

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**FORM 10-K**

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2021

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  
(State or other jurisdiction of  
incorporation or organization)  
  
1261 Liberty Way  
Vista California  
(Address of Principal Executive Offices)

20-0434866  
(I.R.S. Employer  
Identification No.)

92081  
(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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Securities Act

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

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

As of June 30, 2021 (the last business day of the registrant's most recently completed second fiscal quarter), the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately \$158.3 million, based on the closing price of the registrant's common stock on the Nasdaq Global Market of \$14.99 per share.

Total shares of common stock outstanding as of the close of business on March 18, 2022 was 16,231,198.

#### **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 2022 Annual Meeting of Stockholders, which proxy statement will be filed not later than 120 days after the end of the fiscal year covered by this Form 10-K.

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## Part I

### Forward-Looking Statements and Market Data

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

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

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

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

## Item 1. Business.

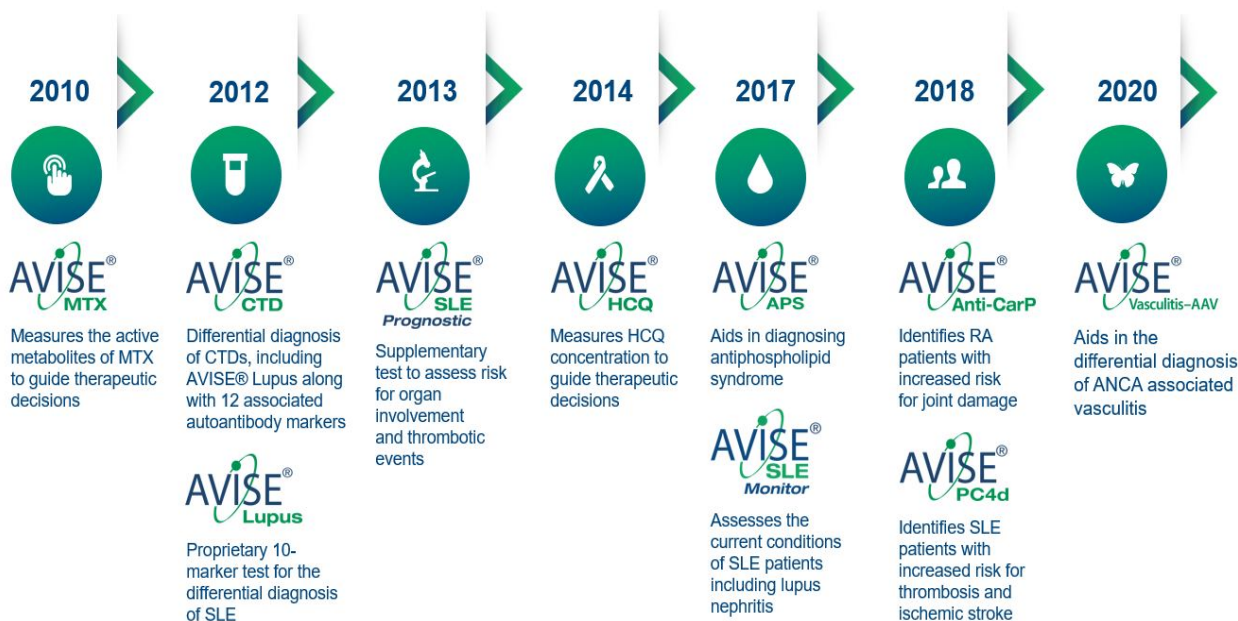
### Company Overview

Exagen is dedicated to transforming the care continuum for patients suffering from debilitating and chronic autoimmune diseases by enabling timely differential diagnosis and optimizing therapeutic intervention. We have developed and are commercializing a portfolio of innovative testing products under our AVISE<sup>®</sup> 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.

We currently market 10 testing products under our AVISE<sup>®</sup> brand that allow for the differential diagnosis, prognosis and monitoring of complex autoimmune and autoimmune-related diseases. Our lead testing product, AVISE<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> CTD may provide clinical utility for over 23 million patients in the United States suffering from these diseases, which include SLE, RA, Sjögren's syndrome, antiphospholipid syndrome, or APS, other autoimmune-related diseases such as autoimmune thyroid, and other disorders that mimic these diseases, such as fibromyalgia. There is an unmet need for rheumatologists to add clarity in their CTD clinical evaluation, and we believe there is a significant opportunity for our tests that enable the differential diagnosis of these diseases, particularly for potentially life-threatening diseases such as SLE.

We are leveraging our portfolio of testing products to establish partnerships with leading pharmaceutical companies, academic research centers and patient advocacy organizations. We also have agreements with other leading pharmaceutical companies and clinical research organizations, including GlaxoSmithKline LLC, or GSK, Labcorp Drug Development and Parexel that leverage our testing products and/or the data generated from such tests. We provide GSK, a leader in lupus therapeutics, our test result data to provide market insight into and help increase awareness of the benefits of an early and accurate diagnosis of SLE and lupus nephritis, and monitoring disease activity. We partner with academic research centers and patient advocacy organizations, such as Brigham and Women's Hospital, Hospital for Special Surgery, Duke University and Emory University as well as the Lupus Foundation of America, to help improve the quality of life for people affected by autoimmune diseases through programs of research, education, support and advocacy. We plan to pursue additional partnerships that are synergistic with our evolving portfolio of testing products.

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



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

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

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 Werfen USA, LLC with the goal of identifying patients prone to more severe disease.

We market our AVISE® testing products using our specialized sales force. Since the launch of AVISE® CTD in 2012 and through December 31, 2021, we have delivered over 615,000 of these tests. For the year ended December 31, 2021, 128,246 AVISE® CTD tests were delivered, representing an approximate 28% increase over the same period in 2020. In the fourth quarter of 2021, the number of ordering healthcare providers reached a record 2,126 compared to 1,690 in the same period in 2020, and we reached a record 739 adopting healthcare providers (defined as those who previously prescribed at least 11 diagnostic tests in the corresponding period) compared to 635 in the same period in 2020. A high percentage of adopting healthcare providers continue to order tests in subsequent quarters, including a retention rate of approximately 99% among adopting healthcare providers from the third quarter of 2021 that order at least one diagnostic test in the fourth quarter of 2021.

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

collaborate with our existing and future pharmaceutical and biotechnology partners to help maximize the full value of our in-house database.

We also believe we can leverage our portfolio of testing products to market therapeutics through our sales channel, targeting the approximately 5,000 rheumatologists across the United States, by integrating testing products and therapeutics to offer targeted solutions to rheumatologists and ultimately, better serve patients. We will continue to rely on our existing testing products to drive revenue growth and intend to leverage our integrated testing and therapeutics strategy to establish partnerships with a focus on the development and commercialization of therapeutics that are synergistic with our testing products.

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

## Our Strategy

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

- **Continue our track record of developing innovative testing products.** Since inception, we have demonstrated a strong track record of developing testing products that address the challenges in the differential diagnosis, prognosis and monitoring of patients with autoimmune and autoimmune-related diseases. We are leveraging our proprietary CB-CAPs and methotrexate polyglutamate, or MTXPG, technologies to develop additional testing products designed to have superior clinical utility for CTDs. We believe our commitment to innovating our portfolio of testing products will further strengthen our relationships with rheumatologists and our value proposition to our existing and future pharmaceutical and biotechnology partners.
- **Drive additional market penetration for our testing products.** Our portfolio of testing products enables the differential diagnosis, prognosis and monitoring of complex autoimmune and autoimmune-related diseases. We have demonstrated a strong track record of commercial growth from our testing products, leveraging our specialized sales force 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 sales force in order to achieve the optimal reach and frequency with rheumatologists. In addition, we will continue to expand our efforts in the targeted promotion and education of rheumatologists and payors as to the clinical and cost benefits of our testing products. We believe these efforts will position us to capture additional market share for our portfolio of testing products.
- **Integrate the promotion of testing products and therapeutics for autoimmune and autoimmune-related diseases and establish partnerships.** We are seeking to leverage our sales and marketing efforts targeting rheumatologists for the commercialization of our testing products to promote therapeutics. We intend to establish partnerships with a focus on the development and commercialization of therapeutics that are synergistic with our testing products to execute on this integrated testing and therapeutics strategy.
- **Maintain meaningful margin.** We believe we are well positioned to maintain meaningful margin through a continued focus on increasing operating leverage through the implementation of certain internal initiatives, such as conducting additional validation and reimbursement oriented clinical studies to facilitate payor coverage of our testing products, capitalizing on our growing reagent purchasing to negotiate improved volume-based pricing and automation in our clinical laboratory to reduce material and labor costs.

## 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<sup>®</sup> CTD test, representing a total addressable market of approximately \$3.6 billion, based on the current Medicare allowable reimbursement rate. We estimate the total addressable market for our AVISE<sup>®</sup> testing products to be approximately \$5 billion, based on estimated patient populations, the current Medicare allowable reimbursement rate and testing frequencies.

### ***Systemic Lupus Erythematosus***

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

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

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

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



In March 2011, the first new biologic targeting treatment of SLE in over 50 years, GSK's Benlysta<sup>®</sup>, was approved by the U.S. Food and Drug Administration, or the FDA, and in December 2020, the FDA approved this biologic drug for the treatment of lupus nephritis. It is the only approved biologic for the treatment of active, antibody-positive SLE who are receiving standard therapy, and in December 2020, the FDA approved this biologic for the treatment of adult patients with active lupus nephritis who are receiving standard therapy. Since Benlysta<sup>®</sup>'s approval, there have been a number of drug development programs that have failed in SLE, which may suggest that guidelines for classifying SLE patients and the endpoints used to determine clinical effectiveness have not adequately addressed the complexity of the disease process and its heterogeneous population. We believe biopharmaceutical companies would benefit from the differential diagnosis enabled by our AVISE<sup>®</sup> 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 120,000 and two 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<sup>®</sup> was approved for RA in 1998 and the latest, SIMPONI<sup>®</sup>, was approved in 2009. The anti-TNFs dominate the therapy for RA and generally are the first biologics chosen to augment methotrexate when patients are not achieving a satisfactory response.

### ***Our Solution***

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

### ***Our Proprietary Technologies***

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

#### ***CB-CAPs***

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

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

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

#### *MTXPGs*

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

#### **Testing Products**

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

#### *Diagnosis*

##### AVISE<sup>®</sup> CTD

Our lead testing product, AVISE<sup>®</sup> 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<sup>®</sup> CTD enables testing for a series of biomarkers 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 larger diagnostic process more efficient and accurate. The clinical performance of our proprietary biomarkers and the convenience of a single blood draw make AVISE<sup>®</sup> CTD an attractive choice among rheumatologists.

##### AVISE<sup>®</sup> Lupus

The AVISE<sup>®</sup> Lupus test employs our proprietary CB-CAPs technology and is the cornerstone of the SLE assessment within our more comprehensive AVISE<sup>®</sup> CTD testing product. AVISE<sup>®</sup> 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<sup>®</sup> CTD test or the more focused AVISE<sup>®</sup> Lupus test based on medical necessity, which is determined by each patient's symptoms and medical history.

##### AVISE<sup>®</sup> APS

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

#### AVISE® Vasculitis AAV

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

#### *Prognosis*

#### AVISE® SLE Prognostic

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

#### AVISE® Anti-CarP

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

#### AVISE® PC4d

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

#### *Monitoring*

#### AVISE® SLE Monitor

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

## AVISE® MTX

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

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

## AVISE® HCQ

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

### **Test Reports**

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

### **AVISE® CTD Report**



Order ID 739814  
 Provider Exagen Provider MD

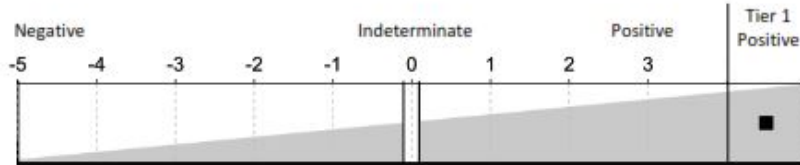
**Specimen**  
 Collected 01/15/2022  
 Received 01/16/2022  
**Test Order**  
 Created 01/16/2022  
 Reported 01/20/2022

**Patient**  
 Gender - DOB Female - 01/01/1996  
 Identifier Received  
 Exagen ID 541163

**Sample,  
 Susan S**

AVISE CTD Test Report

AVISE Lupus Result: **Tier 1 Positive**



Tier 1 Analytes	Value	Interpretation	Reference Range	Tier 1 Assessment
Anti-dsDNA IgG	413.00 IU/mL	POSITIVE	<201 - Negative   201-<302 - Equivocal   ≥302 - Positive	Positive
Confirmation by Crithidia luciliae		Positive anti-dsDNA confirmed by Crithidia		
Anti-Smith IgG	1.0 U/mL	Negative	<7 - Negative   7-10 - Equivocal   >10 - Positive	
CB-CAP: EC4d - Erythrocyte-bound C4d	8 Net MFI	Negative	<15 - Negative   15 -75 - Positive   >75 - Strong Positive	
CB-CAP: BC4d - B-lymphocyte-bound C4d	125 Net MFI	POSITIVE	<61 - Negative   61-200 - Positive   >200 - Strong Positive	
<b>Note:</b> The Tier 1 result is associated with an increased likelihood of SLE and is the product of the following analyte values meeting the Tier 1 criteria: Anti-dsDNA, confirmed by Crithidia IFA				

Tier 2 Analytes	Value	Interpretation	Reference Range	Tier 2 Assessment
ANA IgG	>150 Units	STRONG POSITIVE	<20 - Negative   20-<60 - Positive   ≥60 - Strong Positive	Not assessed due to Tier 1 Positive
CB-CAP: EC4d - Erythrocyte-bound C4d	8 Net MFI	Negative	<15 - Negative   15-75 - Positive   >75 - Strong Positive	
CB-CAP: BC4d - B-lymphocyte-bound C4d	125 Net MFI	POSITIVE	<61 - Negative   61-200 - Positive   >200 - Strong Positive	
Anti-SS-B/La IgG	1.0 U/mL	Negative	<7 - Negative   7-10 - Equivocal   >10 - Positive	
Anti-Scl-70 IgG	1.0 U/mL	Negative	<7 - Negative   7-10 - Equivocal   >10 - Positive	
Anti-Centromere Protein B (CENP) IgG	1.0 U/mL	Negative	<7 - Negative   7-10 - Equivocal   >10 - Positive	
Anti-Jo-1 IgG	1.0 U/mL	Negative	<7 - Negative   7-10 - Equivocal   >10 - Positive	
Anti-CCP IgG	1.0 U/mL	Negative	<7 - Negative   7-10 - Equivocal   >10 - Positive	
<b>Note:</b>				

Approved by: Richard Safrin, MD

*Richard E Safrin MD*

Date: 01-20-2022

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).



Order ID 739814  
 Provider Exagen Provider MD

**Specimen**  
 Collected 01/15/2022  
 Received 01/16/2022  
**Test Order**  
 Created 01/16/2022  
 Reported 01/20/2022

**Patient**  
**Sample, Susan S**  
 Gender - DOB Female - 01/01/1996  
 Identifier Received  
 Exagen ID 541163

SLE-Associated Analytes	Value	Interpretation	Reference Range
++ ANA IgG	>150 Units	STRONG POSITIVE	ELISA: <20 - Negative   20-<60 - Positive   ≥60 - Strong Positive
+ ANA by HEp-2	Titer: 1:320	POSITIVE	IFA: <1:80 - Negative   ≥1:80 - Positive
Nuclear Pattern: Homogeneous Cytoplasmic Pattern: Observed			
+ Anti-dsDNA IgG	413.00 IU/mL	POSITIVE	ELISA: <201 - Negative   201-<302 - Equivocal   ≥302 - Positive
+ Anti-dsDNA by Crithidia (confirmatory)	POSITIVE		IFA: Negative
Anti-Smith IgG	1.0 U/mL	Negative	ELISA: <7 - Negative   7-10 - Equivocal   >10 - Positive
CB-CAP: EC4d - Erythrocyte-bound C4d	8 Net MFI	Negative	FACS: <15 - Negative   15-75 - Positive   >75 - Strong Positive
+ CB-CAP: BC4d - B-lymphocyte-bound C4d	125 Net MFI	POSITIVE	FACS: <61 - Negative   61-200 - Positive   >200 - Strong Positive
Other Autoimmune Disease Auto-Antibodies	Value	Interpretation	Reference Range
Anti-U1RNP IgG	3.0 U/mL	Negative	ELISA: <5 - Negative   5-10 - Equivocal   >10 - Positive
Anti-RNP70 IgG	1.0 U/mL	Negative	ELISA: <7 - Negative   7-10 - Equivocal   >10 - Positive
Anti-Ro52 IgG	5.0 CU	Negative	CIA: <20 - Negative   ≥20 - Positive
Anti-Ro60 IgG	3.0 CU	Negative	CIA: <20 - Negative   ≥20 - Positive
Anti-SS-B/La IgG	1.0 U/mL	Negative	ELISA: <7 - Negative   7-10 - Equivocal   >10 - Positive
Anti-Scl-70 IgG	1.0 U/mL	Negative	ELISA: <7 - Negative   7-10 - Equivocal   >10 - Positive
Anti-RNA Pol III IgG	10.00 Units	Negative	ELISA: <20 - Negative   20 - 80 - Equivocal   >80 - Strong Positive
Anti-Centromere Protein B (CENP) IgG	1.0 U/mL	Negative	ELISA: <7 - Negative   7-10 - Equivocal   >10 - Positive
Anti-Jo-1 IgG	1.0 U/mL	Negative	ELISA: <7 - Negative   7-10 - Equivocal   >10 - Positive
Rheumatoid Arthritis Auto-Antibodies	Value	Interpretation	Reference Range
Rheumatoid Factor IgM	2.0 IU/mL	Negative	ELISA: <3.5 - Negative   3.5-5 - Equivocal   ≥5 - Positive
Rheumatoid Factor IgA	1.0 IU/mL	Negative	ELISA: <14 - Negative   14-20 - Equivocal   ≥20 - Positive
Anti-CCP IgG	1.0 U/mL	Negative	ELISA: <7 - Negative   7-10 - Equivocal   >10 - Positive
Antiphospholipid Syndrome Auto-Antibodies	Value	Interpretation	Reference Range
Anti-Cardiolipin IgM	2.0 U/mL	Negative	ELISA: <10 - Negative   10-40 - Weak Positive   >40 - Positive
Anti-Cardiolipin IgG	4.0 U/mL	Negative	ELISA: <10 - Negative   10-40 - Weak Positive   >40 - Positive
Anti-β2 Glycoprotein 1 IgM	3.0 U/mL	Negative	ELISA: <7 - Negative   7-10 - Equivocal   >10 - Positive
Anti-β2 Glycoprotein 1 IgG	2.0 U/mL	Negative	ELISA: <7 - Negative   7-10 - Equivocal   >10 - 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:**

**References**

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



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 CAP# 7201051 | NYSDOH PFI# 8369

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Provider Relations: 888.452.1522

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This test is used for clinical purposes, though results are not intended to be used as the sole means for clinical diagnosis or patient management decisions. It should not be regarded as investigational or for research. It has not been cleared or approved by the FDA. Exagen is regulated under CLIA as qualified to perform high-complexity testing. SA1267 (2/22)

**Our Pipeline and Growth Opportunities**

We have a Scientific Advisory Board consisting of national experts in the clinical management of rheumatic autoimmune diseases, including RA and lupus, to help guide the organization's leadership team on the design and

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

#### *AVISE<sup>®</sup> RADR Platform*

RA is estimated to affect approximately two million patients in the United States and can be difficult to manage due to the variability in treatment response from patient to patient. Therapeutic agent selection for RA patients remains a significant unmet need. RA patients often try multiple therapies empirically before they find one that lowers their disease activity. The placement of an RA patient on an ineffective therapy risks progression and worsening of the disease, further damage to the joints, and significant wasted spend on expensive therapeutic agents. There are currently no reliable assays for predicting positive patient response prior to the selection of commonly prescribed biological therapeutic agents. In collaboration with Queen Mary University of London, we are aiming to develop a family of patented assays pertaining to RNA expression patterns used in the prediction of patient response to commonly prescribed csDMARD (AVISE<sup>®</sup> RADR 1) and biological therapeutics (AVISE<sup>®</sup> RADR 2) for RA. The assays utilize minimally invasive synovial tissue biopsies as input, which are then assessed for RNA expression data. These data are then run through proprietary machine learning algorithms that provide actionable insights on predicted csDMARD and biological therapeutic response for RA patients based on an individual patient's RNA expression patterns.

#### **Sales and Marketing**

Our specialized sales force 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 goal is for our sales representative to be viewed as a collaborative consultant versus a traditional drug sales representative.

As of December 31, 2021, our overall sales team consisted of approximately 79 members. We have a sales force of 61 representatives, who are managed by a team of seven regional sales directors. Our sales force is organized into seven regions which include, Pacific, Southwest, Midwest, Great Lakes, Southeast, Atlantic and Northeast. As of December 31, 2021, our sales force was covering a total of 63 territories within the seven regions. Our inside sales force helps further our reach with rheumatologists in white space, complementing our decentralized sales force and covering vacant territories. In addition, we intend to continue to evaluate our sales force's reach and frequency of interactions with rheumatologists, including as we launch our pipeline products. 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 sales force and marketing activities and enhances sales efficiency and customer satisfaction by providing personalized customer support.

#### *Right Doctor, Right Message, Right Frequency*

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

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

## **Reimbursement, Clinical Validation and Clinical Utility**

### *Reimbursement*

We seek reimbursement for our testing products from several sources, including commercial third-party payors, government payors and patients. Payment from commercial third-party payors differs depending on whether we have entered into a contract with the payor as a participating provider or do not have a contract and are considered to be an out-of-network provider. When we contract to serve as a participating provider, reimbursements are made pursuant to a percentage of our charges or a negotiated fee schedule amount. Where we are not reimbursed in full, or receive a claim denial, for in-network and out-of-network claims, 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 additional commercial payors, laboratory benefit managers and evidence review organizations. We employ a multi-pronged strategy designed to achieve broad coverage and reimbursement for our AVISE<sup>®</sup> testing products:

- *Meet the evidence standards necessary to be consistent with leading clinical guidelines.* We believe inclusion in leading clinical guidelines plays a critical role in payors' coverage decisions. In order to change clinical guidelines, tests must carry a high level of published evidence demonstrating analytical validity, clinical validity, clinical utility and cost effectiveness. When studies with such evidence are published in peer-reviewed journals, the authors of clinical guidelines may assess the level of evidence and determine whether modifying existing guidelines to include new technology is warranted. For example, we previously conducted peer-reviewed, published clinical studies for AVISE<sup>®</sup> Lupus which helped us secure favorable coverage from various commercial third-party payors. In the future, we also intend to conduct similar studies in order to develop similar supporting literature with respect to our other testing products.
- *Execute an internal managed care policy and claims adjudication function as part of our core business operations.* We employ a team of in-house claims processing and reimbursement specialists who work with patients and payors to obtain maximum reimbursement. In parallel, a managed care team collaborates with our reimbursement specialists to ensure our payor outreach strategy reacts to and anticipates the changing needs of our customer base. Our customer service team is an integral part of our reimbursement strategy, working with patients and rheumatologists to navigate the claims process.
- *Cultivate a network of key opinion leaders.* Key opinion leaders are able to influence clinical practice by publishing research and determining whether new tests should be integrated into clinical guidelines. We collaborate with key opinion leaders early in the development process to ensure our clinical studies are designed and executed in a way that clearly demonstrates the benefits of our testing products to healthcare providers and payors.

### *Clinical Validation*

We demonstrated the clinical validity of AVISE<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> Lupus and CB-CAPs as a marker of complement activation in patients with pSLE and the usefulness of the AVISE<sup>®</sup> 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<sup>®</sup> 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 July 2021, a real-world retrospective analysis of patients tested with the AVISE® Lupus test was published in the journal Lupus Science & Medicine, titled "A multianalyte assay panel with cell-bound complement activation products demonstrates clinical utility in systemic lupus erythematosus clinical utility study summary". A cohort of 161 AVISE® Lupus tested patients from 12 rheumatology centers across the U.S. provided clinical outcome data on diagnosis and treatment decisions following AVISE® Lupus testing. The study findings revealed a 7 to 15-fold increased risk of Lupus diagnosis in AVISE® Lupus Positive and anti-dsDNA negative patients relative to patients negative for both tests. In addition, AVISE® Lupus positive and anti-dsDNA negative patients were at 3 to 4-fold increased odds relative to patients testing negative for both tests of starting a new hydroxychloroquine (cornerstone therapy for Lupus) prescription following AVISE® Lupus testing. Collectively, the study results affirm earlier study findings demonstrating the superior clinical utility and actionability of AVISE® Lupus vs. standard diagnostic testing for the differential diagnosis of Lupus.

### *Healthcare Economics*

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

The above referenced studies are included in the AVISE® Lupus Dossier. In March 2020, we announced coverage and in-network contract with three California Medical Groups followed by coverage and an in-network agreement with TRICARE East Humana Military and Highmark BCBS coverage policy. In February 2021, we entered into a coverage and in-network contract with TRICARE West followed by coverage and an in-network agreement with Inland Empire Health Plan. We anticipate continued coverage determinations and in-network contracting announcements in 2022 and beyond.

