7.4(b) hereof, all Lessee Owned Alterations and Utility Installations shall, at the expiration or termination of this Lease, become the property of Lessor and be surrendered by Lessee with the Premises.

(b) **Removal**. By delivery to Lessee of written notice from Lessor not earlier than 90 and not later than 30 days prior to the end of the term of this Lease, Lessor may require that any or all Lessee Owned Alterations or Utility Installations be removed by the expiration or termination of this Lease. Lessor may require the removal at any time of all or any part of any Lessee Owned Alterations or Utility Installations made without the required consent.

(c) **Surrender; Restoration**. Lessee shall surrender the Premises by the Expiration Date or any earlier termination date, with all of the improvements, parts and surfaces thereof broom clean and free of debris, and in good operating order, condition and state of repair, ordinary wear and tear excepted. "Ordinary wear and tear" shall not include any damage or deterioration that would have been prevented by good maintenance practice. Notwithstanding the foregoing and the provisions of Paragraph 7.1(a), if the Lessee occupies the Premises for 12 months or less, then Lessee shall surrender the Premises in the same condition as delivered to Lessee on the Start Date with NO allowance for ordinary wear and tear. Lessee shall repair any damage occasioned by the installation, maintenance or removal of Trade Fixtures, Lessee owned Alterations and/or Utility Installations, furnishings, and equipment as well as the removal of any storage tank installed by or for Lessee. Lessee shall also remove from the Premises any and all Hazardous Substances brought onto the Premises by or for Lessee, or any third party (except Hazardous Substances which were deposited via underground migration from areas outside of the Project) to the level specified in Applicable Requirements. Trade Fixtures shall remain the property of Lessee and shall be removed by Lessee. Any personal property of Lessee not removed on or before the Expiration Date or any earlier termination date shall be deemed to have been abandoned by Lessee and may be disposed of or retained by Lessor as Lessor may desire. The failure by Lessee to timely vacate the Premises pursuant to this Paragraph 7.4(c) without the express written consent of Lessor shall constitute a holdover under the provisions of Paragraph 26 below.

8. Insurance; Indemnity.

8.1 **Payment of Premiums**. The cost of the premiums for the insurance policies required to be carried by Lessor, pursuant to Paragraphs 8.2(b), 8.3(a) and 8.3(b), shall be a Common Area Operating Expense. Premiums for policy periods commencing prior to, or extending beyond, the term of this Lease shall be prorated to coincide with the corresponding Start Date or Expiration Date.

8.2 **Liability Insurance**.

(a) **Carried by Lessee**. Lessee shall obtain and keep in force a Commercial General Liability policy of insurance protecting Lessee and Lessor as an additional insured against claims for bodily injury, personal injury and property damage based upon or arising out of the ownership, use, occupancy or maintenance of the Premises and all areas appurtenant thereto. Such insurance shall be on an occurrence basis providing single limit coverage in an amount not less than $1,000,000 per occurrence with an annual aggregate of not less than $2,000,000. Lessee shall add Lessor as an additional insured by means of an endorsement at least as broad as the Insurance Service Organization's "Additional Insured-Managers or Lessors of Premises" Endorsement. The policy shall not contain any intra-insured exclusions as between insured persons or organizations, but shall include coverage for liability assumed under this Lease as an "**insured contract**" for the performance of Lessee's indemnity obligations under this Lease. The limits of said insurance shall not, however, limit the liability of Lessee nor relieve Lessee of any obligation hereunder. Lessee shall provide an endorsement on its liability policy(ies) which provides that its insurance shall be primary to and not contributory with any similar insurance carried by Lessor, whose insurance shall be considered excess insurance only.

(b) **Carried by Lessor**. Lessor shall maintain liability insurance as described in Paragraph 8.2(a), in addition to, and not in lieu of, the insurance required to be maintained by Lessee. Lessee shall not be named as an additional insured therein.

8.3 **Property Insurance Building, Improvements and Rental Value**.

(a) **Building and Improvements**. Lessor shall obtain and keep in force a policy or policies of insurance in the name of Lessor, with loss payable to Lessor, any ground-lessor, and to any Lender insuring loss or damage to the Premises. The amount of such insurance shall be equal to the full insurable replacement cost of the Premises, as the same shall exist from time to time, or the amount required by any Lender, but in no event more than the commercially reasonable and available insurable value thereof. Lessee Owned Alterations and Utility Installations, Trade Fixtures, and Lessee's personal property shall be insured by Lessee not by Lessor. If

the coverage is available and commercially appropriate, such policy or policies shall insure against all risks of direct physical loss or damage (except the perils of flood and/or earthquake unless required by a Lender), including coverage for debris removal and the enforcement of any Applicable Requirements requiring the upgrading, demolition, reconstruction or replacement of any portion of the Premises as the result of a covered loss. Said policy or policies shall also contain an agreed valuation provision in lieu of any coinsurance clause, waiver of subrogation, and inflation guard protection causing an increase in the annual property insurance coverage amount by a factor of not less than the adjusted U.S. Department of Labor Consumer Price Index for All Urban Consumers for the city nearest to where the Premises are located. If such insurance coverage has a deductible clause, the deductible amount shall not exceed $5,000 per occurrence.

(b) **Rental Value**. Lessor shall also obtain and keep in force a policy or policies in the name of Lessor with loss payable to Lessor and any Lender, insuring the loss of the full Rent for one year with an extended period of indemnity for an additional 180 days ("Rental Value insurance"). Said insurance shall contain an agreed valuation provision in lieu of any coinsurance clause, and the amount of coverage shall be adjusted annually to reflect the projected Rent otherwise payable by Lessee, for the next 12 month period.

(c) **Adjacent Premises**. Lessee shall pay for any increase in the premiums for the property insurance of the Building and for the Common Areas or other buildings in the Project if said increase is caused by Lessee's acts, omissions, use or occupancy of the Premises.

(d) **Lessee's Improvements**. Since Lessor is the Insuring Party, Lessor shall not be required to insure Lessee Owned Alterations and Utility Installations unless the item in question has become the property of Lessor under the terms of this Lease.

8.4 **Lessee's Property; Business Interruption Insurance; Worker's Compensation Insurance**.

(a) **Property Damage**. Lessee shall obtain and maintain insurance coverage on all of Lessee's personal property, Trade Fixtures, and Lessee Owned Alterations and Utility Installations. Such insurance shall be full replacement cost coverage with a deductible of not to exceed $1,000 per occurrence. The proceeds from any such insurance shall be used by Lessee for the replacement of personal property, Trade Fixtures and Lessee Owned Alterations and Utility Installations.

(b) **Business Interruption**. Lessee shall obtain and maintain loss of income and extra expense insurance in amounts as will reimburse Lessee for direct or indirect loss of earnings attributable to all perils commonly insured against by prudent lessees in the business of Lessee or attributable to prevention of access to the Premises as a result of such perils.

(c) **Worker's Compensation Insurance**. Lessee shall obtain and maintain Worker's Compensation Insurance in such amount as may be required by Applicable Requirements. Such policy shall include a 'Waiver of Subrogation' endorsement. Lessee shall provide Lessor with a copy of such endorsement along with the certificate of insurance or copy of the policy required by paragraph 8.5.

(d) **No Representation of Adequate Coverage**. Lessor makes no representation that the limits or forms of coverage of insurance specified herein are adequate to cover Lessee's property, business operations or obligations under this Lease.

8.5 **Insurance Policies**. Insurance required herein shall be by companies maintaining during the policy term a "General Policyholders Rating" of at least A-, VII, as set forth in the most current issue of "Best's Insurance Guide", or such other rating as may be required by a Lender. Lessee shall not do or permit to be done anything which invalidates the required insurance policies. Lessee shall, prior to the Start Date, deliver to Lessor certified copies of policies of such insurance or certificates with copies of the required endorsements evidencing the existence and amounts of the required insurance. No such policy shall be cancelable or subject to modification except after 30 days prior written notice to Lessor. Lessee shall, at least 10 days prior to the expiration of such policies, furnish Lessor with evidence of renewals or "insurance binders" evidencing renewal thereof, or Lessor may increase his liability insurance coverage and charge the cost thereof to Lessee, which amount shall be payable by Lessee to Lessor upon demand. Such policies shall be for a term of at least one year, or the length of the remaining term of this Lease, whichever is less. If either Party shall fail to procure and maintain the insurance required to be carried by it, the other Party may, but shall not be required to, procure and maintain the same.

8.6 **Waiver of Subrogation**. Without acting any other rights or remedies, Lessee and Lessor each hereby release and relieve the other, and waive their entire right to recover damages against the other, for loss of or damage to its property arising out of or incident to the perils required to be insured against herein. The effect of such releases and waivers is not limited by the amount of insurance carried or required, or by any deductibles applicable hereto. The Parties agree to have their respective property damage insurance carriers waive any right to subrogation that such companies may have against Lessor or Lessee, as the case may be, so long as the insurance is not invalidated thereby.

8.7 **Indemnity**. Except for Lessor's gross negligence or willful misconduct, Lessee shall indemnify, protect, defend and hold harmless the Premises, Lessor and its agents, Lessor's master or ground lessor, partners and Lenders, from and against any and all claims, loss of rents and/or damages, liens, judgments, penalties, attorneys' and consultants' fees, expenses and/or liabilities arising out of, involving, or in connection with, a Breach of the Lease by Lessee and/or the use and/or occupancy of the Premises and/or Project by Lessee and/or by Lessee's employees, contractors or invitees . If any action or proceeding is brought against Lessor by reason of any of the foregoing matters, Lessee shall upon notice defend the same at Lessee's expense by counsel reasonably satisfactory to Lessor and Lessor shall cooperate with Lessee in such defense. Lessor need not have first paid any such claim in order to be defended or indemnified.

8.8 **Exemption of Lessor and its Agents from Liability**. Notwithstanding the negligence or breach of this Lease by Lessor or its agents, neither Lessor nor its agents shall be liable under any circumstances for: (i) injury or damage to the person or goods, wares, merchandise or other property of Lessee, Lessee's employees, contractors, invitees, customers, or any other person in or about the Premises, whether such damage or injury is caused by or results from fire, steam, electricity, gas, water or rain, indoor air quality, the presence of mold or from the breakage, leakage, obstruction or other defects of pipes, fire sprinklers, wires, appliances, plumbing, HVAC or lighting fixtures, or from any other cause, whether the said injury or damage results from conditions arising upon the Premises or upon other portions of the Building, or from other sources or places, (ii) any damages arising from any act or neglect of any other tenant of Lessor or from the failure of Lessor or its agents to enforce the provisions of any other lease in the Project, or (iii) injury to Lessee's business or for any loss of income or profit therefrom. Instead, it is intended that Lessee's sole recourse in the event of such damages or injury be to file a claim on the insurance policy(ies) that Lessee is required to maintain pursuant to the provisions of paragraph 8.

8.9 **Failure to Provide Insurance**. Lessee acknowledges that any failure on its part to obtain or maintain the insurance required herein will expose Lessor to risks and potentially cause Lessor to incur costs not contemplated by this Lease, the extent of which will be extremely difficult to ascertain. Accordingly, for any month or portion thereof that Lessee does not maintain the required insurance and/or does not provide Lessor with the required binders or certificates evidencing the existence of the required insurance, the Base Rent shall be automatically increased, without any requirement for notice to Lessee, by an amount equal to 10% of the then existing Base Rent or $100, whichever is greater. The parties agree that such increase in Base Rent represents fair and reasonable compensation for the additional risk/costs that Lessor will incur by reason of Lessee's failure to maintain the required insurance. Such increase in Base Rent shall in no event constitute a waiver of Lessee's Default or Breach with respect to the failure to maintain such insurance, prevent the exercise of any of the other rights and remedies granted hereunder, nor relieve Lessee of its obligation to maintain the insurance specified in this Lease.

9. Damage or Destruction.

9.1 **Definitions**.

(a) "**Premises Partial Damage**" shall mean damage or destruction to the improvements on the Premises, other than Lessee Owned Alterations and Utility Installations, which can reasonably be repaired in 3 months or less from the date of the damage or destruction, and the cost thereof does not exceed a sum equal to 6 month's Base Rent. Lessor shall notify Lessee in writing within 30 days from the date of the damage or destruction as to whether or not the damage is Partial or Total.

(b) "**Premises Total Destruction**" shall mean damage or destruction to the improvements on the Premises, other than Lessee Owned Alterations and Utility Installations and Trade Fixtures, which cannot reasonably be repaired in 3 months or less from the date of the damage or destruction and/or the cost thereof exceeds a sum equal to 6 month's Base Rent. Lessor shall notify Lessee in writing within 30 days from the date of the damage or destruction as to whether or not the damage is Partial or Total.

(c) "**Insured Loss**" shall mean damage or destruction to improvements on the Premises, other than Lessee Owned Alterations and Utility Installations and Trade Fixtures, which was caused by an event required to be covered by the insurance described in Paragraph 8.3(a), irrespective of any deductible amounts or coverage limits involved.

(d) "**Replacement Cost**" shall mean the cost to repair or rebuild the improvements owned by Lessor at the time of the occurrence to their condition existing immediately prior thereto, including demolition, debris removal and upgrading required by the operation of Applicable Requirements, and without deduction for depreciation.

(e) "**Hazardous Substance Condition**" shall mean the occurrence or discovery of a condition involving the presence of, or a contamination by, a Hazardous Substance, in, on, or under the Premises which requires restoration.

