Exagen®

2023

Annual Report

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Dear Shareholders,

Over the last year, we've worked to deliver the best testing for patients and clinicians, both in terms of testing accuracy and in the service provided. In order to accomplish this goal, the entire company focused on improving every aspect of our core product offering, AVISE CTD. We were successful in accomplishing the goals we set for 2023 and have positioned ourselves to achieve further progress towards operating a profitable company.

2023 Selected Financial Results

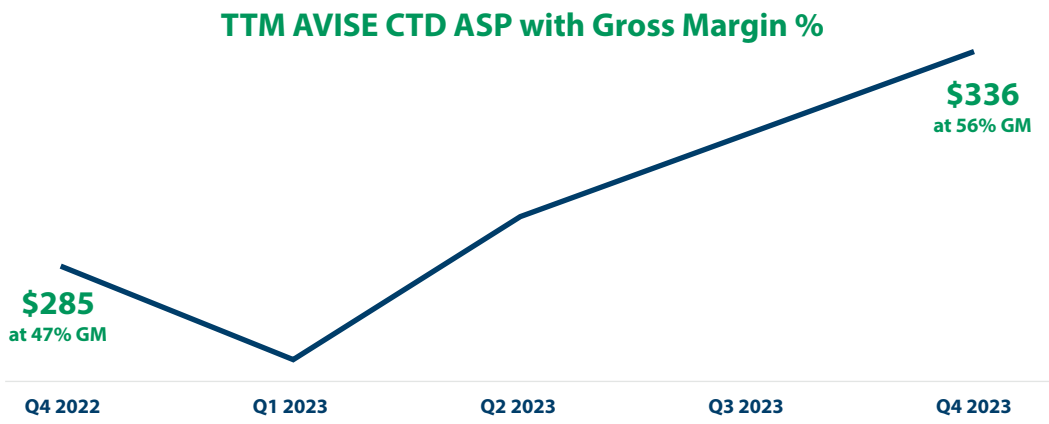
Key Metrics	2023	2022	Growth %
FY Revenue	$52.5M	$45.6M	**15.3%**
FY Volume	137,650	135,210	**1.8%**
TTM ASP	$336	$285	**18.0%**
Gross Margin	56.1%	46.9%	**19.6%**
Adjusted EBITDA	($17.1M)	($39.8M)	**57.1%**
Net Loss	($23.7M)	($47.4M)	**50.0%**

ASP is the Opportunity

Our primary focus this past year, which will continue into 2024, was to improve the realized reimbursed rate we obtain for AVISE CTD, which we commonly refer to as our average selling price, or ASP. When I joined the company, we were in the midst of a pricing and coverage discussion with CMS, our trailing twelve-month ASP sat at $285 at the end of 2022 and was in the process of moving lower due to repricing by Medicare, which was expected to occur in January of 2023. The team here at Exagen has worked extremely hard to not only make up for this headwind, but to further improve our TTM ASP from 2022 levels. As we look back at 2023, we dramatically overhauled our revenue cycle operations, changing personnel, processes and systems. We held claims in the first half of the year in order to better manage filing deadlines with commercial payors and this allowed us to

improve our processes without sacrificing efficacy as the year went on. Our primary goal with improving revenue cycle operations is not only to win individual appeals, but it has strategic implications and specifically, we are working to create awareness at the payor level of who we are,

how our tests are critical to patient care and why it's a financial benefit to be included in their suite of covered services, all of which is included with each appeal. We are still in the infancy of our new appeals efforts, which increased 162% in 2023 and have set ourselves up well for 2024 and beyond. Improvement in our TTM ASP will be key in evaluating the success of our strategy and it's a metric we watch and report on consistently.



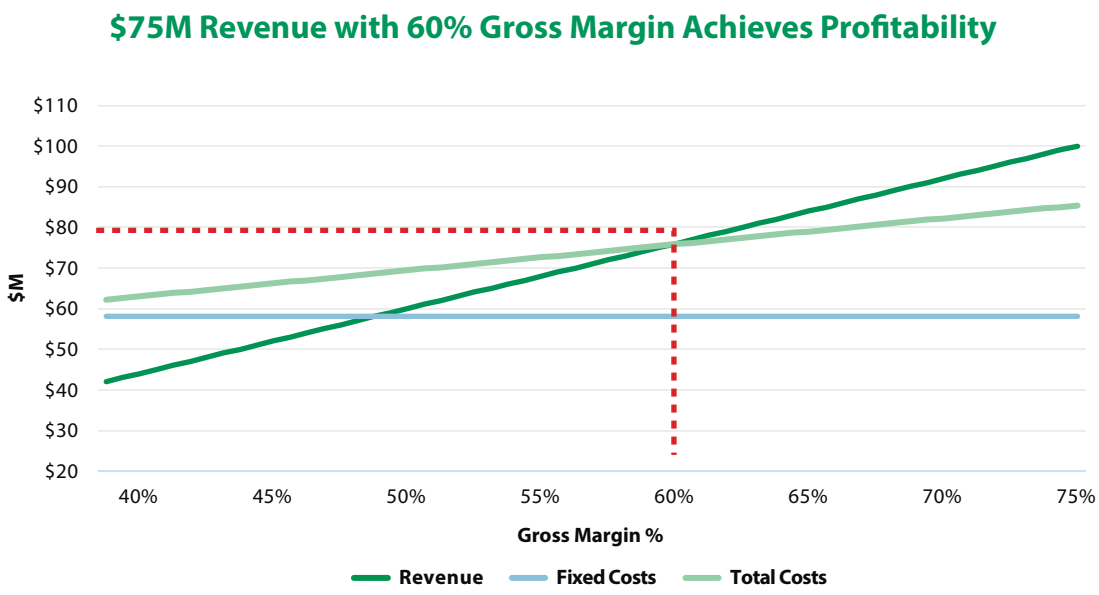
As part of our focus on revenue cycle operations, we needed effective documentation of the clinical utility of each test ordered on a per patient basis to initiate an effective appeal effort. This necessitated us to change the requirements for ordering an AVISE test, such that progress notes, specifically citing the clinical presentation of the patient are needed. This can be cumbersome for office staff in the clinic, which are evermore under constraints to operate efficiently, but are essential in communicating effectively with payors and in pursuing adequate payment of our test. The net impact of these changes has been what I expect to be a one-time reset of our test volume growth trajectory. While we opened 2023 with consecutive quarters of test volume growth, we ended the year with consecutive quarters of test volume more consistent with 2021/2022 performance. Your field-based sales team is working diligently with each of our customers to find the most efficient and effective way to satisfy the needs of insurers with minimal burden to the daily practice of rheumatologic care in their clinics. This adjustment takes time, but we believe the clinical value gained in the use of AVISE CTD for patients who have typically waited on average 6-years or more to arrive at a diagnosis will outweigh the documentation needs we've now imposed. In 2024, I expect the growth at Exagen to be both a combination of improving ASP paired with growth in test volume as we progress to a more profitable and sustainable business model.

Additionally, this year we've substantially revamped our research and development efforts and believe we are now better equipped to devote resources and capital to projects which will have improved prospects of contributing to the success of Exagen in the long-term. From late 2022 to early 2023, we set about a rigorous review of all pipeline efforts, specifically evaluating them against pre-set criteria. We are focused on opportunities which best fit existing customer needs, as identified through exhaustive voice of customer efforts. We have a very good understanding of where Rheumatologists prefer additional information in their clinical practice, and we are working to develop these assets. As a smaller esoteric diagnostic company, we will be successful in the long-term if we develop proprietary offerings; we lack the infrastructure advantages of larger laboratories and therefore need proprietary offerings with unique value propositions to operate effectively in the market. We are also committed to charting out the evidence development pathway at time of undertaking an opportunity. We have thought through how to prove, and what resources are likely to be required in proving, clinical utility of an offering.

This has become an ever-increasing evidentiary threshold for payors, including Medicare. We plan to have Medicare coverage and pricing prior to commercial launch, as it serves as a significant anchor in private payor discussions, given the public nature of CMS's processes and the fact that most commercial insurers service some portion of managed Medicare patients and therefore are required to adhere to coverage policies, when finalized. Lastly, and parallel to the importance of clinical utility, we will have a concerted effort to establish guideline support for new products from the very beginning. We believe that evaluating opportunities against these criteria substantially reduces risk of poor long-term performance, but time will be needed to bear-out our beliefs.

Path to Profitability

In 2023, your company improved its current and long-term prospects of being a dominant contributor to the autoimmune testing ecosystem. The team at Exagen worked extremely hard to execute as quickly and effectively as possible in making Exagen a profitable organization, and real progress was made. Our adjusted EBITDA, which is a reasonable approximation of cash needed to operate the business on an annual basis, reduced by more than half in 2023 vs. 2022. With this progress, your company continued to grow top line revenue, by just over 15% and delivered marked improvement in TTM ASP. We are proud of these accomplishments which have pushed our current operating runway into 2026 with our existing cash balance, but we are not satisfied and will be working hard in 2024 to improve this further.



We very much appreciate your partnership in support of Exagen, we are contributing significantly to patient care in this space and, as owners of the company, are working hard to deliver strong operating returns for you in the coming years.

John Aballi,
President and CEO

Forward Looking Statement

FORWARD-LOOKING STATEMENTS. Exagen cautions you that statements contained in this Annual Report regarding matters that are not historical facts, including estimates, projections, objectives and expected results, are "forward-looking statements" within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and are generally identified by the words "believe," "expect," "anticipate," "intend," "opportunity," "plan," "pipeline," "target," "trajectory," "momentum," "path," "project," "will," "outcomes," "should," "could," "would," "likely," "continue," "sustain," and similar expressions. Forward-looking statements are based on current assumptions that are subject to risks and uncertainties that may cause actual results to differ materially from the forward-looking statements, including the risks and uncertainties discussed in Item 1A – Risk Factors of the Form 10-K included in this Annual Report and any subsequent filings we make with the Securities and Exchange Commission. Such forward looking statements speak only as of the date they are made, and we undertake no obligation to update or revise publicly any forward-looking statements, except as required by law. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

USE of Non-GAAP Financial Measures (Unaudited)

In this presentation, we use the metrics of adjusted EBITDA, which is not calculated in accordance with generally accepted accounting principles in the United States (GAAP) and is a non-GAAP financial measure. Adjusted EBITDA excludes from net loss interest income (expense), income tax expense (benefit), depreciation and amortization expense, and stock-based compensation expense.

We use adjusted EBITDA internally because we believe these metrics provide useful supplemental information in assessing our operating performance reported in accordance with GAAP. We believe adjusted EBITDA may enhance an evaluation of our operating performance because it excludes the impact of prior decisions made about capital investment, financing, investing and certain expenses we believe are not indicative of our ongoing performance. However, this non-GAAP financial measure may be different from non-GAAP financial measures used by other companies, even when the same or similarly titled terms are used to identify such measures, limiting their usefulness for comparative purposes.

This non-GAAP financial measure is not meant to be considered in isolation or used as a substitute for net loss reported in accordance with GAAP, should be considered in conjunction with our financial information presented in accordance with GAAP, has no standardized meaning prescribed by GAAP, is unaudited and is not prepared under any comprehensive set of accounting rules or principles. In addition, from time to time in the future, there may be other items that we may exclude for purposes of these non-GAAP financial measures, and we may in the future cease to exclude items that we have historically excluded for purposes of these non-GAAP financial measures. Likewise, we may determine to modify the nature of adjustments to arrive at these non-GAAP financial measures. Because of the non-standardized definitions of non-GAAP financial measures, the non-GAAP financial measure as used by us in this annual report and the accompanying reconciliation table have limits in their usefulness to investors and may be calculated differently from, and therefore may not be directly comparable to, similarly titled measures used by other companies. Accordingly, investors should not place undue reliance on non-GAAP financial measures.

Reconciliation of Non-GAAP Financial Measures

	Twelve Months Ended December 31	
	2023	2022
(in thousands)		
Adjusted EBITDA		
Net Loss	($23,689)	($47,387)
Other (Income) Expense	(1,516)	(830)
Interest Expense	2,335	2,448
Income Tax Expense (Benefit)	33	(282)
Depreciation and Amortization Expense	2,168	1,557
Stock-Based Compensation Expense	3,617	4,704
Adjusted EBITDA (Non-GAAP)	($17,052)	($39,790)

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, 2023

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

For the transition period from to .