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

### **Laboratory Operations**

We perform all of our AVISE® tests in our approximately 10,000 square foot clinical laboratory located in Vista, California. Our laboratory is certified to perform high-complexity testing under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, and is accredited by the College of American Pathologists, or CAP. Our laboratory also holds a license issued by the California Department of Public Health, and it is licensed by all states requiring out-of-state licensure. Our clinical laboratory reports all AVISE® testing product results within five business days. In the second half of 2021, we began the conversion of approximately 8,000 square feet of warehouse space into additional clinical laboratory space and approximately 6,000 square feet of warehouse space into additional research and development facility space, and expect to complete such conversions by the first quarter of 2022 and mid 2022, respectively. The expansion of our clinical laboratory and research and development facility are expected to allow us to enhance our testing capacity and improve efficiencies as well as allow us to develop molecular and multiomic capabilities and advance our product pipeline. We believe that our existing laboratory facility is adequate to meet our business needs for at least the next 12 months and that additional laboratory space will be available on commercially reasonable terms, if required.

### **Quality Assurance**

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

### **Competition**

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

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

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

### **Agreements with Pharmaceutical Companies**

#### *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, November 2020, December 2021 and February

2022 to, among other things, extend the term of the agreement through December 31, 2020, December 31, 2021, January 31, 2022 and December 31, 2022, respectively.

Under the agreement, we are required to deliver weekly de-identified data files to GSK covering all data obtained from the performance of certain AVISE® testing products, subject to applicable requirements under the Federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, internal policy requirements and other applicable laws. During the term of the agreement and amendments through December 31, 2021, the data we provided to GSK could not be provided, directly or through a third party, to any other pharmaceutical company that was marketing or developing a product for the treatment of SLE, however, the February 2022 amendment eliminated that limitation. GSK made a single upfront payment in exchange for the right to receive the applicable data files. In addition, GSK has agreed to create a joint steering committee to cooperate with us in order to raise awareness and physician support for our AVISE® testing products, including through the development and delivery of approved promotional materials and the implementation of a related training plan for each party's sales personnel.

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

### **Intellectual Property Overview**

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

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

### **Patent Protection for our AVISE® Testing Products**

Our portfolio of patents and patent applications related to our AVISE® testing products generally relates to three aspects: CB-CAPs, red blood cell MTXPG exposure assessments, and anti-MCV antibodies. The patent families which we believe are important for the protection of AVISE® are summarized below in the section entitled "—License Agreements." As of February 22, 2022, our portfolio primarily consisted of the following:

#### *CB-CAPs*

We are the exclusive licensee of five patent families related to CB-CAPs technology from the University of Pittsburgh, or UPitt. We expect that these patent families (U.S. Patent Nos. 7,361,517; 7,390,631; 7,585,640; 7,588,905; 8,080,382; and 8,126,654) will expire in 2024 or 2025. A foreign patent corresponding to U.S. Patent No. 7,361,517 has issued in Europe (EP 1,756,571). Foreign patents corresponding to U.S. Patent No. 7,390,631 have issued in Japan (JP 4570872 and JP 4906898). Foreign patents corresponding to U.S. Patent No. 7,585,640 have issued in Australia (AU 2005242719) and Canada (CA 2,564,492). A foreign patent corresponding to U.S. Patent Nos. 7,588,905 and 8,126,654 has issued in Japan (JP 4550051). We also own one issued patent (US 10,132,813), three pending U.S. nonprovisional patent applications, three pending foreign applications and a pending PCT application that relate to our AVISE® Lupus products. Foreign patents corresponding to our issued U.S. patent and pending U.S. nonprovisional patent applications have issued in Europe (EP 2,673,644 and EP2972365), China (CN105229470), Japan (JP 5,990,542 and JP6453299) and Hong Kong (HK1192316). 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 own four patents that relate to our AVISE<sup>®</sup> MTX product and methods for monitoring methotrexate therapy using red blood cell MTXPG exposure assessments. 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.

## **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<sup>®</sup> 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<sup>®</sup> 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.

#### *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<sup>®</sup> 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 net sales of CB-CAPs products which required us to make a \$2.0 million milestone payment to Royalty Pharma. We paid the applicable \$2.0 million milestone payment in 2016. In February 2017, we amended our agreements with Royalty Pharma relating to the launch of a monitoring product using CB-CAPs technology. As a result of this amendment, a prior obligation to make a one-time payment of \$1.0 million upon the launch of a monitoring product incorporating CB-CAPs technology was replaced with an agreement to pay Royalty Pharma a one-time payment of \$100,000 upon the launch of such a product, plus a 2.5% royalty based on future cash collections from sales of that product which incorporate the licensed technology. Future royalties under this arrangement are limited to the lesser of \$1,200,000 (including the upfront payment of \$100,000) or the total royalty earned through January 1, 2024.

*Dr. Thierry Dervieux and De Novo Diagnostics, Inc.*

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

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

In consideration 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. To date, none of the circumstances under the agreement that would require us to make a payment to Dr. Dervieux or De Novo Diagnostics, Inc. have occurred and, accordingly, we have made no such payment. We have provided a termination notice to Dr. Dervieux and De Novo Diagnostics, Inc. in accordance with the agreement and intend to terminate the agreement on June 9, 2022.

*Exclusive License Agreement and Master Research Collaboration Agreement with Allegheny Health Network Research Institute*

In May 2021, we entered into an exclusive license agreement with Allegheny Health Network Research Institute, or AHN, under which we obtained an exclusive, worldwide license to AHN's patent rights in certain inventions, or the AHN Patent Rights, related to diagnostics for autoimmune rheumatic diseases.

Under the agreement, we are permitted to make, use and sell products and services utilizing the AHN Patent Rights and to sublicense such rights; provided, however, that any such sublicenses may only be granted with AHN's consent. AHN retained the right to practice under the AHN Patent Rights and to use such rights for teaching, research, education, public service, clinical and other research-related purposes. In addition, the agreement is subject to the rights of the United States government with respect to the AHN Patent Rights, including under a funding agreement between AHN and the United States Government and under the Bayh-Dole Act (35 U.S.C. §200, et seq. Pursuant to the Bayh-Dole Act, the United States Government may acquire 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 AHN Patent Rights throughout the world.

In consideration for the rights granted to us under the agreement, we paid an initial license fee to AHN to cover past patent expenses and agreed to pay future direct patent costs related to AHN Patent Rights. We are also required to pay AHN a low single-digit royalty on net sales of products utilizing the AHN Patent Rights through the first quarter of 2024 sold by us or our affiliates, subject to adjustment in certain circumstances. Beginning in the second quarter of 2024, we are required to pay AHN an increased low single-digit royalty or a flat annual minimum royalty amount, which royalty obligations continue for each licensed product on a country-by-country basis until the expiration of the last licensed patent covering the applicable licensed product in such country, pending approvals and commercialization, or the earlier termination of the agreement (excluding payment obligations accruing prior to such termination).

In the event we sublicense any of the AHN Patent Rights, we are obligated to pay AHN a mid double-digit percentage of any sublicense income, whether in the form of royalties or sub-license fees.

The agreement requires that we diligently develop and commercialize products that are covered by the AHN Patent Rights. If, no earlier than May 2023, we elect not to pursue intellectual property rights or expand commercialization to certain territories within a commercially reasonable period, AHN may pursue other licenses and terminate our exclusive license with respect to such territories upon 30 days prior written notice.

We may terminate the agreement upon 60 day written notice to AHN provided we pay a specified termination fee. AHN may terminate the agreement in the event of our nonperformance of any of our material 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 insolvency. Absent early termination, the agreement will continue until expiration date of the longest-lived patent right included in the AHN Patent Rights.

In addition, we entered into a master research collaboration agreement with AHN, focused on the development of novel patented biomarkers for diagnosis, prognosis and monitoring of autoimmune diseases, including SLE. The agreement has a three-year initial term, expiring May 2024, with renewals thereafter for successive one-year terms upon mutual agreement with AHN. Each party may terminate the agreement upon 60 days' notice to the other party. We are required to pay AHN a collaboration fee of \$0.4 million for each year of the agreement and AHN is required to make an in-kind contribution equivalent of \$0.3 million for the initial term and each subsequent one-year term, if any.

#### *Exclusive License Agreement and Collaboration Agreement with Queen Mary University of London*

In November 2021, we entered into an exclusive license agreement with Queen Mary University of London, or QMUL, under which we obtained an exclusive license to QMUL's patent-pending inventions, or the QMUL Patent Rights, related to diagnosis and/or development of diagnostic or companion diagnostics for rheumatoid arthritis.

Under the agreement, we are permitted to make, use and sell products and services utilizing the QMUL Patent Rights and to sublicense such rights; provided, however, that any such sublicenses may only be granted with QMUL's consent. QMUL retained the right to practice under the QMUL Patent Rights and to use such rights for teaching, research, education, public service, clinical and other research-related purposes.

In consideration for the rights granted to us under the agreement, we paid an initial license fee to QMUL and payment of past patent expenses and ongoing patent expenses. We are required to make a \$0.1 million milestone payment upon the first commercial sale of products utilizing the QMUL Patent Rights. In addition, after the first 18 months of commercial sales under the terms of the exclusive license agreement, we are required to pay royalties in the low to high single-digits on net sales of testing products using the assigned patents, pending approvals and commercialization.

In the event we sublicense any of the QMUL Patent Rights, we are obligated to pay QMUL a double-digit percentage of sublicensing income, whether in the form of royalties or sub-license fees.

The agreement requires that we diligently develop and commercialize products that are covered by the QMUL Patent Rights. QMUL may terminate the agreement if we fail to develop the QMUL Patent Rights in the field of diagnosis and/or development of diagnostic or companion diagnostics for rheumatoid arthritis, QMUL may convert our license to non-exclusive.

We may terminate the agreement upon 6 month written notice to QMUL. QMUL may terminate the agreement in the event of our nonperformance of any of our material 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 insolvency. Absent early termination, the agreement will continue for a period of 20 years after the first commercial sale of any licensed product utilizing the QMUL Patent Rights.

In addition, we entered into a collaboration agreement with QMUL for a three-year term, expiring November 2024. The collaboration will focus on development and optimization of patent-pending precision medicine approaches, based on RNA expression signatures, to personalize therapeutic agent selection for RA patients. We or QMUL may terminate the master research collaboration agreement upon 30-day written notice.

## **Regulations**

### *Clinical Laboratory Improvement Amendments of 1988*

As a clinical 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 certification to be eligible to bill for diagnostic services provided to Medicare beneficiaries. Many commercial third-party payors also require CLIA certification as a condition of payment.

Our Vista facility holds a current CLIA certificate. To renew our CLIA certificate, we are subject to survey and inspection every two years to assess compliance with program standards. We elect to participate in the accreditation program of CAP. CMS has deemed CAP standards to be equally or more stringent than CLIA regulations and has approved CAP as a recognized accrediting organization. Inspection by CAP is performed in lieu of inspection by CMS for CAP-accredited laboratories. Because we are accredited by the CAP Laboratory Accreditation Program, we are deemed to also comply with CLIA. 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 or CAP requirements include suspension, limitation or revocation of the laboratory's CLIA or CAP certificate, as well as a directed plan of correction, state on-site monitoring, civil money penalties, civil injunctive suit or criminal penalties, as applicable.

#### *State Laboratory Licensing*

Our Vista facility also holds a state license issued by the California Department of Public Health, or DPH. California law and regulations establish standards for the day-to-day operation of a clinical laboratory, including the training and skills required of laboratory personnel and quality control. In addition, California laws and regulations also mandate proficiency testing, which involves testing of specimens that have been specifically prepared for the laboratory for quality control purposes.

Because we receive specimens from New York, our Vista facility also is required to be licensed by the New York State Department of Health, or NYDOH. New York laws and regulations establish standards in a variety of operational areas, including:

- day-to-day operation of the 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 or outside of New York. If a laboratory is out of compliance with New York's statutory or regulatory standards, the 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. New York's law and regulations are more stringent than CLIA in certain respects. For example, NYDOH must approve an LDT before it 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 and Certain Devices*

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. We perform our tests like AVISE<sup>®</sup> CTD, AVISE<sup>®</sup> SLE Prognostic and AVISE<sup>®</sup> MTX assays in our Vista, California clinical laboratory, and they are primarily regulated under CLIA, as administered by CMS, as well as by applicable state laws, as described above. The FDA regulates diagnostic tests that meet the definition of a medical device, except under specific, narrow circumstances. The Federal Food, Drug and Cosmetic Act, or FDCA, defines a medical device as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory, which is, among other things: 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 and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes." By this definition, in vitro reagents and diagnostic tests are considered medical devices. Specifically, the FDA defines an in vitro diagnostic test, or IVD, as "reagents, instruments, and systems



intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae." Therefore, the FDA generally considers our testing products to be IVDs subject to the agency's regulatory requirements. 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, including IVDs, 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.

The FDCA classifies medical devices into one of three categories based on the risks associated with the device and the level of control necessary to provide reasonable assurance of safety and effectiveness. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices or devices deemed not substantially equivalent to a previously 510(k) cleared device, are categorized as Class III. These devices typically require submission and approval of a premarket approval application, or PMA. Devices deemed to pose lower risk are categorized as either Class I or II, which requires the manufacturer to submit to the FDA a 510(k) premarket notification submission requesting clearance of the device for commercial distribution in the United States. Some low-risk devices are exempted from this requirement. When a 510(k) premarket notification submission is required, the manufacturer must submit to the FDA a premarket notification submission demonstrating that the device is "substantially equivalent" to: (i) a device that was legally marketed prior to May 28, 1976, for which PMA approval is not required, (ii) a legally marketed device that has been reclassified from Class III to Class II or Class I, or (iii) another legally marketed, similar device that has been cleared through the 510(k) clearance process.

After the FDA permits a device to enter commercial distribution, numerous regulatory requirements apply. These include: the Quality System Regulation, which requires manufacturers to follow elaborate design, testing, control, documentation and other quality assurance procedures during the manufacturing process; labeling regulations; the FDA's general prohibition against promoting products for unapproved or "off-label" uses; and 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. The FDA has broad post-market and regulatory and enforcement powers. Failure to comply with the applicable U.S. medical device regulatory requirements could result in, among other things, warning letters, fines, injunctions, consent decrees, civil penalties, repairs, replacements, refunds, recalls or seizures of products, total or partial suspension of production, the FDA's refusal to grant future premarket clearances or approvals, withdrawals or suspensions of current product applications, and criminal prosecution.

Although the FDA has statutory authority to assure that medical devices, including IVDs, are safe and effective for their intended uses, the FDA has generally exercised its enforcement discretion and not enforced applicable regulations with respect to IVDs that are designed, manufactured, and used within a single high-complexity CLIA-certified laboratory for use only in that laboratory. Such tests are referred to as laboratory developed tests, or LDTs. We believe that all of our AVISE<sup>®</sup> test products are LDTs, as are our near-term pipeline candidate tests. As a result, we believe 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.

Even though we commercialize our tests as LDTs, our tests may in the future become subject to more onerous regulation by the FDA. For example, in 2017, the FDA published a Discussion Paper on Laboratory Developed Tests to further public discussion about an appropriate LDT oversight approach and to give congressional committees the opportunity to develop a legislative solution to the competing interests of ensuring the public health and promoting innovation in the clinical testing industry. However, in August 2020, the United States Department of Health and Human Services, or HHS, published a policy announcement that FDA must go through the formal notice-and-comment rulemaking process before requiring premarket review of LDTs rather than making such changes through guidance documents, compliance manuals, or other informal policy statements. HHS's policy statement did not affect proposed legislation for the regulation of LDTs, which is discussed below. In November 2021, the Biden Administration withdrew that HHS policy announcement and ostensibly restored FDA's regulatory oversight of LDTs.

In December 2018, members of Congress released a discussion draft of a possible bill to regulate in vitro clinical tests including LDTs, and provided opportunities for additional stakeholders to also provide input on the proposed reform legislation. On March 5, 2020, U.S. Representatives Diana DeGette (D-CO) and Dr. Larry Bucshon (R-IN) formally introduced the long-awaited legislation, called the Verifying Accurate, Leading-edge IVCT Development, or VALID Act. An identical version of the bill was introduced concurrently in the Senate, demonstrating both bicameral and bipartisan support for the effort to overhaul how the FDA reviews and approves diagnostic tests going forward. The VALID Act would codify into law the term "in vitro clinical test", or IVCT, to create a new medical product

category separate from medical devices that includes products currently regulated as IVDs as well as LDTs. The VALID Act would also create a new system for labs and hospitals to use to submit their tests electronically to the FDA for approval, which is aimed at reducing the amount of time it takes for the agency to approve such tests, and establish a new program to expedite the development of diagnostic tests that can be used to address a current unmet need for patients. A substantively unchanged version of the VALID Act was re-introduced in both houses of Congress on June 24, 2021.

It is unclear whether the VALID Act would be passed by Congress in its current form or signed into law by the President. Until the FDA finalizes its position on regulation of LDTs through formal notice-and-comment rulemaking, or the VALID Act or other federal legislation is passed reforming the government's regulation of LDTs, or alternatively, if the FDA disagrees with our assessment that our tests fall within the definition of an LDT, we could be subject to enforcement of regulatory requirements such as registration and listing requirements, medical device reporting requirements and quality control requirements. Any new legislation or formal FDA regulations affecting LDTs may result in increased regulatory burdens on our ability to continue marketing our tests and to develop and introduce new tests in the future. Additionally, if and when the FDA begins to actively enforce its premarket submission regulations with respect to LDTs generally or our tests in particular, whether as a result of new legislative authority or following formal notice-and-comment rulemaking, we may be required to obtain premarket clearance for our tests under Section 510(k) of the FDCA or approval of a PMA. The process for submitting a 510(k) premarket notification and receiving FDA clearance usually takes from three to 12 months, but it can take significantly longer and clearance is never guaranteed. The process for submitting and obtaining FDA approval of a PMA generally takes from one to three years or even longer and approval is not guaranteed. PMA approval typically requires extensive clinical data and can be significantly longer, more expensive and more uncertain than the 510(k) clearance process. If premarket review is required for some or all of our tests, the FDA could require that we stop selling our products pending clearance or approval and conduct clinical testing prior to making submissions to FDA to obtain premarket clearance or approval. The FDA could also require that we label our tests as investigational or limit the labeling claims we are permitted to make.

We also distribute the AVISE® Touch blood specimen collection kit for collection and transport of blood samples from a healthcare provider to our laboratory. The kit includes a blood specimen collection device that was designed and is manufactured for us by a third-party manufacturer, as well as a biohazard bag and a prepaid envelope for shipping the sample and instructions for use. The FDA regulates a kit that contain multiple copackaged but independent medical devices as a "convenience kit," which is considered a separate medical device from the individual kit components. Many types of convenience kits do not require marketing authorization because the FDA exercises enforcement discretion for such requirements, but they must meet FDA's general controls for medical devices, including that they be manufactured in compliance with applicable quality system regulations for medical devices and adhere to device labeling requirements, among other regulatory controls.

#### *Regulation of Clinical Trials*

We have also conducted and may in the future conduct studies for our AVISE® tests and our other tests in development that involve clinical investigators at sites in the U.S. We may need to conduct additional studies for the AVISE® tests, as well as other tests we may offer in the future, to drive test adoption in the marketplace and reimbursement. Should we not be able to perform these studies, or should their results not provide clinically meaningful data and value for clinicians, adoption of our tests could be impaired and we may not be able to obtain reimbursement for them.

The conduct of clinical trials is also subject to extensive federal and institutional regulations intended to assure that the data and reported results are credible and accurate and that the rights, safety, and welfare of study participants are protected. Most studies involving human participants must be reviewed and approved by, and conducted under the auspices of, a duly-constituted institutional review board, or IRB, which is a multi-disciplinary committee responsible for reviewing and evaluating the risks and benefits of a clinical trial for participating subjects and monitoring the trial on an ongoing basis. Companies sponsoring the clinical trials and investigators also must comply with, as applicable, regulations, guidelines and IRB requirements for obtaining informed consent from the study subjects, following the protocol and investigational plan, adequately monitoring the clinical trial, and timely reporting of adverse events. The sponsoring company or the IRB may suspend or terminate a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk. In addition, studies involving human participants often require significant time and cash resources to complete and are subject to a high degree of risk, including risks of experiencing delays, failing to complete the trial or obtaining unexpected or negative results.

#### *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 of 1933, or PORA, and other comparable state laws. The Stark Law generally prohibits us from billing a patient or any governmental or private payor for certain designated health services, including clinical laboratory services, when the physician ordering the service, or any member of such physician's immediate family, has a financial interest, such as an ownership or investment interest in or compensation arrangement with us, unless the arrangement meets an exception to the prohibition.

Sanctions for a Stark Law violation include the following:

- denial of payment for the services provided in violation of the prohibition;
- refunds of amounts collected 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 penalties of up to three times the amounts assessed for each item or service wrongfully claimed; and
- possible exclusion from federal healthcare programs, including Medicare and Medicaid.

The Stark Law applies regardless of any intent by the parties to induce or reward referrals or the reasons for the financial relationship and the referral. In addition, 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 penalties.

Similarly, PORA makes it unlawful for a physician or certain other healing arts licensees to refer a person for certain healthcare services, including clinical laboratory services, if the licensee has a financial interest with the person or entity that receives the referral, unless an exemption is met. Unlike the Stark Law, PORA applies regardless of the source of payment. PORA also prohibits the submission of claims for services provided pursuant to a prohibited referral, and violation of this prohibition constitutes a public offense and is punishable upon conviction by a fine not exceeding fifteen thousand dollars (\$15,000) for each violation and appropriate disciplinary action. 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 PORA.

#### *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 or in return for the referral of an individual for the furnishing of, or the recommending or arranging for the furnishing of, purchasing, leasing, ordering or arranging for or recommending purchasing, leasing or ordering of any item or service that is reimbursable in whole or in part, under any federal healthcare program. 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. Courts have broadly interpreted the scope of the Anti-kickback Statute and generally have held that the statute may be violated if merely one purpose of a payment arrangement is to induce referrals.

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 or exception, it is deemed not to violate the Anti-Kickback Statute, and the parties are immune from prosecution. 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 an exception or the safe harbor 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.

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 healthcare programs for a minimum of five years. In addition, a violation of the Anti-kickback Statute can serve as the basis of liability under the federal False Claims Act, which is discussed in greater detail below.

Although the Anti-kickback Statute applies only to items and services reimbursable under any federal healthcare program, a number of states, including California, have passed statutes substantially similar to the Anti-Kickback Statute that apply to all third-party payors, including commercial insurers, and, in some states, to patients without insurance. The California Attorney General and courts have interpreted the California anti-kickback and fee-splitting

laws in substantially the same way as HHS and the courts have interpreted the Anti-Kickback Statute. Penalties under such state laws include imprisonment and significant monetary fines.

In addition, in October 2018, the Eliminating Kickbacks in Recovery Act of 2018, or EKRA, was enacted as part of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act. EKRA is an all-payor anti-kickback law that makes it a criminal offense to pay any remuneration to induce referrals to, or in exchange for, patients using the services of a recovery home, a substance use clinical treatment facility, or laboratory. However, unlike the Anti-Kickback Statute, EKRA is not limited to services covered by federal or state healthcare programs but applies more broadly to services covered by "healthcare benefit programs," including private third-party payors. Although EKRA apparently was intended to reach patient brokering and similar arrangements to induce patronage of substance use recovery and treatment, the language in EKRA is broadly written. Further, certain of EKRA's exceptions are inconsistent with the Anti-Kickback Statute and regulations. EKRA permits the U.S. Department of Justice to issue regulations clarifying EKRA's exceptions or adding additional exceptions, but such regulations have not yet been issued.

#### *Other Federal and State Health Care Laws*

In addition to the requirements discussed above, several other healthcare fraud and abuse laws could have an effect on our business. For example, federal law permits the Office of Inspector General for the Department of Health and Human Services to exclude an individual or entity from Medicare or Medicaid for charging Medicare or state healthcare programs, such as Medicaid, substantially in excess of its usual charges for its items or services absent a finding of good cause. 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 to 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 pursuant to its qui tam provisions. Because the complaint in a qui tam action 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 relator succeeds in obtaining redress without the government's involvement, then the relator will receive a percentage of the recovery. In addition, providers and suppliers must report and return any overpayments received from the Medicare and Medicaid programs within 60 days of identification, and failure to identify and return such overpayments exposes the provider or supplier to False Claims Act liability. Violation of the False Claims Act may result payment of up to three times the actual damages sustained by the government, plus significant per-claim civil penalties. Several states, including California, have enacted comparable false claims laws that may be broader in scope and may apply regardless of payor.

The federal civil monetary penalties law, or the CMP Law, prohibits, among other things, (1) the offering or transfer of remuneration (including a waiver of copayments and deductible amounts) to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies; (2) employing or contracting with an individual or entity that the provider knows or should know is excluded from participation in a federal healthcare program; (3) billing for services requested by an unlicensed physician or an excluded provider; (4) billing for medically unnecessary services; and (5) presenting or causing 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 penalties for violating the CMP Law include exclusion, substantial fines, and payment of up to three times the amount billed, depending on the nature of the offense. A person who offers or provides to a Medicare or Medicaid beneficiary any remuneration, including waivers of copayments 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, or coinsurance for Medicare, and deductibles for Medicare and Medicaid beneficiaries can also be held liable under the Anti-Kickback Statute and False Claims Act. One of the statutory exceptions to the prohibition is non-routine, unadvertised waivers of copayments or deductible amounts based on individualized determinations of financial need or exhaustion of reasonable collection efforts. The Office of Inspector General of HHS, or OIG, emphasizes, however, that this exception should only be used occasionally to address special financial needs of a particular patient. Although this prohibition applies only to federal healthcare program beneficiaries, applicable state laws related to, among other things, unlawful schemes to defraud, excessive fees for services, tortious interference with patient contracts and statutory or common law fraud, may also be implicated for similar practices offered to patients covered by commercial payors.