9.2 **Partial Damage Insured Loss**. If a Premises Partial Damage that is an Insured Loss occurs, then Lessor shall, at Lessor's expense, repair such damage (but not Lessee's Trade Fixtures or Lessee Owned Alterations and Utility Installations) as soon as reasonably possible and this Lease shall continue in full force and effect; provided, however, that Lessee shall, at Lessor's election, make the repair of any damage or destruction the total cost to repair of which is $10,000 or less, and, in such event, Lessor shall make any applicable insurance proceeds available to Lessee on a reasonable basis for that purpose. Notwithstanding the foregoing, if the required insurance was not in force or the insurance proceeds are not sufficient to effect such repair, the Insuring Party shall promptly contribute the shortage in proceeds as and when required to complete said repairs. In the event, however, such shortage was due to the fact that, by reason of the unique nature of the improvements, full replacement cost insurance coverage was not commercially reasonable and available, Lessor shall have no obligation to pay for the shortage in insurance proceeds or to fully restore the unique aspects of the Premises unless Lessee provides Lessor with the funds to cover same, or adequate assurance thereof, within 10 days following receipt of written notice of such shortage and request therefor. If Lessor receives said funds or adequate assurance thereof within said 10 day period, the

party responsible for making the repairs shall complete them as soon as reasonably possible and this Lease shall remain in full force and effect. If such funds or assurance are not received, Lessor may nevertheless elect by written notice to Lessee within 10 days thereafter to: (i) make such restoration and repair as is commercially reasonable with Lessor paying any shortage in proceeds, in which case this Lease shall remain in full force and effect, or (ii) have this Lease terminate 30 days thereafter. Lessee shall not be entitled to reimbursement of any funds contributed by Lessee to repair any such damage or destruction. Premises Partial Damage due to flood or earthquake shall be subject to Paragraph 9.3, notwithstanding that there may be some insurance coverage, but the net proceeds of any such insurance shall be made available for the repairs if made by either Party.

9.3 **Partial Damage Uninsured Loss**. If a Premises Partial Damage that is not an Insured Loss occurs, unless caused by a negligent or willful act of Lessee (in which event Lessee shall make the repairs at Lessee's expense), Lessor may either: (i) repair such damage as soon as reasonably possible at Lessor's expense (subject to reimbursement pursuant to Paragraph 4.2), in which event this Lease shall continue in full force and effect, or (ii) terminate this Lease by giving written notice to Lessee within 30 days after receipt by Lessor of knowledge of the occurrence of such damage. Such termination shall be effective 60 days following the date of such notice. In the event Lessor elects to terminate this Lease, Lessee shall have the right within 10 days after receipt of the termination notice to give written notice to Lessor of Lessee's commitment to pay for the repair of such damage without reimbursement from Lessor. Lessee shall provide Lessor with said funds or satisfactory assurance thereof within 30 days after making such commitment. In such event this Lease shall continue in full force and effect, and Lessor shall proceed to make such repairs as soon as reasonably possible after the required funds are available. If Lessee does not make the required commitment, this Lease shall terminate as of the date specified in the termination notice.

9.4 **Total Destruction**. Notwithstanding any other provision hereof, if a Premises Total Destruction occurs, this Lease shall terminate 60 days following such Destruction. If the damage or destruction was caused by the gross negligence or willful misconduct of Lessee, Lessor shall have the right to recover Lessor's damages from Lessee, except as provided in Paragraph 8.6.

9.5 **Damage Near End of Term**. If at any time during the last 6 months of this Lease there is damage for which the cost to repair exceeds one month's Base Rent, whether or not an Insured Loss, Lessor may terminate this Lease effective 60 days following the date of occurrence of such damage by giving a written termination notice to Lessee within 30 days after the date of occurrence of such damage. Notwithstanding the foregoing, if Lessee at that time has an exercisable option to extend this Lease or to purchase the Premises, then Lessee may preserve this Lease by, (a) exercising such option and (b) providing Lessor with any shortage in insurance proceeds (or adequate assurance thereof) needed to make the repairs on or before the earlier of (i) the date which is 10 days after Lessee's receipt of Lessor's written notice purporting to terminate this Lease, or (ii) the day prior to the date upon which such option expires. If Lessee duly exercises such option during such period and provides Lessor with funds (or adequate assurance thereof) to cover any shortage in insurance proceeds, Lessor shall, at Lessor's commercially reasonable expense, repair such damage as soon as reasonably possible and this Lease shall continue in full force and effect. If Lessee fails to exercise such option and provide such funds or assurance during such period, then this Lease shall terminate on the date specified in the termination notice and Lessee's option shall be extinguished.

9.6 **Abatement of Rent; Lessee's Remedies**.

(a) **Abatement**. In the event of Premises Partial Damage or Premises Total Destruction or a Hazardous Substance Condition for which Lessee is not responsible under this Lease, the Rent payable by Lessee for the period required for the repair, remediation or restoration of such damage shall be abated in proportion to the degree to which Lessee's use of the Premises is impaired, but not to exceed the proceeds received from the Rental Value insurance. All other obligations of Lessee hereunder shall be performed by Lessee, and Lessor shall have no liability for any such damage, destruction, remediation, repair or restoration except as provided herein.

(b) **Remedies**. If Lessor is obligated to repair or restore the Premises and does not commence, in a substantial and meaningful way, such repair or restoration within 90 days after such obligation shall accrue, Lessee may, at any time prior to the commencement of such repair or restoration, give written notice to Lessor and to any Lenders of which Lessee has actual notice, of Lessee's election to terminate this Lease on a date not less than 60 days following the giving of such notice. If Lessee gives such notice and such repair or restoration is not commenced within 30 days thereafter, this Lease shall terminate as of the date specified in said notice. If the repair or restoration is commenced within such 30 days, this Lease shall continue in full force and effect. "Commence" shall mean either the unconditional authorization of the preparation of the required plans, or the beginning of the actual work on the Premises, whichever first occurs.

9.7 **Termination; Advance Payments**. Upon termination of this Lease pursuant to Paragraph 6.2(g) or Paragraph 9, an equitable adjustment shall be made concerning advance Base Rent and any other advance payments made by Lessee to Lessor. Lessor shall, in addition, return to Lessee so much of Lessee's Security Deposit as has not been, or is not then required to be, used by Lessor.

10. Real Property Taxes.

10.1 **Definition**. As used herein, the term "**Real Property Taxes**" shall include any form of assessment; real estate, general, special, ordinary or extraordinary, or rental levy or tax (other than inheritance, personal income or estate taxes); improvement bond; and/or license fee imposed upon or levied against any legal or equitable interest of Lessor in the Project, Lessor's right to other income therefrom, and/or Lessor's business of leasing, by any authority having the direct or indirect power to tax and where the funds are generated with reference to the Project address. The term "Real Property Taxes" shall also include any tax, fee, levy, assessment or charge, or any increase therein: (i) imposed by reason of events occurring during the term of this Lease, including but not limited to, a change in the ownership of the Project, (ii) a change in the improvements thereon, and/or (iii) levied or assessed on machinery or equipment provided by Lessor to Lessee pursuant to this Lease. In calculating Real Property Taxes for any calendar year, the Real Property Taxes for any real estate tax year shall be included in the calculation of Real Property Taxes for such calendar year based upon the number of days which such calendar year and tax year have in common.

10.2 **Payment of Taxes**. Except as otherwise provided in Paragraph 10.3, Lessor shall pay the Real Property Taxes applicable to the Project, and said payments shall be included in the calculation of Common Area Operating Expenses in accordance with the provisions of Paragraph 4.2.

10.3 **Additional Improvements**. Common Area Operating Expenses shall not include Real Property Taxes specified in the tax assessor's records and work sheets as being caused by additional improvements placed upon the Project by other lessees or by Lessor for the exclusive enjoyment of such other lessees. Notwithstanding Paragraph 10.2 hereof, Lessee shall, however, pay to Lessor at the time Common Area Operating Expenses are payable under Paragraph 4.2, the entirety of any increase in Real Property Taxes if assessed solely by reason of Alterations, Trade Fixtures or Utility Installations placed upon the Premises by Lessee or at Lessee's request or by reason of any alterations or improvements to the Premises made by Lessor subsequent to the execution of this Lease by the Parties.

10.4 **Joint Assessment**. If the Building is not separately assessed, Real Property Taxes allocated to the Building shall be an equitable proportion of the Real Property Taxes for all of the land and improvements included within the tax parcel assessed, such proportion to be determined by Lessor from the respective valuations assigned in the assessor's work sheets or such other information as may be reasonably available. Lessor's reasonable determination thereof, in good faith, shall be conclusive.

10.5 **Personal Property Taxes**. Lessee shall pay prior to delinquency all taxes assessed against and levied upon Lessee Owned Alterations and Utility Installations, Trade Fixtures, furnishings, equipment and all personal property of Lessee contained in the Premises. When possible, Lessee shall cause its Lessee Owned Alterations and Utility Installations, Trade Fixtures, furnishings, equipment and all other personal property to be assessed and billed separately from the real property of Lessor. If any of Lessee's said property shall be assessed with Lessor's real property, Lessee shall pay Lessor the taxes attributable to Lessee's property within 10 days after receipt of a written statement setting forth the taxes applicable to Lessee's property.

11. Utilities and Services. Lessee shall pay for all water, gas, heat, light, power, telephone, trash disposal and other utilities and services supplied to the Premises, together with any taxes thereon. Notwithstanding the provisions of Paragraph 4.2, if at any time in Lessor's sole judgment, Lessor determines that Lessee is using a disproportionate amount of water, electricity or other commonly metered utilities, or that Lessee is generating such a large volume of trash as to require an increase in the size of the trash receptacle and/or an increase in the number of times per month that it is emptied, then Lessor may increase Lessee's Base Rent by an amount equal to such increased costs. There shall be no abatement of Rent and Lessor shall not be liable in any respect whatsoever for the inadequacy, stoppage, interruption or discontinuance of any utility or service due to riot, strike, labor dispute, breakdown, accident, repair or other cause beyond Lessor's reasonable control or in cooperation with governmental request or directions.

Within fifteen days of Lessor’s written request, Lessee agrees to deliver to Lessor such information, documents and/or authorization as Lessor needs in order for Lessor to comply with new or existing Applicable Requirements relating to commercial building energy usage, ratings, and/or the reporting thereof.

12. Assignment and Subletting.

12.1 **Lessor's Consent Required**.

(a) Lessee shall not voluntarily or by operation of law assign, transfer, mortgage or encumber (collectively, "**assign or assignment**") or sublet all or any part of Lessee's interest in this Lease or in the Premises without Lessor's prior written consent.

(b) Unless Lessee is a corporation and its stock is publicly traded on a national stock exchange, a change in the control of Lessee shall constitute an assignment requiring consent. The transfer, on a cumulative basis, of 25% or more of the voting control of Lessee shall constitute a change in control for this purpose.

(c) The involvement of Lessee or its assets in any transaction, or series of transactions (by way of merger, sale, acquisition, financing, transfer, leveraged buyout or otherwise), whether or not a formal assignment or hypothecation of this Lease or Lessee's assets occurs, which results or will result in a reduction of the Net Worth of Lessee by an amount greater than 25% of such Net Worth as it was represented at the time of the execution of this Lease or at the time of the most recent assignment to which Lessor has consented, or as it exists immediately prior to said transaction or transactions constituting such reduction, whichever was or is

greater, shall be considered an assignment of this Lease to which Lessor may withhold its consent. "**Net Worth of Lessee**" shall mean the net worth of Lessee (excluding any guarantors) established under generally accepted accounting principles.

(d) An assignment or subletting without consent shall, at Lessor's option, be a Default curable after notice per Paragraph 13.1(d), or a noncurable Breach without the necessity of any notice and grace period. If Lessor elects to treat such unapproved assignment or subletting as a noncurable Breach, Lessor may either: (i) terminate this Lease, or (ii) upon 30 days written notice, increase the monthly Base Rent to 110% of the Base Rent then in effect. Further, in the event of such Breach and rental adjustment, (i) the purchase price of any option to purchase the Premises held by Lessee shall be subject to similar adjustment to 110% of the price previously in effect, and (ii) all fixed and non-fixed rental adjustments scheduled during the remainder of the Lease term shall be increased to 110% of the scheduled adjusted rent.

(e) Lessee's remedy for any breach of Paragraph 12.1 by Lessor shall be limited to compensatory damages and/or injunctive relief.

(f) Lessor may reasonably withhold consent to a proposed assignment or subletting if Lessee is in Default at the time consent is requested.

(g) Notwithstanding the foregoing, allowing a de minimis portion of the Premises, ie. 20 square feet or less, to be used by a third party vendor in connection with the installation of a vending machine or payphone shall not constitute a subletting.

12.2 **Terms and Conditions Applicable to Assignment and Subletting**.

(a) Regardless of Lessor's consent, no assignment or subletting shall : (i) be effective without the express written assumption by such assignee or sublessee of the obligations of Lessee under this Lease, (ii) release Lessee of any obligations hereunder, or (iii) alter the primary liability of Lessee for the payment of Rent or for the performance of any other obligations to be performed by Lessee.

(b) Lessor may accept Rent or performance of Lessee's obligations from any person other than Lessee pending approval or disapproval of an assignment. Neither a delay in the approval or disapproval of such assignment nor the acceptance of Rent or performance shall constitute a waiver or estoppel of Lessor's right to exercise its remedies for Lessee's Default or Breach.

(c) Lessor's consent to any assignment or subletting shall not constitute a consent to any subsequent assignment or subletting.

(d) In the event of any Default or Breach by Lessee, Lessor may proceed directly against Lessee, any Guarantors or anyone else responsible for the performance of Lessee's obligations under this Lease, including any assignee or sublessee, without first exhausting Lessor's remedies against any other person or entity responsible therefor to Lessor, or any security held by Lessor.