Commission File Number: 001-39049

EXAGEN INC.

(Exact name of registrant as specified in its charter)

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

(760) 560-1501

(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	**XGN**	**The Nasdaq Global Market**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

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

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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, 2023 (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 $37.3 million, based on the closing price of the registrant's common stock on the Nasdaq Global Market of $2.90 per share.

Total shares of common stock outstanding as of the close of business on March 14, 2024 was 17,235,751.

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 2024 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 (the Annual Report), contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). All statements other than statements of historical facts contained in this Annual Report, including statements regarding our future results of operations and financial position, business strategy, current and future product offerings, reimbursement and coverage, the expected benefits from our commercial 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 may 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 exists to provide clarity in autoimmune disease decision making with the goal of improving patients' clinical outcomes. We have developed and are commercializing a portfolio of innovative testing products, under our AVISE® brand, which allow for the differential diagnosis, prognosis and monitoring of complex autoimmune and autoimmune-related diseases. We believe our strong focus and extensive background in the field of rheumatology, combined with our commitment to exceptional customer service and support, position us well to respond to the needs of rheumatologists and the patients they serve.

We commercially launched our lead testing product, AVISE® CTD, in 2012. AVISE® CTD enables differential diagnosis for patients presenting with symptoms indicative of a wide variety of connective tissue diseases (CTDs) and other related diseases with overlapping symptoms. The comprehensive nature of AVISE® CTD allows for the testing of a number of relevant biomarkers in one convenient blood draw (as opposed to testing serially for individual biomarkers, which adds time and cost to the diagnostic process). We believe AVISE® CTD may provide clinical utility for more than 41 million individuals in the United States, encompassing patients with conditions like systemic lupus erythematosus (SLE); rheumatoid arthritis (RA); Sjögren's syndrome, antiphospholipid syndrome (APS); other autoimmune-related diseases, such as autoimmune thyroid; and disorders that mimic these diseases, such as fibromyalgia. There is an unmet need to add clarity for rheumatologists in their CTD clinical evaluations. As a result, we believe there is a significant market opportunity for our tests, which enable the differential diagnosis of these diseases, particularly, for potentially life-threatening diseases such as SLE.

Included in AVISE® CTD is our proprietary AVISE® Lupus test, which enables the diagnosis of SLE based on levels of erythrocyte bound C4d (EC4d) and B cell C4d (BC4d); along with anti-nuclear antibodies (ANA) and double-stranded DNA antibodies (ds-DNA). AVISE® Lupus provides rheumatologists and their patients with sensitive and specific results that allow for more accurate and potentially faster differential diagnosis of SLE, as compared to other currently-marketed testing methods. Beyond SLE, AVISE® CTD also allows rheumatologists to accurately diagnose other overlapping autoimmune and autoimmune-related diseases (including RA), with the same blood sample.

Our AVISE® SLE Monitor test leverages CB-CAPs technology to measure 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 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 methotrexate polyglutamate (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® Anti-CarP was developed by the Leiden University Medical Center and measures anti-carbamylated protein antibody (anti-CarP). 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, 2023, we have delivered approximately 887,000 of these tests. For the year ended December 31, 2023, 137,650 AVISE® CTD tests were delivered, representing an approximate 2% increase over 2022. In the fourth quarter of 2023, the number of ordering healthcare providers reached 2,383 compared to 2,419 in the same period in 2022.

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 insights from these results have 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.

Our Strategy

We address the unmet needs of those suffering from debilitating and chronic autoimmune disorders through aiding in differential diagnosis, prognosis, monitoring and therapeutic selection, to ultimately improve clinical outcomes for patients. The key tenets of our business strategy include:

- ***Focus on our flagship product, AVISE® CTD.*** We have demonstrated a solid track record of commercial growth of our AVISE® CTD test. We believe we are uniquely positioned to continue expanding our commercial presence within the autoimmune disease market by leveraging our specialized sales force and expansive network of relationships with rheumatologists across the United States. Using our specialty laboratory focused on rheumatology, we plan to build upon industry-leading quality, service and technology to support strong AVISE® CTD adoption and continue to grow our ordering physician base.

- ***Continue developing innovative testing products, using clear criteria for R&D projects and commercialization milestones.*** We intend to leverage our protein and molecular assay development capabilities, bioinformatic team and proprietary technologies to pursue the development of additional testing products designed to have superior clinical utility for CTDs. We undertake research projects that have the potential for impactful results and address the top consumer needs in the rheumatology space. The research projects we support are those that we believe will have a competitive advantage (such as using proprietary technology), a pathway for reimbursement and an established evidence development plan with sufficient market size. Criteria for developed products that we ultimately commercialize include Medicare coverage (specific to patient population), proprietary value-based pricing, published clinical utility and a strategy for medical guideline inclusion.

- ***Maintain meaningful margin.*** We seek to maintain meaningful margin by continuing to focus on increasing operating leverage through the implementation of certain internal initiatives, such as leveraging validation, utility and reimbursement-oriented clinical studies to facilitate payor coverage of our testing products. We center our efforts on long-term reimbursement and average sales price (ASP) growth. This strategy includes optimizing revenue cycle practices, focusing managed care efforts on medical policy expansion and continuing to educate insurance payors on the published, real-world evidence of the clinical utility of our testing products, demonstrating healthcare cost savings and reductions in time to diagnosis.

  We also seek to improve our per-test costs by focusing on profitable, core test offerings, minimizing fixed costs and overhead, and focusing our laboratory resources on AVISE® CTD optimization. Additionally, we employ a streamlined salesforce covering territories which are designed to achieve the most efficient and effective reach and frequency for the promotion of AVISE® CTD.

Autoimmune and Connective Tissue Diseases (CTDs)

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 to test 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, which historically has been difficult to rule out, as well as other autoimmune-related diseases and other disorders that mimic these diseases, such as fibromyalgia. The National Institute of Environmental Health Sciences estimates that there are approximately 41 million patients in the United States with existing cases of autoimmune diseases. Of these patients, we estimate approximately seven million are potentially referable to rheumatologists and would be candidates for an AVISE® CTD test, representing a total addressable market of approximately $7.5 billion, based on the current Medicare allowable reimbursement rate. We estimate the total addressable market for our AVISE® testing products to be approximately $9.2 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 ANA, anti-double stranded DNA (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. According to Dinse et al. (2022), who investigated the increasing prevalence of ANA in the United States using data from the National Health and Nutrition Examination Survey, approximately 0.7%–2.4% 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, the Dinse et al. study reported the estimated prevalence of a positive ANA test in the normal, healthy, U.S. population to be 16.1% (approximately 41.5 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. Many people with SLE have a negative anti-dsDNA antibody test, reaffirming the need for an effective testing product which adds clarity to the rheumatologist's clinical assessment.

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

In March 2011, the first new biologic targeting treatment of SLE in over 50 years, GSK's Benlysta®, was approved by the U.S. Food and Drug Administration (the FDA). In December 2020, the FDA approved this biologic drug for the treatment of adult patients with active lupus nephritis who are receiving standard therapy. Since Benlysta®'s approval, there have been a number of drug development programs that have failed in SLE, which may suggest that guidelines for classifying SLE patients and the endpoints used to determine clinical effectiveness have not adequately addressed the complexity of the disease process and its heterogeneous population.

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 135,000 and 1.5 million, respectively. Patients suffering from RA develop joint damage that is associated with painful inflammation and 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 (RF), anti-cyclic citrullinated peptide (CCP) antibodies and testing for

general, nonspecific inflammation with erythrocyte sedimentation rate (the ESR) and C-reactive protein tests are used to assist in the diagnosis.

The standard of care for the treatment of RA involves the use of Disease Modifying Anti-Rheumatic Drugs (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 and effectiveness, as well as the extensive clinical experience with its use. It is estimated that approximately 90% 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. 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 market testing products under our AVISE® brand that allow for the differential diagnosis, prognosis and monitoring of complex autoimmune and autoimmune-related diseases, including SLE and RA. We are focused on leveraging our sales channel targeting the approximately 4,500 rheumatologists across the United States to promote use of our product portfolio.

Our Proprietary Technologies

We believe the competitive advantage for our testing products is supported by core proprietary technology, namely our AVISE® Lupus test.

AVISE® Lupus Test

Our AVISE® Lupus test, which we offer as a stand-alone test and as part of our AVISE® CTD test panel, is a proprietary, clinically validated method to aid in the diagnosis of SLE that provides a significant improvement in sensitivity, relative to the current standard of care. The AVISE® Lupus test leverages CB-CAPs technology, which 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 combined with algorithmic interpretations, as a support or replacement of standard C3 and C4 measures, is of great value for rheumatologists and their patients. 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 clinical validation study published in 2014 by Chaim Putterman, et al. (the 2014 Study), EC4d and BC4d showed 22% higher sensitivity (66%) than C3 and C4 (44%) in diagnosing SLE, with specificity fixed at 91%.

Our proprietary AVISE® Lupus test integrates EC4d and BC4d with 8 autoantibodies to yield a quantitative and qualitative assessment of SLE risk. The AVISE® Lupus test was designed to improve upon the diagnostic sensitivity of conventional biomarkers used to diagnose SLE while maintaining a high degree of specificity. In the aforementioned 2014 Study, the AVISE® Lupus test demonstrated 80% sensitivity for SLE (meaning 8 out of 10 diagnosed SLE patients tested positive) and 86% specificity for SLE (meaning 86% of non-SLE control subjects with other rheumatic conditions tested negative). A later study published in 2022 by Tyler O'Malley, et al., compared the clinical utility of the AVISE® Lupus test to the conventional biomarker strategy in the diagnosis of SLE, demonstrating 6-fold increased odds of SLE diagnosis and 3-fold increased odds of treatment initiation with a

positive AVISE® Lupus result. We believe this patent-protected test gives us a significant advantage over our competitors.

Testing Products

Since inception, we have been committed to developing and commercializing innovative testing products that address the challenges rheumatologists face in differentially diagnosing, prognosing and monitoring complex autoimmune and autoimmune-related diseases. We estimate the total addressable market for our AVISE® testing products to be approximately $9 billion, based on estimated patient populations, the current Medicare allowable reimbursement rate and testing frequencies.

Diagnosis

AVISE® CTD

Our lead testing product, AVISE® CTD, is a comprehensive test that aids in the differential diagnosis of SLE versus other common CTDs. AVISE® CTD includes our proprietary AVISE® Lupus test, which leverages CB-CAPs technology to specifically measure activation of the complement system. In addition to testing for SLE, AVISE® CTD tests for a series of biomarkers in one convenient blood draw to 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. Use of our test significantly enhances the rheumatologist's ability to exclude SLE and differentiate other CTDs, resulting in a clearer assessment and ultimately increasing the efficiency and accuracy of the broader diagnostic process. The clinical performance of our proprietary AVISE® Lupus test, combined with the convenience of a single blood draw, make AVISE® CTD an attractive choice among rheumatologists.

AVISE® Lupus

Our proprietary AVISE® Lupus test is the cornerstone of the SLE assessment within our more comprehensive AVISE® CTD testing product. AVISE® Lupus begins by quantifying the level of CB-CAPs biomarkers (EC4d and BC4d) in the patient's blood. These biomarkers are elevated in patients with SLE compared to patients with other CTDs. Next, the AVISE® Lupus test integrates these cell-bound complement products with 8 autoantibodies to yield a quantitative and qualitative assessment of SLE risk. Rheumatologists choose to order the comprehensive AVISE® CTD test or the more focused AVISE® Lupus test based on medical necessity, which is determined by each patient's symptoms and medical history.