Federal criminal statutes prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including those administered by private third-party payors, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the Anti-Kickback Statute, this federal criminal statute requires a showing of intent, but 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 Physician Payments Sunshine Act imposes 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 healthcare providers (such as nurse practitioners), 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.

We are also subject to applicable state restrictions on laboratory billing. These laws vary from state to state but generally are intended to prevent a provider who ordered but did not perform the service from billing for that service at a markup. For example, California has an anti-markup statute with which we must comply, which prohibits a provider from charging for any laboratory test that it did not perform unless the provider (a) notifies the patient, client or customer of the name, address, and charges of the laboratory performing the test, and (b) charges no more than what the provider was charged by the clinical laboratory that performed the test except for any other service actually rendered to the patient by the provider (for example, specimen collection, processing and handling). This provision applies, with certain limited exceptions, to licensed persons such as physicians and clinical laboratories regulated under California's Business and Professions Code. A violation of this provision can lead to imprisonment and/or a fine of up to \$10,000. Other states have similar anti-markup and other client billing restrictions with which we must comply. Many states also have "direct-bill" laws, which require the party that performed the service to bill for the service, with certain exceptions.

If our operations are found to be in violation of any of the fraud and abuse laws described above or any other healthcare regulatory 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 healthcare program. In situations involving physicians employed by state-funded institutions or national healthcare agencies, violation of the local anti-kickback law may also constitute a violation of the U.S. Foreign Corrupt Practices Act, or FCPA, and/or other applicable anti-corruption laws.

The FCPA prohibits any U.S. individual, business entity or employee of a U.S. business entity from offering or providing, directly or through a third party, including any potential distributors we may rely on in certain markets, anything of value to a foreign official with corrupt intent to influence an award or continuation of business or to gain an unfair advantage, whether or not such conduct violates local laws. In addition, it is illegal for a company that reports to the SEC to have false or inaccurate books or records or to fail to maintain a system of internal accounting controls. We will also be required to maintain accurate information and control over sales and distributors' activities that may fall within the purview of the FCPA, including its books and records provisions and its anti-bribery provisions.

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

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

### *Privacy and Security Laws*

#### *U.S. Data Privacy and Security Laws*

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, established comprehensive federal standards for the privacy and security of health information. In 2009, Congress enacted Subtitle D of the Health Information Technology for Economic and Clinical Health Act, or HITECH provisions of the American Recovery and Reinvestment Act of 2009. HITECH amended HIPAA and, among other things, expanded and strengthened HIPAA, created new targets for enforcement, imposed new penalties for noncompliance and established new breach notification requirements. HIPAA applies to health plans, healthcare clearing houses, and healthcare providers that conduct certain healthcare transactions electronically, which we refer to collectively as Covered Entities, as well as individuals or entities that perform services for them involving the use, or disclosure of, individually identifiable health information or "protected health information" under HIPAA. Such service providers are called "Business Associates." Under HIPAA, as amended by the HITECH Act, HHS has issued regulations to protect the privacy and security of protected health information, or PHI, used or disclosed by Covered Entities and Business Associates. HIPAA also regulates and standardizes the codes, formats and identifiers used in certain healthcare transactions and standardization of identifiers for health plans and providers, for example insurance billing. Any non-compliance with HIPAA and HITECH and related penalties, could adversely impact our business.

The HIPAA security standards require the adoption of administrative, physical, and technical safeguards and the adoption of written security policies and procedures to maintain the security of protected health information.

The HIPAA privacy regulations address the privacy of PHI by limiting the use and release of such information. 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, request an accounting of disclosures of PHI or to request restrictions on the use or disclosure of PHI. Proposed modifications to the privacy regulations were published in January of 2021 with a public comment period that ended in May of 2021. The content of any final rules and their potential impact on us is unknown. The HIPAA breach notification regulations impose certain reporting requirements on covered entities and their business associates in the event of a breach of PHI.

Covered entities must report breaches of PHI that has not been encrypted or otherwise secured in accordance with guidance from the Secretary of HHS, or the Secretary. Breaches must be reported as soon as reasonably practicable, but no later than sixty days following discovery of the breach. Reports must be made to affected individuals, the HHS Secretary, and depending on the size of the breach, the local and national media. Covered Entities like us are also subject the HHS HIPAA audit program and may be investigated in connection with a privacy or data security complaint.

Significant civil and criminal fines and other penalties may be imposed for violating HIPAA directly, and in connection with acts or omissions of any agents, including a downstream business associates, as determined according to the federal common law of agency. Civil penalties are adjusted for inflation on an annual basis and can exceed one million dollars per year for failure to comply with a HIPAA requirement. A single breach incident can violate multiple requirements. Additionally, a person who knowingly obtains or discloses PHI in violation of HIPAA may face a criminal penalties (including fines and imprisonment), which increase if the wrongful conduct involves false pretenses or the intent to sell, transfer or use PHI for commercial advantage, personal gain or malicious harm. Covered entities are also subject to enforcement by state attorneys general who were given authority to enforce HIPAA.

Additionally, 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.

Further, to the extent that we submit electronic healthcare claims and payment transactions that do not comply with the transaction standards established under HIPAA and HITECH, payments to us may be delayed or denied.

Even when HIPAA does not apply, according to the FTC, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a)

of the Federal Trade Commission Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. The FTC and states' Attorneys General have also brought enforcement actions and prosecuted some data breach cases as unfair and/or deceptive acts or practices under the FTC Act and comparable state laws.

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. Certain state laws govern the privacy and security of health-related and other personal information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. The State of California, for example, has implemented comprehensive laws and regulations. The California Confidentiality of Medical Information Act, or CMIA, imposes restrictive requirements regulating the use and disclosure of health information and other personally identifiable information. California has also recently adopted the California Consumer Privacy Act of 2018, or the CCPA, which went into effect January 1, 2020. The CCPA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. It also creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Although the law includes limited exceptions, including for PHI maintained by a covered entity or business associate under HIPAA and medical information maintained by healthcare providers under the CMIA, it may regulate or impact our processing of personal information depending on the context. Further, the California Privacy Rights Act, or CPRA, recently passed in California. The CPRA will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required.

Numerous other federal and state laws, including consumer protection laws and regulations, govern the collection, dissemination, use, access to, confidentiality and security of patient health information. In addition, Congress and some states are considering new laws and regulations that further protect the privacy and security of medical records or medical information. With the recent increase in publicity regarding data breaches resulting in improper dissemination of consumer information, all 50 states have passed laws regulating the actions that a business must take if it experiences a data breach, as defined by state law, including prompt disclosure within a specified amount of time to affected individuals. In addition to data breach notification laws, some states have enacted statutes and rules requiring businesses to reasonably protect certain types of personal information they hold or to otherwise comply with certain specified data security requirements for personal information. Congress has also been considering similar federal legislation relating to data privacy and data protection.

Many states, such as Massachusetts, have also implemented genetic testing and privacy laws imposing specific patient consent requirements and requirements for protecting test results. The interplay of federal and state laws regulating genetic information may be subject to varying interpretations by courts and government agencies, creating complex compliance issues for us and potentially exposing us to additional expense, adverse publicity, and liability. Further, as regulatory focus on genetic privacy issues continues to increase and laws and regulations concerning the protection of personal information expand and become more complex, these potential risks to our business could intensify.

#### *Information Blocking Rules*

The National Coordinator for Health Information Technology, or ONC, coordinates the ongoing development of standards to enable interoperable health information technology infrastructure nationwide in the healthcare sector. In May 2020, ONC released the final Information Blocking Rule to implement the interoperability and patient access provisions of the 21st Century Cures Act. We will need to continually review our practices for conduct that could be considered as likely to interfere with access, exchange or use of electronic health information, as those practices are prohibited by the Information Blocking Rule, unless one of the exceptions outlined in the Information Blocking Rule applies. Among other things, the Information Blocking Rule requires us to provide patients with on-demand access to laboratory test results. These requirements can be inconsistent with our obligations as a laboratory under

state law and/or medical or ethical standards. It is currently unclear how the ONC will approach delays in providing patient access in these situations. Health care providers including laboratories will be subject to civil monetary penalties for violations of the Information Blocking Rule once the penalty regulations are finalized; the proposed rule allows for up to \$1 million in penalties per violation.

#### *GDPR and Foreign Laws*

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

#### **Billing and Government Reimbursement for Clinical Laboratory Services**

Medicare coverage is limited to items and services that are within the scope of a Medicare benefit category that are reasonable and necessary for the diagnosis or treatment of an illness or injury. With respect to Medicare coverage, Palmetto GBA, the Medicare Administrative Contractor, or MAC, responsible for administering Medicare's molecular diagnostic services program, or MoIDX Program, issued a local coverage determination, or LCD, that provides coverage for our AVISE<sup>®</sup> 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 substantially changed the way in which Medicare sets the payment amounts for clinical laboratory services. Under PAMA, laboratories that receive the majority of their Medicare revenue from payments made under the CLFS or the Physician Fee Schedule are required to report to CMS, beginning in 2017 and every three years thereafter (or annually for "advanced diagnostic laboratory tests"), private payor payment rates and volumes for their tests. Laboratories that fail to report the required payment information may be subject to substantial civil monetary penalties. As required under PAMA, CMS uses the rates and volumes reported by laboratories to develop Medicare payment rates for laboratory tests equal to the volume-weighted median of the private payor payment rates for the tests.

On June 23, 2016, CMS published the final rule implementing the reporting and rate-setting requirements under PAMA. For tests furnished on or after January 1, 2018, Medicare payments for clinical diagnostic laboratory tests are based upon these reported private payor rates. For clinical diagnostic laboratory tests, or CDLTs, that are assigned a new or substantially revised CPT code, CMS will set the initial payment rates using the gap-fill



methodology, as under prior law. Initial payment rates for new advanced diagnostic laboratory tests, or ADLTs, will be based on the actual list charge. Any reductions to payment rates resulting from the new methodology are limited to up to 10% per test per year in each of the years 2018 through 2020 and up to 15% per test per year in each of the years 2021 through 2023. PAMA did not impact Medicare reimbursement for AVISE<sup>®</sup> CTD in 2021 compared to levels experienced in 2020. Additionally, PAMA and changes to the Physician Fee Schedule will not have a significant impact to Medicare reimbursement for AVISE<sup>®</sup> CTD in 2022 compared to levels experienced in 2021. The Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, signed into law on March 27, 2020 provides clinical laboratories a one-year reprieve from reporting requirements under the Protecting Access to Medicare Act, as well as a one-year delay of rate cuts scheduled to take place next year. Reporting was not required between January 1, 2020 to December 31, 2022. Instead, it is required between January 1, 2023 and March 31, 2023. Additionally, the next round of rate cuts was delayed until 2022 to 2023, with tests receiving cuts of up to 15% a year from 2023 through 2025.

On December 20, 2019, the Further Consolidated Appropriations Act, which included the Laboratory Access for Beneficiaries Act, or LAB Act, took effect. The LAB Act delayed by one year the reporting of payment data under PAMA for CDLTs that are not ADLTs until the first quarter of 2021. The Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, which was signed into law on March 27, 2020, delayed the reporting period by an additional year, until the first quarter of 2022. Then, on December 10, 2021, Congress passed the Protecting Medicare and American Farmers from Sequester Cuts Act, which included a provision that further delayed the next PAMA reporting period for CDLTs that are not ADLTs to January 1, 2023 through March 31, 2023. New CLFS rates for CDLTs will be established based on that data beginning in 2024, subject to phase-in limits. As a result, Medicare payment rates determined by data reported in 2017 will continue through December 31, 2023. In addition, under PAMA, as amended, the payment reduction cap will be 15% per test per year in each of the years 2023 through 2025.

PAMA also authorized the adoption of new, temporary billing codes and unique test identifiers for FDA-cleared or approved tests, as well as ADLTs. 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 a particular test. The AMA publishes approved codes on a quarterly basis. While our testing products are not presently identified by any PLA codes, we may seek a specific PLA code or codes to describe some of our testing products in the future.

Billing for diagnostic testing can be complicated. Depending on the billing arrangement and applicable law, we must bill various payors, such as insurance companies, Medicare, Medicaid, physicians, hospitals, employer groups and patients, all of which have different billing requirements. Additionally, compliance with applicable laws and regulations as well as internal compliance policies and procedures adds further complexity to the billing process. Changes in laws and regulations could negatively impact our ability to bill our clients or increase our costs. CMS also establishes new procedures and continuously evaluates and implements changes to the reimbursement process for billing government healthcare 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 United States. The ACA made a number of substantial changes to the way healthcare is financed both by governmental and private payors. Although the ACA included a medical device tax, the tax never went into effect and was fully repealed by Congress with enactment of the 2019 federal spending package signed into law by President Trump on December 20, 2019.

Since the ACA's enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and as a result, certain sections of the ACA have not been fully implemented or were effectively repealed. However,

following several years of litigation in the federal courts, in June 2021, the United States Supreme Court, or the Supreme Court, upheld the ACA when it dismissed a legal challenge to the Act's constitutionality. Further legislative and regulatory changes under the ACA remain possible, although the new Democrat-led presidential administration has been taking steps to strengthen the ACA and the 117th Congress is not expected to have the same interest in repealing the law, in part due to the healthcare economic impacts of the ongoing COVID-19 pandemic on many subsets of the U.S. population. Future changes or additions to the ACA, the Medicare and Medicaid programs, such as changes allowing the federal government to directly negotiate drug prices, and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry in the U.S. The uncertainty around the future of the ACA, and in particular the impact to reimbursement levels and the number of insured individuals, may lead to delay in the purchasing decisions of our customers.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which went into effect on April 1, 2013, and due to subsequent legislative amendments to the statute, will remain in effect through 2030, unless additional Congressional action is taken. The Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") which was signed into law on March 27, 2020, designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030, in order to offset the added expense of the 2020 cancellation. Congress subsequently extended the sequester suspension period to June 30, 2022, with a 1% sequester in effect from April 1, 2022 to June 30, 2022. In addition, the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to certain providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additional state and federal healthcare reform measures may also be adopted in the future, any of which could have a material adverse effect on the clinical laboratory industry.

### **Environmental and Other Regulatory Requirements**

Our laboratory is subject on an ongoing basis to federal, state and local laws and regulations governing the use, storage, handling and disposal of regulated medical waste, hazardous waste and biohazardous waste, including chemicals, biological agents and compounds and blood and other tissue specimens. Typically, we use licensed or otherwise qualified outside vendors to dispose of this waste. However, many of these laws and regulations provide for strict liability, holding a party potentially liable without regard to fault or negligence. As a result, we could be held liable for damages and fines if our, or others', business operations or other actions result in contamination of the environment or personal injury due to exposure to hazardous materials. Our costs for complying with these laws and regulations cannot be estimated or predicted and depends on a number of factors, including the amount and nature of waste we produce (which depends in part on the number of tests we perform) and the terms we negotiate with our waste disposal vendors. In 2021, we disposed of all hazardous and/or medical waste that we produced across our entire business through environmentally sound methods.

Our operations are also subject to extensive requirements established by the U.S. Occupational Safety and Health Administration relating to workplace safety for healthcare employees, including requirements to develop and implement programs to protect workers from exposure to blood-borne pathogens by preventing or minimizing any exposure through needle stick or similar penetrating injuries.

### **Human Capital**

As of December 31, 2021, we had 219 full-time employees, and 3 part-time employees in the United States. These included 47 in laboratory operations, 20 in research and development, 83 in sales and marketing and 69 in general and administrative functions. None of our employees is represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

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

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

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

To address the safety and health of our workforce due to the COVID-19 pandemic, we created a committee consisting of six members of our management team and implemented the following, among other steps:

- Established new safety protocols and procedures;
- Maintained regular communication regarding the impacts of the pandemic on our employees and operations;
- Developed and distributed a playbook to guide the safe return to offices, communities, and work sites;
- Provided paid time-off for those directly impacted by COVID-19, and instructed those who were infected to stay home;
- Increased sanitation protocols across the entire campus;
- Established physical distancing procedures, modified workspaces; and provided personal protective equipment and cleaning supplies for employees who needed to be onsite; and
- Created and refined protocols to address actual and suspected COVID-19 cases and potential exposures of our employees, customers, and trade partners.

We conduct periodic anonymous employee surveys aimed at measuring the overall satisfaction of our team and address issues brought to our attention, such as adherence to social distancing standards and vaccination acceptance. The results consistently show that our employees believe in our mandate and consider their work valuable and meaningful.

### **Diversity and Inclusion**

Our organization recognizes the importance of diversity and inclusion in recruiting, developing and retaining the best available talent. We are committed to further understand and build upon our diversity and inclusion strengths and are in the process of identifying opportunities and developing initiatives.

As of December 31, 2021, our employees were 59.5% female and 40.5% male. Our overall employee population as of December 31, 2021 was 57.6% White, 20.7% Hispanic or Latino, 13.2% Asian, 3.5% Native Hawaiian or other Pacific Islander, 3.0% Black or African-American and 2.0% two or more races (not Hispanic or Latino) and other. In executive positions, which we define as Senior Vice President and above, our employee population as of December 31, 2021 was 85.7% White and 14.3% Asian. Females represented 28.5% of employees in executive positions. In addition, three of our nine Board of Directors are female and two directors are Hispanic or Latino as of December 31, 2021. We are continuing to further assess and understand additional measures of diversity.

### **Environmental, Social and Governance Matters**

In 2020, we undertook a review of our environmental, social and governance, or ESG, matters. In 2021, we released our initial Sustainability Report. In 2022, we created an Environmental, Social and Governance Committee, or the ESG Committee, with the purpose, duties and responsibility to reviewing and recommending our ESG programs, policies and practices relating to ESG issues. The ESG Committee meets formally at least quarterly and plans to make recommendations to our President and Chief Executive Officer to be presented to the Audit Committee of our Board of Directors. For more information regarding our ESG initiatives, please refer to [www.exagen.com/investors](http://www.exagen.com/investors).

## 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, 2021 and 2020 and our total assets as of December 31, 2021 and 2020, is included in our Financial Statements in Item 8 of this Annual Report.

## Corporate Information

We were incorporated under the laws of the state of New Mexico in 2002, under the name Exagen Corporation. In 2003, we changed our state of incorporation from New Mexico to Delaware by merging with and into Exagen Diagnostics, Inc., pursuant to which we change our name to Exagen Diagnostics, Inc. In January 2019, we changed our name to Exagen Inc. Our principal executive offices are located at 1261 Liberty Way, Vista, California 92081. Our telephone number is (760) 560-1501. Our website address is [www.exagen.com](http://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](http://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.

## Item 1A. Risk Factors.

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

### Summary Risk Factors

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

- Our business is subject to risks arising from epidemic diseases, such as the continuing global pandemic of the COVID-19 coronavirus;
- We have a history of losses, we expect to incur net losses in the future and we may not be able to generate sufficient revenue to achieve and maintain profitability;
- In the near-term, we expect that our financial results will depend primarily on sales of our testing products, and we will need to generate sufficient revenue from these testing products to grow our business;
- Our future growth depends, in part, on our ability to execute on our strategy of integrating the promotion of our existing and future proprietary testing products with the promotion of therapeutics through third party collaborations and strategic partnerships, and we may be unsuccessful in our efforts to establish such relationships or our promotion efforts after any such relationships are established, which could adversely affect our ability to implement this strategy;

- If we are unable to secure and maintain partners for our integrated testing and therapeutics strategy, or if our future 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;
- We may be unable to manage our ongoing growth effectively, which could make it difficult to execute our business strategy;
- Our commercial success depends on attaining and maintaining significant market acceptance of our testing products and promoted therapeutics among rheumatologists, patients, third-party payors and others in the medical community;
- We rely on sole suppliers for some of the reagents, equipment and other materials used in our testing products, and we may not be able to fund replacements or transition to alternative suppliers;
- If we are unable to support demand for our current testing products or any of our future testing products or solutions, our business could suffer;
- If third-party payors do not provide coverage and adequate reimbursement for our testing products, or they breach, rescind or modify their contracts or reimbursement policies or delay payments for our testing products or promoted therapeutics, or if we or our partners are unable to successfully negotiate payor contracts, our commercial success could be compromised;
- If we are unable to compete successfully, we may be unable to increase or sustain our revenue or achieve profitability;
- Developing new testing products involves a lengthy and complex process, and we may not be able to commercialize on a timely basis, or at all, other testing products we are developing;
- If our sole laboratory facility becomes damaged or inoperable, we are required to vacate our existing facility or we are unable to expand our existing facility as needed, we will be unable to perform our testing services and our business will be harmed and, in addition, we are in the process of converting warehouse space into additional laboratory facilities, but this may not be successful;
- We may require substantial additional capital to finance our planned operations, which may not be available to us on acceptable terms or at all. Our failure to obtain additional financing when needed on acceptable terms, or at all, could force us to delay, limit, reduce or eliminate our product development programs, commercialization efforts or other operations;
- If we are unable to maintain intellectual property protection our competitive position could be harmed; and
- If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

### **Risks Related to Our Business and Strategy**

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

The current COVID-19 worldwide pandemic has presented substantial public health challenges and is affecting our employees, patients, physicians and other healthcare providers, communities and business operations, as well as the U.S. and global economies and financial markets. International and U.S. governmental authorities in impacted regions have taken actions in an effort to slow the spread of COVID-19, including issuing varying forms of "stay-at-home" orders, restricting business functions outside of one's home, restricting gatherings, restricting travel, and mandating social distancing and face coverings. While many jurisdictions have fully reopened or have begun a phased re-opening, the potential to return to prior restrictions remains if there are future increases (or, in some jurisdictions, continued increases) in new cases of COVID-19 or any of its viral variants, including the Delta and Omicron variants. The duration of any restrictions may also vary depending on the ultimate success of ongoing vaccination efforts. Even in areas where "stay-at-home" restrictions, masking and social distancing measures have been lifted and the number of COVID-19 cases have declined, some jurisdictions may re-impose these measures as and if variant strains emerge or cases rise. Many individuals remain cautious about resuming activities such as preventative-care medical visits. A pandemic, including COVID-19 or other public health epidemic, poses the risk that we or our employees, contractors, suppliers, third-party shipping carriers, government and third-party payors and other members of our supply chain may be prevented from conducting business activities for an indefinite period of time, including due to spread of the disease within these groups or due to shutdowns that may be requested or mandated by governmental authorities. As a result of COVID-19 related limitations and reordering of priorities across the U.S. healthcare system, a reduction in patient flow occurred and our test volumes began to

decrease in the second half of March 2020 and we experienced an AVISE® CTD volume decrease of approximately 5% in the year ended December 31, 2020 as compared to 2019. In the fourth quarter of 2020, our volume of AVISE® CTD tests delivered exceeded our pre-COVID-19 levels. For the three months ended December 31, 2021 as compared to the same period in 2020, we experienced an AVISE® CTD volume increase of approximately 19%. For the year ended December 31, 2021 as compared to the same period in 2020, we experienced an AVISE® CTD test volume increase of approximately 28%. However, the continued spread of COVID-19 and patient hesitancy in seeking preventative medical care, the extent of which are dependent on circumstances that are highly uncertain, may adversely affect testing volumes in future periods. Healthcare providers and patients have canceled or delayed scheduling, and for an extended period of time may continue to cancel or delay scheduling, standard wellness visits and other non-emergency appointments and procedures, contributing to a decline in orders of our testing products. Any economic downturn may also result in closures of the practices of our primary customers.

In addition, we believe there are several other important factors that have impacted, and that we expect will impact our operating performance and results of operations, including shutdowns of our facilities and operations as well as those of our suppliers and courier services, disruptions to the supply chain of material needed for our tests, our sales and commercialization activities and our ability to receive specimens and perform or deliver the results from our tests, delays in reimbursement and coverage decisions from Medicare and third-party payors and in interactions with regulatory authorities, as well as our inability to achieve or re-negotiate volume-based discounts with our key suppliers and to absorb fixed laboratory expenses. For example, we have experienced delays in patient enrollment for ongoing and planned clinical studies involving our tests, which may delay or prevent launch of future test products. Our sales force has been, and for an extended period of time may continue to be, limited to their in-person interactions with healthcare providers, and therefore, also limited their ability to engage in various types of healthcare provider education activities. The portion of our workforce which has been working remotely in an effort to reduce the spread of COVID-19, may be infected from the virus or otherwise impaired. We have also experienced delays, beginning in the first quarter of 2021, in procurement of our testing supplies due in part to disruptions to the global supply chain resulting from the COVID-19 pandemic, which may continue into the future, and our partners, may also experience a disruption in their ability to readily obtain supply. We are facing and may continue to face increased competition for laboratory and scientific employees due to the increased demand in the industry for such personnel. We may inaccurately estimate the duration or severity of the COVID-19 pandemic, which could cause us to misalign our staffing, spending, activities and precautionary measures with market current or future market conditions.