(e) Each request for consent to an assignment or subletting shall be in writing, accompanied by information relevant to Lessor's determination as to the financial and operational responsibility and appropriateness of the proposed assignee or sublessee, including but not limited to the intended use and/or required modification of the Premises, if any, together with a fee of $500 as consideration for Lessor's considering and processing said request. Lessee agrees to provide Lessor with such other or additional information and/or documentation as may be reasonably requested. (See also Paragraph 36)

(f) Any assignee of, or sublessee under, this Lease shall, by reason of accepting such assignment, entering into such sublease, or entering into possession of the Premises or any portion thereof, be deemed to have assumed and agreed to conform and comply with each and every term, covenant, condition and obligation herein to be observed or performed by Lessee during the term of said assignment or sublease, other than such obligations as are contrary to or inconsistent with provisions of an assignment or sublease to which Lessor has specifically consented to in writing.

(g) Lessor's consent to any assignment or subletting shall not transfer to the assignee or sublessee any Option granted to the original Lessee by this Lease unless such transfer is specifically consented to by Lessor in writing. (See Paragraph 39.2)

12.3 **Additional Terms and Conditions Applicable to Subletting**. The following terms and conditions shall apply to any subletting by Lessee of all or any part of the Premises and shall be deemed included in all subleases under this Lease whether or not expressly incorporated therein:

(a) Lessee hereby assigns and transfers to Lessor all of Lessee's interest in all Rent payable on any sublease, and Lessor may collect such Rent and apply same toward Lessee's obligations under this Lease; provided, however, that until a Breach shall occur in the performance of Lessee's obligations, Lessee may collect said Rent. In the event that the amount collected by Lessor exceeds Lessee's then outstanding obligations any such excess shall be refunded to Lessee. Lessor shall not, by reason of the foregoing or any assignment of such sublease, nor by reason of the collection of Rent, be deemed liable to the sublessee for any failure of Lessee to perform and comply with any of Lessee's obligations to such sublessee. Lessee hereby irrevocably authorizes and directs any such sublessee, upon receipt of a written notice from Lessor stating that a Breach exists in the performance of Lessee's obligations under this Lease, to pay to Lessor all Rent due and to become due under the sublease. Sublessee shall rely upon any such notice from Lessor and shall pay all Rents to Lessor without any obligation or right to inquire as to whether such Breach exists, notwithstanding any claim from Lessee to the contrary.

(b) In the event of a Breach by Lessee, Lessor may, at its option, require sublessee to attorn to Lessor, in which event Lessor shall undertake the obligations of the sublessor under such sublease from the time of the exercise of said option to the expiration of such sublease; provided, however, Lessor shall not be liable for any prepaid rents or security deposit paid by such sublessee to such sublessor or for any prior Defaults or Breaches of such sublessor.

(c) Any matter requiring the consent of the sublessor under a sublease shall also require the consent of Lessor.

(d) No sublessee shall further assign or sublet all or any part of the Premises without Lessor's prior written consent.

(e) Lessor shall deliver a copy of any notice of Default or Breach by Lessee to the sublessee, who shall have the right to cure the Default of Lessee within the grace period, if any, specified in such notice. The sublessee shall have a right of reimbursement and offset from and against Lessee for any such Defaults cured by the sublessee.

13. Default; Breach; Remedies.

13.1 **Default; Breach**. A "**Default**" is defined as a failure by the Lessee to comply with or perform any of the terms, covenants, conditions or Rules and Regulations under this Lease. A "**Breach**" is defined as the occurrence of one or more of the following Defaults, and the failure of Lessee to cure such Default within any applicable grace period:

(a) The abandonment of the Premises; or the vacating of the Premises without providing a commercially reasonable level of security, or where the coverage of the property insurance described in Paragraph 8.3 is jeopardized as a result thereof, or without providing reasonable assurances to minimize potential vandalism.

(b) The failure of Lessee to make any payment of Rent or any Security Deposit required to be made by Lessee hereunder, whether to Lessor or to a third party, when due, to provide reasonable evidence of insurance or surety bond, or to fulfill any obligation under this Lease which endangers or threatens life or property, where such failure continues for a period of 3 business days following written notice to Lessee. THE ACCEPTANCE BY LESSOR OF A PARTIAL PAYMENT OF RENT OR SECURITY DEPOSIT SHALL NOT CONSTITUTE A WAIVER OF ANY OF LESSOR'S RIGHTS, INCLUDING LESSOR'S RIGHT TO RECOVER POSSESSION OF THE PREMISES.

(c) The failure of Lessee to allow Lessor and/or its agents access to the Premises or the commission of waste, act or acts constituting public or private nuisance, and/or an illegal activity on the Premises by Lessee, where such actions continue for a period of 3 business days following written notice to Lessee. In the event that Lessee commits waste, a nuisance or an illegal activity a second time then, the Lessor may elect to treat such conduct as a non-curable Breach rather than a Default.

(d) The failure by Lessee to provide (i) reasonable written evidence of compliance with Applicable Requirements, (ii) the service contracts, (iii) the rescission of an unauthorized assignment or subletting, (iv) an Estoppel Certificate or financial statements, (v) a requested subordination, (vi) evidence concerning any guaranty and/or Guarantor, (vii) any document requested under Paragraph 41, (viii) material safety data sheets (MSDS), or (ix) any other documentation or information which Lessor may reasonably require of Lessee under the terms of this Lease, where any such failure continues for a period of 10 days following written notice to Lessee.

(e) A Default by Lessee as to the terms, covenants, conditions or provisions of this Lease, or of the rules adopted under Paragraph 2.9 hereof, other than those described in subparagraphs 13.1(a), (b), (c) or (d), above, where such Default continues for a period of 30 days after written notice; provided, however, that if the nature of Lessee's Default is such that more than 30 days are reasonably required for its cure, then it shall not be deemed to be a Breach if Lessee commences such cure within said 30 day period and thereafter diligently prosecutes such cure to completion.

(f) The occurrence of any of the following events: (i) the making of any general arrangement or assignment for the benefit of creditors; (ii) becoming a "**debtor**" as defined in 11 U.S.C. § 101 or any successor statute thereto (unless, in the case of a petition filed against Lessee, the same is dismissed within 60 days); (iii) the appointment of a trustee or receiver to take possession of substantially all of Lessee's assets located at the Premises or of Lessee's interest in this Lease, where possession is not restored to Lessee within 30 days; or (iv) the attachment, execution or other judicial seizure of substantially all of Lessee's assets located at the Premises or of Lessee's interest in this Lease, where such seizure is not discharged within 30 days; provided, however, in the event that any provision of this subparagraph is contrary to any applicable law, such provision shall be of no force or effect, and not affect the validity of the remaining provisions.

(g) The discovery that any financial statement of Lessee or of any Guarantor given to Lessor was materially false.

(h) If the performance of Lessee's obligations under this Lease is guaranteed: (i) the death of a Guarantor, (ii) the termination of a Guarantor's liability with respect to this Lease other than in accordance with the terms of such guaranty, (iii) a Guarantor's becoming insolvent or the subject of a bankruptcy filing, (iv) a Guarantor's refusal to honor the guaranty, or (v) a Guarantor's breach of its guaranty obligation on an anticipatory basis, and Lessee's failure, within 60 days following written notice of any such event, to provide written alternative assurance or security, which, when coupled with the then existing resources of Lessee, equals or exceeds the combined financial resources of Lessee and the Guarantors that existed at the time of execution of this Lease.

13.2 **Remedies**. If Lessee fails to perform any of its affirmative duties or obligations, within 10 days after written notice (or in case of an emergency, without

notice), Lessor may, at its option, perform such duty or obligation on Lessee's behalf, including but not limited to the obtaining of reasonably required bonds, insurance policies, or governmental licenses, permits or approvals. Lessee shall pay to Lessor an amount equal to 115% of the costs and expenses incurred by Lessor in such performance upon receipt of an invoice therefor. In the event of a Breach, Lessor may, with or without further notice or demand, and without limiting Lessor in the exercise of any right or remedy which Lessor may have by reason of such Breach:

(a) Terminate Lessee's right to possession of the Premises by any lawful means, in which case this Lease shall terminate and Lessee shall immediately surrender possession to Lessor. In such event Lessor shall be entitled to recover from Lessee: (i) the unpaid Rent which had been earned at the time of termination; (ii) the worth at the time of award of the amount by which the unpaid rent which would have been earned after termination until the time of award exceeds the amount of such rental loss that the Lessee proves could have been reasonably avoided; (iii) the worth at the time of award of the amount by which the unpaid rent for the balance of the term after the time of award exceeds the amount of such rental loss that the Lessee proves could be reasonably avoided; and (iv) any other amount necessary to compensate Lessor for all the detriment proximately caused by the Lessee's failure to perform its obligations under this Lease or which in the ordinary course of things would be likely to result therefrom, including but not limited to the cost of recovering possession of the Premises, expenses of reletting, including necessary renovation and alteration of the Premises, reasonable attorneys' fees, and that portion of any leasing commission paid by Lessor in connection with this Lease applicable to the unexpired term of this Lease. The worth at the time of award of the amount referred to in provision (iii) of the immediately preceding sentence shall be computed by discounting such amount at the discount rate of the Federal Reserve Bank of the District within which the Premises are located at the time of award plus one percent. Efforts by Lessor to mitigate damages caused by Lessee's Breach of this Lease shall not waive Lessor's right to recover any damages to which Lessor is otherwise entitled. If termination of this Lease is obtained through the provisional remedy of unlawful detainer, Lessor shall have the right to recover in such proceeding any unpaid Rent and damages as are recoverable therein, or Lessor may reserve the right to recover all or any part thereof in a separate suit. If a notice and grace period required under Paragraph 13.1 was not previously given, a notice to pay rent or quit, or to perform or quit given to Lessee under the unlawful detainer statute shall also constitute the notice required by Paragraph 13.1. In such case, the applicable grace period required by Paragraph 13.1 and the unlawful detainer statute shall run concurrently, and the failure of Lessee to cure the Default within the greater of the two such grace periods shall constitute both an unlawful detainer and a Breach of this Lease entitling Lessor to the remedies provided for in this Lease and/or by said statute.

(b) Continue the Lease and Lessee's right to possession and recover the Rent as it becomes due, in which event Lessee may sublet or assign, subject only to reasonable limitations. Acts of maintenance, efforts to relet, and/or the appointment of a receiver to protect the Lessor's interests, shall not constitute a termination of the Lessee's right to possession.

(c) Pursue any other remedy now or hereafter available under the laws or judicial decisions of the state wherein the Premises are located. The expiration or termination of this Lease and/or the termination of Lessee's right to possession shall not relieve Lessee from liability under any indemnity provisions of this Lease as to matters occurring or accruing during the term hereof or by reason of Lessee's occupancy of the Premises.

13.3 **Inducement Recapture.** Any agreement for free or abated rent or other charges, the cost of tenant improvements for Lessee paid for or performed by Lessor, or for the giving or paying by Lessor to or for Lessee of any cash or other bonus, inducement or consideration for Lessee's entering into this Lease, all of which concessions are hereinafter referred to as "**Inducement Provisions**," shall be deemed conditioned upon Lessee's full and faithful performance of all of the terms, covenants and conditions of this Lease. Upon Breach of this Lease by Lessee, any such Inducement Provision shall automatically be deemed deleted from this Lease and of no further force or effect, and any rent, other charge, bonus, inducement or consideration theretofore abated, given or paid by Lessor under such an Inducement Provision shall be immediately due and payable by Lessee to Lessor, notwithstanding any subsequent cure of said Breach by Lessee. The acceptance by Lessor of rent or the cure of the Breach which initiated the operation of this paragraph shall not be deemed a waiver by Lessor of the provisions of this paragraph unless specifically so stated in writing by Lessor at the time of such acceptance.

13.4 **Late Charges**. Lessee hereby acknowledges that late payment by Lessee of Rent will cause Lessor to incur costs not contemplated by this Lease, the exact amount of which will be extremely difficult to ascertain. Such costs include, but are not limited to, processing and accounting charges, and late charges which may be imposed upon Lessor by any Lender. Accordingly, if any Rent shall not be received by Lessor within 5 days after such amount shall be due, then, without any requirement for notice to Lessee, Lessee shall immediately pay to Lessor a one-time late charge equal to 10% of each such overdue amount or $100, whichever is greater. The parties hereby agree that such late charge represents a fair and reasonable estimate of the costs Lessor will incur by reason of such late payment. Acceptance of such late charge by Lessor shall in no event constitute a waiver of Lessee's Default or Breach with respect to such overdue amount, nor prevent the exercise of any of the other rights and remedies granted hereunder. In the event that a late charge is payable hereunder, whether or not collected, for 3 consecutive installments of Base Rent, then notwithstanding any provision of this Lease to the contrary, Base Rent shall, at Lessor's option, become due and payable quarterly in advance.

13.5 **Interest**. Any monetary payment due Lessor hereunder, other than late charges, not received by Lessor, when due shall bear interest from the 31st day after it was due. The interest ("**Interest**") charged shall be computed at the rate of 10% per annum but shall not exceed the maximum rate allowed by law. Interest is payable in addition to the potential late charge provided for in Paragraph 13.4.

13.6 **Breach by Lessor**.