AVISE® APS

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

AVISE® Vasculitis AAV

AVISE® Vasculitis AAV 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 (ANCA) associated vasculitis (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, developed by the Leiden University Medical Center, measures anti-CarP. 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. With the introduction of AVISE® Anti-CarP in 2018, we became the first commercial laboratory to make testing for anti-CarP available in the United States. This test uniquely addresses two major challenges facing rheumatologists today – (1) patients presenting with RA symptoms but lacking the common confirmatory blood tests for anti-RF or anti-CCP, known as sero-negative patients, and (2) the lack of a serologic indicator, which indicates a poor prognosis and helps guide treatment decisions. Anti-CarP can be positive in up to 26% of RA patients who are negative for anti-CCP. Furthermore, RA patients positive for Anti-CarP have an increased risk for more severe RA disease, including permanent joint damage.

Monitoring

AVISE® SLE Monitor

AVISE® SLE Monitor is a blood test that employs 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, 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 these leave the rheumatologists looking for greater insights, especially in cases where patients under report their symptoms, a bias which healthcare providers may not fully appreciate. 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. 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. AVISE® MTX can allow rheumatologists to make more informed therapeutic decisions in their efforts to optimize methotrexate therapy and give patients their best chance at achieving an optimal response.

AVISE® HCQ

AVISE® HCQ is a blood test designed to help rheumatologists objectively monitor levels of hydroxychloroquine (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.

Test Reports

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

AVISE® CTD Report

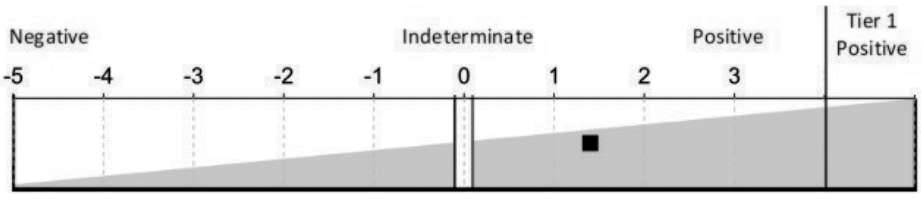
AVISE® CTD

Order ID 739813
Provider Exagen Provider MD

Specimen		Patient	Sample, Susan S.
Collected	01/19/2023		
Received	01/20/2023	Gender - DOB	Female - 01/01/1996
Test Order		Identifier Received	
Created	01/20/2023		
Reported	01/25/2023	Exagen ID	541163

AVISE CTD Test Report

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



Tier 1 Analytes	Value	Interpretation	Reference Range	Tier 1 Assessment
Anti-dsDNA IgG	20.00 IU/mL	Negative	<201 - Negative | 201-<302 - Equivocal |≥302 - Positive	Negative
Confirmation by Crithidia luciliae		N/A		
Anti-Smith IgG	1.0 U/mL	Negative	<7 - Negative | 7-10 - Equivocal | >10 - Positive	
CB-CAP: EC4d - Erythrocyte-bound C4d	25 Net MFI	POSITIVE	<15 - Negative | 15 -75 - Positive | >75 - Strong Positive	
CB-CAP: BC4d - B-lymphocyte-bound C4d	100 Net MFI	POSITIVE	<61 - Negative | 61-200 - Positive | >200 - Strong Positive	

Note:
Criteria for Tier 1 Positive not met.

Tier 2 Analytes	Value	Interpretation	Reference Range	Tier 2 Assessment
ANA IgG	40.00 Units	POSITIVE	<20 - Negative | 20-<60 - Positive | ≥60 - Strong Positive	Positive
CB-CAP: EC4d - Erythrocyte-bound C4d	25 Net MFI	POSITIVE	<15 - Negative | 15-75 - Positive | >75 - Strong Positive	
CB-CAP: BC4d - B-lymphocyte-bound C4d	100 Net MFI	POSITIVE	<61 - Negative | 61-200 - Positive | >200 - Strong Positive	
Anti-SS-B/La IgG	1.0 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	

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

Approved by: Richard Safrin, MD Richard E Safrin MD Date: 1-25-2023

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

AVISE® CTD

Order ID 739813
Provider Exagen Provider MD

Specimen
Collected 01/19/2023
Received 01/20/2023

Test Order
Created 01/20/2023
Reported 01/25/2023

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

SLE-Associated Analytes	Value	Interpretation	Reference Range
+ ANA IgG	40.00 Units	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: Speckled			
Cytoplasmic Pattern: Not Observed			
Anti-dsDNA IgG	20.00 IU/mL	Negative	ELISA: <201 - Negative | 201-<302 - Equivocal | ≥302 - Positive
Confirmation by Crithidia luciliae	N/A		IFA: Negative
Anti-Smith IgG	1.0 U/mL	Negative	ELFA: <7 - Negative | 7-10 - Equivocal | >10 - Positive
+ CB-CAP: EC4d - Erythrocyte-bound C4d	25 Net MFI	POSITIVE	FACS: <15 - Negative | 15-75 - Positive | >75 - Strong Positive
+ CB-CAP: BC4d - B-lymphocyte-bound C4d	100 Net MFI	POSITIVE	FACS: <61 - Negative | 61-200 - Positive | >200 - Strong Positive

Other Autoimmune Disease Auto-Antibodies	Value	Interpretation	Reference Range
+ Anti-U1RNP IgG	20.0 U/mL	POSITIVE	ELFA: <5 - Negative | 5-10 - Equivocal | >10 - Positive
Anti-RNP70 IgG	5.0 U/mL	Negative	ELFA: <7 - Negative | 7-10 - Equivocal | >10 - Positive
Anti-Ro52 IgG	5.0 U/mL	Negative	ELFA: <7 - Negative | 7-10 - Equivocal | >10 - Positive
Anti-Ro60 IgG	5.0 U/mL	Negative	ELFA: <7 - Negative | 7-10 - Equivocal | >10 - Positive
Anti-SS-B/La IgG	1.0 U/mL	Negative	ELFA: <7 - Negative | 7-10 - Equivocal | >10 - Positive
Anti-Scl-70 IgG	1.0 U/mL	Negative	ELFA: <7 - Negative | 7-10 - Equivocal | >10 - Positive
Anti-RNA Pol III IgG	4.0 U/mL	Negative	ELFA: <7 - Negative | 7-10 - Equivocal | >10 - Positive
Anti-Centromere Protein B (CENP) IgG	1.0 U/mL	Negative	ELFA: <7 - Negative | 7-10 - Equivocal | >10 - Positive
Anti-Jo-1 IgG	1.0 U/mL	Negative	ELFA: <7 - Negative | 7-10 - Equivocal | >10 - Positive

Rheumatoid Arthritis Auto-Antibodies	Value	Interpretation	Reference Range
Rheumatoid Factor IgM	2.0 IU/mL	Negative	ELFA: <3.5 - Negative | 3.5-5 - Equivocal | >5 - Positive
Rheumatoid Factor IgA	1.0 IU/mL	Negative	ELFA: <14 - Negative | 14-20 - Equivocal | >20 - Positive
Anti-CCP IgG	1.0 U/mL	Negative	ELFA: <7 - Negative | 7-10 - Equivocal | >10 - Positive

Antiphospholipid Syndrome Auto-Antibodies	Value	Interpretation	Reference Range
Anti-Cardiolipin IgM	2.0 U/mL	Negative	ELFA: <10 - Negative | 10-40 - Weak Positive | >40 - Positive
Anti-Cardiolipin IgG	4.0 U/mL	Negative	ELFA: <10 - Negative | 10-40 - Weak Positive | >40 - Positive
Anti-β2 Glycoprotein 1 IgM	3.0 U/mL	Negative	ELFA: <7 - Negative | 7-10 - Equivocal | >10 - Positive
Anti-β2 Glycoprotein 1 IgG	2.0 U/mL	Negative	ELFA: <7 - Negative | 7-10 - Equivocal | >10 - Positive

Thyroid Auto-Antibodies	Value	Interpretation	Reference Range
Anti-Thyroglobulin IgG	<12 IU/mL	Negative	ELFA: <40 - Negative | 40-60 - Equivocal | >60 - Positive
Anti-Thyroid Peroxidase IgG	<4 IU/mL	Negative	ELFA: <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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Our Pipeline and Growth Opportunities

We regularly confer with national experts in the clinical management of rheumatic autoimmune diseases 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 technologies by integrating 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. We believe the stability and reliability of CB-CAPs technology, in combination with increased specificity provided by our patent-protected AVISE® Lupus test, will allow us to produce meaningful and differentiated proprietary solutions for rheumatologists.

TC4d, TIgG and TIgM Biomarkers

Our collaborative efforts with the Allegheny Health Network Research Institute (AHN) have resulted in further development of three innovative biomarkers (TC4d, TIgG, and TIgM), for which we obtained an exclusive, worldwide license from AHN in May 2021. These markers exhibit a high degree of specificity for lupus and are more sensitive for lupus compared to conventional biomarkers. The objective is to incorporate these three biomarkers into the AVISE® Lupus test in order to enhance the diagnostic sensitivity for lupus beyond its current 80% level. Additionally, TC4d represents a proprietary expansion of our existing CB-CAPs portfolio, involving a similar biochemical process wherein complement activation products are measured on T-cells. We believe the inclusion of these markers in our AVISE® Lupus test could further amplify its sensitivity, thus facilitating earlier detection of disease, and further differentiating our test in the market.

CTD RA Sub-Profile

Approximately 70-80% of RA patients show serological evidence of RA, identified by key biomarkers: anti-CCP and Rheumatoid Factor. The remaining 20-30% of patients, despite lacking these serological markers, are clinically diagnosed with RA; this subgroup is referred to as "seronegative RA." These patients often face delays in diagnosis due to the absence of serological evidence. In cases of early inflammatory arthritis, differential diagnosis is broad, including conditions like reactive arthritis, crystal arthropathy, spondyloarthropathy, and other systemic rheumatic diseases such as SLE and Sjogren's syndrome, alongside seronegative RA. Accordingly, identifying unique biomarkers specific to seronegative RA may bridge this diagnostic gap, enabling more timely and targeted treatment plans for these patients.

Lupus Nephritis Biomarkers

Lupus nephritis (LN) is an autoimmune disease and a frequent complication in people who have SLE. It causes the immune system to produce proteins called autoantibodies that attack the body's own tissues and organs, including the kidneys. If left untreated, LN can lead to significant health problems, permanent kidney damage and even death. Early diagnosis and treatment are key to managing LN and to preventing it from escalating. Although early onset of LN is not typically noticeable by patients, nearly 40% of SLE patients go on to develop LN. Currently, urinary protein to creatine ratio measurement is the standard means of assessing kidney involvement; however, it is not necessarily indicative of kidney prognosis or treatment response. We aim to leverage intellectual property licensed from Johns Hopkins University (JHU) to develop a test for detecting protein analytes in urine that can aid rheumatologists in the ongoing management and risk stratification of patients suffering from LN.

AVISE® SLE Monitor (2.0)

SLE is characterized by a chronic, systemic inflammatory burden, and disease progression is defined by the accumulation of irreversible organ damage typically resulting from chronic inflammation and/or chronic corticosteroid use. Among the challenges for rheumatologists responsible for the care of lupus patients is the unpredictability of the disease course defined by periods of waxing and waning episodes of inflammation. The unpredictable nature of SLE and the lack of reliable conventional biomarkers indicative of present and near-term disease activity results in a significant unmet need for a surrogate method to monitor disease activity. Our goal is to leverage clinical and laboratory data collected across multiple longitudinal SLE cohorts to identify a set of biomarkers that can inform an AI-developed algorithm aimed at guiding ongoing treatment decisions throughout the course of a lupus patient's journey.

Sales and Marketing

We employ a specialized sales force focused on targeting the approximately 4,500 rheumatologists across the United States. Our sales representatives generally have extensive experience in healthcare sales with backgrounds

in rheumatology, diagnostics and/or pharmaceutical sales. 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 resource to the rheumatologists and their practice.

Our field-based sales force is organized into 40 territories within the following four regions: West, Central, Northeast and Southeast. We also maintain an inside sales force that helps further our access to rheumatologists located in rural and outlying areas of the United States and works to increase our brand awareness with healthcare providers in these areas. We continually evaluate our sales force's reach and frequency of interactions with rheumatologists, including as we launch our pipeline products. Our specialized sales force and marketing activities are further augmented by our centralized, dedicated client services department. Our client services department uses its high level of technical training to enhance sales efficiency and customer satisfaction by providing personalized customer support.