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

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

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

We have incurred net losses since our inception. For the years ended December 31, 2021 and 2020, we incurred net losses of \$26.9 and \$16.7 million, respectively, and we expect to incur additional losses in 2022 and in future years. As of December 31, 2021, we had an accumulated deficit of \$208.1 million. Over the next several years, we expect to continue to devote substantially all of our resources to increase adoption of, and reimbursement for, our testing products, to develop future testing products and intend to continue to pursue our integrated testing and therapeutics strategy. We have experienced and may continue to experience decreases in test volumes due to the impact of the COVID-19 pandemic. We may not be able to generate sufficient revenue to achieve and maintain profitability. Our failure to achieve and maintain profitability in the future could cause the market price of our common stock to decline.

***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<sup>®</sup> 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<sup>®</sup> 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 through third party collaborations and strategic partnerships, and we may be unsuccessful in our efforts to establish such relationships or our promotion efforts after any such relationships are established, which could adversely affect our ability to implement this strategy.***

We intend to integrate our historical testing products business with the promotion of therapeutics in an integrated testing and therapeutics strategy. Our integrated testing and therapeutics strategy would leverage our sales and marketing efforts, targeting rheumatologists for the commercialization of our testing products in co-promotion with therapeutics. As a result, our future growth is dependent, in part, on the success of this strategy. The Janssen Agreement was terminated effective as of August 31, 2021. While we remain optimistic about the strategy of providing an integrated testing and therapeutics model, we may be unsuccessful in our efforts to establish relationships with collaborators in the future. Even if we successfully establish these relationships, our ability to effectively implement this strategy will depend on our or our collaborator's ability to create demand for the applicable therapeutic through our or our collaborator's commercial and sales activities. Moreover, we may encounter difficulties in maintaining an effective sales force in furtherance of these co-promotion efforts. 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 establish and maintain relationships with these collaborators and strategic partners, 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 adversely affected.

***If we are unable to secure and maintain partners for our integrated testing and therapeutics strategy, or if our future 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.***

We intend to opportunistically evaluate, and may continue to enter into, agreements with pharmaceutical companies to integrate the promotion of our testing products with their therapeutics. We have also entered into, and may continue to enter into, other agreements that leverage our testing products and/or data generated from such tests. For example, we provide GSK our test result data to provide market insights for their commercial organization.

The amount and timing of resources applied by our potential future partners may be largely outside of our control. For example, we had limited control over, and relied on Janssen for, numerous activities that were critical to our ability to successfully promote SIMPONI<sup>®</sup>, such as pricing decisions, manufacture and supply of SIMPONI<sup>®</sup>, reimbursement support, marketing materials, the prosecution and enforcement of patents and other intellectual property rights related to SIMPONI<sup>®</sup> and public communications and presentations regarding SIMPONI<sup>®</sup>. We likewise had limited control of how our other partners use the information provided by our testing products. The Janssen Agreement was terminated effective as of August 31, 2021.

If any of our 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 our future partners will change their strategic focus, pursue alternative technologies or develop alternative products, either on their own or in collaboration with others. The effectiveness of our future partners, if any, in marketing the applicable therapeutics

will also affect our revenue and earnings. In addition, if our future 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.

With respect to any of our partners with which we enter into co-promotion agreements, we rely on the partner to provide, on a timely basis, an adequate and reliable supply of the relevant therapeutic product. Any delay or interruption of supply or the partner's failure to comply with regulatory or other requirements could limit our or our partners' ability to make, or cause it to cease sales, of the therapeutic product. Any manufacturing defect or error discovered after the partner's therapeutic product 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, the partner or its respective third-party manufacturers and suppliers may experience difficulties related to their overall business and financial stability. To the extent the partner faces manufacturing difficulties or are unable to provide an adequate and reliable supply of the relevant therapeutic product on a timely basis, our reputation could be harmed and our business could have suffered.

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 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, depending on our agreements with our future partners, we may be prohibited from selling or promoting certain types of products that are used to treat the same indications that such partner's therapeutic is used to treat. We may not be able to successfully negotiate any additional agreements to promote therapeutics and, if established, these relationships may not be successful. For example, potential partners, particularly those that are actively marketing their own therapeutics, may be unwilling to license commercialization rights to us or otherwise enter into terms that allow us to meaningfully participate in sales growth for their products, which could limit the potential availability and value to us of additional agreements to promote therapeutics. The inability to enter into agreements for additional therapeutics could limit the overall growth of our business and adversely affect our business, financial condition and results of operations. Disputes could also arise between us and our existing or future partners, as to a variety of matters, including financial and intellectual property matters or other obligations under our agreements. These disputes would be both expensive and time-consuming and may result in delays in the success of therapeutics or could damage our relationship with a partner.

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

In addition to the need to scale our testing capacity, our future growth plans will also impose significant added responsibilities on management, including the need to identify, recruit, train and integrate additional employees and the need to manage additional relationships with various partners, suppliers and other third parties. In particular, we have 61 representatives as of December 31, 2021 compared to 53 representatives as of December 31, 2020, and expect to continue to evaluate the reach and frequency with rheumatologists, including as we launch our pipeline products. 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.

***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 2021, we were featured in eight scientific presentations at the 2021 American College of Rheumatology's (ACR) Virtual Annual Conference, ACR Convergence 2021. We will also need to generate demand



for both our testing products and, to the extent we are successful in establishing partnerships granting us the necessary rights, promoted therapeutics, through one-on-one education by our sales force. We also plan to focus on educating patients about the benefits of these testing products and potentially therapeutics, which we believe will be necessary to generate further demand. In addition, our inability to obtain and maintain coverage and adequate reimbursement from third-party payors may limit adoption by rheumatologists, as well as third-party payors exerting pressure on rheumatologists and healthcare providers to order in-network testing products which could adversely affect our revenue.

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

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

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

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

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

***The sizes of the markets for our testing products 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 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 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 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 may in the future focus on specific 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<sup>®</sup> testing products;
- the extent to which our current testing and future testing products, if any, are eligible for coverage and reimbursement from third-party payors;
- public health crises such as the COVID-19 pandemic;
- the timing and cost of, and level of investment in, research, development, regulatory approval and commercialization activities relating to our testing products, which may change from time to time, and our ability to successfully commercialize new testing products;
- the cost of supplies, equipment and materials used for our testing products and laboratory operations, which may vary depending on the quantity of production and the terms of our agreements with third-party suppliers and manufacturers;
- expenditures that we may incur to acquire, develop or commercialize additional testing products and technologies;
- the level of demand for our testing products and any therapeutics we may promote in the future, which may vary significantly;
- the receipt, timing and mix of revenue for our testing products and any therapeutics we may promote in the future;
- future accounting pronouncements or changes in our accounting policies;
- the rate and extent to which payors make an overpayment determination and require us to return all or some portion of payments which we received in a prior period; and
- the timing and success or failure of competing products, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- differences between the list price for our testing products and the reimbursement rates of third-party payors;
- compliance with complex federal and state regulations related to billing Medicare;
- disputes among third-party payors as to which party is responsible for payment;
- differences in coverage among third-party payors;

- the effect of patient deductibles, co-payments or co-insurance;
- differences in information and billing requirements among third-party payors;
- changes to billing codes used for our testing products;
- risk of government audits related to billing;
- incorrect or missing billing information; and
- the resources required to manage the billing and claims appeals process.

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

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

Our billing activities require us to implement compliance procedures and oversight, train and monitor our employees, and undertake internal audits to evaluate compliance with applicable laws and regulations as well as internal compliance policies and procedures. When payors deny our claims, in order to obtain reimbursement for services that we provide, we may challenge coverage and payment denials. Payors also conduct external audits to evaluate payments, which add further complexity to the billing process. If the payor makes an overpayment determination, there is a risk that we may be required to return all or some portion of prior payments we have received. Additionally, providers and suppliers must report and return overpayments received from 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 the federal False Claims Act.

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

In 2021, Noridian posted the calendar year 2022 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, 2022. We do not expect that PAMA or changes to the Physician Fee Schedule will have a significant impact to Medicare reimbursement for AVISE<sup>®</sup> CTD in 2022 compared to levels experienced in 2021. Revenue from Medicare comprised 19% and 20% of our revenue for the years ended December 31, 2021 and 2020, respectively. Revenue from the sale of our AVISE<sup>®</sup> CTD testing products comprised 81% and 70% of our revenue for the years ended December 31, 2021 and 2020, respectively.

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

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

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

protect our trade secrets, a competitor's discovery of our proprietary technology and confidential information or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business, financial condition, results of operations and prospects.

***Significant safety or efficacy issues could arise for our promoted therapeutics, if any, 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, any promotion partner we may have could 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 a 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 future partners' needs, our business may be adversely affected.***

We sell our testing products through our own specialized sales force and have increased our sales force 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 sales force is integral to our integrated testing and therapeutics strategy. As such, we believe it is necessary to maintain a sales force that includes sales representatives with specific technical backgrounds and industry expertise. For example, we have a sales force of 61 representatives as of December 31, 2021, and expect to continue to evaluate the reach and frequency with rheumatologists, including as we launch our pipeline products. Agreements for the promotion of therapeutics may require us to further expand our specialized sales force. Training of additional sales representatives can be costly and time consuming, particularly given the level of experience and sophistication we seek in our sales force. In addition, our sales representatives do not currently promote any therapeutics and, until recently, not all of our sales representatives had promoted therapeutics as part of our organization, and they will need to complete additional training in order to effectively promote any therapeutic that we promote through future 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 sales force. If we are unsuccessful in this regard, it could negatively impact our revenue growth and potential profitability.

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

Our principal competition for our testing products is traditional methods used by healthcare providers to test patients with CTD-like symptoms. Such traditional methods include testing for a broad range of diagnostic, immunology and chemistry biomarkers, such as anti-nuclear antibodies, or ANA, and anti-double-stranded DNA, or anti-dsDNA, and serum complement biomarkers, such as C3 and C4. We also face competition from commercial laboratories, such as Laboratory Corporation of America Holdings, Quest Diagnostics Incorporated, ARUP Laboratories, Inc. and the Mayo Clinic, all of which have existing infrastructures to support the commercialization of diagnostic services. Large, multispecialty group medical clinics, health systems and academic medical university-based clinics may provide in-house clinical laboratories offering autoimmune and autoimmune-related disease testing services. Additionally, we

compete against regional clinical laboratories providing testing in the autoimmune and autoimmune-related disease field, including Rheumatology Diagnostics Laboratories, Inc. (acquired by Laboratory Corporation of America in June 2020). Other potential competitors include companies that might develop diagnostic or disease or drug monitoring products, such as Prognetec Diagnostics Inc., Scipher Medicine Corporation, Genalyte Inc., Oncimmune plc, DxTerity Diagnostics Inc., Immunovia AB and EpicGenetics, Inc. In the future, we may also face competition from companies developing new products or technologies.

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

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

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

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

We will continue to devote considerable resources to the research and development of our planned future testing products and enhancements to our current testing products. We may not be able to develop testing products with the clinical utility necessary to be useful and commercially successful. There are certain products for which a commercial launch would trigger additional payment obligations to licensors of the technology. In these cases, if the economic projections of the product do not outweigh the additional obligations, we may not launch these products. In order to develop and commercialize testing products, we need to:

- expend significant funds to conduct substantial research and development;
- conduct successful verification, validation and utility studies;
- develop and scale our laboratory processes to accommodate different tests;
- achieve and maintain required regulatory certifications, including the hiring of appropriately licensed laboratory personnel;
- 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;
- obtaining patient consent inclusive of genetic analysis;
- difficulty in accessing archival patient specimens, especially specimens with known clinical results; or
- failure of clinical validation, utility and outcome 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 the second half of 2021, we began the conversion of approximately 8,000 square feet of warehouse space into additional clinical laboratory space and approximately 6,000 square feet of warehouse space into additional research and development facility space in order to, among other things, develop molecular and multiomic capabilities. We have not yet developed any molecular or multiomic testing products nor do we have experience developing and integrating molecular biomarkers into new or existing testing products, and we may never be successful doing so in the future. As a result, there is considerable risk that the expansion of our clinical laboratory

and research and development facility may not lead to the development of additional testing products that generate meaningful revenue. Further, as we begin to expand our clinical laboratory and research and development facility in order to develop molecular and multiomic capabilities, we expect to need to make significant investments in key personnel and highly trained scientists with relevant experience to handle the increased operations and development of molecular biomarkers.

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 current and future testing products and any future promoted therapeutics 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 any therapeutics we promote in the future become obsolete and we are unable to expand the applicable agreements or find new partners, our sales at that time could decline and our competitive position could be harmed.

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

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

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

The marketing, sale and use of our testing products could lead to liability claims if someone were to allege that any such testing product failed to perform as it was designed. We may also be subject to liability for errors in the results we provide to rheumatologists or for a misunderstanding of, or inappropriate reliance upon, the information we provide. We may also be subject to similar types of claims related to testing products we may develop in the future. Any errors or omissions or professional liability claim could result in substantial damages and be costly and time consuming for us to defend. Although we maintain professional liability insurance, we cannot assure you that our insurance would fully protect us from the financial impact of defending against these types of claims or any judgments, fines or settlement costs arising out of any such claims. Any errors or omissions or professional liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any product liability lawsuit could cause injury to our reputation or cause us to suspend sales of our testing products. Similarly, any product liability lawsuit affecting our partners could also cause injury to our reputation or cause the applicable partner to suspend sales of its therapeutics. We may also initiate a correction or removal for one of our testing products, issue a safety alert or undertake a field action or recall to reduce a risk to health posed by potential failure of our products to perform as designed, which could lead increase costs and lead to increased scrutiny by regulatory authorities and our customers regarding the quality and safety of our testing products and to negative publicity, including safety alerts, press releases or administrative or judicial actions. The occurrence of any of these events could have an adverse effect on our business and results of operations.

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

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

In addition, our research and development programs and commercial laboratory operations depend on our ability to attract and retain highly skilled scientists, including licensed clinical laboratory scientists and biostatisticians. We

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

***If our sole laboratory facility becomes damaged or inoperable, we are required to vacate our existing facility or we are unable to expand our existing facility as needed, we will be unable to perform our testing services and our business will be harmed and, in addition, we are in the process of converting warehouse space into additional laboratory facilities, but this may not be successful.***

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

In order to rely on a third party to perform the tests contained in our testing products (even assuming we are able to do so in compliance with applicable regulations), we would need to engage another facility with established state licensure and Clinical Laboratory Improvement Amendments of 1988, or CLIA, certification 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 additional clinical reference laboratory facilities, we have to spend considerable time and money securing or converting adequate space which may include constructing additional facilities, 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 any new or converted facility. Additionally, any new clinical reference laboratory facility opened by us, including the pending warehouse conversions, would be subject to certification under CLIA and licensing by several states, including, as applicable, 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. We may need to further expand our laboratory space at a faster rate than we expect. Any future expansion and the warehouse conversions currently in process could disrupt laboratory operations, resulting in an inability to meet customer turnaround time expectations, and could be delayed, resulting in slower realization of laboratory efficiencies anticipated from the use of the expanded facilities. Adverse

consequences resulting from a delay in the laboratory expansion could harm our relationships with our customers and our reputation, and could affect our ability to generate revenue.

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

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

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

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

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

- patient specimens must be received, tracked and processed on a timely basis;
- test results must be reported on a timely basis;
- billings and collections for all customers must be managed efficiently and accurately;
- third-party ancillary billing services require proper tracking and reporting;
- pricing and other information related to our services is needed by our sales force 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 protected health information (including test results), personally identifiable information and credit card information. We also store business and financial information, intellectual property, research and development information, trade secrets, and other proprietary and business critical information, including that of our customers, payors and third-party partners. 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 and risks associated with the need to reconstruct any lost or stolen data. In addition, we have limited control over the storage of sensitive data by our third-party therapeutics partners as well as risks related to the transfer and sale of de-identified data files to such partners.

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

In addition, the interpretation and application of federal and state consumer, health-related and data protection laws in the United States are often uncertain, contradictory and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices, systems and compliance procedures in a manner adverse to our business. Additionally, in connection with the ongoing COVID-19 pandemic, most of our employees have the ability to work remotely, which may increase the risk of security breaches, loss of data, and other disruptions as a consequence of more employees accessing sensitive and critical information from remote locations.

If we are unable to prevent such security breaches or privacy violations or implement satisfactory remedial measures in connection with security incidents, we may suffer loss of reputation, financial loss, and civil or criminal fines or other penalties. In addition, these breaches and other forms of inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above.

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

Expedited, reliable shipping is essential to our operations. We have been utilizing both United Parcel Service and Federal Express Corporation for reliable and secure point-to-point transport of patient specimens to our laboratory and enhanced tracking of these patient specimens. Should Federal Express, United Parcel Service, or any other

carrier we may use in the future, encounter delivery performance issues such as loss, damage or destruction of a specimen, it may be difficult to replace our patient specimens in a timely manner and such occurrences may damage our reputation and lead to decreased utilization from rheumatologists for our testing services and increased cost and expense to our business. In addition, any significant increase in shipping time or disruption to delivery service, whether due to bad weather, natural disaster (which may be exacerbated due to climate change), public health epidemics or pandemics (including, for example, the COVID-19 pandemic), terrorist attacks or threats, or for other reasons, could adversely affect our ability to receive and process patient specimens on a timely basis.

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

***Inflation could adversely affect our business and financial results.***

Inflation, which increased significantly during 2021, may adversely affect us by increasing the costs of products, materials (including reagents and laboratory supplies), and labor needed to operate our business in future periods. Actions by the government to stimulate the economy may increase the risk of significant inflation, which may have an adverse impact on our business or financial results. Moreover, we may not be able to pass those costs along in the products we sell. As such, inflationary pressures could have a material adverse effect on our performance and financial statements.

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

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

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

In September 2017, we entered into the loan and security agreement with Innovatus Life Sciences Lending Fund I, LP, or Innovatus, which we subsequently amended in November 2019 and November 2021, or the Amended Loan Agreement. The Amended Loan Agreement is collateralized by substantially all of our personal property, including our intellectual property. The Amended Loan Agreement also subjects us to certain affirmative and negative covenants, including limitations on our ability to transfer or dispose of assets, merge with or acquire other companies, make investments, pay dividends, incur additional indebtedness and liens and conduct transactions with affiliates. We are also subject to certain covenants that require us to maintain a minimum liquidity of at least \$2.0 million and achieve certain minimum amounts of annual revenue, as measured on a rolling twelve-month basis, and are required under certain conditions to make mandatory prepayments of outstanding principal. As a result of these covenants, we have certain limitations on the manner in which we can conduct our business, and we may be restricted from engaging in favorable business activities or financing future operations or capital needs until

our current debt obligations are paid in full or we obtain the consent of Innovatus, which we may not be able to obtain. As of December 31, 2021, there was \$25.0 million in principal outstanding under the term loan and an additional \$2.3 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, 2024. At December 31, 2021, we were in compliance with all covenants of the Amended Loan Agreement. We cannot be certain that we will be able to generate sufficient cash flow or revenue to meet the financial covenants or pay the principal and accrued interest on our debt.

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

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

We expect capital expenditures and operating expenses to increase over the next several years as we expand our infrastructure, commercial operations and research and development activities. We believe, based on our current plan, that our current cash and cash equivalents and anticipated future revenue, will be sufficient to meet our anticipated cash requirements for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our operating plans and other demands on our cash resources may change as a result of many factors currently unknown to us, including as a result of the COVID-19 pandemic, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other sources, such as strategic collaborations. If our available cash balances and anticipated future revenue are insufficient to satisfy our liquidity requirements, including because of lower demand for our testing products or lower-than-expected rates of reimbursement from commercial third-party payors and government payors, or other risks described in this "Risk Factors" section, we may seek to raise additional capital through equity offerings, debt financings, collaborations or licensing arrangements. In the case of the incurrence of further indebtedness, the Amended Loan Agreement, subject to certain customary exceptions, restricts our ability to incur additional indebtedness or encumber any of our property without the prior consent of Innovatus. Under the Amended Loan Agreement, we are required to make monthly interest payments at a rate equal to 8.0% (provided that 2.0% of the 8.0% 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, and would have to work with a partner on any promoted therapeutics or market development programs, which could lower the economic value of those products or programs to our company.

### **Risks Related to Regulatory and Compliance Matters**

***Healthcare policy changes, including recently enacted and proposed new legislation reforming the U.S. healthcare system, could cause significant harm to our business, operations and financial condition.***

The ACA made a number of substantial changes to the way healthcare is financed both by governmental and private payors. The ACA also introduced mechanisms to reduce the per capita rate of growth in Medicare spending if expenditures exceed certain targets. Any such reductions could affect reimbursement payments for our tests. 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.

In April 2014, Congress passed PAMA, which included substantial changes to the way in which clinical laboratory services are paid under Medicare Clinical Laboratory Fee Schedule. Under PAMA, certain clinical laboratories are required to periodically report to CMS private payor payment rates and volumes for their tests, and laboratories that fail to report the required payment information may be subject to substantial civil monetary penalties. Medicare reimbursement for clinical laboratory diagnostic tests is based on the weighted-median of the payments made by private payors for these tests, rendering private payor payment levels even more significant than in the past. As a result, future Medicare payments may fluctuate more often and become subject to the willingness of private payors to recognize the value of diagnostic tests generally and any given test individually. The impact of this payment system on rates for our tests, including any current or future tests we may develop, is uncertain.

We cannot predict whether or when these or other recently enacted healthcare initiatives will be implemented at the federal or state level or how any such legislation or regulation may affect us. For instance, the payment reductions imposed by the ACA and the changes to reimbursement amounts paid by Medicare for tests such as ours based on the procedure set forth in PAMA, could limit the prices we will be able to charge or the amount of available reimbursement for our tests, which would reduce our revenue. Additionally, these healthcare policy changes could be amended or additional healthcare initiatives could be implemented in the future. For instance, the new Democrat-led presidential administration has been taking steps to strengthen the ACA and, following several years of litigation in the federal courts, in June 2021, the U.S. Supreme Court upheld the ACA when it dismissed a legal challenge to the ACA's constitutionality. Legislation related to precision medicine is also being considered in Congress and, if passed and signed into law, such legislation may affect genetic or genomic testing and related clinical laboratory offerings.

Further, the impact on our business of the expansion of the federal and state governments' role in the U.S. healthcare industry generally, including the social, governmental and other pressures to reduce healthcare costs while expanding individual benefits, is uncertain. Any future changes or initiatives could have a materially adverse effect on our business, financial condition, results of operations and cash flows.

***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.

***We conduct business in a heavily regulated industry. Complying with the numerous statutes and regulations pertaining to our business is expensive and time-consuming, and any failure by us, our consultants or commercial partners to comply could result in substantial penalties.***

Our industry and our operations are heavily regulated by various federal, state, local and foreign laws and regulations, and the regulatory environment in which we operate could change significantly and adversely in the future. These laws and regulations currently include, among others:

- CLIA's and CAP's regulation of our laboratory activities;
- FDA laws and regulations, including but not limited to requirements for offering LDTs;
- federal and state laws and standards affecting reimbursement by government payors, including certain coding requirements to obtain reimbursement and certain changes to the payment mechanism for clinical laboratory services resulting from the Protecting Access to Medicare Act of 2014, or PAMA;
- HIPAA and HITECH, which establish comprehensive federal standards with respect to the privacy and security of PHI, and requirements for the use of certain standardized electronic transactions with respect to transmission of such information, as well as similar laws protecting other types of personal information;



- state laws governing the maintenance of personally identifiable information of state residents, including medical information, and which impose varying breach notification requirements, some of which allow private rights of action by individuals for violations and also impose penalties for such violations;
- the federal Anti-Kickback Statute, which generally prohibits knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, in return for or to induce a person to refer to an individual any good, facility, item or service that is reimbursable under a federal healthcare program;
- the federal Stark Law, which generally prohibits a physician from making a referral for certain designated health services covered by the Medicare program, including laboratory and pathology services, if the physician or an immediate family member has a financial relationship with the entity providing the designated health services;
- the federal False Claims Act, which imposes civil penalties, and provides for civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Civil Monetary Penalties Law, which generally prohibits, among other things, the offering or transfer of remuneration to a Medicare or Medicaid beneficiary if it is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of services reimbursable by Medicare or Medicaid;
- EKRA, which imposes criminal penalties for knowing or willful payment or offer, or solicitation or receipt, of any remuneration, whether directly or indirectly, overtly or covertly, in cash or in kind, in exchange for the referral or inducement of laboratory testing (among other healthcare services) covered by healthcare benefit programs (including commercial insurers) unless a specific exception applies;
- the ACA, which, among other things, establishes a requirement for providers and suppliers to report and return any overpayments received from the Medicare and Medicaid programs;
- other federal and state fraud and abuse laws, such as anti-kickback laws, prohibitions on self-referral, fee-splitting restrictions, insurance fraud laws, anti-markup laws, prohibitions on the provision of tests at no or discounted cost to induce physician or patient adoption and false claims acts, some of which may extend to services reimbursable by any third-party payor, including private payors;
- the prohibition on reassignment of Medicare claims and other Medicare and Medicaid billing and coverage requirements;
- state laws that prohibit other specified healthcare practices, such as billing physicians for tests that they order, waiving coinsurance, copayments, deductibles and other amounts owed by patients, business corporations practicing medicine or employing or engaging physicians to practice medicine and billing a state Medicaid program at a price that is higher than what is charged to one or more other payors;
- the FCPA, and applicable foreign anti-bribery laws;
- federal, state and local regulations relating to the handling and disposal of regulated medical waste, hazardous waste and biohazardous waste and workplace safety for healthcare employees;
- laws and regulations relating to health and safety, labor and employment, public reporting, taxation and other areas applicable to businesses generally, all of which are subject to change, including, for example, the significant changes to the taxation of business entities were enacted in December 2017; and
- similar foreign laws and regulations that apply to us in the countries in which we operate or may operate in the future.