(a) **Notice of Breach**. Lessor shall not be deemed in breach of this Lease unless Lessor fails within a reasonable time to perform an obligation required to be performed by Lessor. For purposes of this Paragraph, a reasonable time shall in no event be less than 30 days after receipt by Lessor, and any Lender whose name and address shall have been furnished to Lessee in writing for such purpose, of written notice specifying wherein such obligation of Lessor has not been performed; provided, however, that if the nature of Lessor's obligation is such that more than 30 days are reasonably required for its performance, then Lessor shall not be in breach if performance is commenced within such 30 day period and thereafter diligently pursued to completion.

(b) **Performance by Lessee on Behalf of Lessor**. In the event that neither Lessor nor Lender cures said breach within 30 days after receipt of said notice, or if having commenced said cure they do not diligently pursue it to completion, then Lessee may elect to cure said breach at Lessee's expense and offset from Rent the actual and reasonable cost to perform such cure, provided however, that such offset shall not exceed an amount equal to the greater of one month's Base Rent or the Security Deposit, reserving Lessee's right to reimbursement from Lessor for any such expense in excess of such offset. Lessee shall document the cost of said cure and supply said documentation to Lessor.

14. Condemnation. If the Premises or any portion thereof are taken under the power of eminent domain or sold under the threat of the exercise of said power (collectively "**Condemnation**"), this Lease shall terminate as to the part taken as of the date the condemning authority takes Title or possession, whichever first occurs. If more than 10% of the floor area of the Unit, or more than 25% of the parking spaces is taken by Condemnation, Lessee may, at Lessee's option, to be exercised in writing within 10 days after Lessor shall have given Lessee written notice of such taking (or in the absence of such notice, within 10 days after the condemning authority shall have taken possession) terminate this Lease as of the date the condemning authority takes such possession. If Lessee does not terminate this Lease in accordance with the foregoing, this Lease shall remain in full force and effect as to the portion of the Premises remaining, except that the Base Rent shall be reduced in proportion to the reduction in utility of the Premises caused by such Condemnation. Condemnation awards and/or payments shall be the property of Lessor, whether such award shall be made as compensation for diminution in value of the leasehold, the value of the part taken, or for severance damages; provided, however, that Lessee shall be entitled to any compensation paid by the condemnor for Lessee's relocation expenses, loss of business goodwill and/or Trade Fixtures, without regard to whether or not this Lease is terminated pursuant to the provisions of this Paragraph. All Alterations and Utility Installations made to the Premises by Lessee, for purposes of Condemnation only, shall be considered the property of the Lessee and Lessee shall be entitled to any and all compensation which is payable therefor. In the event that this Lease is not terminated by reason of the Condemnation, Lessor shall repair any damage to the Premises caused by such Condemnation.

15. Brokerage Fees.

15.1 **Additional Commission**. In addition to the payments owed pursuant to Paragraph 1.10 above, Lessor agrees that: (a) if Lessee exercises any Option, (b) if Lessee or anyone affiliated with Lessee acquires from Lessor any rights to the Premises or other premises owned by Lessor and located within the Project, (c) if Lessee remains in possession of the Premises, with the consent of Lessor, after the expiration of this Lease, or (d) if Base Rent is increased, whether by agreement or operation of an escalation clause herein, then, Lessor shall pay Brokers a fee in accordance with the fee schedule of the Brokers in effect at the time the Lease was executed.

15.2 **Assumption of Obligations**. Any buyer or transferee of Lessor's interest in this Lease shall be deemed to have assumed Lessor's obligation hereunder. Brokers shall be third party beneficiaries of the provisions of Paragraphs 1.10, 15, 22 and 31. If Lessor fails to pay to Brokers any amounts due as and for brokerage fees pertaining to this Lease when due, then such amounts shall accrue Interest. In addition, if Lessor fails to pay any amounts to Lessee's Broker when due, Lessee's Broker may send written notice to Lessor and Lessee of such failure and if Lessor fails to pay such amounts within 10 days after said notice, Lessee shall pay said monies to its Broker and offset such amounts against Rent. In addition, Lessee's Broker shall be deemed to be a third party beneficiary of any commission agreement entered into by and/or between Lessor and Lessor's Broker for the limited purpose of collecting any brokerage fee owed.

15.3 **Representations and Indemnities of Broker Relationships**. Lessee and Lessor each represent and warrant to the other that it has had no dealings with any person, firm, broker, agent or finder (other than the Brokers and Agents, if any) in connection with this Lease, and that no one other than said named Brokers and Agents is entitled to any commission or finder's fee in connection herewith. Lessee and Lessor do each hereby agree to indemnify, protect, defend and hold the other harmless from and against liability for compensation or charges which may be claimed by any such unnamed broker, finder or other similar party by reason of any dealings or actions of the indemnifying Party, including any costs, expenses, attorneys' fees reasonably incurred with respect thereto.

16. Estoppel Certificates.

(a) Each Party (as "**Responding Party**") shall within 10 days after written notice from the other Party (the "**Requesting Party**") execute, acknowledge and deliver to the Requesting Party a statement in writing in form similar to the then most current "**Estoppel Certificate**" form published BY AIR CRE, plus such additional information, confirmation and/or statements as may be reasonably requested by the Requesting Party.

(b) If the Responding Party shall fail to execute or deliver the Estoppel Certificate within such 10 day period, the Requesting Party may execute an Estoppel Certificate stating that: (I) the Lease is in full force and effect without modification except as may be represented by the Requesting Party, (ii) there are no uncured defaults in the Requesting Party's performance, and (iii) if Lessor is the Requesting Party, not more than one month's rent has been paid in advance. Prospective Purchasers and encumbrancers may rely upon the Requesting Party's Estoppel Certificate, and the Responding Party shall be estopped from denying the truth of the facts contained in said Certificate. In addition, Lessee acknowledges that any failure on its part to provide such an Estoppel Certificate will expose Lessor to risks and potentially cause Lessor to incur costs not contemplated by this Lease, the extent of which will be extremely difficult to ascertain. Accordingly, should the Lessee fail to execute and/or deliver a requested Estoppel Certificate in a Timely fashion the monthly Base Rent shall be automatically increased, without any requirement for notice to Lessee, by an amount equal to 10% of the then existing Base Rent or $100, whichever is greater for remainder of the Lease. The Parties agree that such increase in Base Rent represents fair and reasonable compensation for the additional risk/costs that Lessor will incur by reason of Lessee's failure to provide the Estoppel Certificate. Such increase in Base Rent shall in no event constitute a waiver of Lessee's Default or Breach with respect to the failure to provide the Estoppel Certificate nor prevent the exercise of any of the other rights and remedies granted hereunder.

(c) If Lessor desires to finance, refinance, or sell the Premises, or any part thereof, Lessee and all Guarantors shall within 10 days after written notice from Lessor deliver to any potential lender or purchaser designated by Lessor such financial statements as may be reasonably required by such lender or purchaser, including but not limited to Lessee's financial statements for the past 3 years. All such financial statements shall be received by Lessor and such lender or purchaser in confidence and shall be used only for the purposes herein set forth.

17. Definition of Lessor. The term "**Lessor**" as used herein shall mean the owner or owners at the time in question of the fee title to the Premises, or, if this is a sublease, of the Lessee's interest in the prior lease. In the event of a transfer of Lessor's title or interest in the Premises or this Lease, Lessor shall deliver to the transferee or assignee (in cash or by credit) any unused Security Deposit held by Lessor. Upon such transfer or assignment and delivery of the Security Deposit, as aforesaid, the prior Lessor shall be relieved of all liability with respect to the obligations and/or covenants under this Lease thereafter to be performed by the Lessor. Subject to the foregoing, the obligations and/or covenants in this Lease to be performed by the Lessor shall be binding only upon the Lessor as hereinabove defined.

18. Severability. The invalidity of any provision of this Lease, as determined by a court of competent jurisdiction, shall in no way affect the validity of any other provision hereof.

19. Days. Unless otherwise specifically indicated to the contrary, the word "**days**" as used in this Lease shall mean and refer to calendar days.

20. Limitation on Liability. The obligations of Lessor under this Lease shall not constitute personal obligations of Lessor, or its partners, members, directors, officers or shareholders, and Lessee shall look to the Premises, and to no other assets of Lessor, for the satisfaction of any liability of Lessor with respect to this Lease, and shall not seek recourse against Lessor's partners, members, directors, officers or shareholders, or any of their personal assets for such satisfaction.

21. Time of Essence. Time is of the essence with respect to the performance of all obligations to be performed or observed by the Parties under this Lease.

22. No Prior or Other Agreements; Broker Disclaimer. This Lease contains all agreements between the Parties with respect to any matter mentioned herein, and no other prior or contemporaneous agreement or understanding shall be effective. Lessor and Lessee each represents and warrants to the Brokers that it has made, and is relying solely upon, its own investigation as to the nature, quality, character and financial responsibility of the other Party to this Lease and as to the use, nature, quality and character of the Premises. Brokers have no responsibility with respect thereto or with respect to any default or breach hereof by either Party.

23. Notices.

23.1 **Notice Requirements**. All notices required or permitted by this Lease or applicable law shall be in writing and may be delivered in person (by hand or by courier) or may be sent by regular, certified or registered mail or U.S. Postal Service Express Mail, with postage prepaid, or by facsimile transmission, or by email, and shall be deemed sufficiently given if served in a manner specified in this Paragraph 23. The addresses noted adjacent to a Party's signature on this Lease shall be that Party's address for delivery or mailing of notices. Either Party may by written notice to the other specify a different address for notice, except that upon Lessee's taking possession of the Premises, the Premises shall constitute Lessee's address for notice. A copy of all notices to Lessor shall be concurrently transmitted to such party or parties at such addresses as Lessor may from time to time hereafter designate in writing.

23.2 **Date of Notice**. Any notice sent by registered or certified mail, return receipt requested, shall be deemed given on the date of delivery shown on the receipt card, or if no delivery date is shown, the postmark thereon. If sent by regular mail the notice shall be deemed given 72 hours after the same is addressed as required herein and mailed with postage prepaid. Notices delivered by United States Express Mail or overnight courier that guarantees next day delivery shall be deemed given 24 hours after delivery of the same to the Postal Service or courier. Notices delivered by hand, or transmitted by facsimile transmission or by email shall be deemed delivered upon actual receipt. If notice is received on a Saturday, Sunday or legal holiday, it shall be deemed received on the next business day.

23.3 **Options.** Notwithstanding the foregoing, in order to exercise any Options (see paragraph 39), the Notice must be sent by Certified Mail (return receipt requested), Express Mail (signature required), courier (signature required) or some other methodology that provides a receipt establishing the date the notice was received by the Lessor.

24. Waivers.

(a) No waiver by Lessor of the Default or Breach of any term, covenant or condition hereof by Lessee, shall be deemed a waiver of any other term, covenant or condition hereof, or of any subsequent Default or Breach by Lessee of the same or of any other term, covenant or condition hereof. Lessor's consent to, or approval of, any act shall not be deemed to render unnecessary the obtaining of Lessor's consent to, or approval of, any subsequent or similar act by Lessee, or be construed as the basis of an estoppel to enforce the provision or provisions of this Lease requiring such consent.

(b) The acceptance of Rent by Lessor shall not be a waiver of any Default or Breach by Lessee. Any payment by Lessee may be accepted by Lessor on account of monies or damages due Lessor, notwithstanding any qualifying statements or conditions made by Lessee in connection therewith, which such statements and/or conditions shall be of no force or effect whatsoever unless specifically agreed to in writing by Lessor at or before the time of deposit of such payment.

(c) THE PARTIES AGREE THAT THE TERMS OF THIS LEASE SHALL GOVERN WITH REGARD TO ALL MATTERS RELATED THERETO AND HEREBY WAIVE THE PROVISIONS OF ANY PRESENT OR FUTURE STATUTE TO THE EXTENT THAT SUCH STATUTE IS INCONSISTENT WITH THIS LEASE.

25. Disclosures Regarding The Nature of a Real Estate Agency Relationship.

(a) When entering into a discussion with a real estate agent regarding a real estate transaction, a Lessor or Lessee should from the outset understand what type of agency relationship or representation it has with the agent or agents in the transaction. Lessor and Lessee acknowledge being advised by the Brokers in this transaction, as follows:

(i) *Lessor's Agent*. A Lessor's agent under a listing agreement with the Lessor acts as the agent for the Lessor only. A Lessor's agent or subagent has the following affirmative obligations: *To the Lessor*: A fiduciary duty of utmost care, integrity, honesty, and loyalty in dealings with the Lessor. *To the Lessee and the Lessor*: (a) Diligent exercise of reasonable skills and care in performance of the agent's duties. (b) A duty of honest and fair dealing and good faith. (c) A duty to disclose all facts known to the agent materially affecting the value or desirability of the property that are not known to, or within the diligent attention and observation of, the Parties. An agent is not obligated to reveal to either Party any confidential information obtained from the other Party which does not involve the affirmative duties set forth above.

(ii) *Lessee's Agent*. An agent can agree to act as agent for the Lessee only. In these situations, the agent is not the Lessor's agent, even if by agreement the agent may receive compensation for services rendered, either in full or in part from the Lessor. An agent acting only for a Lessee has the following affirmative obligations. *To the Lessee*: A fiduciary duty of utmost care, integrity, honesty, and loyalty in dealings with the Lessee. *To the Lessee and the Lessor*: (a) Diligent exercise of reasonable skills and care in performance of the agent's duties. (b) A duty of honest and fair dealing and good faith. (c) A duty to disclose all facts known to the agent materially affecting the value or desirability of the property that are not known to, or within the diligent attention and observation of, the Parties. An agent is not obligated to reveal to either Party any confidential information obtained from the other Party which does not involve the affirmative duties set forth above.