Adoption and Growth through Quality Testing and Service

Our focus on quality allows for a dedicated sales approach based on a commitment to understanding the needs of both provider and patient. By raising awareness of the benefits AVISE® testing provides, our sales team is able to deliver quality testing and support services to providers, and ultimately, their patients. To ensure our marketing and sales efforts are reaching those that we believe could benefit most from AVISE®, we emphasize 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 therapeutic usage and diagnostic product 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 and medical societies, such as the American College of Rheumatology (ACR). We have also established strong relationships with multiple rheumatology care management organizations (Super Groups), which can be key in influencing favorable reimbursement. Our AVISE® MTX testing product has been included in the clinical guidelines for two of these groups. We believe our experience with advancing a testing product from initial development through clinical adoption differentiates us and uniquely positions us to replicate success with our other testing products. Beyond working with these Super 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

The primary source of revenue for our products is reimbursement from third-party payors and client bill arrangements. Third-party payors include government payors (such as Medicare and Medicaid) and commercial payors (such as insurance companies). Achieving and maintaining broad coverage and reimbursement from third-party payors, including Medicare, for our commercialized and pipeline products is a key determinant of our revenue, financial results and future growth.

We are actively engaged in efforts to achieve broad commercial coverage and reimbursement for our current and future products, including contracting with commercial payors. Achieving positive coverage reduces the need for appeals and reduces failures to collect from the patient’s insurance. Additionally, achieving in-network contracts with commercial payors can shorten the time required to receive payments. Our approach to commercial payment is centered on working toward inclusion in clinical guidelines and individual payor medical policies. We seek to accomplish this through continued evidence development and publication, medical director engagement and individual claim-based appeal efforts, detailed as follows:

- *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.

- *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. Overall, we work to address payors at the national level in addition to high-claim-volume regional payors we have identified based on our current territory coverage.

- *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.

While we have contracts for reimbursement with a limited number of commercial payors, we are actively pursuing additional commercial payor contracts. 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. For in-network and out-of-network claims for which we are not reimbursed in full (or receive a claim denial), we may elect to appeal the insurer's underpayment (or denial of payment) or seek payment from the patient.

Clinical Validation

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

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

Clinical Utility

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

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

In early 2018, we initiated CARE for Lupus, a prospective, randomized, multi-site study to assess the performance of AVISE® Lupus versus standard diagnostic laboratory tests (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 among patients who tested positive for AVISE® Lupus (n=9) showed 44% in the AVISE® Lupus group had a higher likelihood of SLE, compared with 9% in the SDLT group ($p=0.127$). 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 (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 United States 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.

In July 2022, we announced new, real-world evidence illustrating that AVISE® testing can enable decisive clinical action in the differential diagnosis of lupus. The "Complement Activation Products vs Standard ANA Testing: Treatment Outcomes, Diagnosis, and Economic Impact in Systemic Lupus Erythematosus" (CAPSTONE) study was the largest comparative utility study in lupus diagnostics and was published in the Journal of Managed Care & Specialty Pharmacy. The study leveraged multiple databases encompassing electronic health records and linked insurance claims data on nearly 50,000 patients tested with AVISE® or standard of care labs from hundreds of rheumatologists across the United States, comparing diagnosis, treatment and cost of care outcomes for new patients tested with AVISE® Lupus and those tested with a traditional ANA (tANA) approach, including specific autoantibodies. The CAPSTONE study supports that the AVISE® Lupus test is more clinically effective, both for patients who test positive and those who test negative, as compared to the current standard of care. Important key findings of the CAPSTONE study included, among other things, a: (i) 2x decrease in diagnostic testing costs in the first six-month follow-up period for AVISE® Lupus [-] vs. tANA[-]; (ii) 3.5x less frequent repeat testing overall when using AVISE® Lupus vs. tANA; (iii) 6x increased odds of establishing a new SLE diagnosis with AVISE® Lupus [+] vs. tANA[+]; and (iv) 3x increased odds of initiating one or more SLE treatments with AVISE® Lupus [+] vs. tANA[+]. The CAPSTONE study exemplifies the advantages of the AVISE® Lupus test for patients, providers and payors. Delayed diagnosis leads to increased disease burden and diminished quality of life for the patient relative to the current standard of care. By receiving conclusive results, providers are able to initiate treatment early, reducing the need for more aggressive approaches down the road that can lead to irreversible consequences for the patient. Additionally, a conclusive negative test allows providers to lower the number of repeat tests and follow-up visits which is a critical step for achieving diagnostic clarity for the patient.

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 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 ($1,991 per patient). In addition, the study findings from the economic model estimated a $0.7 million dollar savings in total cost of care with AVISE® Lupus versus a conventional SLE biomarker testing approach, as a result of the increased diagnostic sensitivity of the AVISE® Lupus test leading to fewer in-patient hospitalization costs. On a per tested basis, the AVISE® Lupus test is estimated to reduce total cost of care by $655 per eligible patient in the first year.

Laboratory Operations

We perform all of our AVISE® tests in our approximately 13,000 square-foot laboratory located in Vista, California. Our laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and accredited by the College of American Pathologists (CAP). Our laboratory is certified for performance of high-complexity testing by the Centers for Medicare & Medicaid Services (CMS) in accordance with CLIA and is licensed by California and all states requiring out-of-state licensure, including the New York State Department of Health (NYSDOH). Our clinical laboratory typically reports AVISE® testing product results within five business days.

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 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

The traditional methods used by healthcare providers to test patients with CTD-like symptoms are the main competitors of our AVISE® testing products. 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, disease or drug monitoring products, such as Progentec Diagnostics Inc., Scipher Medicine Corporation, Genalyte Inc., Oncimmune plc, DxTerity Diagnostics Inc., AMPEL BioSolutions, and Immunovia AB. 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. We rely upon independent sources for phlebotomy to obtain patient samples; interruptions to this capability could dramatically impact patient access to our tests.

Many of our potential competitors have widespread brand recognition and substantially greater financial, technical and research and development resources; in addition to greater selling and marketing capabilities. Others may develop products with prices lower than ours or have preferred network status that could be viewed by rheumatologists and payors as functionally equivalent to our solution or offer solutions at prices designed to promote market penetration. This 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.

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 or 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. It will also depend on our ability to defend and enforce our patents, maintain our licenses to use intellectual property owned by third parties, preserve the confidentiality of our trade secrets and 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 red blood cell MTXPG exposure assessments. 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 two aspects: the AVISE® Lupus test and the AVISE® MTX test. As of February 21, 2024, our portfolio primarily consisted of the following:

AVISE® Lupus Test

We own five issued patents (US 10,132,813, US 11,360,099, US 11,531,033, US 11,761,965, and US 11,885,812), six U.S. nonprovisional patent applications, one US provisional patent application, and ten foreign patents that relate to our AVISE® Lupus products. The foreign patents have issued in Europe (EP 2,673,644 and EP2972365), China (CN105229470), Japan (JP6453299) and Hong Kong (HK1192316). These patents cover the AVISE® Lupus algorithm. The patent applications expire between 2032 and 2040. Any patent claiming priority to the U.S. provisional patent application will expire in 2044.

MTX Exposure Assessment Products and Services

We own two patents that relate to our AVISE® MTX product and methods for monitoring methotrexate therapy using red blood cell MTXPG exposure assessments. These patents include U.S. Patent Nos. 7,582,282 and 7,695,908, which are expected to expire between 2026 and 2027.

CB-CAPs

We previously held licenses to five patent families related to CB-CAPs technology from the University of Pittsburgh (UPitt). We have terminated these license agreements (related to U.S. Patent Nos. 7,361,517, 7,390,631, 7,585,640, 7,588,905, 8,080,382, 8,126,654, and foreign equivalents thereof), effective March 22, 2024. Our royalty obligations continue on cash collected in future periods for testing services provided prior to the royalty expiration date of March 23, 2024.

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. (Cypress) in 2010 (the Cypress Purchase) and to obtain an exclusive license to UPitt’s patent rights in certain inventions (the UPitt Patent Rights) related to the use of CB-CAPs technology in the diagnosis, prognosis and monitoring of diseases, including certain patents related to our AVISE® testing products.

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 U.S. 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 only until

March 23, 2024, which is the date of the expiration of the last licensed patent covering the applicable licensed product or service.

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 AHN, under which we obtained an exclusive, worldwide license to AHN's patent rights in certain inventions (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 U.S. government with respect to the AHN Patent Rights, including under a funding agreement between AHN and the U.S. government and under the Bayh-Dole Act (35 U.S.C. §200, et seq.). Pursuant to the Bayh-Dole Act, the U.S. 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 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 (QMUL), under which we obtained an exclusive license to QMUL's patent-pending inventions (the QMUL Patent Rights), related to diagnosis and/or development of diagnostic or companion diagnostics for RA.

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.

In April 2023, we discontinued development of our AVISE® RADR platform, which was being developed using the QMUL Patent Rights. We also discontinued the associated clinical trials. We are permitted to terminate the license agreement upon six 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. We or QMUL may terminate the master research collaboration agreement upon 30-day written notice.

Exclusive License Agreement Johns Hopkins University

In November 2023, we entered into an exclusive license agreement with Johns Hopkins University, under which we obtained an exclusive, worldwide license to JHU's patent rights in certain inventions (the JHU Patent Rights) related to methods of using urinary protein biomarkers as a means of risk stratifying lupus nephritis patients and predicting treatment response.

Under the agreement, we are permitted to make, use, import, export, offer and sell products and services utilizing the JHU Patent Rights and to sublicense such rights, subject to certain limitations. JHU retained the right to practice under the JHU Patent Rights and to use such rights for teaching, research, education, public service, clinical and other research related purposes; in addition to make, use and sell products and services to a qualified humanitarian organization for humanitarian purposes in so-called "least developed countries," as defined by the United Nations Country Classification.

In consideration for the rights granted to us under the agreement, we paid an initial license fee and past patent expenses and agreed to pay future direct patent costs related to the JHU Patent Rights. Under the terms of the exclusive license agreement, we are required to pay royalties in the low single-digits on net sales of products using the assigned patents, subject to annual minimums, as well as certain milestone payments.

In the event we sublicense any of the JHU Patent Rights, we are obligated to pay JHU a double-digit percentage of sublicensing income; however, royalties we receive on sales made by sublicensees will be treated as if we made the sale.

The agreement requires that we diligently develop and commercialize products that are covered by the JHU Patent Rights, and we have agreed to meet certain development and commercial milestones. JHU may terminate the agreement if we fail to develop, commercialize and sell the licensed products. Additionally, JHU may terminate the agreement for cause upon 60-day written notice 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. JHU may terminate the agreement immediately upon written notice to Exagen in the event of a material breach that is incapable of cure. Absent early termination, the agreement will continue for the longer of (i) expiration of the last to expire patent included in the license agreement, (ii) 10 years after the first commercial sale of any licensed product utilizing the JHU Patent Rights, or (iii) if no patents issue, 20 years from the effective date of the agreement (November 8, 2023). We may terminate the agreement upon ninety days' advance written notice to JHU.

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 categories 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 (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 is also required to be licensed by the NYSDOH New York laws and regulations establish standards in a variety of operational areas, including:

- day-to-day operation of the laboratory, including training, supervision 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 NYSDOH, 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, NYSDOH must approve a laboratory developed test (LDT) before it is offered in New York. We have received written approval from NYSDOH 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® CTD, AVISE® SLE Prognostic and AVISE® MTX assays in our Vista, California clinical laboratory, and they are currently primarily regulated under CLIA, as administered by CMS, as well as by applicable state laws, as described above. The FDA regulates any diagnostic tests that meet the definition of a medical device, except under specific, narrow circumstances. The Federal Food, Drug and Cosmetic Act (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 (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 diagnostic testing products like ours 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. Many of the instruments, reagents, kits or other consumable products used within our laboratories are regulated as medical devices and therefore must comply with FDA quality system regulations and certain other device requirements. We have policies and procedures in place to ensure that we source such materials from suppliers that are in compliance with any applicable medical device regulatory requirements.