Any future growth of our business, including, in particular, continued reliance on consultants, commercial partners and other third parties, may increase the potential for violating these laws. In some cases, our risk of violating these or other laws and regulations is further increased because of the lack of their complete interpretation by applicable regulatory authorities or courts, and their provisions are thus open to a variety of interpretations.

We have adopted policies and procedures designed to comply with these laws and regulations and, in the ordinary course of our business, we conduct internal reviews of our compliance with these laws. Our compliance is also subject to review by applicable government agencies. It is not always possible to identify and deter misconduct by employees, distributors, consultants and commercial partners and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with applicable laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. Any action brought against us for violation of these or other laws or regulations,

even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business and harm our reputation. If our operations, including the conduct of our employees, consultants and commercial partners, are found to be in violation of any of these laws and regulations, we may be subject to applicable penalties associated with the violation, including administrative, civil and criminal penalties, damages, fines, individual imprisonment, exclusion from participation in federal healthcare programs, refunding of payments received by us and curtailment or cessation of our operations. Any of these consequences could seriously harm our business and our financial results.

It is possible that some of our business activities could be subject to challenge under one or more of such laws. 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 healthcare 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.

***We may be required to modify our business practices, pay fines, incur significant expenses or experience losses due to litigation or governmental investigations.***

From time to time and in the ordinary course of our business, we may be subject to litigation or governmental investigation on a variety of matters in the United States or foreign jurisdictions, including, without limitation, regulatory, intellectual property, product liability, antitrust, consumer, false claims, whistleblower, Qui Tam, privacy, anti-kickback, anti-bribery, environmental, commercial, securities and employment litigation and claims and other legal proceedings that may arise from the conduct of our business. Our activities relating to our products and services are subject to extensive regulation in the United States and foreign jurisdictions. Like many companies in our industry, we have in the ordinary course of business received inquiries, subpoenas, civil investigative demands, and other types of information requests from government authorities. For example, in February 2022, we received a subpoena issued by the U.S. Department of Justice requesting documents related to its investigation of potential federal regulatory healthcare offenses. We are fully cooperating with the U.S. Department of Justice to promptly respond to the requests for information in this subpoena, but we cannot predict when the investigation will be resolved, the outcome of the investigation or its potential impact on our business which may ultimately be greater than we expect. In addition, responding to this subpoena, and any litigation or government investigation generally, diverts the attention of our management team and diverts resources from our core business. As such, the time and attention of our management team in responding to these matters may limit their time available to devote to our business, and we may also incur significant expenses or experience losses in relation to these matters. As a result of these matters, we may also be required to alter the conduct of our operations or pay penalties. Any of these circumstances may adversely affect our business, prospects, reputation and results of operations.

***The FDA may disagree with our assessment that our AVISE<sup>®</sup> test products and any other tests we may develop are LDTs and determine that such test products are medical devices subject to the FDCA and FDA regulations.***

The FDA regulates diagnostic tests that meet the definition of a medical device, except under specific, narrow circumstances. The Federal Food, Drug and Cosmetic Act, or FDCA, defines a medical device as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is, among other things: 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 and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes." By this definition, in vitro reagents and diagnostic tests are considered medical devices. Specifically, the FDA

defines an in vitro diagnostic test, or IVD, is defined as “reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae.” Therefore, the FDA generally considers our testing products to be IVDs subject to the agency’s regulatory requirements. However, the FDA has generally exercised its enforcement discretion and not enforced applicable regulations with respect to LDTs, which are IVDs that are designed, manufactured, and used within a single high-complexity CLIA-certified laboratory for use only in that laboratory. We believe that all of our AVISE® test products are LDTs, as are our near-term pipeline candidate tests.

If the FDA were to disagree with our conclusion that our AVISE® test products fall within the scope of the agency’s LDT definition and determines that the AVISE® tests are thus subject to FDA’s medical device authorities and implementing regulations, we would become subject to extensive regulatory requirements and may be required to stop selling our existing test or not launch any other tests we may develop. In particular, the FDA may require us to obtain PMAs or another type of device marketing authorization in order for us to commercialize our AVISE® tests. The premarket review process for diagnostic products can be lengthy, expensive, time-consuming, and unpredictable. As part of the process to prepare regulatory submissions for FDA review, we may be required to conduct formal clinical trials before applying for commercial marketing authorization. Performing additional, new clinical studies and trials in order to obtain product approval from the FDA, if any were to become necessary, would take a significant amount of time and would substantially delay our ability to commercialize our AVISE® tests, all of which would adversely impact our business.

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

***The FDA may undertake rulemaking to regulate LDTs or Congress may reform the current legal requirements applicable to LDTs, in which case we may become subject to extensive regulatory requirements and may be required to conduct additional clinical trials prior to continuing to sell our existing tests or launching any other tests we may develop, which may increase the cost of conducting, or otherwise harm, our business.***

We currently market our AVISE® tests as LDTs and may in the future market other tests as LDTs. The FDA has adopted a policy of enforcement discretion with respect to LDTs whereby the FDA does not generally actively enforce its regulatory requirements for such tests. However, in the past the FDA has stated its intention to modify its enforcement discretion policy with respect to LDTs. If there are changes in FDA regulations and legislative authorities such that the agency begins to exercise oversight over LDTs, we may become subject to extensive regulatory requirements and may be required to stop selling our existing test or launching any other tests we may develop and to conduct additional clinical trials or take other actions prior to continuing to market our tests. If the FDA allows our tests to remain on the market but there is uncertainty about our tests, if they are labeled investigational by the FDA or if labeling claims the FDA allows us to make are very limited, orders from healthcare providers or reimbursement for our tests may decline.

Since 2017, Congress has been working on legislation to create an LDT and IVD, regulatory framework that would be separate and distinct from the existing medical device regulatory framework. In March 2020, a bipartisan group of members from both chambers of Congress formally introduced the Verifying Accurate, Leading-edge IVCT Development, or VALID Act, which would codify the term “in vitro clinical test,” or IVCT, and create a new medical product category separate from medical devices that includes products currently regulated as IVDs as well as LDTs, among other provisions. The VALID Act would also create a new system for laboratories to use to submit their tests electronically to the FDA for approval, which is aimed at reducing the amount of time it would take for the agency to approve such tests, and establish a new program to expedite the development of diagnostic tests that can be used to address a current unmet need for patients. A substantively unchanged version of the VALID Act was reintroduced in both houses of Congress on June 24, 2021.

Moreover, HHS published a policy announcement in August 2020 stating that FDA must go through a notice-and-comment rulemaking process before requiring premarket review of LDTs as medical devices, rather than making such a change through guidance documents, compliance manuals, or other informal policy statements. HHS’s policy statement did not affect proposed legislation for the regulation of LDTs, such as the VALID Act described above. In November 2021, the Biden Administration withdrew that HHS policy announcement and ostensibly restored FDA’s regulatory oversight of LDTs.

If Congress were to pass the VALID Act or any other legislation applicable to the FDA's regulation of LDTs, we will likely be subject to increased regulatory burdens such as registration and listing requirements, adverse event reporting requirements, and quality control requirements. Any legislation or formal FDA regulatory framework affecting LDTs is also likely to have premarket application requirements prohibiting commercialization without FDA authorization and controls regarding modification to the tests that may require further FDA submissions. Any such process would likely be costly and time-consuming.

The outcome and ultimate impact on our business of any changes to the federal government's regulation of LDTs is difficult to predict. Potential future increased regulation of our LDTs could result in increased costs and administrative and legal actions for noncompliance, including warning letters, fines, penalties, product suspensions, product recalls, injunctions and other civil and criminal sanctions, which could have a material and adverse effect upon our business, operating results, and financial condition.

Furthermore, should it be required in the future, we cannot be sure that our AVISE<sup>®</sup> tests, or any new tests that we may develop, will be reviewed and authorized for marketing by the FDA in a timely or cost-effective manner, if authorized at all. Even if such tests are authorized for marketing by the FDA, the agency could limit the test's indications for use, which may significantly limit the market for that product and may adversely affect our business and financial condition.

***The Federal Trade Commission and/or state enforcement or regulatory agencies may object to the methods and materials we use to promote our tests and initiate enforcement against us, which could adversely affect our business and financial condition.***

The FTC and/or state enforcement or regulatory agencies (including but not limited to the offices of state attorneys general) may object to the materials and methods we use to promote our current tests or other LDTs we may develop in the future, including with respect to the product claims in our promotional materials, and may initiate enforcement actions against us. Enforcement actions by the FTC may include, among others, injunctions, civil penalties, and equitable monetary relief.

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

Any failure or perceived failure by us to comply with federal or state laws or regulations, our internal policies and procedures or our contracts governing our use and disclosures of personal information could result in negative publicity, government investigations and enforcement actions including significant penalties, claims by third parties, and damage to our reputation, any of which could have a material adverse effect on our operations, financial performance, and business.

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

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

HIPAA also includes 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 healthcare providers, are required to conform to such transaction set standards, known as the Standards for Electronic Transactions, pursuant to HIPAA. Submission of electronic healthcare claims and payment transactions that do not comply with the HIPAA electronic data transmission standards could result in delayed or denied payments.

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

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

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. Further, the CPRA recently passed in California and may increase our compliance costs and potential liability, imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and adds opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws (for example Virginia's Consumer Data Protection Act that was enacted in February 2021), any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

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

The regulatory framework governing the collection, storage, use, and sharing of certain information, particularly financial and other personal information, is rapidly evolving and is likely to continue to be subject to uncertainty and varying interpretations. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our existing practices. Any failure or perceived failure by us, or any third parties with which we do business, to comply with our privacy policies, changing expectations, evolving laws, rules and regulations, industry standards, or

contractual obligations to which we or such third parties are or may become subject, may result in actions or other claims against us by governmental entities or private actors, the expenditure of substantial costs, time and other resources or the incurrance of significant fines, penalties or other liabilities. In addition, any such action, particularly to the extent we were found to be guilty of violations or otherwise liable for damages, would damage our reputation and adversely affect our business, financial condition, and results of operations.

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

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

Our future growth may depend, in part, on our ability to develop and commercialize our testing products and/or 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 future 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 such as the current conflict in Ukraine, or natural disasters which may be exacerbated due to climate change, 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<sup>®</sup> 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 11 issued U.S. patents, and certain corresponding foreign counterpart patents, relevant to our AVISE® testing products. We own one issued U.S. patent, three pending U.S. patent applications, a pending PCT patent application and certain corresponding foreign counterpart patents and patent applications relevant to our AVISE® testing products. While we intend to pursue additional patent applications, it is possible that our pending patent applications and any future applications may not result in issued patents. Even if such patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful opposition to our patents could deprive us of exclusive rights necessary for the further development of our AVISE® testing products. Furthermore, even if they are unchallenged, our patents may not adequately protect our intellectual property, provide exclusivity for our AVISE® testing products or prevent others from designing around our claims.

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

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our AVISE® testing products and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. While we use commercially reasonable efforts to protect our trade secrets, our licensors, employees, consultants, contractors and other advisors may unintentionally or willfully disclose such trade secret information to third parties and competitors. We attempt to protect our proprietary technology in large part by entering into confidentiality and non-disclosure agreements with our employees, consultants and other contractors. We cannot assure you, however, that these agreements will not be breached, that we will have adequate remedies for any breach or that competitors will not know of, or independently discover, our trade secrets. We cannot assure you that others will not independently develop substantially equivalent proprietary information or be issued patents that may prevent the sale of our testing products, technologies, services or know-how or require licensing and the payment of significant fees or royalties by us in order to produce our testing products, technologies or services. Further, we cannot be certain that the steps we have taken will prevent the misappropriation of our trade secrets and other confidential information.

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

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

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

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

Our success is heavily dependent on intellectual property, particularly on obtaining and enforcing patents. Obtaining and enforcing patents in the diagnostics industry involves both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. The United States has enacted and is currently implementing wide-

ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. We may not develop additional proprietary products, methods and technologies that are patentable.

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

Some of the intellectual property rights we have acquired or licensed or may acquire or license in the future may have been generated through the use of U.S. government funding and may therefore be subject to certain federal regulations. For example, some of the research and development work related to our CB-CAPs technology was funded by government research grants. As a result, the U.S. government may have certain rights to intellectual property embodied in our testing products pursuant to the Bayh-Dole Act of 1980, or Bayh-Dole Act. These U.S. government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as “march-in rights”). The U.S. government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. industry may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. To the extent any of our future intellectual property is also generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply.

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

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

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in



foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

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

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

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

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

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

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

We are a party to a number of license agreements under which we are granted intellectual property rights that are important to our business. For example, certain patent rights related to AVISE® Lupus are licensed from the University of Pittsburgh. 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 future partners, if any, may be unable to acquire any necessary rights for any 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 future partners, if any, consider necessary or attractive in order to promote their therapeutics. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

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

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

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

We cannot assure you that any of our current or future AVISE® testing products will not infringe existing or future patents. Although we are not aware of any issued patents that will prevent us from marketing our AVISE® testing products, there may be third-party patents of which we are currently unaware with claims to materials or methods of manufacture related to the use or manufacture of our AVISE® testing products. If a third party that owns such a patent asserts it successfully against one of our current or future AVISE® testing products, we may be unable to market our product, which could materially harm our business and because patent applications can take many years to issue and may be confidential for 18 months or more after filing, there may be currently pending third-party patent applications which may later result in issued patents that our AVISE® testing products or our technologies may infringe, or which such third parties claim are infringed by the use of our technologies.

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

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

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

Third parties may infringe, misappropriate or otherwise violate our existing patents, patents that may issue to us in the future, or the patents of our licensors that are licensed to us. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. We may not be able to

prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

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

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

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

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our patents or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders. We are not aware of any third-party infringement of our intellectual property rights that would have a materially adverse impact on our business. In addition, there can be no assurance that our licensors will be willing to bring and enforce claims to prevent third parties from infringing intellectual property that is licensed to us, particularly if the affected intellectual property is less important to the licensor's business than to ours. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

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

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

## **Risks Related to Our Common Stock**

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

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

- actual or anticipated variations in our and our competitors' financial condition and results of operations;
- announcements by us or our competitors of new products, strategic partnerships or capital commitments;
- changes in reimbursement by current or potential third-party payors;
- issuance of new securities analysts' reports or changed recommendations for our stock;
- actual or anticipated changes in regulatory oversight of our testing products;

- developments or disputes concerning our intellectual property or other proprietary rights;
- commencement of, or our involvement in, litigation;
- announced or completed acquisitions of businesses or technologies by us or our competitors;
- any major change in our management;
- changes in accounting principles;
- announcement or expectation of additional financing efforts;
- future sales of our common stock by our executive officers, directors and other stockholders; and
- general economic conditions and slow or negative growth of our markets, including as a result of the COVID-19 pandemic and the current conflict in Ukraine.

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

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

***Future sales of shares by existing stockholders could cause our stock price to decline.***

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur could significantly reduce the trading price of our common stock and impair our ability to raise adequate capital through the sale of additional equity securities.

In addition, our directors and executive officers have and may continue to 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, particularly if the trading volume of our common stock is relatively low at the time of these sales.

In addition, the holders of 5,117,230 shares of common stock and holders of warrants to purchase 409,108 shares of common stock are entitled to rights with respect to registration of such shares under the Securities Act pursuant to an investors' rights agreement between such holders and us. If such holders, by exercising their registration rights, sell a large number of shares, they could adversely affect the market price for our common stock. If we file a registration statement for the purpose of selling additional shares to raise capital and are required to include shares held by these holders pursuant to the exercise of their registration rights, our ability to raise capital may be impaired.

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

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

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors, unless the board of directors grants such right to the stockholders, to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- the required approval of at least 66-2/3% of the shares entitled to vote to remove a director for cause, and the prohibition on removal of directors without cause;

- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- the ability of our board of directors to alter our amended and restated bylaws without obtaining stockholder approval;
- the required approval of at least 66-2/3% of the shares entitled to vote to adopt, amend or repeal our amended and restated bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- an exclusive forum provision providing that the Court of Chancery of the State of Delaware will be the exclusive forum for certain actions and proceedings;
- the requirement that a special meeting of stockholders may be called only by the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

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

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

Our amended and restated certificate of incorporation provide that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation, or any action asserting a claim against us that is governed by the internal affairs doctrine; provided, that, this provision would not apply to suits brought to enforce a duty or liability created by the 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.***

Based on their most recent publicly filed beneficial ownership reports, our greater than 5% stockholders collectively own approximately 72% of our outstanding capital stock and our greater than 5% stockholders, directors and officers collectively own (without duplication) approximately 73% of our outstanding capital stock as of February 15, 2022. As a result, such persons, acting together, have the ability to control or significantly influence all matters submitted to our stockholders for approval, including the election and removal of directors and approval of any significant transaction, as well as our management and business affairs. This concentration of ownership may have

the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders.

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

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

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

Prior to our IPO, there had been no public market for our common stock. Our common stock only recently began trading on the Nasdaq Global Market, or Nasdaq, but we can provide no assurance that we will be able to develop and sustain an active trading market for our common stock. Even if an active trading market is developed, it may not be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses or technologies using our shares as consideration, which, in turn, could materially adversely affect our business. Since 2020, our average daily trading volume has been approximately 47,000 shares.

#### **General Risk Factors**

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

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

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

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

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

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or 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 has been 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 begins its Section 404 reviews, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

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

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

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

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

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

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department’s Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA

PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our testing products outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

***We could be subject to securities class action litigation.***

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

**Item 1B. Unresolved Staff Comments.**

Not applicable.

## **Item 2. Properties.**

Our corporate headquarters are located in Vista, California, where we lease approximately 27,000 square feet of office and laboratory space under a lease that expires in 2027, with an option to extend a portion of the lease for an additional five-year period.

We lease an additional approximately 19,500 square feet office space in Vista, California, under a lease that is co-terminus with our other lease expiring in 2027, with an option to extend the lease for an additional five-year period. We also lease an additional approximately 28,000 square feet office space in Carlsbad, California, under a sublease that is co-terminus with our other leases expiring in 2027. 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 18, 2022, there were approximately 41 stockholders of record of our common stock. This number was derived from our shareholder records and does not include beneficial owners of our common stock whose shares are held in "street" name with various dealers, clearing agencies, banks, brokers and other fiduciaries.

#### Dividend Policy

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

#### Securities Authorized for Issuance under Equity Compensation Plans

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

#### Performance Graph

Not applicable.

#### Recent Sales of Unregistered Securities

None.

#### Use of Proceeds

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

As of December 31, 2021, we have used approximately \$39.5 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. [Reserved.]**

## 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<sup>®</sup> brand, several of which are based on our proprietary CB-CAPs technology. Our goal is to enable healthcare providers to improve care for patients through the differential diagnosis, prognosis and monitoring of complex autoimmune and autoimmune-related diseases, including SLE and RA. Our business model of integrating testing products and therapeutics positions us to offer targeted solutions to rheumatologists and, ultimately, better serve patients.

We currently market 10 testing products under our AVISE<sup>®</sup> brand that allow for the differential diagnosis, prognosis and monitoring of complex autoimmune and autoimmune-related diseases. Our lead testing product, AVISE<sup>®</sup> 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<sup>®</sup> CTD in 2012 and revenue from this product comprised 81% and 70% of our revenue for the years ended December 31, 2021 and 2020, respectively. There is an unmet need for rheumatologists to add clarity in their CTD clinical evaluation, and we believe there is a significant opportunity for our tests that enable the differential diagnosis of these diseases, particularly for potentially life-threatening diseases such as SLE.

We are leveraging our portfolio of testing products to establish partnerships with leading pharmaceutical companies, academic research centers and patient advocacy organizations. We also have agreements with GSK, Labcorp Drug Development and Parexel, among others, that leverage our testing products and/or the information generated from such tests. We provide GSK, a leader in lupus therapeutics, our test result data to provide market insight into and help increase awareness of the benefits of early and accurate diagnosis of SLE and lupus nephritis, and monitoring disease activity. We partner with academic research centers and patient advocacy organizations, such as Brigham and Women's Hospital, Hospital for Special Surgery, Duke University and Emory University as well as the Lupus Foundation of America, to help improve the quality of life for people affected by autoimmune diseases through programs of research, education, support and advocacy. We plan to pursue additional strategic partnerships that are synergistic with our evolving portfolio of testing products.

We perform all of our AVISE<sup>®</sup> tests in our approximately 10,000 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 and is licensed by all states requiring out-of-state licensure. Our clinical laboratory reports all AVISE<sup>®</sup> testing product results within five business days. In the second half of 2021, we began the conversion of approximately 8,000 square feet of warehouse space into additional clinical laboratory space and approximately 6,000 square feet of warehouse space into additional research and development facility space, and expect to complete such conversions by the first quarter of 2022 and mid 2022, respectively. The expansion of our clinical laboratory and research and development facility are expected to allow us to enhance our testing capacity and improve efficiencies as well as allow us to develop molecular and multiomic capabilities and advance our product pipeline, including support of development of tests for fibromyalgia, RA, thrombosis and lupus nephritis.

We market our AVISE<sup>®</sup> testing products using our specialized sales force. As of December 31, 2021, we have a sales force of 61 representatives covering a total of 63 territories. Unlike many diagnostic sales forces that are

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

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

Since inception we have devoted substantially all of 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, 2021 we had an accumulated deficit of \$208.1 million. We incurred net losses of \$26.9 million and \$16.7 million for the years ended December 31, 2021 and 2020, 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. We completed our initial public offering, or IPO, in September 2019, raising net proceeds from the offering of approximately \$50.4 million, net of underwriting discounts, commissions and other offering expenses, for aggregate expenses of approximately \$7.5 million. In March 2021, we completed a public offering of 4,255,000 shares of our common stock at a public offering price of \$16.25 per share. Net proceeds from the offering were approximately \$64.7 million, net of underwriting discounts and commissions and offering costs of \$4.4 million. As of December 31, 2021, we had \$99.4 million of cash and cash equivalents.

### **Impact of COVID-19**

The current COVID-19 worldwide pandemic has presented substantial public health challenges and is affecting our employees, patients, physicians and other healthcare providers, communities and business operations, as well as the U.S. and global economies and financial markets. International and U.S. governmental authorities in impacted regions have taken actions in an effort to slow the spread of COVID-19, including issuing varying forms of "stay-at-home" orders, restricting business functions outside of one's home, restricting gatherings, restricting travel, and mandating social distancing and face coverings. While many jurisdictions have fully reopened or have begun a phased re-opening, the potential to return to prior restrictions remain if there are future increases (or, in some jurisdictions, continued increases) in new cases of COVID-19 or any of its viral variants, including the Delta and Omicron variants. Even in areas that have fully reopened and where the number of COVID-19 cases has declined, many individuals remain cautious about resuming activities such as preventative-care medical visits. As a result of COVID-19 related limitations and reordering of priorities across the U.S. healthcare system, a reduction in patient flow occurred and our test volumes began to decrease in the second half of March 2020 and we experienced an AVISE<sup>®</sup> CTD volume decrease of approximately 5% in the year ended December 31, 2020 as compared to 2019. In the fourth quarter of 2020, our volume of AVISE<sup>®</sup> CTD tests delivered exceeded our pre-COVID-19 levels. For the three months ended December 31, 2021 as compared to the same period in 2020, we experienced an AVISE<sup>®</sup> CTD volume increase of approximately 19%. For the year ended December 31, 2021 as compared to the same period in 2020, we experienced an AVISE<sup>®</sup> CTD test volume increase of approximately 28%. However, the continued spread of COVID-19 and patient hesitancy in seeking preventative medical care, each of which are dependent on circumstances that are highly uncertain, may adversely affect testing volumes in future periods.

In addition, we believe there are several other important factors that have impacted, and that we expect will impact our operating performance and results of operations, including shutdowns of our facilities and operations as well as those of our suppliers and courier services, disruptions to the supply chain of material needed for our tests, our sales and commercialization activities and our ability to receive specimens and perform or deliver the results from our tests, delays in reimbursement and coverage decisions from Medicare and third-party payors and in interactions with regulatory authorities, as well as our inability to achieve volume-based pricing discounts with our key suppliers and absorb fixed laboratory expenses. For example, we have experienced delays in patient enrollment for ongoing and planned clinical studies involving our tests, which may delay or prevent launch of future test products. We have also experienced delays, beginning in the first quarter of 2021, in procurement of our testing supplies due in part to disruptions to the global supply chain resulting from the COVID-19 pandemic, which may continue into the future, and our partners, may also experience a disruption in their ability to readily obtain supply. Our sales force has been,

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

In response to the COVID-19 pandemic, we initially curtailed non-essential travel and have equipped most of our employees with the ability to work remotely with the exception of our clinical laboratory employees, and implemented measures to protect the health of our employees and to support the functionality of our clinical laboratory, such as providing personal protective equipment (including face masks or shields) and maintaining social distancing. In addition, in the second quarter of 2020, our sales force recommenced certain field-based interactions and scaled marketing spend, although access to healthcare providers remains limited and the use of virtual sales tools has increased. From March 2020 through December 31, 2020, as a result of the COVID-19 pandemic, we terminated our temporary employees and 18 full-time employees, which included three employees at the vice president level. During 2021, we returned to normalized personnel levels. The full extent of which the COVID-19 pandemic will directly or indirectly continue to impact our business, results of operations and financial condition and will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain it or treat COVID-19, including success of ongoing vaccination efforts, the emergence and prevalence of variant strains of COVID-19, the institution or reinstatement of shutdowns, "stay-at-home-orders" and other public health measures, as well as the related economic impact of these matters on local, regional and international markets.