(iii) *Agent Representing Both Lessor and Lessee*. A real estate agent, either acting directly or through one or more associate licenses, can legally be the agent of both the Lessor and the Lessee in a transaction, but only with the knowledge and consent of both the Lessor and the Lessee. In a dual agency situation, the agent has the following affirmative obligations to both the Lessor and the Lessee: (a) A fiduciary duty of utmost care, integrity, honesty and loyalty in the dealings with either Lessor or the Lessee. (b) Other duties to the Lessor and the Lessee as stated above in subparagraphs (i) or (ii). In representing both Lessor and Lessee, the agent may not, without the express permission of the respective Party, disclose to the other Party confidential information, including, but not limited to, facts relating to either

Lessee's or Lessor's financial position, motivations, bargaining position, or other personal information that may impact rent, including Lessor's willingness to accept a rent less than the listing rent or Lessee's willingness to pay rent greater than the rent offered. The above duties of the agent in a real estate transaction do not relieve a Lessor or Lessee from the responsibility to protect their own interests. Lessor and Lessee should carefully read all agreements to assure that they adequately express their understanding of the transaction. A real estate agent is a person qualified to advise about real estate. If legal or tax advice is desired, consult a competent professional. Both Lessor and Lessee should strongly consider obtaining tax advice from a competent professional because the federal and state tax consequences of a transaction can be complex and subject to change.

(b) Brokers have no responsibility with respect to any default or breach hereof by either Party. The Parties agree that no lawsuit or other legal proceeding involving any breach of duty, error or omission relating to this Lease may be brought against Broker more than one year after the Start Date and that the liability (including court costs and attorneys' fees), of any Broker with respect to any such lawsuit and/or legal proceeding shall not exceed the fee received by such Broker pursuant to this Lease; provided, however, that the foregoing limitation on each Broker's liability shall not be applicable to any gross negligence or willful misconduct of such Broker.

(c) Lessor and Lessee agree to identify to Brokers as "Confidential" any communication or information given Brokers that is considered by such Party to be confidential.

26. No Right To Holdover. Lessee has no right to retain possession of the Premises or any part thereof beyond the expiration or termination of this Lease. In the event that Lessee holds over, then the Base Rent shall be increased to 150% of the Base Rent applicable immediately preceding the expiration or termination. Holdover Base Rent shall be calculated on monthly basis. Nothing contained herein shall be construed as consent by Lessor to any holding over by Lessee.

27. Cumulative Remedies. No remedy or election hereunder shall be deemed exclusive but shall, wherever possible, be cumulative with all other remedies at law or in equity.

28. Covenants and Conditions; Construction of Agreement. All provisions of this Lease to be observed or performed by Lessee are both covenants and conditions. In construing this Lease, all headings and titles are for the convenience of the Parties only and shall not be considered a part of this Lease. Whenever required by the context, the singular shall include the plural and vice versa. This Lease shall not be construed as if prepared by one of the Parties, but rather according to its fair meaning as a whole, as if both Parties had prepared it.

29. Binding Effect; Choice of Law. This Lease shall be binding upon the Parties, their personal representatives, successors and assigns and be governed by the laws of the State in which the Premises are located. Any litigation between the Parties hereto concerning this Lease shall be initiated in the county in which the Premises are located. Signatures to this Lease accomplished by means of electronic signature or similar technology shall be legal and binding.

30. Subordination; Attornment; Non-Disturbance.

30.1 **Subordination**. This Lease and any Option granted hereby shall be subject and subordinate to any ground lease, mortgage, deed of trust, or other hypothecation or security device (collectively, "**Security Device**"), now or hereafter placed upon the Premises, to any and all advances made on the security thereof, and to all renewals, modifications, and extensions thereof. Lessee agrees that the holders of any such Security Devices (in this Lease together referred to as "**Lender**") shall have no liability or obligation to perform any of the obligations of Lessor under this Lease. Any Lender may elect to have this Lease and/or any Option granted hereby superior to the lien of its Security Device by giving written notice thereof to Lessee, whereupon this Lease and such Options shall be deemed prior to such Security Device, notwithstanding the relative dates of the documentation or recordation thereof.

30.2 **Attornment**. In the event that Lessor transfers title to the Premises, or the Premises are acquired by another upon the foreclosure or termination of a Security Device to which this Lease is subordinated (i) Lessee shall, subject to the non-disturbance provisions of Paragraph 30.3, attorn to such new owner, and upon request, enter into a new lease, containing all of the terms and provisions of this Lease, with such new owner for the remainder of the term hereof, or, at the election of the new owner, this Lease will automatically become a new lease between Lessee and such new owner, and (ii) Lessor shall thereafter be relieved of any further obligations hereunder and such new owner shall assume all of Lessor's obligations, except that such new owner shall not: (a) be liable for any act or omission of any prior lessor or with respect to events occurring prior to acquisition of ownership; (b) be subject to any offsets or defenses which Lessee might have against any prior lessor, (c) be bound by prepayment of more than one month's rent, or (d) be liable for the return of any security deposit paid to any prior lessor which was not paid or credited to such new owner.

30.3 **Non-Disturbance**. With respect to Security Devices entered into by Lessor after the execution of this Lease, Lessee's subordination of this Lease shall be subject to receiving a commercially reasonable non-disturbance agreement (a "**Non-Disturbance Agreement**") from the Lender which Non-Disturbance Agreement provides that Lessee's possession of the Premises, and this Lease, including any options to extend the term hereof, will not be disturbed so long as Lessee is not in Breach hereof and attorns to the record owner of the Premises. Further, within 60 days after the execution of this Lease, Lessor shall, if requested by Lessee, use its commercially reasonable efforts to obtain a Non-Disturbance Agreement from the holder of any pre-existing Security Device which is secured by the Premises. In the event that Lessor is unable to provide the Non-Disturbance Agreement within said 60 days, then Lessee may, at Lessee's option, directly contact Lender and attempt to negotiate for the execution and delivery of a Non-Disturbance Agreement.

30.4 **Self-Executing**. The agreements contained in this Paragraph 30 shall be elective without the execution of any further documents; provided, however, that, upon written request from Lessor or a Lender in connection with a sale, financing or refinancing of the Premises, Lessee and Lessor shall execute such further writings as may be reasonably required to separately document any subordination, attornment and/or Non-Disturbance Agreement provided for herein.

31. Attorneys' Fees. If any Party or Broker brings an action or proceeding involving the Premises whether founded in tort, contract or equity, or to declare rights hereunder, the Prevailing Party (as hereafter defined) in any such proceeding, action, or appeal thereon, shall be entitled to reasonable attorneys' fees. Such fees may be awarded in the same suit or recovered in a separate suit, whether or not such action or proceeding is pursued to decision or judgment. The term, "**Prevailing Party**" shall include, without limitation, a Party or Broker who substantially obtains or defeats the relief sought, as the case may be, whether by compromise, settlement, judgment, or the abandonment by the other Party or Broker of its claim or defense. The attorneys' fees award shall not be computed in accordance with any court fee schedule, but shall be such as to fully reimburse all attorneys' fees reasonably incurred. In addition, Lessor shall be entitled to attorneys' fees, costs and expenses incurred in the preparation and service of notices of Default and consultations in connection therewith, whether or not a legal action is subsequently commenced in connection with such Default or resulting Breach ($200 is a reasonable minimum per occurrence for such services and consultation).

32. Lessor's Access; Showing Premises; Repairs. Lessor and Lessor's agents shall have the right to enter the Premises at any time, in the case of an emergency, and otherwise at reasonable times after reasonable prior notice for the purpose of showing the same to prospective purchasers, lenders, or tenants, and making such alterations, repairs, improvements or additions to the Premises as Lessor may deem necessary or desirable and the erecting, using and maintaining of utilities, services, pipes and conduits through the Premises and/or other premises as long as there is no material adverse effect on Lessee's use of the Premises. All such activities shall be without abatement of rent or liability to Lessee.

33. Auctions. Lessee shall not conduct, nor permit to be conducted, any auction upon the Premises without Lessor's prior written consent. Lessor shall not be obligated to exercise any standard of reasonableness in determining whether to permit an auction.

34. Signs. Lessor may place on the Premises ordinary "For Sale" signs at any time and ordinary "For Lease" signs during the last 6 months of the term hereof. Except for ordinary "For Sublease" signs which may be placed only on the Premises, Lessee shall not place any sign upon the Project without Lessor's prior written consent. All signs must comply with all Applicable Requirements.

35. Termination; Merger. Unless specifically stated otherwise in writing by Lessor, the voluntary or other surrender of this Lease by Lessee, the mutual termination or cancellation hereof, or a termination hereof by Lessor for Breach by Lessee, shall automatically terminate any sublease or lesser estate in the Premises; provided, however, that Lessor may elect to continue any one or all existing subtenancies. Lessor's failure within 10 days following any such event to elect to the contrary by written notice to the holder of any such lesser interest, shall constitute Lessor's election to have such event constitute the termination of such interest.

36. Consents. All requests for consent shall be in writing. Except as otherwise provided herein, wherever in this Lease the consent of a Party is required to an act by or for the other Party, such consent shall not be unreasonably withheld or delayed. Lessor's actual reasonable costs and expenses (including but not limited to architects', attorney's', engineers' and other consultants' fees) incurred in the consideration of, or response to, a request by Lessee for any Lessor consent, including but not limited to consents to an assignment, a subletting or the presence or use of a Hazardous Substance, shall be paid by Lessee upon receipt of an invoice and supporting documentation therefor. Lessor's consent to any act, assignment or subletting shall not constitute an acknowledgment that no Default or Breach by Lessee of this Lease exists, nor shall such consent be deemed a waiver of any then existing Default or Breach, except as may be otherwise specifically stated in writing by Lessor at the time of such consent. The failure to specify herein any particular condition to Lessor's consent shall not preclude the imposition by Lessor at the time of consent of such further or other conditions as are then reasonable with reference to the particular matter for which consent is being given. In the event that either Party disagrees

with any determination made by the other hereunder and reasonably requests the reasons for such determination, the determining party shall furnish its reasons in writing and in reasonable detail within 10 business days following such request.

37. Guarantor.

37.1 **Execution**. The Guarantors, if any, shall each execute a guaranty in the form most recently published BY AIR CRE.

37.2 **Default**. It shall constitute a Default of the Lessee if any Guarantor fails or refuses, upon request to provide: (a) evidence of the execution of the guaranty, including the authority of the party signing on Guarantor's behalf to obligate Guarantor, and in the case of a corporate Guarantor, a certified copy of a resolution of its board of directors authorizing the making of such guaranty, (b) current financial statements, (c) an Estoppel Certificate, or (d) written confirmation that the guaranty is still in effect.

38. Quiet Possession. Subject to payment by Lessee of the Rent and performance of all of the covenants, conditions and provisions on Lessee's part to be observed and performed under this Lease, Lessee shall have quiet possession and quiet enjoyment of the Premises during the term hereof.

39. Options. If Lessee is granted any option, as defined below, then the following provisions shall apply.

39.1 **Definition**. "**Option**" shall mean: (a) the right to extend or reduce the term of or renew this Lease or to extend or reduce the term of or renew any lease that Lessee has on other property of Lessor; (b) the right of first refusal or first offer to lease either the Premises or other property of Lessor; (c) the right to purchase, the right of first offer to purchase or the right of first refusal to purchase the Premises or other property of Lessor.

39.2 **Options Personal To Original Lessee**. Any Option granted to Lessee in this Lease is personal to the original Lessee, and cannot be assigned or exercised by anyone other than said original Lessee and only while the original Lessee is in full possession of the Premises and, if requested by Lessor, with Lessee certifying that Lessee has no intention of thereafter assigning or subletting.

39.3 **Multiple Options**. In the event that Lessee has any multiple Options to extend or renew this Lease, a later Option cannot be exercised unless the prior Options have been validly exercised.

39.4 **Effect of Default on Options**.

(a) Lessee shall have no right to exercise an Option: (i) during the period commencing with the giving of any notice of Default and continuing until said Default is cured, (ii) during the period of time any Rent is unpaid (without regard to whether notice thereof is given Lessee), (iii) during the time Lessee is in Breach of this Lease, or (iv) in the event that Lessee has been given 3 or more notices of separate Default, whether or not the Defaults are cured, during the 12 month period immediately preceding the exercise of the Option.

(b) The period of time within which an Option may be exercised shall not be extended or enlarged by reason of Lessee's inability to exercise an Option because of the provisions of Paragraph 39.4(a).

(c) An Option shall terminate and be of no further force or effect, notwithstanding Lessee's due and timely exercise of the Option, if, after such exercise and prior to the commencement of the extended term or completion of the purchase, (i) Lessee fails to pay Rent for a period of 30 days after such Rent becomes due (without any necessity of Lessor to give notice thereof), or (ii) if Lessee commits a Breach of this Lease.

40. Security Measures. Lessee hereby acknowledges that the Rent payable to Lessor hereunder does not include the cost of guard service or other security measures, and that Lessor shall have no obligation whatsoever to provide same. Lessee assumes all responsibility for the protection of the Premises, Lessee, its agents and invitees and their property from the acts of third parties.

41. Reservations. Lessor reserves the right: (i) to grant, without the consent or joinder of Lessee, such easements, rights and dedications that Lessor deems necessary, (ii) to cause the recordation of parcel maps and restrictions, and (iii) to create and/or install new utility raceways, so long as such easements, rights, dedications, maps, restrictions, and utility raceways do not unreasonably interfere with the use of the Premises by Lessee. Lessee agrees to sign any documents reasonably requested by Lessor to effectuate such rights.