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 (PMA). Devices deemed to pose lower risk are categorized as either Class I or II. For most Class II devices, a manufacturer must 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 Class II 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 a predicate device, which is: (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. Class II devices may also be subject to special controls such as performance standards, post-market surveillance, FDA guidelines, or particularized labeling. Most Class I devices are exempt from 510(k) premarket notification requirements, but like Class II and Class III devices, are subject to general controls, such as registration and listing, quality system, labeling, and reporting requirements.

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 the malfunction 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 device 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 LDTs. We believe that all of our AVISE® test products are LDTs, as are our near-term pipeline candidate tests. However, in October 2023, the FDA issued a proposed rule aimed at regulating LDTs under the current medical device framework and proposing to phase out its existing enforcement discretion policy for this category of diagnostic tests; the public comment period ended in early December 2023. The proposal envisions that the LDT enforcement policy phase-out process would occur in gradual stages over a total period of four years, with pre-market approval applications for high-risk tests to be submitted by the 3.5-year mark, although more details are expected to be provided with the upcoming final rule. The likelihood of the FDA finalizing the proposed rule in April 2024 (as is currently projected), as well as potential litigation challenging the agency’s authority to take such action, is uncertain at this time. Affected stakeholders continue to press for a comprehensive legislative solution to create a harmonized paradigm for oversight of LDTs by

both the FDA and CMS, instead of implementation of the proposed FDA administrative action, which may be disruptive to the industry and to patient access to certain diagnostic tests.

Even though we presently commercialize our tests as LDTs, the FDA may disagree that our marketed tests are within the scope of its current enforcement discretion criteria for LDTs, our tests may in the future become subject to more onerous regulation by the FDA. For several years, members of Congress have been working with stakeholders on a possible bill to regulate in vitro clinical tests including LDTs. For example, as drafted and re-introduced for consideration by the current Congress, legislation called the Verifying Accurate, Leading-edge IVCT Development (VALID Act), has been garnering bipartisan and bicameral support. The VALID Act would codify into law the term "in vitro clinical test" (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.

It is unclear whether the VALID Act would be passed by Congress in its current form or signed into law by the President. If the FDA finalizes its position on regulation of LDTs through the ongoing notice-and-comment rulemaking process, 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, for the first time, 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 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 culmination of the current notice-and-comment rulemaking process, 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 the 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.

Regulation of Clinical Trials

We have also conducted and may in the future conduct research studies for our AVISE® tests and our other tests in development that involve clinical investigators and human subjects (or stored specimens from human subjects) at sites in the United States. We may need to conduct additional clinical trials 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 (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, trials involving human subjects 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.

Advertising of Laboratory Services or LDTs

Advertising for laboratory services and diagnostic testing products is subject to federal truth-in-advertising laws enforced by the Federal Trade Commission (FTC), as well as comparable state consumer protection laws, whether or not such services are regulated by the FDA as Class I or Class II devices or not directly subject to enforcement

discretion with respect to the FDA's device requirements as LDTs. Under the Federal Trade Commission Act (FTC Act), the FTC is empowered, among other things, to (a) prevent unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce; (b) seek monetary redress and other relief for conduct injurious to consumers; and (c) gather and compile information and conduct investigations relating to the organization, business, practices, and management of entities engaged in commerce. The FTC has very broad enforcement authority, and failure to abide by the substantive requirements of the FTC Act and other consumer protection laws can result in administrative or judicial penalties, including civil penalties, injunctions affecting the manner in which we would be able to market services or products in the future, or criminal prosecution.

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 (PORA), and other comparable state laws. The Stark Law generally prohibits us from billing Medicare or Medicaid 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 relationship with us, unless the arrangement meets an exception to the prohibition. A financial relationship can be a compensation arrangement or an ownership or investment interest.

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 a 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 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 (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 healthcare programs but applies more broadly to services covered by “healthcare benefit programs,” including commercial 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 Healthcare 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 U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG), to exclude an individual or entity from Medicare or Medicaid for charging federal healthcare programs, including Medicare or 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, and the HHS OIG has withdrawn multiple versions of a proposed rule intended to implement the statute.

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. Regardless of whether the government intervenes in the action, the relator, if successful, 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 federal False Claims Act liability. Violation of the federal False Claims Act may result payment of up to three times the actual damages sustained by the government, plus significant per-claim civil penalties, as well as mandatory exclusion from government healthcare programs. Several states, including California, have enacted comparable false claims laws that may apply regardless of payor.

The federal civil monetary penalties law (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 Medicaid 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 Medicaid, 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 healthcare 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 may include exclusion, substantial fines, and payment of up to three times the amount billed, depending on the nature of the offense.

As noted, a person who offers or provides to a Medicare or Medicaid beneficiary any remuneration, including waivers of co-payments, co-insurance 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 held liable under the CMP Law. Moreover, in certain cases, providers who routinely waive amounts owed by federal healthcare program beneficiaries can also be held liable under the Anti-Kickback Statute and the federal False Claims Act. One of the exceptions to the prohibition under the CMP Law covers non-routine, unadvertised waivers of copayments or deductible amounts based on individualized determinations of financial need or exhaustion of reasonable collection efforts, and the Anti-Kickback Statute has a safe harbor. The HHS OIG, has emphasized in guidance documents that this exception should only be used on a case-by-case basis to address the financial needs of each 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 commercial 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 in vitro diagnostic tests solely for use by or within our own laboratory, we believe that we are exempt from these reporting requirements. We may become subject to such reporting requirements under the terms of current CMS regulations, however, if enacted federal legislation renders our tests regulated by FDA, or if FDA finalizes its recently initiated notice-and-comment rulemaking to exercise authority over LDTs as medical devices or otherwise requires us to obtain premarket clearance or approval for one or more of our tests. 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 (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 $2.0 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 Organisation for Economic Co-Operation and Development Anti-Bribery Convention members, have similar anti-corruption regulations, such as the U.K. Bribery Act.

When marketing our testing products outside of the United States, 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 United States or the import of tissue into the United States, and marketing approval. These requirements vary by jurisdiction, differ from those in the United States and may in some cases require us to perform additional pre-clinical or clinical testing. In many countries outside of the United States, coverage, pricing and reimbursement approvals are also required.

Privacy and Security Laws

U.S. Data Privacy and Security Laws

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 (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 (collectively, 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" (PHI) under HIPAA (Business Associates). Under HIPAA, as amended by the HITECH Act, HHS has issued regulations to protect the privacy and security of 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. Also, federal agencies are increasing their focus on the importance of cybersecurity in protecting health information. For example, HHS outlined its cybersecurity strategy for the health care sector on December 6, 2023, which builds on a national strategy published by the White House on March 1, 2023, and on February 16, 2024, the HHS Office for Civil Rights (OCR) and the National Institute of Standards and Technology (NIST) announced the publication of a cybersecurity resource guide for implementing HIPAA.

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. 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 (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 Secretary, and depending on the size of the breach, the local and national media. Covered Entities like us are also

subject to 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 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 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 FTC 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 (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 (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 (CPRA) went into effect January 1, 2023 strengthening the CCPA. The CPRA 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 opt outs for certain uses of sensitive data and expands the application of the CCPA to all human resources personal information of our California-based employees. It also created a new California data protection agency authorized to issue substantive regulations and is expected to result in increased privacy and information security enforcement. Various states such as Colorado, Connecticut, Delaware, Florida, Indiana, Iowa, Montana, Oregon, Tennessee, Texas, Utah and Virginia have enacted their own privacy laws similar to the CCPA, and other states are considering proposals for such laws, all of which increases the complexity of compliance and the risk of failures to comply.

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 Office of the National Coordinator for Health Information Technology (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. Healthcare providers including laboratories will be subject to civil monetary penalties for violations of the Information Blocking Rule once the penalty regulations are finalized. The amount of such penalties for laboratories is unknown, but the regulations for health industry networks (HINs), health information exchanges (HIEs), and certified developers of health information technology allow for up to $1.0 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 United States, Europe and elsewhere are often uncertain, contradictory and in flux. In Europe, the General Data Protection Regulation (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 pseudonymized (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 (EU), and European Economic Area (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 EU and the United States remains uncertain. For example, in 2016, the EU and the United States agreed to a transfer framework for data transferred from the EU to the United States, called the Privacy Shield, but the Court of Justice of the EU invalidated the Privacy Shield when it decided the case *Maximilian Schrems vs. Facebook* (Case C-311-18), known as *Schrems II*. However, on July 10, 2023, the European Commission adopted an adequacy decision for a new mechanism for transferring data from the EU to the United States – the EU-US Data Privacy Framework, which provides EU individuals with several new rights, including the right to obtain access to their data, or obtain correction or deletion of incorrect or unlawfully handled data. The adequacy decision followed the signing of an executive order introducing new binding safeguards to address the points raised in the *Schrems II* decision. Notably, the new obligations were geared to ensure that data can be accessed by U.S. intelligence agencies only to the extent necessary and proportionate and to establish an independent and impartial redress mechanism to handle complaints from Europeans concerning the collection of their data for national security purposes. The European Commission will continually review developments in the United States along with its adequacy decision. Adequacy decisions can be adapted or even withdrawn in the event of developments affecting the level of protection in the

applicable jurisdiction. Future actions of EU data protection authorities are difficult to predict. Some customers or other service providers may respond to these evolving laws and regulations by asking us to make certain privacy or data-related contractual commitments that we are unable or unwilling to make. This could lead to the loss of current or prospective customers or other business relationships.

Relatedly, following the United Kingdom's withdrawal from the EU, the GDPR was implemented in the United Kingdom as the U.K. GDPR with the U.K. GDPR sits alongside the amended U.K. Data Protection Act 2018, retains the GDPR in U.K. national law. Under the U.K. GDPR, companies not established in the United Kingdom but who process personal data in relation to the offering of goods or services to individuals in the United Kingdom, or to monitor their behavior will be subject to the U.K. GDPR – the requirements of which are (at this time) largely aligned with those under the EU GDPR and as such, may lead to similar compliance and operational costs with potential fines of up to £17.5 million or 4% of global turnover In June of 2021, the European Commission issued a decision, which will sunset on June 27, 2025 without further action, that the United Kingdom ensures an adequate level of protection for personal data transferred under the EU GDPR from the EU to the United Kingdom. The Parliament of the United Kingdom is currently considering the Data Protection and Digital Information Bill to harmonize the 2018 Data Protection Act, U.K. GDPR, and the Privacy and Electronic Communications Regulations under one legislative framework.

Billing and Government Reimbursement for Clinical Laboratory Services

Medicare

Medicare coverage is limited to items and services, 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 (MAC) responsible for administering Medicare's molecular diagnostic services program (MolDX Program), issued a Local Coverage Determination (LCD) that provides coverage for our AVISE® MTX test. The MAC responsible for administering Medicare claims submitted by our laboratory, Noridian Healthcare Solutions (Noridian), 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 (CLFS) with payment amounts assigned to specific procedure billing codes. In April 2014, Congress passed the Protecting Access to Medicare Act (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 (PFS) are required to report to CMS, beginning in 2017 and every three years thereafter (or annually for "advanced diagnostic laboratory tests" (ADLTs)), 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 (CDLTs) are based upon these reported private payor rates. For CDLTs assigned a new or substantially revised Current Procedural Terminology (CPT), because there is no comparable existing CDLT, CMS will set the initial payment rates using the gap-fill methodology, as under prior law. Initial payment rates for new 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. As noted below, federal law has delayed implementation of further reductions until 2024, at which time the reduction cap will rise to 15% per test per year. PAMA did not impact Medicare reimbursement for AVISE® CTD in 2022 compared to levels experienced in 2021. Additionally, PAMA and changes to the PFS will not have a significant impact to Medicare reimbursement for AVISE® CTD in 2024 compared to levels experienced in 2023.