### Factors Affecting Our Performance

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

- **Continued Adoption of Our Testing Products.** Since the launch of AVISE® CTD in 2012 and through December 31, 2021, we have delivered over 615,000 of these tests. For the year ended December 31, 2021, 128,246 AVISE® CTD tests were delivered, representing approximately 28% growth over the same period in 2020. In the fourth quarter of 2021, the number of ordering healthcare providers reached a record 2,126, representing an approximate 26% increase over the same period in 2020, and we had a record 739 adopting healthcare providers (defined as those who previously prescribed at least 11 diagnostic tests in the corresponding period) compared to 635 in the same period in 2020. A high percentage of adopting healthcare providers continue to order tests in subsequent quarters, as approximately 99% of adopting healthcare providers from the third quarter of 2021 ordered at least one diagnostic test in the fourth quarter of 2021. Revenue growth for our testing products will depend on our ability to continue to expand our base of ordering healthcare providers and increase our penetration with existing healthcare providers.
- **Reimbursement for Our Testing Products.** Our revenue depends on achieving broad coverage and reimbursement for our tests from third-party payors, including both commercial and government payors such as Medicare. Payment from third-party payors differs depending on whether we have entered into a contract with the payors as a "participating provider" or do not have a contract and are considered a "non-participating provider." Payors will often reimburse non-participating providers, if at all, at a lower amount than participating providers. We have received a substantial portion of our revenue from a limited number of third-party commercial payors, most of which have not contracted with us to be a participating provider. Historically, we have experienced situations where commercial payors proactively reduced the amounts they were willing to reimburse for our tests, and in other situations, commercial payors have determined that the amounts they previously paid were too high and have sought to recover those perceived excess payments by deducting such amounts from payments otherwise being made. When we contract to serve as a participating provider, reimbursements are made pursuant to a negotiated fee schedule and are limited to only covered indications. If we are not able to obtain or maintain coverage and adequate reimbursement from third-party payors, we may not be able to effectively increase our testing volume and revenue as



expected. Additionally, retrospective reimbursement adjustments can negatively impact our revenue and cause our financial results to fluctuate.

- **Synergistic Partnerships.** In August 2021, we mutually agreed to terminate the Janssen Agreement regarding our promotion efforts with SIMPONI<sup>®</sup> effective August 31, 2021. Our SIMPONI<sup>®</sup> promotion efforts contributed approximately \$1.2 million and \$5.1 million in revenue for the years ended December 31, 2021 and 2020, respectively. We will continue to rely on our existing testing products to drive revenue growth.
- **Development of Additional Testing Products.** We rely on sales of our AVISE<sup>®</sup> CTD test to generate the significant majority of our revenue. We expect to continue to invest in research and development in order to develop additional testing products and expect these costs to increase. Our success in developing new testing products will be important in our efforts to grow our business by expanding the potential market for our testing products and diversifying our sources of revenue.
- **Maintain Meaningful Margin.** We believe we are well positioned to maintain meaningful margin through a continued focus on increasing operating leverage through the implementation of certain internal initiatives, such as conducting additional validation and reimbursement oriented clinical studies to facilitate payor coverage of our testing products, capitalizing on our growing reagent purchasing to negotiate improved volume-based pricing and automation in our clinical laboratory to reduce material and labor costs.
- **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<sup>®</sup> testing products. Spending on research and development for both experiments and studies may vary significantly by quarter depending on the timing of these various expenses.
- **How We Recognize Revenue.** We record revenue on an accrual basis based on our estimate of the amount that will be ultimately realized for each test upon delivery based on a historical analysis of amounts collected by test and by payor. Changes to such estimates may increase or decrease revenue recognized in future periods.

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

### Janssen Promotion Agreement

In December 2018, we entered into the Janssen Agreement, under which we were responsible for the costs associated with our sales force in promoting SIMPONI<sup>®</sup> in the United States. In August 2021, we and Janssen mutually agreed to terminate the Janssen Agreement effective August 31, 2021. Pursuant to the Janssen Agreement, Janssen was responsible for all other costs associated with our promotion of SIMPONI<sup>®</sup> under the Janssen Agreement. In exchange for our sales and co-promotional services, we were entitled to a quarterly tiered promotion fee based on the incremental increase in total prescribed units of SIMPONI<sup>®</sup> for that quarter over a predetermined baseline. For the year ended December 31, 2020, the tiered promotion fee ranged from \$750 to \$1,250 per prescription over a predetermined baseline. Due in part to COVID-19, in June 2020 we amended the Janssen Agreement, to adjust the predetermined average baseline for the third and fourth quarters of 2020. In December 2020, we further amended the Janssen Agreement, to adjust the average baseline for total prescribed units of SIMPONI<sup>®</sup> for the quarters ending December 31, 2020, March 31, 2021, subject to further adjustment under certain circumstances. In June 2021, the Janssen Agreement was again amended to proportionally increase the baseline for prescribed units for the quarter ending June 30, 2021 to reflect the addition of certain geographies to the sales territories covered by the Janssen Agreement. For the first and second quarters of 2021, we earned the minimum promotion fee of \$0.3 million. Upon termination of the Janssen Agreement on August 31, 2021, we became entitled to receive an aggregate \$0.6 million in consideration, which was earned in the year ended December 31, 2021. Pursuant to the terms of the termination, we are restricted from promoting any other biologic or Janus kinase inhibitor used for treatment of indications covered by the Janssen Agreement without first obtaining Janssen's written consent until May 31, 2022.

We recognized approximately \$1.2 million and \$5.1 million in revenue for the years ended December 31, 2021 and 2020, respectively, for our promotional efforts under the Janssen Agreement.

### **Seasonality**

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

### **Financial Overview**

#### **Revenue**

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

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

Our ability to increase our revenue will depend on our ability to further penetrate the market for our current and future testing products, and increase our reimbursement and collection rates for tests delivered.

As discussed above, our volume of AVISE<sup>®</sup> CTD tests delivered substantially recovered to pre-COVID-19 levels in the fourth quarter of 2020. However, the continued spread of COVID-19, including any of its viral variants, may adversely affect testing volumes in future periods, and the extent of any such adverse effects is highly uncertain.

#### **Operating Expenses**

##### *Costs of Revenue*

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

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

Assuming future testing volumes are not negatively impacted by the continued spread of COVID-19, we expect that our costs of revenue will increase in absolute dollars as the number of tests we perform increases. However, we expect that the cost per test will decrease over time due to volume discounts on materials and other volume efficiencies we may gain as the number of tests we perform increases. The decrease in cost per test may be partially offset due to increased depreciation and allocated overhead associated with our clinical laboratory expansion as well as increased labor, material and shipping costs (including as a result of inflation) associated with the commercialization of our portfolio products. As discussed above, the continued spread of COVID-19 may adversely affect testing volumes which may result in an increase in cost per test due to our inability to realize volume efficiencies.

##### *Selling, General and Administrative Expenses*

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

We expect that our selling, general and administrative expenses will increase in absolute dollars in 2022 as compared to 2021, due to expected additions to headcount and associated increases for personnel costs, including stock-based compensation.

#### *Research and Development Expenses*

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

We expect that our research and development expenses will increase in absolute dollars in 2022 as compared to 2021, as we continue to invest in research and development activities related to our existing testing products and product candidates, including the expansion of our clinical research and development facility, expected additions to headcount and associated increases for personnel costs, including stock-based compensation.

#### *Interest Expense*

Interest expense consists of cash and non-cash interest expense associated with our financing arrangements, including the borrowings under our amended loan and security agreement with Innovatus Life Sciences Lending Fund I, LP, or Innovatus.

We expect interest expense to decrease in the near term due to lower interest rates related to our amended loan and security agreement with Innovatus.

#### *Other Income, Net*

Other income, net, consists primarily of interest income earned on our cash and cash equivalents and an amount received under the CARES Act Provider Relief Fund in the second quarter of 2020.

#### *Income Tax (Expense) Benefit*

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

### **Results of Operations**

**Comparison of the Years Ended December 31, 2021 and 2020:**

	Years Ended December 31,		Change
	2021	2020	
	(in thousands)		
Revenue	\$ 48,299	\$ 41,975	\$ 6,324
Operating expenses:			
Costs of revenue	20,588	16,559	4,029
Selling, general and administrative expenses	44,541	37,033	7,508
Research and development expenses	7,237	3,568	3,669
Total operating expenses	72,366	57,160	15,206
Loss from operations	(24,067)	(15,185)	(8,882)
Interest expense	(2,625)	(2,565)	(60)
Other income, net	16	984	(968)
Loss before income taxes	(26,676)	(16,766)	(9,910)
Income tax (expense) benefit	(175)	79	(254)
Net loss	\$ (26,851)	\$ (16,687)	\$ (10,164)

**Revenue**

Revenue increased \$6.3 million, or 15.1%, for the year ended December 31, 2021 compared to the year ended December 31, 2020, primarily due to an increase in the number of diagnostic tests delivered resulting in part from volume reductions experienced in late March 2020 as a result of the COVID-19 pandemic. The number of AVISE<sup>®</sup> CTD tests delivered, which accounted for 81% and 70% of revenue for the years ended December 31, 2021 and 2020, respectively, increased to 128,246 tests delivered in the year ended December 31, 2021 compared to 100,450 tests delivered in the same 2020 period. The number of AVISE<sup>®</sup> CTD tests increased to 34,147 for the three months ended December 31, 2021 compared to 28,601 tests delivered in the same 2020 period. The number of ordering healthcare providers increased to 2,126 for the three months ended December 31, 2021 compared to 1,690 in the same 2020 period. The increase in revenue was partially offset by a decrease in revenue resulting from the Janssen Agreement during the year ended December 31, 2021 to approximately \$1.2 million compared to approximately \$5.1 million for the year ended December 31, 2020.

**Costs of Revenue**

Costs of revenue increased \$4.0 million, or 24.3%, for the year ended December 31, 2021 compared to the year ended December 31, 2020. This increase was primarily due to increased direct costs such as materials and supplies, labor and shipping and handling associated with the increase in test volume in 2021 compared to 2020, partially offset by decreased royalty costs. Gross margin as a percentage of revenue decreased to 57.4% for the year ended December 31, 2021, compared to 60.6% for the year ended December 31, 2020. This was primarily attributable to a decrease in revenue resulting from the Janssen Agreement.

**Selling, General and Administrative Expenses**

Selling, general and administrative expenses increased \$7.5 million, or 20.3%, for the year ended December 31, 2021 compared to the year ended December 31, 2020. This increase was primarily due to an increase of \$5.7 million of employee related expenses, including stock-based compensation and recruitment expenses, increases related to insurance expenses of \$0.5 million, marketing expenses of \$0.5 million and audit and professional services of \$0.2 million. The first quarter of 2020 included one-time restructuring charges of approximately \$0.2 million.

**Research and Development Expenses**

Research and development expenses increased \$3.7 million, or 102.8%, for the year ended December 31, 2021 compared to the year ended December 31, 2020. The increase was primarily due to an increase of \$1.2 million of employee related expenses, including stock-based compensation and recruitment expenses, and increases related

to clinical study expenses of \$0.9 million, license fees of \$0.8 million, laboratory supplies expense of \$0.3 million and collaboration expenses of \$0.3 million.

### ***Interest Expense***

Interest expense remained substantially consistent for the year ended December 31, 2021 compared to the year ended December 31, 2020.

### ***Other Income, Net***

Other income, net, decreased \$1.0 million for the year ended December 31, 2021 compared to the year ended December 31, 2020. This decrease was primarily driven by the \$0.7 million we received under the CARES Act Provider Relief Fund due to lost revenues attributable to COVID-19 in the second quarter of 2020 and lower money market interest rates in 2021 compared to 2020.

### ***Income Tax (Expense) Benefit***

Income tax expense increased \$0.3 million for the year ended December 31, 2021 compared to the year ended December 31, 2020 due to an expiration of benefits under the CARES Act.

### **Liquidity and Capital Resources**

We have incurred net losses since our inception. For the years ended December 31, 2021 and 2020, we incurred a net loss of \$26.9 million and \$16.7 million, respectively, and we expect to incur additional losses and increased operating expenses in future periods. As of December 31, 2021, we had an accumulated deficit of \$208.1 million. To date, we have generated only limited revenue, and we may never achieve revenue sufficient to offset our expenses.

Our primary sources of capital have primarily been sales of our common stock and redeemable convertible preferred stock, the sale of our common stock of our IPO, and, to a lesser extent, borrowings under various debt financings. On November 10, 2020, we filed a registration statement on Form S-3, or the Shelf Registration Statement, covering the offering, from time to time, of up to \$150.0 million of common stock, preferred stock, debt securities, warrants and units, which Shelf Registration Statement became effective on November 19, 2020. In March 2021, we completed a public offering of 4,255,000 shares of our common stock at a public offering price of \$16.25 per share, which shares were sold under the Shelf Registration Statement. Net proceeds from the offering were approximately \$64.7 million, net of underwriting discounts and commissions and other offering expenses of \$4.4 million. As of December 31, 2021, we had \$99.4 million of cash and cash equivalents. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Currently, our funds are held in cash and money market funds.

In September 2017, we entered into the loan and security agreement with Innovatus under which we immediately drew down \$20.0 million. In December 2018, we borrowed an additional \$5.0 million under the loan agreement. In each of November 2019 and November 2021, we amended the loan and security agreement with Innovatus, which we collectively refer to as the Amended Loan Agreement. Pursuant to the Amended Loan Agreement, the loan term is for nine years with a final maturity date of November 2026. The Amended Loan Agreement accrues interest at an annual rate of 8.0%, of which 2.0% will be payable in-kind. Paid in-kind interest is added to the principal balance each period. After December 1, 2024, the entire 8.0% will be paid in cash at the end of each period. On or after November 1, 2022, we may, at our option, prepay the term loan borrowings by paying the lender a prepayment premium. The prepayment premium was 3% as of November 2021 and decreases by 1% on each of November 1, 2022, November 1, 2023 and November 1, 2024.

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, performance covenants to achieve certain minimum amounts of revenue, and covenants limiting our ability to dispose of assets, undergo a change in control, merge with or acquire other entities, incur debt, incur liens, pay dividends or other distributions to holders of our capital stock, repurchase stock and make investments, in each case subject to certain exceptions. The consequences of failing to achieve the performance covenant will be cured if, within sixty days of failing to achieve the performance covenant, we issue additional equity securities or subordinated debt with net proceeds sufficient to fund any cash flow deficiency generated from operations, as defined in the Amended Loan Agreement. At December 31, 2021, we were in compliance with all

covenants of the Amended Loan Agreement. In addition, upon the occurrence of an event of default, Innovatus, among other things, can declare all indebtedness due and payable immediately, which would adversely impact our liquidity and reduce the availability of our cash flows to fund working capital needs, capital expenditures and other general corporate purposes.

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

### **Funding Requirements**

Our primary uses of cash are to fund our operations as we continue to grow our business. We expect to continue to incur operating losses in the near term as our operating expenses will be increased to support the growth of our business. We expect that our costs of revenue, selling, general and administrative expenses, and research and development expenses will continue to increase as we increase our test volume, expand our marketing efforts and increase our internal sales force to drive increased adoption of and reimbursement for our AVISE® testing products, prepare to commercialize new testing products, continue our research and development efforts and further develop our product pipeline. We believe we have sufficient laboratory capacity to support increased test volume. We expect to make significant investments for laboratory equipment and capital expenditures in the near term related to our laboratory facilities and expansion of research capabilities, including an investment to convert approximately 8,000 square feet of warehouse space into additional clinical laboratory space and approximately 6,000 square feet of warehouse space into additional research and development facility space. We began such conversion in the second half of 2021 and expect to complete the conversion for the clinical laboratory space by the first quarter of 2022 and expect to complete the conversion for the additional research and development facility by mid 2022. The expansion of our clinical laboratory and research and development facility are expected to allow us to enhance our testing capacity and improve efficiencies as well as allow us to develop molecular and multiomic capabilities and advance our product pipeline, including support of the development of tests for fibromyalgia, RA, thrombosis and lupus nephritis. Cash used to fund operating expenses is impacted by the timing of when we pay expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

We expect that our near- and longer-term liquidity requirements will continue to consist of working capital and general corporate expenses associated with the growth of our business, including payments we may be required to make upon the achievement of previously negotiated milestones associated with intellectual property we have licensed, payments related to non-cancelable purchase obligations with one supplier for reagents, payments related to our principal and interest under our long term borrowing arrangements, payments for operating leases related to our office and laboratory space in Vista, California and our office space in Carlsbad, California, and payments for capital leases related to our laboratory equipment (see Note 4 and Note 5 in the audited financial statements included in this Annual Report on Form 10-K). Based on our current business plan, we believe that our existing cash and cash equivalents and our anticipated future revenue, will be sufficient to meet our anticipated cash requirements for at least the next 12 months from the date of this filing.

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

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

- the costs associated with our promotion of other therapeutics, if any, including the expansion of our sales capabilities, and the extent and timing of generating revenue from each such promotion, if any.

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 commercial and strategic relationships. 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:

	<b>Years Ended December 31,</b>	
	<b>2021</b>	<b>2020</b>
<b>(in thousands)</b>		
Net cash provided by (used in):		
Operating activities	\$ (20,269)	\$ (14,084)
Investing activities	(2,420)	(455)
Financing activities	64,683	(97)
Net change in cash, cash equivalents and restricted cash	<u>\$ 41,994</u>	<u>\$ (14,636)</u>

### Cash Flows from Operating Activities

Net cash used in operating activities for the year ended December 31, 2021 was \$20.3 million and primarily resulted from (i) our net loss of \$26.9 million adjusted for non-cash charges of \$6.6 million related to stock-based compensation, depreciation, amortization, non-cash interest and deferred income taxes and (ii) changes in our net operating assets of \$0.1 million primarily related to net increases in accounts receivable, net and net decreases in accounts payable, partially offset by net decreases in prepaid expenses and other current assets and net increases in accrued liabilities and other current liabilities.

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

### Cash Flows from Investing Activities

Net cash used in investing activities for the year ended December 31, 2021 and 2020 was \$2.4 million and \$0.5 million, respectively, 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, 2021 was \$64.7 million and primarily resulted from the net proceeds received from our public offering in March 2021 of \$64.7 million and proceeds from the Exagen Inc. 2019 Employee Stock Purchase Plan, or the ESPP, purchases, partially offset by principal payments on capital lease obligations.

Net cash used in financing activities for the year ended December 31, 2020 was \$0.1 million and primarily resulted from principal payments on capital lease obligations, as well as proceeds from our unsecured loan pursuant to the U.S. Small Business Administration Paycheck Protection Program under the CARES Act, which we subsequently repaid in May 2020, partially offset by proceeds from ESPP purchases.

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

#### ***Revenue Recognition***

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

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

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

The process for estimating revenues and the ultimate collection of accounts receivable involves significant judgment and estimation by management. We continually assess the state of our cash collections in order to identify areas of risk and opportunity that allow us to appropriately estimate receivables and revenue. Should we later determine the judgements underlying estimated collections change, our financial results could be impacted in future periods. Revenue recognized during the years ended December 31, 2021 and 2020 related to performance obligations satisfied in prior periods was approximately \$0.7 million and \$0.8 million, respectively, which relates to a change in estimate of the transaction price.

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® were a series of single performance obligations since Janssen simultaneously received and consumed 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 was cancelable. In August 2021, we and Janssen mutually agreed to terminate the Janssen Agreement effective August 31, 2021.

#### ***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, 2021 and 2020.

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 \$4.7 million and \$2.7 million for the years ended December 31, 2021 and 2020, 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 8 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 and purchases under our ESPP rights in the years ended December 31, 2021 and 2020.

### ***Determination of the Fair Value of Our Common Stock***

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.

### ***Income Taxes***

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

At December 31, 2021, our deferred tax assets are primarily comprised of federal and state tax NOL carryforwards. We previously completed a study to assess whether an ownership change, as defined by Section 382 of the Code, had occurred from our formation through December 31, 2019. Based upon this study, we determined that ownership changes had occurred in 2003, 2008, 2012, 2017 and 2019, and that our ability to use a significant portion of our NOL carryforwards is subject to limitation under Section 382 of the Code as a result of a prior ownership change. In addition, federal NOL carryforwards generated in periods after December 31, 2017, may be carried forward indefinitely but, in taxable years beginning after December 31, 2020, may only be used to offset 80% of our taxable income.

We are required to reduce our deferred tax assets by a valuation allowance if it is more likely than not that some or all of our deferred tax assets will not be realized. We must use judgment in assessing the potential need for a valuation allowance, which requires an evaluation of both negative and positive evidence. The weight given to the potential effect of negative and positive evidence should be commensurate with the extent to which it can be objectively verified. In determining the need for and amount of our valuation allowance, if any, we assess the likelihood that we will be able to recover our deferred tax assets using historical levels of income, estimates of future income and tax planning strategies. As a result of historical cumulative losses and uncertainties surrounding our ability to generate future taxable income and, based on all available evidence, we believe it is more likely than not that our recorded net deferred tax assets will not be realized. Accordingly, we have recorded a valuation allowance against all of our net deferred tax assets at December 31, 2021. We will continue to maintain a full valuation allowance on our deferred tax assets until there is sufficient evidence to support the reversal of all or some portion of this allowance.

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

### **Recent Accounting Pronouncements**

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

### **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 will occur in 2024. However, if certain events occur prior to the end of this 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 this anniversary.

## **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 reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that the information required to be disclosed by us in such reports is accumulated and communicated to our management, including our principal executive officer and principal financial officer, or persons performing similar functions, 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, 2021, 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***

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP. Our internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets, (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors, and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the

financial statements. Because of its inherent limitations, internal controls over financial reporting may not prevent or detect all misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

As of December 31, 2021, our management assessed the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework. Based on this assessment, our management concluded that, as of December 31, 2021, our internal control over financial reporting was effective based on those criteria.

***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, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. Other Information.**

Not applicable.

**Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.**

Not applicable.

## 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 2022 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 11. Executive Compensation.**

The information required by this item is incorporated herein by reference to our Proxy Statement with respect to our 2022 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 2022 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 2022 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.**

Our independent public accounting firm is BDO USA, LLP, San Diego, California, PCAOB ID #243.

The information required by this item is incorporated herein by reference to our Proxy Statement with respect to our 2022 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 94.