42. Performance Under Protest. If at any time a dispute shall arise as to any amount or sum of money to be paid by one Party to the other under the provisions hereof, the Party against whom the obligation to pay the money is asserted shall have the right to make payment "under protest" and such payment shall not be regarded as a voluntary payment and there shall survive the right on the part of said Party to institute suit for recovery of such sum. If it shall be adjudged that there was no legal obligation on the part of said Party to pay such sum or any part thereof, said Party shall be entitled to recover such sum or so much thereof as it was not legally required to pay. A Party who does not initiate suit for the recovery of sums paid "under protest" within 6 months shall be deemed to have waived its right to protest such payment.

43. Authority; Multiple Parties; Execution.

(a) If either Party hereto is a corporation, trust, limited liability company, partnership, or similar entity, each individual executing this Lease on behalf of such entity represents and warrants that he or she is duly authorized to execute and deliver this Lease on its behalf. Each Party shall, within 30 days after request, deliver to the other Party satisfactory evidence of such authority.

(b) If this Lease is executed by more than one person or entity as "Lessee", each such person or entity shall be jointly and severally liable hereunder. It is agreed that any one of the named Lessees shall be empowered to execute any amendment to this Lease, or other document ancillary thereto and bind all of the named Lessees, and Lessor may rely on the same as if all of the named Lessees had executed such document.

(c) This Lease may be executed by the Parties in counterparts, each of which shall be deemed an original and all of which together shall constitute one and the same instrument.

44. Conflict. Any conflict between the printed provisions of this Lease and the typewritten or handwritten provisions shall be controlled by the typewritten or handwritten provisions.

45. Offer. Preparation of this Lease by either party or their agent and submission of same to the other Party shall not be deemed an offer to lease to the other Party. This Lease is not intended to be binding until executed and delivered by all Parties hereto.

46. Amendments. This Lease may be modified only in writing, signed by the Parties in interest at the time of the modification. As long as they do not materially change Lessee's obligations hereunder, Lessee agrees to make such reasonable non-monetary modifications to this Lease as may be reasonably required by a Lender in connection with the obtaining of normal financing or refinancing of the Premises.

47. Waiver of Jury Trial. THE PARTIES HEREBY WAIVE THEIR RESPECTIVE RIGHTS TO TRIAL BY JURY IN ANY ACTION OR PROCEEDING INVOLVING THE PROPERTY OR ARISING OUT OF THIS AGREEMENT.

48. Arbitration of Disputes. An Addendum requiring the Arbitration of all disputes between the Parties and/or Brokers arising out of this Lease ☐ is ☑ is not attached to this Lease.

49. Accessibility; Americans with Disabilities Act.

(a) The Premises:

☑ have not undergone an inspection by a Certified Access Specialist (CASp). Note: A Certified Access Specialist (CASp) can inspect the subject premises and determine whether the subject premises comply with all of the applicable construction-related accessibility standards under state law. Although state law does not require a CASp inspection of the subject premises, the commercial property owner or lessor may not prohibit the lessee or tenant from obtaining a CASp inspection of the subject premises for the occupancy or potential occupancy of the lessee or tenant, if requested by the lessee or tenant. The parties shall mutually agree on the arrangements for the time and manner of the CASp inspection, the payment of the fee for the CASp inspection, and the cost of making any repairs necessary to correct violations of construction-related accessibility standards within the premises.

☐ have undergone an inspection by a Certified Access Specialist (CASp) and it was determined that the Premises met all applicable construction-related accessibility standards pursuant to California Civil Code §55.51 et seq. Lessee acknowledges that it received a copy of the inspection report at least 48 hours prior to executing this Lease and agrees to keep such report confidential.

☐ have undergone an inspection by a Certified Access Specialist (CASp) and it was determined that the Premises did not meet all applicable construction-related accessibility standards pursuant to California Civil Code §55.51 et seq. Lessee acknowledges that it received a copy of the inspection report at least 48 hours prior to executing this Lease and agrees to keep such report confidential except as necessary to complete repairs and corrections of violations of construction related accessibility standards.

In the event that the Premises have been issued an inspection report by a CASp the Lessor shall provide a copy of the disability access inspection certificate to Lessee within 7 days of the execution of this Lease.

(b) Since compliance with the Americans with Disabilities Act (ADA) and other state and local accessibility statutes are dependent upon Lessee's specific use of the Premises, Lessor makes no warranty or representation as to whether or not the Premises comply with ADA or any similar legislation. In the event that Lessee's use of the Premises requires modifications or additions to the Premises in order to be in compliance with ADA or other accessibility statutes, Lessee agrees to make any such necessary modifications and/or additions at Lessee's expense.

LESSOR AND LESSEE HAVE CAREFULLY READ AND REVIEWED THIS LEASE AND EACH TERM AND PROVISION CONTAINED HEREIN, AND BY THE EXECUTION OF THIS LEASE SHOW THEIR INFORMED AND VOLUNTARY CONSENT THERETO. THE PARTIES HEREBY AGREE THAT, AT THE TIME THIS LEASE IS EXECUTED, THE TERMS OF THIS LEASE ARE COMMERCIALLY REASONABLE AND EFFECTUATE THE INTENT AND PURPOSE OF LESSOR AND LESSEE WITH RESPECT TO THE PREMISES.

ATTENTION: NO REPRESENTATION OR RECOMMENDATION IS MADE BY AIR CRE OR BY ANY BROKER AS TO THE LEGAL SUFFICIENCY, LEGAL EFFECT, OR TAX CONSEQUENCES OF THIS LEASE OR THE TRANSACTION TO WHICH IT RELATES. THE PARTIES ARE URGED TO:
1. SEEK ADVICE OF COUNSEL AS TO THE LEGAL AND TAX CONSEQUENCES OF THIS LEASE.
2. RETAIN APPROPRIATE CONSULTANTS TO REVIEW AND INVESTIGATE THE CONDITION OF THE PREMISES. SAID INVESTIGATION SHOULD INCLUDE BUT NOT BE LIMITED TO: THE POSSIBLE PRESENCE OF HAZARDOUS SUBSTANCES, THE ZONING OF THE PREMISES, THE STRUCTURAL INTEGRITY, THE CONDITION OF THE ROOF AND OPERATING SYSTEMS, COMPLIANCE WITH THE AMERICANS WITH DISABILITIES ACT AND THE SUITABILITY OF THE PREMISES FOR LESSEE'S INTENDED USE.

WARNING: IF THE PREMISES ARE LOCATED IN A STATE OTHER THAN CALIFORNIA, CERTAIN PROVISIONS OF THE LEASE MAY NEED TO BE REVISED TO COMPLY WITH THE LAWS OF THE STATE IN WHICH THE PREMISES ARE LOCATED.

The parties hereto have executed this Lease at the place and on the dates specified above their respective signatures.

Executed at:	Executed at: Vista, CA
On: 3/16/2020	On: 3/6/2020
By LESSOR: RGS Properties	**By LESSEE:** Exagen Diagnostics, Inc.
By: /s/ Scott Smith	By: /s/ Ron Rocca
Name Printed: Scott Smith	Name Printed: Ron Rocca
Title:	Title: CEO
Phone:	Phone:
Fax:	Fax:
Email:	Email:
By: /s/ Greg Smith	By:
Name Printed: Greg Smith	Name Printed:
Title:	Title:
Phone: (858) 454-0101	Phone:
Fax:	Fax:
Email:	Email:
Address: RGS Properties c/o Harmen Asset Management	Address:
P.O. Box 2463	Federal ID No.:
La Jolla, CA 92038-2463	
Federal ID No.:	

BROKER	**BROKER**
Lee & Associates Commercial Real Estate Services, Inc. - NSDC	CBRE
Attn: Peter Merz & Daniel Knoke	Attn: Andrew Ewald & Blake Wilson
Title:	Title:
Address: 1900 Wright Place, Ste 200	Address: 5780 Fleet St, Ste 100
Carlsbad, CA 92008	Carlsbad, CA 92008
Phone: (760) 448-1362	Phone:
Fax: (760)493-4074	Fax:
Email: pmerz@lee-associates.com	Email:
Federal ID No:	Federal ID No.:
Broker DRE License #: 01096996	Broker DRE License #: 00409987
Agent DRE License #: 01269042 | 01215373	Agent DRE License #: 01308891 | 02001878

EXHIBIT A

1261 LIBERTY WAY, SUITE A, VISTA, CA 92081

RENT ADJUSTMENT(S)
STANDARD LEASE ADDENDUM

Dated: February 27, 2020
By and Between
Lessor: RGS Properties
Lessee: Exagen Diagnostics, Inc
Property Address: 1261 Liberty Way, Ste A, Vista, CA 92081
(street address, city, state, zip)

Paragraph: 54

A. RENT ADJUSTMENTS:

The monthly rent for each month of the adjustment period(s) specified below shall be increased using the method(s) indicated below: (Check Method(s) to be Used and Fill in Appropriately)

☑ **III. Fixed Rental Adjustment(s) (FRA)**

The Base Rent shall be increased to the following amounts on the dates set forth below:

On (Fill in FRA Adjustment Date(s)):	The New Base Rent shall be:
February 1, 2022 - January 31, 2023	$13,106.00 per month
February 1, 2023 - January 31, 2024	$13,499.00 per month
February 1, 2024 - January 31, 2025	$13,904.00 per month
February 1, 2025 - January 31, 2026	$14,321.00 per month

DISCLOSURE REGARDING REAL ESTATE AGENCY RELATIONSHIP

(As required by the Civil Code)

1261 Liberty Way, Ste A, Vista, CA 92081

When you enter into a discussion with a real estate agent regarding a real estate transaction, you should from the outset understand what type of agency relationship or representation you wish to have with the agent in the transaction.

SELLER'S AGENT

A Seller's agent under a listing agreement with the Seller acts as the agent for the Seller only. A Seller's agent or a subagent of that agent has the following affirmative obligations:
To the Seller: A fiduciary duty of utmost care, integrity, honesty and loyalty in dealings with the Seller.
To the Buyer and the Seller:

(a) Diligent exercise of reasonable skill and care in performance of the agent's duties.

(b) A duty of honest and fair dealing and good faith.

(c) A duty to disclose all facts known to the agent materially affecting the value or desirability of the property that are not known to, or within the diligent attention and observation of, the parties.

An agent is not obligated to reveal to either party any confidential information obtained from the other party that does not involve the affirmative duties set forth above.

BUYER'S AGENT

A Buyer's agent can, with a Buyer's consent, agree to act as agent for the Buyer only. In these situations, the agent is not the Seller's agent, even if by agreement the agent may receive compensation for services rendered, either in full or in part from the Seller. An agent acting only for a Buyer has the following affirmative obligations:
To the Buyer: A fiduciary duty of utmost care, integrity, honesty and loyalty in dealings with the Buyer. To the Buyer and the Seller:

(a) Diligent exercise of reasonable skill and care in performance of the agent's duties.

(b) A duty of honest and fair dealing and good faith.

(c) A duty to disclose all facts known to the agent materially affecting the value or desirability of the property that are not known to, or within the diligent attention and observation of, the parties.

An agent is not obligated to reveal to either party any confidential information obtained from the other party that does not involve the affirmative duties set forth above.

AGENT REPRESENTING BOTH SELLER AND BUYER

A real estate agent, either acting directly or through one or more salesperson and broker associates, can legally be the agent of both the Seller and the Buyer in a transaction, but only with the knowledge and consent of both the Seller and the Buyer.
In a dual agency situation, the agent has the following affirmative obligations to both the Seller and the Buyer:

(a) A fiduciary duty of utmost care, integrity, honesty and loyalty in the dealings with either the Seller or the Buyer. (b) Other duties to the Seller and the Buyer as stated above in their respective sections.

In representing both Seller and Buyer, a dual agent may not, without the express permission of the respective party, disclose to the other party confidential information, including, but not limited to, facts relating to either the Buyer's or Seller's financial position, motivations, bargaining position, or other personal information that may impact price, including the Seller's willingness to accept a price less than the listing price or the Buyer's willingness to pay a price greater than the price offered.

SELLER AND BUYER RESPONSIBILITIES

Either the purchase agreement or a separate document will contain a confirmation of which agent is representing you and whether that agent is representing you exclusively in the transaction or acting as a dual agent. Please pay attention to that confirmation to make sure it accurately reflects your understanding of your agent's role. The above duties of the agent in a real estate transaction do not relieve a Seller or Buyer from the responsibility to protect his or her own interests. You should carefully read all agreements to assure that they adequately express your understanding of the transaction. A real estate agent is a person qualified to advise about real estate. If legal or tax advice is desired, consult a competent professional. If you are a Buyer, you have the duty to exercise reasonable care to protect yourself, including as to those facts about the property which are known to you or within your diligent attention and observation. Both Sellers and Buyers should strongly consider obtaining tax advice from a competent professional because the federal and state tax consequences of a transaction can be complex and subject to change.