Since December 2019, Congress has passed a series of laws to modify PAMA's statutory requirements related to the data reporting period and phase-in of payment reductions under the CLFS or CDLTs that are not ADLTs Most recently, the Further Continuing Appropriations and Other Extensions Act of 2024 (Pub.L. 118-22, enacted on November 16, 2023) further delayed the reporting requirement as well as the application of the 15% phase-in reduction. Under these statutory provisions, the next data reporting period for CDLTs that are not ADLTs will be January 1, 2025 through March 31, 2025, and will be based on the most recent data collection period of January 1, 2019 through June 30, 2019. After this data reporting period, the three-year data reporting cycle for these tests will resume (e.g., 2028, 2031, etc.).

The same series of laws modified the phase-in of payment reductions resulting from private payor rate implementation so that a 0.0% reduction limit was applied for calendar years (CYs) 2021 through 2023, as compared to the payment amounts for a test the preceding year. The Further Continuing Appropriations and Other Extensions Act of 2024 further applied a 0.0% reduction limit for CY 2024. Consequently, payment may not be reduced by more than 15% per year for CYs 2025 through 2027 as compared to the payment amounts established for a test the prior year.

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 American Medical Association's (AMA) CPT Editorial Panel approved a proposal to create a new section of billing codes called Proprietary Laboratory Analyses (PLA) codes, to facilitate implementation of this section of PAMA. The AMA publishes approved codes on a quarterly basis. We requested a PLA code and in the quarter ended March 31, 2022, CMS agreed, effective April 1, 2022, to recognize a new PLA code for our protein-based test, AVISE® Lupus.

Billing for diagnostic testing can be complicated. Depending on the billing arrangement and applicable law, we must bill various parties, such as commercial payors, 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. Failing to bill timely or correctly may have negative consequences for us, such as not being reimbursed for our services or experiencing an increase in the aging of our accounts receivable, which could adversely impact 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 Affordable Care Act (ACA) was enacted in the United States and 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 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 U.S. Supreme Court (the Supreme Court) upheld the ACA when it dismissed a legal challenge to the ACA’s constitutionality. Further legislative and regulatory changes under the ACA remain possible, although the current Democrat-led presidential administration has been taking steps to strengthen the ACA. Future changes or additions to the ACA, the Medicare and Medicaid programs 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 United States. 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.

In addition to the ACA, there will likely continue to be proposals by legislators at both the federal and state levels, regulators and private third-party payors to reduce costs while expanding individual healthcare benefits.

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. Since inception, we have 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, 2023, we had a total of 179 employees: 174 full-time employees and 5 part-time employees. This includes 44 in laboratory operations, 9 in research and development, 49 in sales and marketing and 72 in general and administrative functions. All of our employees are located in the United States, none of which are represented by a labor union or covered by a collective bargaining agreement. We consider relations 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, retaining and expanding our workforce, as needed, 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 efforts to ensure our employees' voices are heard.

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.

We conduct periodic anonymous employee surveys aimed at measuring the overall satisfaction of our team and make efforts to address issues brought to our attention. The results consistently show that our employees consider their work valuable and meaningful.

Information About Our Directors and Executive Officers

The following persons currently serve as the directors and executive officers of Exagen:

Directors and Executive Officers	Position
Executive Officers	
John Aballi	President, Chief Executive Officer and Director
Kamal Adawi	Chief Financial Officer and Corporate Secretary
Tina Nova, Ph.D.	Executive Chairman of the Board of Directors
Directors	
Brian Birk	Managing Partner, Co-Founder, Sun Mountain Capital
Ana Hooker	Senior Vice President, Chief Laboratory Officer, Exact Sciences Corporation
Wendy Johnson	Chief Business Officer, Reneo Pharmaceuticals, Inc.
Paul Kim	Chief Financial Officer, Fulgent Genetics, Inc.
Ebetual Pallares, Ph.D.	Managing Member, Proficio Capital Management, LLC
Bruce Robertson, Ph.D.	Managing Director, H.I.G Capital, LLC
Frank Stokes	Chief Financial Officer, Castle Biosciences, Inc.

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 understanding and building upon our diversity and inclusion strengths and are continuing the process of identifying opportunities and developing initiatives.

As of December 31, 2023, 58.6% of our employees identified as female, 33.9% identified as male and 7.5% of our employees identified as other or declined to self-identify. Additionally, 47.9% of our employees identified as White, 24.2% as Hispanic or Latino, 15.1% as Asian, 3.8% as Black or African-American, 3.2% as two or more races (not Hispanic or Latino), 0.6% as Native Hawaiian or other Pacific Islander, and 0.6% as American Indian or Alaska Native. 4.9% of our employees identified as other or declined to self-identify.

Environmental, Social and Governance Matters

In 2020, we undertook a review of our environmental, social and governance (ESG), matters. In 2021, we released our initial Sustainability Report. In 2022, we created an Environmental, Social and Governance Committee (ESG Committee) with the purpose, duties and responsibility of reviewing and recommending our programs, policies and practices relating to ESG issues. The ESG Committee meets formally at least annually and plans to make recommendations to our President and Chief Executive Officer to be presented to the audit committee of our board of directors (the Audit Committee) when warranted. For more information regarding our ESG initiatives, please refer to 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, 2023 and 2022 and our total assets as of December 31, 2023 and 2022, 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 changed our name to Exagen Diagnostics, Inc. In January 2019, we changed our name to Exagen Inc. Our principal executive offices are located at 1261 Liberty Way, Vista, California 92081. Our telephone number is (760) 560-1501. Our website address is www.exagen.com. The information

contained in, or accessible through, our website is not part of, and is not incorporated by reference into, this Annual Report. Investors should not rely on any such information in deciding whether to purchase our common stock.

Available Information

We file Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, proxy and information statements and other information with the Securities and Exchange Commission (SEC). Our filings with the SEC are available free of charge on the SEC's website 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. The SEC maintains an internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC at www.sec.gov.

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:

- 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;
- 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 if we or our partners are unable to successfully negotiate payor contracts, our commercial success could be materially compromised;
- 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;
- We may be unable to manage our 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 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 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 clinical laboratory facility becomes damaged or inoperable, we are required to vacate our existing facility or we are unable to expand our existing facility as needed, we will be unable to perform our testing services and our business will be harmed;

- We may require substantial additional capital to finance our planned operations, which may not be available to us on acceptable terms or at all. Our failure to obtain additional financing when needed on acceptable terms, or at all, could force us to delay, limit, reduce or eliminate our product development programs, commercialization efforts or other operations;
- 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;
- We have previously and may again in the future be required to modify our business practices, pay fines, incur significant expenses or experience losses due to litigation or governmental investigations;
- The FDA may disagree with our assessment that our AVISE® 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;
- 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

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, 2023 and 2022, we incurred net losses of $23.7 million and $47.4 million, respectively, and we expect to incur additional losses in 2024 and in future years. As of December 31, 2023, we had an accumulated deficit of $279.2 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 and to develop future testing products. 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 and materially and adversely affect our prospects and business.

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 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 commercial payors. For the testing products that we develop and commercialize, 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.

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 and have been used by third-party payors and healthcare providers as grounds to deny coverage for or refuse to use a test or procedure, including our tests. 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 MolDx Program, assigned the AVISE® MTX assay a unique identifier and determined that the test meets the applicable Medicare coverage criteria to support dose optimization and therapeutic decision making for patients diagnosed with RA on methotrexate. Our current Medicare Administrative Contractor, Noridian, has adopted this coverage policy. In addition, and effective April 1, 2022, CMS agreed to recognize a new PLA code for our protein-based test, AVISE® Lupus. Noridian priced this PLA code at $1,085 per test. To determine pricing beyond 2022, CMS recommended crosswalking AVISE® Lupus (0312U) to Vectra (81490) at a rate of $840.65 per test. This pricing was finalized on the 2023 CLFS and is effective from January 1, 2023 through December 31, 2025. A pricing determination is not synonymous with a coverage determination. Having a price associated with the PLA code for any particular test does not secure coverage or reimbursement for that PLA code from Medicare or any other third-party payor. So, in an effort to improve transparency regarding Medicare support of AVISE® Lupus, we submitted a formal request to Noridian for coverage of our AVISE® Lupus test under the new PLA Code. On September 27, 2022, we received notice that Noridian has deemed our application for an LCD to be valid. Ultimately receiving a favorable LCD is uncertain and may be time-consuming, resource intensive and require multiple quarterly or annual periods to complete. We have faced and may again face or continue to face challenges relating to commercial payor claim processing and revenue with our tests.

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 commercial payors issued non-coverage policies with respect to AVISE® Lupus, determining that AVISE® Lupus does not meet the medical criteria for coverage and is considered investigational and/or experimental.

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

If we are not successful in reversing existing non-coverage policies, or if other third-party payors issue negative coverage policies, these policies could have a material adverse effect on our business and operations. Even if many third-party payors currently reimburse for our testing products, such payors have in the past and may again 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 could materially reduce our revenue.

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

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

The demand for our testing products may decrease or may not continue to increase at historical rates for a number of reasons. In addition, at any point in time we may decide to no longer commercialize any of our testing products for any number of reasons. While we have experienced revenue growth from the sale of our testing products, we may not be able to sustain this growth or maintain existing revenue levels. Further, we cannot ensure the continued availability of our testing products in commercial quantities at acceptable costs. If we are unable to increase sales of our testing products, expand reimbursement for our testing products, or successfully develop and commercialize

additional testing products, our revenue and our ability to achieve and sustain profitability would be impaired, and the market price of our common stock could decline.

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 the Middle East, 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.

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 is required to report upon the effectiveness of our internal control over financial reporting. 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 may need to upgrade our information technology systems; implement additional financial and management controls, reporting systems and procedures; and/or hire additional accounting and finance staff as we grow. 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.

On November 13, 2022, management and the Audit Committee determined that we made certain errors in revenue resulting from erroneous and duplicate billings related to changes in billing practices. The errors were due to the inadequate design, implementation and precision of internal controls and procedures to evaluate and monitor the accounting for revenue recognition. As a result, revenue and accounts receivable were overstated and other liabilities was understated for the quarter and year to date periods ended June 30, 2022.

We concluded that these were material errors in the financial statements requiring a restatement of the Form 10-Q for the three and six months ended June 30, 2022. Accordingly, management determined that this control deficiency constituted a material weakness as of December 31, 2022.

In response to the material weaknesses, and as previously disclosed in Item 9A of our annual report on Form 10-K for the year ended December 31, 2022, we implemented a remediation plan which included, but was not limited to, evaluating the staffing level, skills and qualification of accounting department personnel, enhancement of our existing control structure and processes for revenue recognition and improving the detailed review process of our revenue recognition models. The enhancements made to our control environment were in place as of December 31, 2023, and based on the evaluation of relevant internal controls, management has concluded that the material weaknesses previously identified have been remediated as of December 31, 2023.

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

We may be unable to manage our 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 may 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 addition, if we were to experience rapid and significant growth, our administrative and operational infrastructure may be strained, requiring 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.

Our commercial success depends upon attaining and maintaining significant market acceptance of our testing products 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 that are recognized and accepted as safe, effective, reliable and cost effective, and any testing product that we offer may not gain or maintain market acceptance among rheumatologists, third-party payors, patients or the medical community. Market acceptance of our testing products 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 over alternative products;
- the demonstration of the performance and clinical validity of our testing products in clinical studies, the results of which, may not replicate the positive results from earlier studies;
- the introduction of new tests that compete with our testing products;
- the product cost in relation to alternative products;
- publicity concerning our testing products 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/or impact market acceptance of our other testing products. Further, our AVISE® 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® CTD test were to encounter any issues, we may experience an impact in the overall success of AVISE® CTD as a whole, including a reduction in ASP or overall revenue, until such time as it can be remedied. Moreover, if our testing products 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 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 may require significant resources and may never be successful.

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

If we are unable to create or maintain demand for our testing products 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 2023, we were featured in five scientific presentations at the 2023 ACR Annual Conference, ACR Convergence 2023. We will also need to generate demand for our testing products through one-on-one education by our sales force. We also plan to focus on educating patients about the benefits of these testing products, 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.

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, 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 and fail to capitalize on other testing products 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. 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, we may forego other similar arrangements which would have been more advantageous for us to pursue.