##### (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**

	<b>Page</b>
<a href="#"><u>Report of Independent Registered Public Accounting Firm</u></a> (PCAOB ID No. 243)	<a href="#"><u>94</u></a>
<a href="#"><u>Balance Sheets as of December 31, 2021 and 2020</u></a>	<a href="#"><u>95</u></a>
<a href="#"><u>Statements of Operations for the Years Ended December 31, 2021 and 2020</u></a>	<a href="#"><u>96</u></a>
<a href="#"><u>Statements of Stockholders' Equity for the Years Ended December 31, 2021 and 2020</u></a>	<a href="#"><u>97</u></a>
<a href="#"><u>Statements of Cash Flows for the Years Ended December 31, 2021 and 2020</u></a>	<a href="#"><u>98</u></a>
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## 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, 2021 and 2020, the related statements of operations, stockholders' equity, and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2021 and 2020, 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 22, 2022

**Exagen Inc.**  
**Balance Sheets**  
(in thousands, except share and per share data)

	December 31,	
	2021	2020
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 99,442	\$ 57,448
Accounts receivable, net	9,654	8,910
Prepaid expenses and other current assets	3,638	4,159
Total current assets	112,734	70,517
Property and equipment, net	4,772	2,102
Goodwill	5,506	5,506
Other assets	433	250
Total assets	\$ 123,445	\$ 78,375
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 2,492	\$ 3,014
Accrued and other current liabilities	6,826	5,757
Total current liabilities	9,318	8,771
Borrowings-non-current portion, net of discounts and debt issuance costs	27,478	26,659
Deferred tax liabilities	306	158
Other non-current liabilities	1,407	948
Total liabilities	38,509	36,536
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized, no shares issued or outstanding at December 31, 2021 and December 31, 2020	—	—
Common stock, \$0.001 par value; 200,000,000 shares authorized at December 31, 2021 and December 31, 2020; 16,164,994 and 12,652,308 shares issued and outstanding at December 31, 2021 and December 31, 2020, respectively	16	13
Additional paid-in capital	293,060	223,115
Accumulated deficit	(208,140)	(181,289)
Total stockholders' equity	84,936	41,839
Total liabilities and stockholders' equity	\$ 123,445	\$ 78,375

*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,	
	2021	2020
Revenue	\$ 48,299	\$ 41,975
Operating expenses:		
Costs of revenue	20,588	16,559
Selling, general and administrative expenses	44,541	37,033
Research and development expenses	7,237	3,568
Total operating expenses	<u>72,366</u>	<u>57,160</u>
Loss from operations	(24,067)	(15,185)
Interest expense	(2,625)	(2,565)
Other income, net	16	984
Loss before income taxes	(26,676)	(16,766)
Income tax (expense) benefit	(175)	79
Net loss	<u>\$ (26,851)</u>	<u>\$ (16,687)</u>
Net loss per share, basic and diluted (Note 2)	<u>\$ (1.68)</u>	<u>\$ (1.32)</u>
Weighted-average number of shares used to compute net loss per share, basic and diluted (Note 2)	<u>15,972,256</u>	<u>12,632,780</u>

*The accompanying notes are an integral part of these financial statements*

**Exagen Inc.**  
**Statements of Stockholders' Equity**  
(in thousands, except share and per share amounts)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
<b>Balances at December 31, 2019</b>	12,560,990	\$ 13	\$ 220,248	\$ (164,602)	\$ 55,659
Exercise of stock options	47,549	—	13	—	13
Issuance of stock under Employee Stock Purchase Plan	11,649	—	142	—	142
Stock-based compensation	—	—	2,694	—	2,694
Exercise of common stock warrants	32,120	—	18	—	18
Net loss	—	—	—	(16,687)	(16,687)
<b>Balances at December 31, 2020</b>	12,652,308	13	223,115	(181,289)	41,839
Issuance of stock in public offering, net of issuance costs of \$4,435	4,255,000	4	64,705	—	64,709
Retirement of common stock in exchange for common stock warrant	(804,951)	(1)	(12,774)	—	(12,775)
Issuance of common stock warrant in exchange for retirement of common stock	—	—	12,775	—	12,775
Exercise of stock options	11,950	—	89	—	89
Issuance of stock under Employee Stock Purchase Plan	32,968	—	390	—	390
Stock-based compensation	—	—	4,728	—	4,728
Exercise of common stock warrants	17,719	—	32	—	32
Net loss	—	—	—	(26,851)	(26,851)
<b>Balances at December 31, 2021</b>	16,164,994	\$ 16	\$ 293,060	\$ (208,140)	\$ 84,936

*The accompanying notes are an integral part of these financial statements*

**Exagen Inc.**  
**Statements of Cash Flows**  
**(in thousands)**

	<b>Years Ended December 31,</b>	
	<b>2021</b>	<b>2020</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (26,851)	\$ (16,687)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	948	546
Amortization of debt discount and debt issuance costs	279	274
Non-cash interest expense	540	531
Deferred income taxes	148	(106)
Stock-based compensation	4,728	2,694
Changes in assets and liabilities:		
Accounts receivable, net	(744)	(3,195)
Prepaid expenses and other current assets	521	(708)
Other assets	(167)	(15)
Accounts payable	(655)	986
Accrued and other current liabilities	984	1,596
Net cash used in operating activities	<u>(20,269)</u>	<u>(14,084)</u>
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(2,370)	(455)
Purchase of other assets	(50)	—
Net cash used in investing activities	<u>(2,420)</u>	<u>(455)</u>
<b>Cash flows from financing activities:</b>		
Proceeds from exercise of stock options	89	13
Proceeds from common stock issued under Employee Stock Purchase Plan	390	142
Proceeds from exercise of common stock warrants	32	18
Principal payment on capital lease obligations	(525)	(249)
Proceeds from Paycheck Protection Program loan	—	2,865
Repayment of Paycheck Protection Program loan	—	(2,865)
Proceeds from the issuance of common stock in public offering, gross	69,144	—
Payment of issuance costs related to public offering	(4,407)	—
Payments of deferred offering costs	(40)	(21)
Net cash provided by (used in) financing activities	<u>64,683</u>	<u>(97)</u>
Net change in cash, cash equivalents and restricted cash	41,994	(14,636)
Cash, cash equivalents and restricted cash, beginning of period	57,548	72,184
Cash, cash equivalents and restricted cash, end of period	<u>\$ 99,542</u>	<u>\$ 57,548</u>
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid for interest expense	\$ 1,815	\$ 1,758
<b>Supplemental disclosure of non-cash items:</b>		
Equipment purchased under capital lease obligations	\$ 1,111	\$ 260
Costs incurred, but not paid, in connection with capital expenditures	\$ 685	\$ 553
Deferred offering costs included in accounts payable and accrued and other current liabilities	\$ —	\$ 40
Deferred offering costs reclassified to equity	\$ 28	\$ —

*The accompanying notes are an integral part of these financial statements*

**Exagen Inc.**  
**Notes to Financial Statements**

**Note 1. Organization**

***Description of Business***

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

***Liquidity***

The Company has incurred recurring losses and negative cash flows from operating activities since inception. The Company anticipates that it will continue to incur net losses into the foreseeable future. At December 31, 2021, the Company had cash and cash equivalents of \$99.4 million and had an accumulated deficit of \$208.1 million. Since inception, the Company has financed its operations primarily through a combination of equity financings of common stock and private placements of preferred securities, debt financing arrangements, and revenue from sales of the Company's products. 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) and net deferred tax assets (and related valuation allowance). The Company evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could materially differ from those estimates.

***Concentration of Credit Risk and Other Risk and Uncertainties***

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

Significant payors and customers are those which represent more than 10% of the Company's total revenue or accounts receivable balance at each respective balance sheet date. For each significant payor and customer, 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,	
	2021	2020
Medicare	19 %	20 %
Medicare Advantage	13 %	11 %
Blue Shield	12 %	11 %
Janssen (SIMPONI <sup>®</sup> )	*	12 %

\* Less than 10%.

	Accounts Receivable	
	December 31,	
	2021	2020
Blue Shield	19 %	11 %
United Healthcare	18 %	*
Janssen (SIMPONI <sup>®</sup> )	— %	35 %

\* Less than 10%.

For the years ended December 31, 2021 and 2020, approximately 81% and 70% of the Company's revenue was related to the AVISE<sup>®</sup> CTD test, respectively.

The Company is dependent on key suppliers for certain laboratory materials. For each of the years ended December 31, 2021 and 2020, approximately 97% of the Company's diagnostic testing supplies were purchased from two suppliers. An interruption in the supply of these materials would impact the Company's ability to perform testing services.

### **Disaggregation of Revenue**

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

	Years Ended December 31,	
	2021	2020
Revenue:		
Healthcare insurers	\$ 27,499	\$ 22,456
Government	9,221	8,446
Client(1)	9,288	5,109
Other(2)	1,091	836
Janssen (SIMPONI <sup>®</sup> )	1,200	5,128
Total revenue	<u>\$ 48,299</u>	<u>\$ 41,975</u>

(1) Includes hospitals, other laboratories, etc.

(2) Includes patient self-pay.

### **Fair Value Measurements**

The carrying value of the Company's cash and cash equivalents approximate fair value due to the short-term nature of these items. The estimated fair value of the Company's long-term borrowings are determined by Level 2 inputs and is based primarily on quoted market prices for the same or similar issues. The recorded value of the Company's

long-term borrowings approximates the current fair value as the interest rate and other terms are that which are currently available to the Company.

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.

### ***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.

The Company has 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):

	<b>December 31,</b>	
	<b>2021</b>	<b>2020</b>
Cash and cash equivalents	\$ 99,442	\$ 57,448
Restricted cash	100	100
	<u>\$ 99,542</u>	<u>\$ 57,548</u>

### ***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. No impairment was recognized for any of the 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. Payments made prior to the completion of clinical study services are capitalized until the services are rendered. Expenses associated with clinical study activities are recorded in research and development expenses in the accompanying statement of operations.

### ***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 (each, a payor) consist of healthcare insurers, government payors (primarily Medicare and Medicaid), client payors (i.e., hospitals, other laboratories, etc.), and patient self-pay. The Company's service is a single performance obligation that is completed upon the delivery of test results to the prescribing physician which triggers revenue recognition.

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

Collection of the Company's net revenues from payors is normally a function of providing complete and correct billing information to the healthcare insurers and generally occurs within 30 to 90 days of billing. Contracts do not contain significant financing components based on the typical period of time between performance of services and collection of consideration. Revenue recognized during the years ended December 31, 2021 and 2020 related to performance obligations satisfied in previous periods was approximately \$0.7 million and \$0.8 million, respectively, which relates to a change in estimate of the transaction price.

### *Janssen Promotion Agreement*

In December 2018, the Company entered into a co-promotion agreement (as amended from time to time, the Janssen Agreement) with Janssen Biotech, Inc. (Janssen) to co-promote SIMPONI® in the United States. In August 2021, the Company and Janssen mutually agreed to terminate the Janssen Agreement effective on August 31, 2021.

Pursuant to the Janssen Agreement, the Company was responsible for the costs associated with its sales force over the course of such co-promotion. Janssen was 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 was entitled to a quarterly tiered promotion fee based on the incremental increase in total prescribed units of SIMPONI® for that quarter over a predetermined baseline. For the year ended December 31, 2020, the tiered promotion fee ranged from \$750 to \$1,250 per prescription over a predetermined baseline. Due in part to COVID-19, in June 2020, the Janssen Agreement was amended to adjust the predetermined average baseline for the third and fourth quarters of 2020. The Janssen Agreement was further amended in June 2020 and December 2020 to adjust the predetermined average baseline for prescribed units for the quarters ending December 31, 2020 and March 31, 2021 and was subject to further adjustment under certain circumstances. In June 2021, the Janssen Agreement was again amended to proportionally increase the baseline for prescribed units for the quarter ended June 30, 2021 to reflect the addition of certain geographies to the sales territories covered by the Janssen Agreement. For the first and second quarters of 2021, the Company earned the minimum promotion fee of \$0.3 million.

Upon the termination of the Janssen Agreement on August 31, 2021, the Company became entitled to receive an aggregate of \$0.6 million in consideration, which was earned in the year ended December 31, 2021. Pursuant to the terms of the termination, the Company is restricted from promoting any other biologic or Janus kinase inhibitor used for treatment of indications covered by the Janssen Agreement without first obtaining Janssen's written consent until May 31, 2022.

The Company's obligations relating to sales and co-promotion services for SIMPONI® were a series of single performance obligations since Janssen simultaneously received and consumed benefits provided by the Company's sales and co-promotional services. The method for measuring progress towards satisfying the performance obligations was based on prescribed units in excess of the contractual baseline at the contractual rate earned per unit since the Amended Janssen Agreement was cancelable. The Company recognized co-promotion revenue of approximately \$1.2 million and \$5.1 million during the years ended December 31, 2021 and 2020, respectively. The related expenses for marketing SIMPONI® are included in selling, general and administrative expenses and are expensed as incurred.

### **Research and Development**

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

### **Advertising and Marketing Costs**

Costs associated with advertising and marketing activities are expensed as incurred. Total advertising and marketing costs were approximately \$1.7 million and \$1.3 million for the years ended December 31, 2021 and 2020, 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 \$2.1 million and \$1.4 million, for the years ended December 31, 2021 and 2020, 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 and purchases under the Company's 2019 Employee Stock Purchase Plan (ESPP) rights is determined using the Black-Scholes-Merton (BSM) option pricing model, which requires management to make certain assumptions regarding a number of complex and subjective variables. Equity award forfeitures are recorded as they occur.

The BSM option pricing model incorporates various estimates, including the fair value of the Company's common stock, expected volatility, expected term and risk-free interest rates. The weighted-average expected term of options was calculated using the simplified method. 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.

The fair value of each restricted stock unit is determined on the grant date using the closing price of the Company's common stock on the grant date and generally vest from the grant date in four equal annual installments subject to the holder's continued service with the Company. The Company issues new shares to satisfy restricted stock units upon vesting.

The fair value of the Company's common stock is determined by using the closing price of its common stock on the corresponding date.

### ***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. The weighted-average number of shares in 2021 used to compute basic and diluted shares includes shares issuable upon the exercise of pre-funded warrants at a nominal price. Potentially dilutive common stock equivalents are comprised of warrants for the purchase of common stock, options and restricted stock units outstanding under the Company's 2019 Incentive Award Plan (the 2019 Plan) and shares of the Company's common stock pursuant to the ESPP. For the years ended December 31, 2021 and 2020,

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,	
	2021	2020
Warrants to purchase common stock	409,108	426,827
Common stock options	2,014,330	1,975,761
Restricted stock units	415,325	—
Employee stock purchase plan	20,193	11,640
<b>Total</b>	<b>2,858,956</b>	<b>2,414,228</b>

### **Government Assistance Grant Income**

Absent authoritative accounting standards, interpretive guidance issued and commonly applied by financial statement preparers allows for the selection of accounting policies amongst acceptable alternatives. Based on the facts and circumstances of the government assistance received by the Company as discussed in Note 11, the Company determined it most appropriate to account for the transaction by analogy to International Accounting Standards 20 (IAS 20), *Accounting for Government Grants and Disclosure of Government Assistance*. IAS 20 permits for the recognition in earnings either separately under a general heading such as other income, or as a reduction of the related expenses.

### **Segment Reporting**

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. The Company views its operations as, and manages its business in, one operating segment.

### **Recent Accounting Pronouncements Not Yet Adopted**

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

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

related to the recognition of a new right-of-use asset and lease liability at January 1, 2022 on the Company's balance sheet for its office and laboratory space operating leases.

### Recently Adopted Accounting Standards

In December 2019, the FASB issued ASU 2019-12, *Simplifying the Accounting for Income Taxes*. The new guidance removes certain exceptions to the general principles of ASC 740 in order to simplify the complexities of its application. These changes include eliminations to the exceptions for intraperiod tax allocation, recognizing deferred tax liabilities related to outside basis differences, and year-to-date losses in interim periods, among others. The effective date of this guidance for public companies is for fiscal years, and interim period within those fiscal years, beginning after December 15, 2020. The Company adopted this guidance on January 1, 2021, and the adoption did not have a material impact on its financial statements.

In November 2021, the FASB issued ASU 2021-10, *Government Assistance* (Topic 832). The update requires certain annual disclosures about transactions with a government that are accounted for by applying a grant or contribution model by analogy. The amendments in this update are effective for fiscal years beginning after December 15, 2021. Early application of the amendments is permitted. The Company early adopted these disclosure requirements and applied them to its disclosure of the funding received as part of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) in 2020.

### 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,	
	2021	2020
Diagnostic testing supplies	\$ 1,091	\$ 1,203
Prepaid product royalties	49	68
Prepaid maintenance and insurance contracts	2,008	2,229
Other prepaid and other current assets	490	659
Prepaid and other current assets	\$ 3,638	\$ 4,159

#### Property and Equipment

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

	December 31,	
	2021	2020
Furniture and fixtures	\$ 83	\$ 64
Laboratory equipment	4,361	2,679
Computer equipment and software	1,206	927
Leasehold improvements	1,151	1,072
Construction in progress	1,855	301
Total property and equipment	8,656	5,043
Less: accumulated depreciation and amortization	(3,884)	(2,941)
Property and equipment, net	\$ 4,772	\$ 2,102

Depreciation and amortization expense for the years ended December 31, 2021 and 2020, was approximately \$0.9 million and \$0.5 million, respectively. At December 31, 2021 and December 31, 2020, the gross book value of assets under capital lease was \$2.5 million and \$1.2 million, respectively, and is classified in "Laboratory equipment" in the table above. At December 31, 2021, \$1.5 million relates to leasehold improvements in connection

with the conversion of the Company's warehouse space into additional clinical laboratory space and research and development facility space, which is expected to be placed in service in calendar year 2022.

### **Accrued and Other Current Liabilities**

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

	December 31,	
	2021	2020
Accrued payroll and related expenses	\$ 4,048	\$ 3,589
Accrued interest	139	147
Accrued purchases of goods and services	510	311
Accrued royalties	180	221
Accrued clinical study activity	254	228
Capital lease obligations, current portion	587	308
Other accrued liabilities	1,108	953
Accrued and other current liabilities	<u>\$ 6,826</u>	<u>\$ 5,757</u>

### **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. The 2017 Term Loan was subsequently amended in November 2019 and November 2021. At December 31, 2021, no additional amounts remain available to borrow under the 2017 Term Loan.

In November 2021, the Company executed the Second Amendment to the Loan and Security Agreement (the 2017 Loan Amendment). The interest rate on all borrowings under the 2017 Loan Amendment is 8.0%, of which 2.0% is paid in-kind in the form of additional term loans (PIK Loans) until December of 2024, after which interest accrues at an annual rate of 8.0%. The Company has estimated the effective interest rate of this loan to be approximately 8.5%. Accrued interest is due and payable monthly, unless the Company elects to pay paid-in-kind interest. The outstanding principal and accrued interest on the 2017 Loan Amendment will be repaid in twenty-four equal monthly installments commencing in December 2024. Upon repayment of the final installment under the 2017 Loan Amendment, the Company is required to pay an additional fee of \$1.0 million. This obligation is being accreted into interest expense over the term of Loan Amendment using the effective interest method. For each of the years ended December 31, 2021 and 2020, the Company issued PIK Loans totaling \$0.5 million.

The 2017 Loan Amendment requires a prepayment premium of 3% of the aggregate outstanding principal. The prepayment premium decreases by 1% on November 1, 2022, 2023 and 2024.

The 2017 Loan Amendment is collateralized by a first priority security interest in substantially all of the Company's assets, including intellectual property. The affirmative covenants of the 2017 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, 2022. The consequences of failing to achieve the performance covenant may be cured if, within sixty days of failing to achieve the performance covenant, the Company issues additional equity securities or subordinated debt with net proceeds sufficient to fund

any cash flow deficiency generated from operations, as defined. The 2017 Loan Amendment requires that the Company maintain certain levels of minimum liquidity and maintains 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, 2021, the Company was in compliance with all covenants of the 2017 Loan Amendment.

Upon an event of default in any of the 2017 Loan Amendment covenants, the repayment of the 2017 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 2017 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 2017 Loan Amendment due beyond twelve months of the balance sheet date as non-current.

#### *Future Minimum Payments on the Outstanding Borrowings*

As of December 31, 2021, future minimum aggregate payments, including interest, for outstanding borrowings under the Loan Amendment are as follows (in thousands):

	<b>Years Ending December 31,</b>
2022	\$ 1,653
2023	1,686
2024	2,980
2025	16,152
2026	14,786
Total	<u>37,257</u>
Less:	
Unamortized debt discount and issuance costs	(208)
Interest	<u>(9,571)</u>
Total borrowings, net of discounts and debt issuance costs	<u>\$ 27,478</u>

## **Note 5. Commitments and Contingencies**

### **Leases**

As of December 31, 2021, the Company leases office and laboratory space in Vista, California, under leases that expire in April 2027, with an option to extend a portion of the lease for an additional 5-year period. The Company also leases additional office space in Vista, California, under a lease that expires in April 2027 with an option to extend the lease for an additional 5-year period. The Company's lease payments under each of these leases are subject to escalation clauses. In addition, effective on August 23, 2021, the Company entered into a sub-lease agreement for an additional office space in Carlsbad, California. The sub-lease commenced in October 2021 and expires in April 2027.

Minimum annual lease payments under non-cancelable lease arrangements at December 31, 2021 are as follows (in thousands):

Years Ending December 31,	Capital Leases	Operating Leases
2022	\$ 641	\$ 1,337
2023	566	1,445
2024	313	1,489
2025	66	1,533
2026	—	1,584
Thereafter	—	539
Total minimum lease payments	1,586	\$ 7,927
Less: amount representing interest	(116)	
Present value of future minimum lease payments	1,470	
Less: current portion	(587)	
Long-term capital lease obligations	\$ 883	

For the years ended December 31, 2021 and 2020, rent expense was \$0.9 million and \$0.6 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. One such license agreement, the license agreement, dated September 13, 2007, between the Company and Prometheus Laboratories, Inc. (the Prometheus License), was terminated by mutual agreement on September 28, 2021. In consideration for terminating the Prometheus License, including with respect to the remaining potential milestone payments thereunder, the Company agreed to pay Prometheus Laboratories, Inc. a fee of approximately \$0.1 million and acquired the intellectual property previously licensed to the Company pursuant to the Prometheus Agreement.

The Company has ongoing royalty payment obligations of 2.5% on net sales of products which incorporate certain acquired technologies. Future royalties payable under these arrangements are limited to the lesser of (i) an aggregate of \$1.2 million (including an upfront payment of \$100,000) and (ii) 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 ranging from 1.5% to 7.0% on net sales of products which incorporate licensed technology, as defined in such agreements. Royalties are accrued when earned and recorded in costs of revenue in the accompanying statement of operations.

In May 2021, the Company entered into an exclusive license agreement with Allegheny Health Network Research Institute, or AHN, to obtain an exclusive license to AHN's patent rights in certain inventions, pursuant to which the Company paid AHN an initial license fee of \$0.4 million. In addition, under the terms of the exclusive license agreement, the Company is required to pay the greater of royalties in the low single digits on net sales of diagnostic tests using the assigned patents or a flat annual minimum royalty amount, pending approvals and commercialization.

In November 2021, the Company entered into an exclusive license agreement with Queen Mary University of London, or QMUL, to obtain an exclusive license to QMUL's patent rights in certain inventions, pursuant to which the Company is required to pay QMUL an initial license fee of \$0.4 million. The Company is obligated to make a one-time payment of \$0.1 million relating to the first commercial sale of the licensed products. In addition, after the first 18 months of commercial sales under the terms of the exclusive license agreement, the Company is required to



pay royalties in the high single-digits on net sales of testing products using the assigned patents, pending approvals and commercialization.

### Supply Agreement

In December 2021, the Company entered into an amended supply agreement with one supplier for reagents which includes minimum annual purchase commitments of \$3.7 million and \$6.0 million for the years ended December 31, 2021 and 2022, respectively, with a 15% annual increase thereafter for unconditional minimum purchase commitments through the year ended December 31, 2025.

### Collaboration Obligations

In May 2021, the Company entered into a master research collaboration agreement with AHN, pursuant to which the Company is required to pay AHN a collaboration fee of \$0.4 million for each year during the initial term of the agreement. Collaboration expenses under the master research collaboration agreement were \$0.3 million for the year ended December 31, 2021. Collaboration expenses under the AHN collaboration are included in research and development expenses.

### Contingencies

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

### Litigation

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

## Note 6. Fair Value Measurements

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

	December 31, 2021			
	Total	Level 1	Level 2	Level 3
<b>Assets:</b>				
Money market funds, included in cash and cash equivalents	\$ 95,761	\$ 95,761	\$ —	\$ —
	December 31, 2020			
	Total	Level 1	Level 2	Level 3
<b>Assets:</b>				
Money market funds, included in cash and cash equivalents	\$ 34,507	\$ 34,507	\$ —	\$ —

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

## Note 7. Stockholders' Equity

### Common Stock

On November 10, 2020, the Company filed a registration statement on Form S-3 (the Shelf Registration Statement), covering the offering, from time to time, of up to \$150.0 million of common stock, preferred stock, debt securities, warrants and units, which Shelf Registration Statement became effective on November 19, 2020.

On March 25, 2021, the Company completed a public offering of 4,255,000 shares of its common stock at a public offering price of \$16.25 per share. Net proceeds from the offering were approximately \$64.7 million, after deducting underwriting discounts, commissions and other offering expenses of \$4.4 million. The shares were registered pursuant to the Company's Shelf Registration Statement discussed above.

### **Exchange Agreement**

On June 22, 2021, the Company entered into an exchange agreement (the Exchange Agreement) with an Investor and its affiliates (the Exchanging Stockholders), pursuant to which the Company exchanged an aggregate of 804,951 shares of the Company's common stock owned by the Exchanging Stockholders for pre-funded warrants (the Exchange Warrants) to purchase an aggregate of 804,951 shares of common stock (subject to adjustment in the event of any stock dividends and splits, reverse stock split, recapitalization, reorganization or similar transaction, as described in the Exchange Warrants), with an exercise price of \$0.001 per share. The Exchange Warrants do not expire and are exercisable at any time except that the Exchange Warrants cannot be exercised by the Exchanging Stockholders if, after giving effect thereto, the Exchanging Stockholders would beneficially own more than 4.99% of the Company's common stock, which percentage may change at the Exchanging Stockholder's election to any other percentage upon 61 days' notice to the Company. The Company recorded the retirement of common stock exchanged as a reduction of common shares outstanding and additional paid-in-capital at the fair value of the Exchange Warrants on the issuance date. The Exchange Warrants are classified as equity and the fair value of the Exchange Warrants was recorded as an increase to additional paid-in-capital and is not subject to remeasurement. The Company determined that the fair value of the Exchange Warrants is substantially similar to the fair value of the retired shares on the issuance date due to the negligible exercise price for the Exchange Warrants. As of December 31, 2021, none of the Exchange Warrants have been exercised.

### **Outstanding Warrants**

The following equity classified warrants to purchase common stock were outstanding as of December 31, 2021:

	Shares	Exercise Price	Issuance date	Expiration date
Common stock warrants	237,169	\$ 1.84	January 19, 2016	January 19, 2026
Common stock warrants	67,086	1.84	March 31, 2016	March 31, 2026
Common stock warrants	131	1.84	April 1, 2016	April 1, 2026
Common stock warrants	83,778	14.32	September 7, 2017	September 7, 2024
Common stock warrants	20,944	14.32	December 7, 2018	December 7, 2025
Common stock warrants (Exchange Warrants)	804,951	0.001	June 22, 2021	None
	1,214,059			

During the year ended December 31, 2021, warrants to purchase common stock were exercised resulting in the issuance of 17,719 shares of the Company's common stock and cash proceeds of an immaterial amount.

## **Note 8. Stock Option Plan**

### **2019 Incentive Award Plan**

In September 2019, the Company's Board of Directors adopted, and the Company's stockholders approved, the 2019 Plan. Under the 2019 Plan, which expires in September 2029, the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units and other awards to individuals who are then employees, officers, non-employee directors or consultants of the Company or its subsidiaries. The options generally expire ten years after the date of grant and are exercisable to the extent vested. Vesting is established by the Board of Directors and is generally four years from the date of grant. The 2019 Plan contains an "evergreen provision" that allows annual increases in the number of shares available for issuance on the first day of each calendar year through January 1, 2029 in an amount equal to the lesser of: (i) 4% of the outstanding capital stock on each

December 31st, or (ii) such lesser amount determined by the Board of Directors. As of December 31, 2021, 1,179,571 shares remained available for future awards. Under the evergreen provision, on January 1, 2022, an additional 646,599 shares became available for issuance under the 2019 Plan.