Throughout your real property transaction you may receive more than one disclosure form, depending upon the number of agents assisting in the transaction. The law requires each agent with whom you have more than a casual relationship to present you with this disclosure form. You should read its contents each time it is presented to you, considering the relationship between you and the real estate agent in your specific transaction. **This disclosure form includes the provisions of Sections 2079.13 to 2079.24, inclusive, of the Civil Code set forth on page 2. Read it carefully. I/WE ACKNOWLEDGE RECEIPT OF A COPY OF THIS DISCLOSURE AND THE PORTIONS OF THE CIVIL CODE PRINTED ON THE BACK (OR A SEPARATE PAGE).**

☐ Buyer ☐ Seller ☑ Lessor ☐ Lessee /s/ Scott Smith Date: 3/16/2020
Scott Smith

☐ Buyer ☐ Seller ☑ Lessor ☐ Lessee /s/ Greg Smith Date: 3/17/2020
Greg Smith

Agent: Lee & Associates Commercial Real Estate Services, Inc. - NSDC DRE Lic. #: 01096996
Real Estate Broker (Firm)

By: Peter Merz & Daniel Knoke DRE Lic. #: 01269042 | 01215373 Date:
(Salesperson or Broker Associate)

DISCLOSURE REGARDING REAL ESTATE AGENCY RELATIONSHIP
CIVIL CODE SECTIONS 2079.13 THROUGH 2079.24 (2079.16 APPEARS ON THE FRONT)

2079.13. As used in Sections 2079.7 and 2079.14 to 2079.24, inclusive, the following terms have the following meanings:
(a) "Agent" means a person acting under provisions of Title 9 (commencing with Section 2295) in a real property transaction, and includes a person who is licensed as a real estate broker under Chapter 3 (commencing with Section 10130) of Part 1 of Division 4 of the Business and Professions Code, and under whose license a listing is executed or an offer to purchase is obtained. The agent in the real property transaction bears responsibility for that agent's salespersons or broker associates who perform as agents of the agent. When a salesperson or broker associate owes a duty to any principal, or to any buyer or seller who is not a principal, in a real property transaction, that duty is equivalent to the duty owed to that party by the broker for whom the salesperson or broker associate functions. **(b)** "Buyer" means a transferee in a real property transaction, and includes a person who executes an offer to purchase real property from a seller through an agent, or who seeks the services of an agent in more than a casual, transitory, or preliminary manner, with the object of entering into a real property transaction. "Buyer" includes vendee or lessee of real property. **(c)** "Commercial real property" means all real property in the state, except (1) single-family residential real property, (2) dwelling units made subject to Chapter 2 (commencing with Section 1940) of Title 5, (3) a mobilehome, as defined in Section 798.3, (4) vacant land, or (5) a recreational vehicle, as defined in Section 799.29. **(d)** "Dual agent" means an agent acting, either directly or through a salesperson or broker associate, as agent for both the seller and the buyer in a real property transaction. **(e)** "Listing agreement" means a written contract between a seller of real property and an agent, by which the agent has been authorized to sell the real property or to find or obtain a buyer, including rendering other services for which a real estate license is required to the seller pursuant to the terms of the agreement. **(f)** "Seller's agent" means a person who has obtained a listing of real property to act as an agent for compensation. **(g)** "Listing price" is the amount expressed in dollars specified in the listing for which the seller is willing to sell the real property through the seller's agent. **(h)** "Offering price" is the amount expressed in dollars specified in an offer to purchase for which the buyer is willing to buy the real property. **(i)** "Offer to purchase" means a written contract executed by a buyer acting through a buyer's agent that becomes the contract for the sale of the real property upon acceptance by the seller. **(j)** "Real property" means any estate specified by subdivision (1) or (2) of Section 761 in property, and includes (1) single-family residential property, (2) multiunit residential property with more than four dwelling units, (3) commercial real property, (4) vacant land, (5) a ground lease coupled with improvements, or (6) a manufactured home as defined in Section 18007 of the Health and Safety Code, or a mobilehome as defined in Section 18008 of the Health and Safety Code, when offered for sale or sold through an agent pursuant to the authority contained in Section 10131.6 of the Business and Professions Code. **(k)** "Real property transaction" means a transaction for the sale of real property in which an agent is retained by a buyer, seller, or both a buyer and seller to act in that transaction, and includes a listing or an offer to purchase. **(l)** "Sell," "sale," or "sold" refers to a transaction for the transfer of real property from the seller to the buyer and includes exchanges of real property between the seller and buyer, transactions for the creation of a real property sales contract within the meaning of Section 2985, and transactions for the creation of a leasehold exceeding one year's duration. **(m)** "Seller" means the transferor in a real property transaction and includes an owner who lists real property with an agent, whether or not a transfer results, or who receives an offer to purchase real property of which he or she is the owner from an agent on behalf of another. "Seller" includes both a vendor and a lessor of real property. **(n)** "Buyer's agent" means an agent who represents a buyer in a real property transaction.

2079.14. A seller's agent and buyer's agent shall provide the seller and buyer in a real property transaction with a copy of the disclosure form specified in Section 2079.16, and shall obtain a signed acknowledgment of receipt from that seller and buyer, except as provided in Section 2079.15, as follows: **(a)** The seller's agent, if any, shall provide the disclosure form to the seller prior to entering into the listing agreement. **(b)** The buyer's agent shall provide the disclosure form to the buyer as soon as practicable prior to execution of the buyer's offer to purchase. If the offer to purchase is not prepared by the buyer's agent, the buyer's agent shall present the disclosure form to the buyer not later than the next business day after receiving the offer to purchase from the buyer.

2079.15. In any circumstance in which the seller or buyer refuses to sign an acknowledgment of receipt pursuant to Section 2079.14, the agent shall set forth, sign, and date a written declaration of the facts of the refusal.

2079.16 Reproduced on Page 1 of this AD form.

2079.17(a) As soon as practicable, the buyer's agent shall disclose to the buyer and seller whether the agent is acting in the real property transaction as the buyer's agent, or as a dual agent representing both the buyer and the seller. This relationship shall be confirmed in the contract to purchase and sell real property or in a separate writing executed or acknowledged by the seller, the buyer, and the buyer's agent prior to or coincident with execution of that contract by the buyer and the seller, respectively. **(b)** As soon as practicable, the seller's agent shall disclose to the seller whether the seller's agent is acting in the real property transaction as the seller's agent, or as a dual agent representing both the buyer and seller. This relationship shall be confirmed in the contract to purchase and sell real property or in a separate writing executed or acknowledged by the seller and the seller's agent prior to or coincident with the execution of that contract by the seller.
(C) CONFIRMATION: The following agency relationships are confirmed for this transaction.

Seller's Brokerage Firm DO NOT COMPLETE, SAMPLE ONLY License Number
Is the broker of (check one): ☐ the seller; or ☐ both the buyer and seller. (dual agent)
Seller's Agent DO NOT COMPLETE, SAMPLE ONLY License Number
Is (check one): ☐ the Seller's Agent. (salesperson or broker associate); or ☐ both the Buyer's Agent and the Seller's Agent. (dual agent) Buyer's Brokerage Firm DO NOT COMPLETE, SAMPLE ONLY License Number
Is the broker of (check one): ☐ the buyer; or ☐ both the buyer and seller. (dual agent)
Buyer's Agent DO NOT COMPLETE, SAMPLE ONLY License Number
Is (check one): ☐ the Buyer's Agent. (salesperson or broker associate); or ☐ both the Buyer's Agent and the Seller's Agent. (dual agent)

(d) The disclosures and confirmation required by this section shall be in addition to the disclosure required by Section 2079.14. An agent's duty to provide disclosure and confirmation of representation in this section may be performed by a real estate salesperson or broker associate affiliated with that broker.

2079.18 (Repealed pursuant to AB1289, 201718 California Legislative session)

2079.19 The payment of compensation or the obligation to pay compensation to an agent by the seller or buyer is not necessarily determinative of a particular agency relationship between an agent and the seller or buyer. A listing agent and a selling agent may agree to share any compensation or commission paid, or any right to any compensation or commission for which an obligation arises as the result of a real estate transaction, and the terms of any such agreement shall not necessarily be determinative of a particular relationship.

2079.20 Nothing in this article prevents an agent from selecting, as a condition of the agent's employment, a specific form of agency relationship not specifically prohibited by this article if the requirements of Section 2079.14 and Section 2079.17 are complied with.

2079.21 (a) A dual agent may not, without the express permission of the seller, disclose to the buyer any confidential information obtained from the seller. **(b)** A dual agent may not, without the express permission of the buyer, disclose to the seller any confidential information obtained from the buyer. **(c)** "Confidential information" means facts relating to the client's financial position, motivations, bargaining position, or other personal information that may impact price, such as the seller is willing to accept a price less than the listing price or the buyer is willing to pay a price greater than the price offered. **(d)** This section does not alter in any way the duty or responsibility of a dual agent to any principal with respect to confidential information other than price.

2079.22 Nothing in this article precludes a seller's agent from also being a buyer's agent. If a seller or buyer in a transaction chooses to not be represented by an agent, that does not, of itself, make that agent a dual agent.

2079.23 (a) A contract between the principal and agent may be modified or altered to change the agency relationship at any time before the performance of the act which is the object of the agency with the written consent of the parties to the agency relationship. **(b)** A lender or an auction company retained by a lender to control aspects of a transaction of real property subject to this part, including validating the sales price, shall not require, as a condition of receiving the lender's approval of the transaction, the homeowner or listing agent to defend or indemnify the lender or auction company from any liability alleged to result from the actions of the lender or auction company. Any clause, provision, covenant, or agreement purporting to impose an obligation to defend or indemnify a lender or an auction company in violation of this subdivision is against public policy, void, and unenforceable.

2079.24 Nothing in this article shall be construed to either diminish the duty of disclosure owed buyers and sellers by agents and their associate licensees, subagents, and employees or to relieve agents and their associate licensees, subagents, and employees from liability for their conduct in connection with acts governed by this article or for any breach of a fiduciary duty or a duty of disclosure.

Exhibit 10.36

FIRST AMENDMENT TO LOAN AND SECURITY AGREEMENT

This **FIRST AMENDMENT TO LOAN AND SECURITY AGREEMENT** (this "**Agreement**") is entered into as of November 19, 2019, by and among INNOVATUS LIFE SCIENCES LENDING FUND I, LP, a Delaware limited partnership (together with its successors and assigns, "**Innovatus**"), as collateral agent (in such capacity, together with its successors and assigns in such capacity, "**Collateral Agent**"), the Lenders listed on Schedule 1.1 thereof or otherwise a party thereto from time to time (each a "**Lender**" and collectively, "**Lenders**"), and EXAGEN INC., a Delaware corporation (f/k/a EXAGEN DIAGNOSTICS, INC.) ("**Borrower**").

Recitals

A. Collateral Agent, Lenders, and Borrower have entered into that certain Loan and Security Agreement dated as of September 7, 2017 (as the same may from time to time be amended, modified, supplemented or restated, the "**Loan Agreement**").

B. Lenders have extended credit to Borrower for the purposes permitted in the Loan Agreement.

C. Borrower has requested that Collateral Agent and Lenders amend the Loan Agreement as more fully set forth herein.

D. Collateral Agent and Lenders have agreed to amend certain provisions of the Loan Agreement, but only to the extent, in accordance with the terms, subject to the conditions and in reliance upon the representations and warranties set forth below.

E. As of the date hereof, the outstanding principal balance of the Term Loans, including payable in-kind interest which has been capitalized, is $26,161,884.94 (See Annex X).

Agreement

Now, Therefore, in consideration of the foregoing recitals and other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, and intending to be legally bound, the parties hereto agree as follows:

1. Definitions. Capitalized terms used but not defined in this Agreement shall have the meanings given to them in the Loan Agreement.

2. Amendments.

2.1 Section 2.2 (Term Loans). Section 2.2(b) of the Loan Agreement is amended and restated as follows:

(b) Repayment. Borrower shall make monthly payments of interest only commencing on the second (2nd) Payment Date following the Funding Date of the Term Loan, and continuing on the Payment Date of each successive month thereafter through and including the Payment Date immediately preceding the Amortization Date. Borrower agrees to pay, on the Funding Date of the Term Loan, any initial partial monthly interest payment otherwise due for the period between the Funding Date of such Term Loan and the first Payment Date after such Funding Date. Commencing on the Amortization Date, and continuing on the Payment Date of each month thereafter, Borrower shall make consecutive equal monthly payments of principal,

plus interest, in arrears, to each Lender, as calculated by Collateral Agent (which calculations shall be deemed correct absent manifest error) based upon: (1) the amount of such Lender's Term Loan, (2) the effective rate of interest, as determined in Section 2.3(a), and (3) a repayment schedule equal to twenty-four (24) months. All unpaid principal and accrued and unpaid interest with respect to the Term Loan is due and payable in full on the Maturity Date. The Term Loan may only be prepaid in accordance with Sections 2.2(c) and 2.2(d).

2.2 Section 2.2 (Term Loans). Section 2.2(d) of the Loan Agreement is amended and restated as follows:

(d) Permitted Prepayment of Term Loan. After the first anniversary of the First Amendment Effective Date only, Borrower shall have the option to prepay all or part of the Term Loan advanced by the Lenders under this Agreement, provided Borrower (i) provides written notice to Collateral Agent of its election to prepay the Term Loan at least five (5) days prior to such prepayment, (ii) in the event of a partial prepayment, prepays such part of the Term Loan in a denomination that is a whole number multiple of Five Million Dollars ($5,000,000.00), and (iii) pays to the Lenders on the date of such prepayment, payable to each Lender in accordance with its respective Pro Rata Share, an amount equal to the sum of (A) the portion of outstanding principal of the Term Loan being prepaid plus all accrued and unpaid interest thereon through the prepayment date, (B) the applicable Final Payment with respect to the portion of the Term Loan being prepaid, (C) all other Obligations that are then due and payable, including Lenders' Expenses and interest at the Default Rate with respect to any past due amounts pursuant to the terms of this Agreement, and (D) the applicable Prepayment Fee with respect to the portion of the Term Loan being prepaid. For the sake of clarity, any partial prepayment shall be applied pro-rata to all outstanding amounts under the Term Loan, and shall be applied on a pro-rata basis to all remaining payments outstanding in inverse order of maturity.