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

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

- our ability to successfully market and sell our AVISE® testing products;
- the extent to which our current testing and future testing products, if any, are eligible for coverage and reimbursement from third-party payors;
- 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, which may vary significantly;
- the receipt, timing and mix of revenue for our testing products;
- future accounting pronouncements or changes in our accounting policies;
- our ability to collect timely reimbursement for our tests;

- 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. For instance during 2023, our operating results varied due, in part, to our efforts regarding revenue cycle management. 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 of operations.

We rely on sole suppliers for some of the reagents, equipment and other materials used in our testing products, and a sole third-party fulfillment center used to supply healthcare providers with our testing products, and we may not be able to find replacements or transition to alternative suppliers or fulfillment centers.

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 specimen collection and 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, 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. Additionally, if we are unable to remedy future potential quality issues with unique reagent suppliers, or otherwise find a supplier for future biomarkers with issues, we may experience difficulties obtaining market acceptance for our products. Moreover, any issues with quality may result in a change from time to time of the composition of our tests, including our AVISE® CTD test, which could impact the average selling price and revenues received from sales of such test.

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

We rely on a third party as our sole fulfillment center in Florida to supply healthcare providers with our testing products. Our sole fulfillment center could be harmed or rendered inoperable by natural or man-made disasters, including fire, earthquake, hurricane, flooding, pandemics or other disease outbreaks and power outages, which may render it difficult or impossible for us to supply healthcare providers with our testing products for some period of time. The inability to supply healthcare providers with our testing products or the backlog of tests that could develop if our sole fulfillment center is inoperable for even a short period of time, may result in the loss of customers or harm to our reputation or business relationships, and we may be unable to regain those customers or repair our reputation in the future. Furthermore, our sole fulfillment center could be costly and time-consuming to repair or replace. If our sole fulfillment center is destroyed or otherwise rendered inoperable, we may have difficulty replacing this fulfillment center and there can be no assurance we could do so in a timely manner, on terms favorable to us or at all.

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.

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 Medicaid, and commercial payors, 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 and Medicaid;
- 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. 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 have in the past and may again result in uneven cash flow or impact the timing of revenue recognized with these payors. With respect to payments received from government healthcare 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 2023, Noridian posted the calendar year 2024 Medicare Physician Fee Schedule (MPFS), and CLFS, which establishes the reimbursement rates to be paid by Medicare for our jurisdiction for services performed on or after January 1, 2024. PAMA and changes to the PFS did not have a significant impact to Medicare reimbursement for AVISE® CTD in 2024 compared to levels experienced in 2023. Revenue from Medicare comprised 34% and 39% of our revenue for the years ended December 31, 2023 and 2022, respectively. Revenue from the sale of our AVISE® CTD testing products comprised 88% and 84% of our revenue for the years ended December 31, 2023 and 2022, 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.

If we are unable to maintain or expand our sales and marketing force, as needed, 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. Our testing products compete in a concentrated specialty market of autoimmune and autoimmune-related diseases, and utilizing a specialized sales force is integral to our strategy. As such, we believe it is necessary to maintain a sales force that includes sales representatives with specific technical backgrounds and industry expertise and expect to continue to evaluate the reach and frequency with rheumatologists, including as we launch our pipeline products. We may be required to expand our specialized sales force as our company grows. 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. If we are unable to effectively retain, train and integrate additional sales representatives, as needed, 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 ANA and anti-dsDNA and serum complement biomarkers, such as C3 and C4. We

also face competition from commercial laboratories, such as ARUP Laboratories, Inc.; Laboratory Corporation of America Holdings; the Mayo Clinic; and Quest Diagnostics Incorporated, 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 AMPEL BioSolutions, LLC; DxTerity Diagnostics Inc.; Genalyte Inc.; Immunovia AB; Oncimmune plc; Progentec Diagnostics Inc.; and Scipher Medicine Corporation. 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. We rely upon independent sources for phlebotomy to obtain patient samples; interruptions to this capability could dramatically impact patient access to our tests.

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.

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 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 addition, as we develop testing products, we may 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 ours, 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 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 diagnostic industry is subject to rapidly changing technology, which could make our current and future testing products 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.

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. 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 to increased 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 John Aballi, 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. 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.

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

We currently derive all of our revenue from tests conducted at a single laboratory facility located in Vista, California. Vista is situated on or near earthquake fault lines. Our facility and equipment could be harmed or rendered inoperable by natural or man-made disasters which may be exacerbated due to climate change, including earthquake, fire, flood, power loss, communications failure or terrorism, or public health crises. 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, 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 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 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 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 in the future. Any future expansion could disrupt laboratory operations, resulting in an inability to meet customer turnaround time expectations, and could be delayed, resulting in slower realization of laboratory efficiencies anticipated from the use of the expanded facilities. Adverse consequences resulting from a delay in the laboratory expansion could harm our relationships with our customers and our reputation, and could affect our ability to generate revenue.

We carry insurance for damage to our property and the disruption of our business, but this insurance may not cover all 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® Lupus and AVISE® CTD products, we utilize a number of flow cytometers that require calibration and performance validation according to the requirements of the 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 PHI (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 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, 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, and liability under laws that protect the privacy of personal information, such as HIPAA, as amended by the HITECH Act, and their implementing regulations and similar state data privacy and security laws and regulations including civil and criminal 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, as well as private litigation, which could adversely affect our business. Moreover, these laws and their interpretations are constantly evolving and may become more stringent or inclusive over time. For example, increasing concerns about health information privacy have recently prompted the federal government to issue guidance taking a newly expansive view of the scope of the laws and regulations that they enforce. 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.

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.

Our financial condition, commercialization efforts and results of operations has been and may again in the future be adversely affected by outbreaks of contagious diseases.

Any outbreak of a contagious disease, or other adverse public health developments, could have a material and adverse effect on our business operations. Such adverse effects could include disruptions or restrictions on the ability of our, our collaborators', or our suppliers' personnel to travel, and could result in temporary closures of our facilities or the facilities of our collaborators or suppliers, including our sole laboratory. While the impact of the COVID-19 pandemic on our business, financial condition, results of operations and cash flows has subsided, the extent to which COVID-19 will affect our operations in the future will depend on future developments, which are highly uncertain and cannot be predicted with confidence.

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 (Federal Express) 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, terrorist attacks or threats, labor strikes, work stoppages or boycotts, 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 materially and adversely affect our business, reputation, results of operations and financial condition.

Inflation could adversely affect our business and financial results.

Inflation increased significantly during 2022 and continued to increase through 2023. The current inflationary environment has resulted in higher prices, which have impacted our costs incurred to generate revenue from our laboratory testing services, costs to attract and retain personnel, and other operating costs. The severity and duration of the current inflationary environment remains uncertain and may continue to impact our financial condition and results of operations. Inflation may continue to 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.

The failure of financial institutions or transactional counterparties could adversely affect our current and projected business operations and our financial condition and results of operations.

On March 10, 2023, Silicon Valley Bank (SVB) was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (FDIC) as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. A statement by the Department of the Treasury, the Federal Reserve and the FDIC stated that all depositors of SVB would have access to all of their money after only one business day of closure, including funds held in uninsured deposit accounts. Although we do not have any funds deposited with SVB and Signature Bank, we regularly maintain cash balances with other financial institutions in excess of the FDIC insurance limit. A failure of a depository institution to return deposits could impact access to our invested cash or cash equivalents and could adversely impact our operating liquidity and financial performance.

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 (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 (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 (the 2017 Term Loan) with Innovatus Life Sciences Lending Fund I, LP (Innovatus), which we subsequently amended in November 2019, November 2021 and April 2023 (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, achieve certain minimum amounts of annual revenue, as measured on a rolling twelve-month basis, periodically deliver financial statements to Innovatus with an unqualified opinion (including no "going concern") from our independent certified public accounting firm, 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, 2023, there was $15.0 million in principal outstanding under the term loan and an additional $3.2 million outstanding representing interest payable in-kind by adding the paid in-kind interest 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 ten-month period commencing on April 1, 2026. At December 31, 2023, 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 $0.5 million 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 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 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 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.

On November 17, 2023, we filed a shelf registration statement on Form S-3, as amended by Amendment No. 1 to Form S-3 filed on November 27, 2023, that provides for aggregate offerings of up to $150.0 million of our securities subject to various limitations. We filed a prospectus on November 29, 2023 pursuant to this registration statement, registering sales of our common stock in an amount not to exceed $50.0 million, pursuant to a sales agreement by

and between us and Cowen and Company, LLC (TD Cowen), as amended by Amendment No. 1 to Sales Agreement dated November 17, 2023 (the Amended Sales Agreement). Using a shelf registration statement to raise capital generally takes less time and is less expensive than other means, such as conducting an offering under a registration statement on Form S-1 and companies may be able to receive more favorable terms by raising capital pursuant to a shelf registration statement on Form S-3. Our ability to raise capital under our current shelf registration statement (and any future registration statement on Form S-3) is, and may again in the future be, limited by, among other things, current and future SEC rules and regulations impacting the eligibility of smaller companies to use Form S-3 without restrictions. As of the date of this Annual Report, we are subject to the "baby shelf rule" because the market value of our outstanding shares of common stock held by non-affiliates, or public float, was less than $75.0 million as of the date of this Annual Report. As a result, for sales following the date of this Annual Report and until we again have a public float with a value in excess of $75.0 million, if ever, we will be unable to use our shelf registration statement on Form S-3 or the Amended Sales Agreement to raise additional funds to the extent the aggregate market value of securities sold by us or on our behalf pursuant to Instruction I.B.6. of Form S-3 during the 12 calendar months immediately prior to, and including, any intended sale does not exceed one-third of the aggregate market value of our public float, calculated in accordance with the instructions to Form S-3.

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 the sum (the Basic Rate) of (a) the greater of 8.0% or The Wall Street Journal prime rate (the Prime Rate), plus (b) 2.0% (provided that 1.5% of the Basic Rate 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; 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 (similar to our current obligations pursuant to the Amended Loan Agreement), 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 or market development programs, which could lower the economic value of those products or programs to our company.

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 (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 IPO, or December 31, 2024. 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 $1.235 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.

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 commercial 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.

In April 2014, Congress passed PAMA, which included substantial changes to the way in which clinical laboratory services are paid under the CLFS. 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 CDLTs 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 laws, regulations and policies could be amended or additional healthcare initiatives could be implemented in the future.

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 because we are accredited to perform testing by CAP. To renew this certificate, we are subject to survey and inspection every two years. Moreover, inspectors from CMS or CAP 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 NYSDOH on a product-by-product basis before they are offered in New York. We are also subject to periodic inspection by the NYSDOH and required to demonstrate ongoing compliance with NYSDOH regulations and standards. To the extent NYSDOH 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 NYSDOH 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 payment mechanisms for clinical laboratory services resulting from 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 Medicare or Medicaid, 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 and 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. However, these laws and regulations are subject to change and additional interpretation and guidance from regulatory authorities. For instance, in April 2022, the HHS OIG issued a new advisory opinion indicating that a particular clinical laboratory's practice of contracting with hospitals for the collection of samples for testing could, based on the facts provided and assuming the requisite intent, be a violation of the federal Anti-Kickback Statute. If this Advisory Opinion ultimately limits our ability to collect samples in a hospital setting, we may be required to contract for sample collection with other collection sites or sources, such as mobile phlebotomists, that could be more expensive and less convenient for patients, which could adversely affect both demand for our tests and the margins and profitability of our tests.

Given the complexity of these existing and changing rules and regulations, 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. For additional information see the risk factor below entitled *"We have previously and may again in the future be required to modify our business practices, pay fines, incur significant expenses or experience losses due to litigation or governmental investigations."* 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, and similar programs outside the United States, 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.

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.

We have previously and may again in the future 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 have been and 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. In addition, any litigation or government investigation generally, diverts the attention of our management team and resources from our core business and limits the time and attention of our management team otherwise available to devote to our business. Government investigation and litigation in general may cause us to incur significant expenses, to experience significant losses, and, as a result of such matters, we may also be required to materially alter the conduct of our operations or pay significant penalties. For example, pursuant to a settlement agreement, we made a single lump-sum remittance to the government in the amount of $0.7 million plus interest in October 2023, the U.S. Attorney's Office dismissed this "covered conduct" in the *qui tam* with prejudice, while non-covered conduct was dismissed without prejudice. In November 2023, the complaint was unsealed and served on Exagen. Exagen filed a motion to dismiss the complaint. In February 2024, the relator filed a motion for leave to amend the complaint. Exagen opposed this motion, and all motions are still pending. The Company intends to vigorously defend against the claims being asserted in the complaint.