### 2019 Employee Stock Purchase Plan

In September 2019, the Board of Directors adopted, and the Company's stockholders approved, 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. The number of shares of common stock available for issuance under the ESPP will be annually increased on the first day of each calendar year during the term of the ESPP through January 1, 2029 in an amount equal to the lesser of (i) 1% of the outstanding capital stock on each December 31st, or (ii) such lesser amount determined by the Board of Directors. As of December 31, 2021, 327,516 shares of common stock remained available for issuance under the ESPP. Under the evergreen provision, on January 1, 2022, an additional 161,649 shares became available for issuances under the ESPP.

### Stock Options

Stock option activity under the Company's 2019 Plan is set forth below:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding, December 31, 2020	1,975,761	\$ 11.81	8.71	\$ 6,750
Granted	229,850	\$ 16.79		
Exercised	(11,950)	\$ 7.40		
Forfeited	(128,665)	\$ 14.44		
Expired	(50,666)	\$ 17.18		
Outstanding, December 31, 2021	2,014,330	\$ 12.10	7.87	\$ 5,428
Vested and expected to vest, December 31, 2021	2,014,330	\$ 12.10	7.87	\$ 5,428
Options exercisable, December 31, 2021	1,050,036	\$ 10.17	7.53	\$ 4,262

The weighted-average grant date fair value per share of employee options granted to employees during the years ended December 31, 2021 and 2020 was \$8.83 and \$7.55, 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 \$11.63 and \$13.20 per share at December 31, 2021 and 2020, respectively. The intrinsic value of options exercised for the years ended December 31, 2021 and 2020 was \$0.1 million and \$1.0 million, respectively. As of December 31, 2021, total unrecognized compensation cost related to option awards was \$6.3 million, which is expected to be recognized over a remaining weighted-average vesting period of 2.0 years.

### Restricted Stock Units

Restricted stock unit activity under the Company's 2019 Plan is set forth below:

	Number of Shares	Weighted-Average Grant Date Fair Value	Aggregate Intrinsic Value
Outstanding, December 31, 2020	—	\$ —	\$ —
Awards granted	449,000	\$ 16.51	
Awards released	—	\$ —	
Awards canceled	(33,675)	\$ 16.24	
Outstanding, December 31, 2021	415,325	\$ 16.54	\$ 4,830

As of December 31, 2021, all of the outstanding restricted stock units are unvested. As of December 31, 2021, total unrecognized compensation cost related to restricted stock units was \$5.6 million, which is expected to be recognized over a remaining weighted-average vesting period of 3.3 years.

## Stock-Based Compensation Expense

### Stock Options

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,	
	2021	2020
Expected volatility	56%-60%	47%-53%
Risk-free interest rate	0.8%-1.1%	0.4%-1.7%
Dividend yield	—	—
Expected term (in years)	5.50-6.08	5.5-6.08

### Employee Stock Purchase Plan

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

	Years Ended December 31,	
	2021	2020
Expected volatility	45%-60%	58.0%-83.0%
Risk-free interest rate	0.1%	0.1%-1.1%
Dividend yield	—	—
Expected term (in years)	0.5	0.5

Stock-based compensation expense related to the ESPP for the years ended December 31, 2021 and 2020 was \$0.2 million and less than \$0.1 million, respectively. As of December 31, 2021, total unrecognized compensation cost related to stock purchase rights granted under the ESPP was less than \$0.1 million, which is expected to be recognized over a remaining weighted-average vesting period of 0.2 years.

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

	Years Ended December 31,	
	2021	2020
Cost of revenue	\$ 164	\$ 33
Selling, general and administrative	3,943	2,419
Research and development	621	242
Total	\$ 4,728	\$ 2,694

Common stock reserved for future issuance consists of the following at December 31, 2021:

Warrants to purchase common stock	1,214,059
Common stock option grants issued and outstanding	2,014,330
Common stock reserved for issuance upon vesting of outstanding restricted stock units	415,325
Common shares available for grant under the 2019 Plan	1,179,571
Common shares available for future issuance under ESPP	327,516
Total	5,150,801

## Note 9. Income Taxes

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

	Years Ended December 31,	
	2021	2020
Current:		
Federal	\$ —	\$ —
State	27	27
Total current	27	27
Deferred:		
Federal	137	(117)
State	11	11
Total deferred	148	(106)
Provision (benefit) for income tax	\$ 175	\$ (79)

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

	Years Ended December 31,	
	2021	2020
Federal statutory tax rate	(21.0)%	(21.0)%
State income taxes, net of federal tax benefits	(3.8)%	(3.9)%
Research and development tax credits	(1.2)%	(0.5)%
Stock compensation	0.9 %	1.0 %
Non-deductible expenses	1.1 %	1.1 %
Change in valuation allowance	24.6 %	22.6 %
Other	— %	0.2 %
Effective tax rate	0.6 %	(0.5)%

Significant components of the Company's deferred tax assets at December 31, 2021 and 2020 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,	
	2021	2020
Deferred tax assets:		
Net operating loss carryforwards	\$ 22,365	\$ 17,733
Research and development tax credits	1,102	629
Accruals, reserves and other	1,055	920
Interest expense	1,953	1,306
Basis differences in fixed and intangible assets	—	117
Stock compensation	1,407	528
Total gross deferred tax assets	27,882	21,233
Less: valuation allowance	(27,158)	(20,596)
Deferred tax assets, net	724	637
Deferred tax liabilities:		
Financing and acquisition-related liabilities	(335)	(336)
Indefinite lived assets	(521)	(459)
Basis differences in fixed and intangible assets	(175)	—
Deferred tax liabilities, net	(1,031)	(795)
Net deferred tax liabilities	\$ (307)	\$ (158)

Changes in the valuation allowance for deferred tax assets during the years ended December 31, 2021 and 2020, which related primarily to increases in net operating loss (NOL) carryforwards, accrued revenue and accruals and reserves were as follows (in thousands):

	December 31,	
	2021	2020
Valuation allowance at the beginning of the year	\$ 20,596	\$ 16,797
Decreases recorded as benefits to income tax provision	—	—
Increases recorded to income tax provision	6,562	3,799
Valuation allowance at the end of the year	\$ 27,158	\$ 20,596

At December 31, 2021 and 2020, the Company had federal NOL carryforwards of approximately \$89.4 million and \$70.6 million, respectively. At December 31, 2021 and 2020, the Company had state NOL carryforwards of \$61.0 million and \$48.9 million, respectively. Approximately \$43.5 million of the federal tax loss carryforwards will begin to expire in 2022, unless previously utilized. The federal NOL carryforwards generated in after December 31, 2017 of \$45.9 million will carryforward indefinitely. The Company's state tax loss carryforwards will expire in 2032, unless previously utilized.

At December 31, 2019, the Company's deferred tax assets are primarily comprised of federal and state tax NOL 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 NOL 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, 2021 and 2020, 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 10. 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 each of the years ended December 31, 2021 and 2020, the Company made contributions to the Plan at 3% of qualified employee compensation, which totaled approximately \$0.5 million. Effective January 1, 2022, the Company will make contributions to the Plan at 4% of qualified employee compensation.

#### **Note 11. COVID-19**

During 2020, due to the worldwide COVID-19 pandemic, the Company experienced a reduction in patient test volumes, delays in patient enrollment in ongoing and planned clinical studies, and delays in the procurement of its testing supplies. In response to the pandemic, the Company has curtailed non-essential employee travel, equipped employees with the ability to work remotely with the exception of clinical laboratory employees, and reduced marketing spend and employee headcount. The full extent to which the COVID-19 pandemic will directly or indirectly continue to impact the Company's business, results of operations and financial condition, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat COVID-19, including, the success of ongoing vaccination efforts, the emergence and prevalence of variant strains of COVID-19, the institution or reinstatement of shutdowns, "stay-at-home-orders" and other public health measures as well as the related economic impact of these matters on local, regional and international markets.

On March 27, 2020, the CARES Act was enacted in response to the COVID-19 pandemic. The CARES Act, among other things, permits NOL carryovers and carrybacks to offset 100% of taxable income for taxable years beginning before 2021. The CARES Act did not have a material impact on the Company's effective tax rate or income tax provision for the year ended December 31, 2020. Under the Tax Cuts and Jobs Act (TCJA), NOLs generated post TCJA were allowed to be carried forward indefinitely but were only allowed to offset 80% of taxable income. As a result of the CARES Act and the change to permit NOLs generated in taxable years 2018, 2019 and 2020 to offset 100% of taxable income, the Company released valuation allowance against its deferred tax assets in the amount of \$0.1 million. The release of valuation allowance resulted in a discrete tax benefit of \$0.1 million for the year ended December 31, 2020. As of the year ended December 31, 2021, some tax benefits under the CARES Act have expired including the ability to use certain NOLs to offset 100% of taxable income. Accordingly, the Company increased its valuation allowance that resulted in a tax expense of \$0.1 million for the year ended December 31, 2021.

In April 2020, the Company received \$0.7 million of funding under the CARES Act Provider Relief Fund, subject to the Company's agreement to comply with the Department of Health & Human Services' (HHS) standard terms and conditions. The CARES Act Provider Relief Fund is a federal fund allocated for general distributions to Medicare facilities and providers impacted by the COVID-19 pandemic and is intended to support COVID-related expenses or lost revenue attributable to COVID-19. The funding received is considered a government grant which is recognized when there is reasonable assurance that the grant will be received and that conditions attached to the grant have been met. The Company accepted the terms and conditions of the grant in May 2020. For the year ended December 31, 2020, the Company recognized \$0.7 million due to lost revenue attributable to COVID-19, which is reflected in other income, net, on its statements of operations and as an operating activity in the statement of cash flows.

On April 16, 2020, the Company entered into a promissory note (the Note) with BOKF, NA dba Bank of Oklahoma (BofO), the lender, evidencing an unsecured loan pursuant to the U.S. Small Business Administration (SBA) Paycheck Protection Program (PPP) of the CARES Act of approximately \$2.9 million (the PPP Loan). The Company applied for and received the PPP Loan pursuant to the then published PPP qualification and certification requirements. On April 23, 2020, the SBA, in consultation with the Department of Treasury, issued new guidance that created uncertainty regarding the qualification requirements for the PPP Loan (the New Guidance). In light of the New Guidance, on May 11, 2020, the Company paid off in full the principal and interest on the PPP Loan, resulting in the termination of the Note.

On December 27, 2020, the Consolidated Appropriations Act, 2021 was signed into law. It provides additional COVID-19 focused relief and extends certain provisions of the CARES Act. The Consolidated Appropriations Act, 2021 did not have a material impact on the Company's financial statements.



## Index to Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed/Furnished Herewith
		Form	File No.	Exhibit	
3.1	<a href="#">Amended and Restated Certificate of Incorporation.</a>	8-K	001-39049	3.1	9/23/2019
3.2	<a href="#">Amended and Restated Bylaws.</a>	8-K	001-39049	3.1	3/22/2021
4.1	<a href="#">Specimen stock certificate evidencing the shares of common stock.</a>	S-1/A	333-233446	4.1	9/9/2019
4.2	<a href="#">Amended and Restated Investors' Rights Agreement, dated July 12, 2019, by and among the Company and certain of its stockholders.</a>	S-1/A	333-233446	4.2	9/9/2019
4.3	<a href="#">Amended and Restated Stockholders' Agreement, dated July 12, 2019, by and among the Company and certain of its stockholders.</a>	S-1/A	333-233446	4.3	9/9/2019
4.4	<a href="#">Form of Common Stock Purchase Warrant issued to investors by the Company in connection with private placement financings.</a>	S-1/A	333-233446	4.4	9/9/2019
4.5	<a href="#">Form of Common Stock Purchase Warrant to purchase common stock issued to investors by the Company in 2016.</a>	S-1/A	333-233446	4.8	9/9/2019
4.6	<a href="#">Form of Warrant to Purchase Stock issued to Innovatus Life Sciences Lending Fund I, LP in connection with the Company's 2018 loan agreement.</a>	S-1/A	333-233446	4.9	9/9/2019
4.7	<a href="#">Form of Exchange Warrant.</a>	10-Q	001-39049	4.5	8/9/2021
10.1#	<a href="#">Exagen Corporation 2002 Stock Option Plan, as amended, and form of option agreement thereunder.</a>	S-1/A	333-233446	10.1	9/9/2019
10.2#	<a href="#">Exagen Diagnostics, Inc. 2013 Stock Option Plan, as amended, and form of option agreement thereunder.</a>	S-1/A	333-233446	10.2	9/9/2019
10.3#	<a href="#">Exagen Inc. 2019 Incentive Award Plan.</a>	S-1/A	333-233446	10.3	9/9/2019
10.4#	<a href="#">Form of Option Agreement under Exagen Inc. 2019 Incentive Award Plan.</a>	S-1/A	333-233446	10.4	9/9/2019
10.5#	<a href="#">Form of Restricted Stock Unit Agreement under Exagen Inc. 2019 Incentive Award Plan.</a>	10-K	001-39049	10.5	3/16/2021
10.6#	<a href="#">Exagen Inc. 2019 Employee Stock Purchase Plan.</a>	S-1/A	333-233446	10.5	9/9/2019
10.7†	<a href="#">License Agreement, dated September 13, 2007, by and between Prometheus Laboratories Inc. and the Company (as successor in interest to Proprius, Inc.).</a>	S-1/A	333-233446	10.6	9/9/2019
10.8†	<a href="#">First Amendment to License Agreement, dated October 23, 2013, by and between Prometheus Laboratories Inc. and the Company (as successor in interest to Cypress Bioscience, Inc.).</a>	S-1/A	333-233446	10.7	9/9/2019
10.9	<a href="#">Letter Agreement, dated September 28, 2021, by and between the Company and Prometheus Laboratories Inc.</a>	10-Q	001-39049	10.6	11/10/2021
10.10†	<a href="#">Asset Purchase Agreement, dated October 8, 2010, by and between Cypress Bioscience, Inc., Proprius, Inc. and the Company.</a>	S-1/A	333-233446	10.11	9/9/2019
10.11†	<a href="#">Amendment No. One to Asset Purchase Agreement, dated March 10, 2011, by and between Cypress Bioscience, Inc., Proprius, Inc. and the Company.</a>	S-1/A	333-233446	10.12	9/9/2019

10.12	<a href="#">Amendment No. Two to Asset Purchase Agreement, dated August 21, 2012, by and between Royalty Pharma Collection Trust, Proprius, Inc. and the Company.</a>	S-1/A	333-233446	10.13	9/9/2019
10.13†	<a href="#">Amendment No. Three to Asset Purchase Agreement, dated February 6, 2013, by and between Royalty Pharma Collection Trust, Proprius, Inc. and the Company.</a>	S-1/A	333-233446	10.14	9/9/2019
10.14	<a href="#">Amendment No. Four to Asset Purchase Agreement, dated October 8, 2013, by and between Royalty Pharma Collection Trust, Proprius, Inc. and the Company.</a>	S-1/A	333-233446	10.15	9/9/2019
10.15	<a href="#">Amendment No. Five to Asset Purchase Agreement, dated January 26, 2016, by and between Royalty Pharma Collection Trust, Proprius, Inc. and the Company.</a>	S-1/A	333-233446	10.16	9/9/2019
10.16†	<a href="#">Amendment No. Six to Asset Purchase Agreement, dated February 16, 2017, by and between Royalty Pharma Collection Trust, Proprius, Inc. and the Company.</a>	S-1/A	333-233446	10.17	9/9/2019
10.17†	<a href="#">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 Company.</a>	S-1/A	333-233446	10.18	9/9/2019
10.18†	<a href="#">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 Company.</a>	S-1/A	333-233446	10.19	9/9/2019
10.19†	<a href="#">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 Company.</a>	S-1/A	333-233446	10.20	9/9/2019
10.20	<a href="#">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 Company.</a>	S-1/A	333-233446	10.21	9/9/2019
10.21†	<a href="#">Exclusive License Agreement, dated September 30, 2013, by and between the University of Pittsburgh-Of the Commonwealth System of Higher Education and the Company.</a>	S-1/A	333-233446	10.22	9/9/2019
10.22†	<a href="#">Exclusive License Agreement, dated September 5, 2011, by and between Thierry Dervieux, Ph.D. and the Company.</a>	S-1/A	333-233446	10.23	9/9/2019
10.23†	<a href="#">Co-Promotion Agreement, dated December 10, 2018, by and between Janssen Biotech, Inc. and the Company.</a>	S-1/A	333-233446	10.24	9/9/2019
10.24†	<a href="#">Amendment #1 to Co-Promotion Agreement, dated January 1, 2019 by and between Janssen Biotech, Inc. and the Company.</a>	10-Q	001-39049	10.1	7/28/2020
10.25†	<a href="#">Amendment #2 to Co-Promotion Agreement, dated June 18, 2020 by and between Janssen Biotech, Inc. and the Company.</a>	10-Q	001-39049	10.2	7/28/2020
10.26†	<a href="#">Amendment #3 to Co-Promotion Agreement, dated December 23, 2020 by and between Janssen Biotech, Inc. and the Company.</a>	10-K	001-39049	10.25	3/16/2021
10.27†	<a href="#">Amendment #4 to Co-Promotion Agreement, dated June 30, 2021 by and between Janssen Biotech, Inc. and the Company.</a>	10-Q	001-39049	10.1	8/9/2021
10.28	<a href="#">Standard Industrial/Commercial Multi-Tenant Lease, dated January 13, 2012, by and between RGS Properties and the Company.</a>	10-Q	001-39049	10.1	7/28/2020

10.29	<a href="#">First Amendment to Standard Industrial/Commercial Multi-Tenant Lease, dated December 1, 2013, by and between RGS Properties and the Company.</a>	10-Q	001-39049	10.2	7/28/2020
10.30	<a href="#">Second Amendment to Standard Industrial/Commercial Multi-Tenant Lease, dated April 29, 2016, by and between RGS Properties and the Company.</a>	10-K	001-39049	10.27	3/25/2020
10.31	<a href="#">Third Amendment to Standard Industrial/Commercial Multi-Tenant Lease, dated June 16, 2017, by and between RGS Properties and the Company.</a>	10-K	001-39049	10.28	3/25/2020
10.32	<a href="#">Fourth Amendment to Standard Industrial/Commercial Multi-Tenant Lease, dated March 16, 2020, by and between RGS Properties and the Company.</a>	10-K	001-39049	10.29	3/25/2020
10.33	<a href="#">Fifth Amendment to Standard Industrial/Commercial Multi-Tenant Lease, dated October 19, 2021, by and between RGS Properties and the Company.</a>	10-Q	001-39049	10.3	11/10/2021
10.34	<a href="#">Standard Industrial/Commercial Single-Tenant Lease, dated September 4, 2014, by and between Geiger Court, LLC and the Company.</a>	S-1/A	333-233446	10.31	9/9/2019
10.35	<a href="#">First Amendment to Standard Industrial/Commercial Single-Tenant Lease, dated August 2, 2017, by and between Geiger Court, LLC and the Company.</a>	10-K	001-39049	10.31	3/25/2020
10.36	<a href="#">Extension of Lease to Standard Industrial/Commercial Single-Tenant Lease, dated March 12, 2020, by and between Liberty Vista and the Company.</a>	10-K	001-39049	10.32	3/25/2020
10.37	<a href="#">First Amendment to Standard Industrial/Commercial Single-Tenant Lease, dated January 6, 2021, by and between Liberty Vista and the Company.</a>	10-K	001-39049	10.34	3/16/2021
10.38	<a href="#">Second Amendment to Standard Industrial/Commercial Single-Tenant Lease, dated October 11, 2021, by and between Liberty Vista and the Company.</a>	10-Q	001-39049	10.2	11/10/2021
10.39	<a href="#">Standard Industrial/Commercial Multi-Tenant Lease, dated March 17, 2020 by and between RGS Properties and the Company.</a>	10-K	001-39049	10.33	3/25/2020
10.40	<a href="#">First Amendment to Standard Industrial/Commercial Multi-Tenant Lease, dated October 19, 2021, by and between RGS Properties and the Company.</a>	10-Q	001-39049	10.4	11/10/2021
10.41†	<a href="#">Sublease Agreement, dated August 19, 2021, by and between Plum Healthcare Group, LLC and the Company.</a>	10-Q	001-39049	10.1	11/10/2021
10.42	<a href="#">Master Lease Agreement, dated February 1, 2018, by and between Celtic Commercial Finance, a division of MB Equipment Finance, LLC and the Company.</a>	S-1/A	333-233446	10.32	9/9/2019
10.43	<a href="#">Loan and Security Agreement, dated September 7, 2017, by and between Innovatus Life Sciences Lending Fund I, LP and the Company.</a>	S-1/A	333-233446	10.33	9/9/2019
10.44	<a href="#">First Amendment to Loan and Security Agreement, dated November 19, 2019, by and between Innovatus Life Sciences Lending I, LP and the Company.</a>	10-K	001-39049	10.36	3/25/2020
10.45	<a href="#">Acknowledgement Letter to Loan and Security Agreement, dated October 7, 2020, by and between Innovatus Life Sciences Lending Fund I, LP and the Company.</a>	10-Q	001-39049	10.1	11/10/2020
10.46	<a href="#">Second Amendment to Loan and Security Agreement, dated November 1, 2021, by and among Innovatus Life Sciences Lending Fund I, LP, other lenders and the Company.</a>	10-Q	001-39049	10.5	11/10/2021

10.47#	<a href="#">Offer Letter, dated October 12, 2010, by and between Thierry Dervieux, Ph.D. and the Company, as amended on September 9, 2011 and September 6, 2019.</a>	S-1/A	333-233446	10.34	9/9/2019	
10.48	<a href="#">Form of Indemnification Agreement for Directors and Officers.</a>	S-1/A	333-233446	10.35	9/9/2019	
10.49#	<a href="#">Offer Letter, dated October 7, 2011, by and between Fortunato Ron Rocca and the Company, as amended on September 4, 2019.</a>	S-1/A	333-233446	10.36	9/9/2019	
10.50#	<a href="#">Offer Letter, dated May 16, 2017, by and between Kamal Adawi and the Company, as amended on September 4, 2019.</a>	S-1/A	333-233446	10.37	9/9/2019	
10.51#	<a href="#">Offer Letter dated February 21, 2020, by and between Debra Zack, MD Ph.D. and the Company.</a>	10-K	001-39049	10.41	3/25/2020	
10.52#	<a href="#">Non-Employee Director Compensation Program.</a>	S-1/A	333-233446	10.38	9/9/2019	
10.53#	<a href="#">Executive Change in Control Severance Plan.</a>	10-K	001-39049	10.46	3/16/2021	
23.1	<a href="#">Consent of Independent Registered Public Accounting Firm.</a>					X
24.1	<a href="#">Power of Attorney (included on signature page).</a>					X
31.1	<a href="#">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.</a>					X
31.2	<a href="#">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.</a>					X
32.1*	<a href="#">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.</a>					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
104	The cover page from the Company's Annual Report on Form 10-K for the year ended December 31, 2021, has been formatted in Inline XBRL.					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 22, 2022

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.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
<u>/s/ Fortunato Ron Rocca</u> Fortunato Ron Rocca	President, Chief Executive Officer and Director (Principal Executive Officer)	March 22, 2022
<u>/s/ Kamal Adawi</u> Kamal Adawi	Chief Financial Officer and Corporate Secretary (Principal Financial and Accounting Officer)	March 22, 2022
<u>/s/ Brian Birk</u> Brian Birk	Chairman of the Board of Directors	March 22, 2022
<u>/s/ Ana Hooker</u> Ana Hooker	Director	March 22, 2022
<u>/s/ Wendy S. Johnson</u> Wendy S. Johnson	Director	March 22, 2022
<u>/s/ Tina S. Nova, Ph.D.</u> Tina S. Nova, Ph.D.	Director	March 22, 2022
<u>/s/ Ebetuel Pallares, Ph.D.</u> Ebetuel Pallares, Ph.D.	Director	March 22, 2022
<u>/s/ Bruce C. Robertson, Ph.D.</u> Bruce C. Robertson, Ph.D.	Director	March 22, 2022
<u>/s/ Frank Stokes</u> Frank Stokes	Director	March 22, 2022
<u>/s/ James L.L. Tullis</u> James L.L. Tullis	Director	March 22, 2022

Consent of Independent Registered Public Accounting Firm

Exagen Inc.  
Vista, California

We hereby consent to the incorporation by reference in the Registration Statement Form S-3 (No. 333-250015) and Form S-8 (Nos. 333-233878 and 333-256014) of Exagen Inc. of our report dated March 22, 2022, relating to the financial statements, which appears in this Annual Report on Form 10-K.

/s/ BDO USA, LLP

San Diego, California  
March 22, 2022

**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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
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 22, 2022

/s/ Fortunato Ron Rocca

Fortunato Ron Rocca

President and Chief Executive Officer

(Principal Executive Officer)

**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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
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 22, 2022

/s/ Kamal Adawi

Kamal Adawi

Chief Financial Officer

(Principal Financial and Accounting Officer)

**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, 2021 (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 22, 2022

/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, 2021 (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 22, 2022

/s/ Kamal Adawi

Kamal Adawi

Chief Financial Officer (Principal Financial and Accounting  
Officer)