2.3 Section 2.3 (Payment of Interest on the Term Loan). Section 2.3(a) of the Loan Agreement is amended and restated as follows:

(a) Interest Rate. Subject to Section 2.3(b), the principal amount outstanding under the Term Loan shall accrue interest at a fixed per annum rate equal to eight and one-half percent (8.50%), which interest shall be payable monthly in arrears in accordance with Sections 2.2(b) and 2.3(e); provided that two percent (2.00%) of such eight and one-half percent (8.50%) interest rate shall be payable in-kind through the Amortization Date by adding an amount equal to such two percent (2.00%) interest to the then outstanding principal balance on a monthly basis so as to increase the outstanding principal balance of such Term Loan on each Payment Date and which amount shall be payable when the principal amount of the Term Loan is payable in accordance with Sections 2.2(b) and 2.3(e) and on which principal amount interest shall be owed pursuant to Section 2.3(a).

2.4 Section 6.11 (Minimum Liquidity). Section 6.11 of the Loan Agreement is amended and restated as follows:

6.11 Minimum Liquidity. Borrower shall at all times maintain minimum unrestricted cash and Cash Equivalents, in an account subject to a control agreement in favor of Collateral Agent, in an amount equal to Two Million Dollars ($2,000,000.00).

2.5 Section 6.15 (Performance to Plan). A new Section 6.15 is added to the Loan Agreement as follows:

6.15 Performance to Plan. So long as the Performance Period is not in effect, Borrower shall achieve minimum trailing twelve (12) month revenue under GAAP,

measured at the end of each calendar quarter commencing with the quarter ending December 31, 2019, greater than seventy percent (70%) of projected revenue under GAAP (such projections attached hereto as Annex Q, the "**Management Plan**") (the "**Performance Covenant**"). Borrower's failure to maintain the Performance Covenant may be cured by the Equity Cure. Upon the Equity Cure, the Performance Covenant shall be based on the New Management Plan.

2.6 Section 8.2 (Covenant Default). Section 8.2(a) of the Loan Agreement is amended and restated as follows:

(a) Borrower or any of its Subsidiaries fails or neglects to perform any obligation in Sections 6.2 (Financial Statements, Reports, Certificates), 6.4 (Taxes), 6.5 (Insurance), 6.6 (Operating Accounts), 6.7 (Protection of Intellectual Property Rights), 6.11 (Minimum Liquidity), 6.15 (Performance to Plan) or Borrower violates any provision in Section 7; or

2.7 Section 13 (Definitions). The following terms and their definition are added to or amended and restated in Section 13 of the Loan Agreement as follows:

"**Amortization Date**" is the thirty-seventh (37th) Payment Date following the First Amendment Effective Date.

"**Cash Flow**" is an amount equal to (i) Borrower's cash flow from operations, minus (ii) Borrower's capital expenditures.

"**Equity Cure**" means Borrower's receipt, within sixty (60) days (or such longer period as acceptable to Collateral Agent and Innovatus in their sole reasonable discretion based on Borrower's good faith efforts to complete the Equity Cure) of any failure to achieve the Performance Covenant, of gross proceeds from the sale and issuance of Borrower's equity securities or Subordinated Debt, which in each case will not have any redemption, clawback, escrow or similar terms of at least an amount necessary for Borrower to achieve Cash Flow of at least Zero Dollars ($0) prior to the Maturity Date based on a new management plan provided by the Borrower (the "**New Management Plan**"), which is subject to Collateral Agent's and Innovatus' approval in their sole reasonable discretion.

"**First Amendment Effective Date**" is November 19, 2019.

"**Maturity Date**" is November 19, 2024.

"**Performance Period**" is, provided no Event of Default has occurred and is continuing, the period (a) commencing on the day that Borrower provides to Collateral Agent and Lenders a written report that (i) Borrower has achieved trailing twelve (12) month revenue under GAAP of at least One Hundred Million Dollars ($100,000,000.00), and (ii) Borrower has been cash flow positive for at least two (2) consecutive quarters (collectively, the "**Performance Requirement**"), and (b) terminating on the earlier to occur of (i) the occurrence of an Event of Default, and (ii) the first day thereafter in which Borrower fails to maintain the Performance Requirement as disclosed in any Compliance Certificate.

"**Prepayment Fee**" is, with respect to any Term Loan subject to prepayment prior to the Maturity Date, whether by mandatory or voluntary prepayment, acceleration or otherwise, as indicated, an additional fee payable to the Lenders in amount equal to:

(i) for any prepayment made after the First Amendment Effective Date through and including the first anniversary of the First Amendment Effective Date, which, pursuant to Section 2.2(d), may not be a voluntary prepayment, three percent (3.00%) of the principal amount of the Term Loan prepaid;

(ii) for any prepayment made after the first anniversary of the First Amendment Effective Date through and including the second anniversary of the First Amendment Effective Date, two percent (2.00%) of the principal amount of the Term Loan prepaid;

(iii) for any prepayment made after the second anniversary of the First Amendment Effective Date through and including the third anniversary of the First Amendment Effective Date, one percent (1.00%) of the principal amount of the Term Loan prepaid; and

(iv) for any prepayment made after the third anniversary of the First Amendment Effective Date, zero percent (0%) of the principal amount of the Term Loan prepaid.

2.8 Section 13 (Definitions). The following terms and their definitions are deleted in their entirety from Section 13 of the Loan Agreement:

"**Gross Margin**"; "**Gross Profit**"; "**Interest-Only Milestones"**; **"I/O Gross Margin Milestone"**; **"I/O Gross Profit Milestone"**; **"I/O Revenue Milestone"**; **"Permitted Prepayment Mandatory Warrant"**; **"Permitted Prepayment Reason"**; **"Prepayment Mandatory Fee"**.

2.9 Exhibit C (Compliance Certificate) to the Loan Agreement is replaced with Exhibit C attached hereto.

2.10 Annex Q (Management Plan) to the Loan Agreement is replaced with Annex Q attached hereto.

2.11 Annex X (Loan Interest Rate and Payment of Principal Schedule) attached hereto is added to the Loan Agreement.

2.12 Schedule I (Prepayment Mandatory Fee) to the Loan Agreement is deleted in its entirety.

3. Limitation of Agreement.

3.1 This Agreement is effective for the purposes set forth herein and shall be limited precisely as written and shall not be deemed to (a) be a consent to any amendment, waiver or modification of any other term or condition of any Loan Document, or (b) otherwise prejudice any right or remedy which Collateral Agent and Lenders may now have or may have in the future under or in connection with any Loan Document.

3.2 This Agreement shall be construed in connection with and as part of the Loan Documents, and all terms, conditions, representations, warranties, covenants and agreements set forth in the Loan Documents are hereby ratified and confirmed and shall remain in full force and effect.

4. Representations and Warranties. Borrower represents and warrants to Collateral Agent and Lenders as follows:

4.1 (a) the representations and warranties contained in the Loan Documents are true, accurate and complete in all material respects as of the date hereof (except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct as of such date), and (b) no Event of Default has occurred and is continuing immediately before and after giving effect to this Agreement;

4.2 Borrower has the power and authority to execute and deliver this Agreement and to perform its obligations under the Loan Agreement;

4.3 The organizational documents of Borrower delivered to Collateral Agent and Lenders on the Effective Date or subsequent thereto remain true, accurate and complete and have not been amended, supplemented or restated and are and continue to be in full force and effect;

4.4 The execution and delivery by Borrower of this Agreement and the performance by Borrower of its obligations under the Loan Agreement have been duly authorized by all necessary action on the part of Borrower;

4.5 The execution and delivery by Borrower of this Agreement and the performance by Borrower of its obligations under the Loan Agreement do not and will not contravene (a) any law or regulation binding on or affecting Borrower, (b) any contractual restriction with a Person binding on Borrower, (c) any order, judgment or decree of any court or other governmental or public body or authority, or subdivision thereof, binding on Borrower, or (d) the organizational documents of Borrower;

4.6 The execution and delivery by Borrower of this Agreement and the performance by Borrower of its obligations under the Loan Agreement do not require any order, consent, approval, license, authorization or validation of, or filing, recording or registration with, or exemption by any governmental or public body or authority, or subdivision thereof, binding on either Borrower, except as already has been obtained or made; and

4.7 This Agreement has been duly executed and delivered by Borrower and is the binding obligation of Borrower, enforceable against Borrower in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application and equitable principles relating to or affecting creditors' rights.

5. Prior Agreement. The Loan Documents are hereby ratified and reaffirmed and shall remain in full force and effect. This Agreement is not a novation and the terms and conditions of this Agreement shall be in addition to and supplemental to all terms and conditions set forth in the Loan Documents. In the event of any conflict or inconsistency between this Agreement and the terms of such documents, the terms of this Agreement shall be controlling, but such document shall not otherwise be affected or the rights therein impaired.

6. Integration. This Agreement and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Agreement and the Loan Documents merge into this Agreement and the Loan Documents.

7. Counterparts. This Agreement may be executed in any number of counterparts and all of such counterparts taken together shall be deemed to constitute one and the same instrument.

8. Conditions to Effectiveness. This Agreement shall be deemed effective upon the due execution and delivery to Collateral Agent and Lenders, in form and substance reasonably satisfactory to Collateral Agent and each Lender, such documents, and completion of such other matters, as Collateral Agent and each Lender may reasonably deem necessary or appropriate (and requested in writing at least three Business Days prior to the date hereof), including, without limitation:

a) this Agreement duly executed by each party hereto;

b) a duly executed corporate borrowing certificate dated as of the date hereof; and

c) Borrower's payment of all Lenders' Expenses incurred through the date of this Agreement to the extent due and payable pursuant to Sections 2.4(d) or 12.2 of the Loan Agreement, which amount for the documentation and negotiation of this Agreement shall not exceed Fifteen Thousand Dollars ($15,000).

9. Miscellaneous.

9.1 This Agreement shall constitute a Loan Document under the Loan Agreement; the failure to comply with the covenants contained herein shall constitute an Event of Default under the Loan Agreement; and all obligations included in this Agreement (including, without limitation, all obligations for the payment of principal, interest, fees, and other amounts and expenses) shall constitute obligations under the Loan Agreement and secured by the Collateral.

9.2 Each provision of this Agreement is severable from every other provision in determining the enforceability of any provision.

10. Governing Law. This Agreement and the rights and obligations of the parties hereto shall be governed by and construed in accordance with the laws of the State of New York.

[Signature pages follow.]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the date first written above.

BORROWER:

EXAGEN INC.

By: /s/Kamal Adawi

Name: Kamal Adawi

Title: Chief Financial Officer

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the date first written above.

COLLATERAL AGENT AND LENDER:

INNOVATUS LIFE SCIENCES LENDING FUND I, LP

By: Innovatus Life Sciences GP, LP
Its: General Partner

By: /s/ Andrew Hobson

Name: Andrew Hobson

Title: Authorized Signatory

EXHIBIT C

Compliance Certificate

ANNEX Q

(Management Plan)

ANNEX X

(Loan Interest Rate and Payment of Principal Schedule)

Exhibit 10.41

EXAGEN INC.

February 21, 2020

Debra Zack, MD Ph.D.

Dear Dr. Zack,

I am pleased to confirm our offer for you to join Exagen Inc. as Chief Medical Officer with a start date of 3/24/2020. This offer is contingent upon the successful completion of a pre-employment background check and proof of work eligibility. This is an exempt position and will report to Ron Rocca. We are offering you a bi-weekly salary of $14,615.38 ($380,000.00 annualized).

You are eligible for achievement incentive compensation which will be contingent on you meeting certain performance goals. Your annual incentive compensation will be worth 45% of your annual salary and will be pro-rated in the first year to start date. In addition, you will receive 100,000 options to purchase the company's common stock contingent upon the approval of the Exagen Board of Directors, the timing of which will also be subject to the Board's discretion.

You are eligible to participate in the Exagen benefits program, a summary of which you will receive under separate cover. You will accrue 3 weeks (or 120 hours) of paid time off a year in addition to the ten holidays currently recognized by Exagen.

Exagen currently has a safe harbor 40l(k) plan and contributes an amount equal to 3% of your annual income into your 40l(k). There is no vesting period in the 40l(k). You must be employed by Exagen for 3 months before becoming eligible to participate in the 40l(k).

Employment at Will: This letter is intended to communicate certain terms and conditions of employment with Exagen Inc. but is not intended to be and should not be considered an employment contract. Your employment is not for a specific duration and may be terminated by you or Exagen Inc. at any time, for any reason or for no reason whatsoever, with or without notice and with or without cause unless otherwise specified by law. Your employment is "at will." The "at will" status of your employment may not be altered except by a separate written contract signed by the Chief Financial Officer of Exagen Inc. No one other than the Chief Financial Officer has the authority to enter into an employment contract with you.

I look forward to working with you as a member of the Exagen team. We are excited about the contributions you will make to the success of our company. If you have any further questions, please do not hesitate to contact me.

Sincerely,

/s/ Kamal Adawi
Kamal Adawi
Chief Financial Officer

I Accept the Offer Stated Above
/s/ Debra Zack
Debra Zack, MD Ph.D.

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-8 (No. 333-233878) of Exagen Inc. of our report dated March 25, 2020, relating to the financial statements, which appears in this Form 10-K.

/s/ BDO USA, LLP

San Diego, California
March 25, 2020

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 25, 2020

/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 25, 2020

/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, 2019 (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 25, 2020

/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, 2019 (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 25, 2020

/s/ Kamal Adawi

Kamal Adawi

Chief Financial Officer (Principal Financial and Accounting Officer)