Any of these circumstances may adversely affect our business, prospects, reputation and results of operations.

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 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.

The FDA may disagree with our assessment that our AVISE® 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 any diagnostic test that meets the definition of a medical device, except under specific, narrow circumstances. The 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 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 diagnostic testing products to be IVDs subject to the agency's regulatory requirements for IVDs. 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. 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 tests or refrain from launching 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 testing 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 nonclinical studies or clinical 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. Any finding by the FDA or another regulatory authority 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.

The FDA may finalize its rulemaking to regulate LDTs or Congress may take action to reform the current legal requirements applicable to LDTs, and in either 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. Although historically the FDA has applied a policy of enforcement discretion with respect to LDTs whereby the FDA does not generally actively enforce its regulatory requirements for such tests, in October 2023, the FDA issued a proposed rule to regulate LDTs under the current medical device framework. The agency's proposal also includes a plan to phase out its current enforcement discretion policy over several years. This FDA rulemaking was initiated after years of failed congressional attempts to harmonize the regulatory paradigms applicable to LDTs and other *in vitro* diagnostic tests, as discussed further below. The likelihood of the FDA finalizing the proposed rule following a public comment period, as well as potential litigation challenging its authority to take such action, is uncertain at this time as stakeholders continue to press for a comprehensive legislative solution instead of administrative agency action.

If there are changes in FDA regulations or legislative authorities such that the agency begins to exercise oversight over LDTs, or if the FDA disagrees that our marketed tests are within the scope of its criteria used for defining LDTs, we may become subject to extensive regulatory requirements and may be required to stop selling our existing tests or launching any other tests we may develop and to conduct additional clinical trials or take other actions prior to continuing to market our tests. If the FDA allows our tests to remain on the market but there is uncertainty about our tests, if they are labeled investigational by the FDA or if labeling claims the FDA allows us to make do not include the claims necessary or desirable for successful commercialization, orders from healthcare providers or reimbursement for our tests may decline.

In addition, as noted above, Congress had 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. Reform legislation called the VALID Act garnered bipartisan and bicameral support in recent years but failed to move out of committee during the last congressional session. As drafted and re-introduced for consideration by the current Congress, the VALID Act would codify the term IVCT to create a new medical product category separate from medical devices to include 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. The FDA's October 2023 publication of an LDT proposed rule that would apply the existing medical device framework to laboratory-developed products has renewed stakeholder calls for a more targeted approach to modernizing the federal government's oversight of clinical diagnostic tests. It remains possible that congressional action in this area could displace the need for the FDA to complete its recently proposed rulemaking.

If Congress were to pass the VALID Act or any other legislation applicable to the FDA's regulation of LDTs, or if the FDA were to successfully promulgate new regulations for such products through the recently initiated notice-and-comment rulemaking or a future rulemaking proceeding, 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. The premarket review process can be lengthy, expensive, time-consuming and unpredictable. Further, obtaining premarket clearance may involve, among other things, successfully completing clinical trials, which require significant time and cash resources 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. If we are required to obtain premarket clearance or approval and/or conduct premarket clinical trials, our development costs could significantly increase, marketing of any new tests we may develop may be delayed, and sales of our existing tests could be interrupted or stopped. Any of these outcomes could reduce our revenue or increase our costs and materially adversely affect our business, prospects, results of operations or financial condition.

The outcome and ultimate impact on our business of any changes to the federal government's regulation of LDTs is difficult to predict. Failure to comply with any applicable FDA requirements could trigger a range of enforcement actions, including warning letters, fines, penalties, suspension of operations, product recalls or seizures, denial of applications for clearance or approval, injunctions and other civil or 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® 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 FTC 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 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 (Privacy Standards) and the Security Standards for the Protection of Electronic Protected Health Information (Security Standards) under HIPAA establish a set of basic national privacy and security standards for the protection of individually identifiable health information by Covered Entities and their Business Associates. 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 HIPAA requirements 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 apply more broadly or be more stringent than HIPAA. For example, 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 went into effect in California amending the CCPA 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 also created a new regulatory authority, the California Privacy Protection Agency (CPPA), which is authorized to issue substantive regulations and could result in increased privacy and information security enforcement. 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 and other similar laws that recently went into effect in in other states, such as Utah, Colorado, Connecticut, Delaware, Florida, Indiana, Iowa, Montana, Oregon, Tennessee, and Texas), 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 EU. In July 2023, however, the European Commission adopted an adequacy decision for a new mechanism for transferring data from the EU to the United States – the EU-US Data Privacy Framework, which provides EU individuals with several new rights, including the right to obtain access to their data, or obtain correction or deletion of incorrect or unlawfully handled data. The adequacy decision followed

the signing of an executive order introducing new binding safeguards addressing the reasons behind the Court of Justice of the EU's invalidation of the original Privacy Shield. The European Commission will continually review developments in the United States along with its adequacy decision. However, future actions of EU data protection authorities are difficult to predict.

Relatedly, following the United Kingdom's withdrawal from the EU, the GDPR was implemented in the United Kingdom as the U.K. GDPR. The U.K. GDPR sits alongside the amended U.K. Data Protection Act 2018, which implements certain derogations in the EU GDPR into U.K. law. The U.K. 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. In June of 2021, the European Commission issued a decision, which will sunset on June 27, 2025 without further action, that the United Kingdom ensures an adequate level of protection for personal data transferred under the EU GDPR from the EU to the United Kingdom. The Parliament of the United Kingdom is currently considering the Data Protection and Digital Information Bill to harmonize the 2018 Data Protection Act, U.K. GDPR, and the Privacy and Electronic Communications Regulations under one legislative framework.

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. Additionally, increasing concerns about health information privacy have recently prompted the federal government to issue guidance taking a newly expansive view of the scope of the laws and regulations that they enforce. 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 incurrence 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 in foreign markets. We are not permitted to market or promote any of our testing products before we receive regulatory approval from applicable regulatory authorities in foreign markets, and we may never receive such regulatory approvals for any of our testing products. To obtain separate regulatory approval in many other countries, we and our collaborators and service providers 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 obtain regulatory approval of our testing products and ultimately commercialize our testing products in foreign markets, we would be subject to additional risks and uncertainties, including any or all of the following:

- different regulatory requirements for approval of IVDs 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;

- inflationary pressures, such as those the global market is currently experiencing, which have and may increase costs for materials, supplies, and services;
- 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 current conflicts in Ukraine and the Middle East; natural disasters which may be exacerbated due to climate change, including earthquakes, typhoons, floods and fires; outbreak of disease; boycotts; or other business restrictions.

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 the AVISE® Lupus test, affects our ability to compete and to achieve sustained profitability. We rely on a combination of U.S. and foreign patents and patent applications, copyrights, trademarks and trademark applications, and contractual restrictions to protect our intellectual property rights. We cannot be certain that the claims in our granted patents and pending patent applications covering our AVISE® testing products will be considered patentable or enforceable by the United States Patent and Trademark Office (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 have an exclusive license to 12 issued U.S. patents, one Patent Cooperation Treaty application, and certain corresponding foreign counterpart patents, relevant to our AVISE® testing products. We own five issued U.S. patents, six pending U.S. patent applications, one pending U.S. provisional patent application and certain corresponding foreign counterpart patents 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.

We previously held licenses to five patent families related to CB-CAPs technology from the University of Pittsburgh (UPitt). We have terminated these license agreements (related to U.S. Patent Nos. 7,361,517, 7,390,631, 7,585,640, 7,588,905, 8,080,382, 8,126,654, and foreign equivalents thereof), effective March 22, 2024, and as a result may face increased competition with respect to the portion of our testing products previously protected by these patents.

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 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 (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, we license certain patent rights from AHN, QMUL and JHU. Our existing license agreements 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 UPitt 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. 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. 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 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 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 brings 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 be issued 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 current conflict in the Ukraine and the Middle East.

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.

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 provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which

could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our 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 64% of our outstanding capital stock and our greater than 5% stockholders, directors and executive officers collectively own (without duplication) approximately 65% of our outstanding capital stock as of February 15, 2024. 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 initial public offering (IPO), there had been no public market for our common stock. Our common stock began trading on The Nasdaq Global Market (Nasdaq) relatively recently, 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. During 2023, our average daily trading volume has been approximately 25,040 shares.

Our failure to meet the continued listing requirements of Nasdaq or The Nasdaq Stock Market LLC 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 downgrade our common stock or otherwise issue adverse opinions or commentary 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 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 life sciences and diagnostics 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 1C. Cybersecurity.

We recognize the critical importance of maintaining the trust and confidence of physicians, patients, business partners and employees toward our business and are committed to protecting the confidentiality, integrity and availability of our business operations and systems. Our board of directors is actively involved in oversight of our risk management activities, and cybersecurity represents an important element of our overall approach to risk management. Our cybersecurity policies, standards, processes and practices are based on recognized frameworks established by NIST and other applicable industry standards, as well as the HIPAA Security Rule and other recognized frameworks. In general, we seek to address cybersecurity risks through a comprehensive, cross-functional approach that is focused on preserving the confidentiality, security and availability of the information that we collect and store by identifying, preventing and mitigating cybersecurity threats and effectively responding to cybersecurity incidents when they occur.

Cybersecurity Risk Management and Strategy; Effect of Risk

We face risks related to cybersecurity such as unauthorized access, cybersecurity attacks and other security incidents, including as perpetrated by hackers and unintentional damage or disruption to hardware and software systems, loss of data, and misappropriation of confidential information. To identify and assess material risks from cybersecurity threats, we maintain a comprehensive cybersecurity program to ensure our systems are effective and prepared for information security risks, including regular oversight of our programs for security monitoring for internal and external threats to ensure the confidentiality and integrity of our information assets. We consider risks from cybersecurity threats in addition to other company risks as part of our overall risk assessment process. We employ a range of tools and services, including regular network and endpoint monitoring, audits, vulnerability assessments, and penetration testing to inform our risk identification and assessment. As discussed in more detail under "Cybersecurity Governance" below, our Audit Committee provides oversight of our cybersecurity risk management and strategy processes, which are led by our Vice President of Information Services.

We also identify our cybersecurity threat risks by comparing our processes to standards set by NIST, as well as performing intrusion detection and prevention. To provide for the availability of critical data and systems, maintain

regulatory compliance, manage our material risks from cybersecurity threats, and protect against and respond to cybersecurity incidents, we undertake the following activities:

a. monitor emerging data protection laws and implement changes to our processes that are designed to comply with such laws;

b. through our policies, practices and contracts (as applicable), require employees, as well as third parties that provide services on our behalf, to treat confidential information and data with care;

c. employ technical safeguards that are designed to protect our information systems from cybersecurity threats, including firewalls, intrusion prevention and detection systems, anti-malware functionality and access controls, which are evaluated and improved through vulnerability assessments and cybersecurity threat intelligence;

d. provide regular, mandatory training for our employees regarding cybersecurity threats as a means to equip them with effective tools to address cybersecurity threats, and to communicate our evolving information security policies, standards, processes and practices;

e. conduct regular phishing email simulations for all employees with access to our email systems to enhance awareness and responsiveness to possible threats;

f. conduct monthly cybersecurity management and incident training for employees involved in our systems and processes that handle sensitive data;

g. leverage internal and external resources to help us identify, protect, detect, respond and recover when there is an actual or potential cybersecurity incident; and

h. carry information security risk insurance that provides protection against the potential losses arising from a cybersecurity incident

Our incident response plan coordinates the activities we take to prepare for, detect, respond to and recover from cybersecurity incidents, which include processes to triage, assess severity for, escalate, contain, investigate and remediate the incident, as well as to comply with potentially applicable legal obligations and mitigate damage to our business and reputation. As part of the above processes, we rely on internal resources rather than consultants, auditors or other third parties, to review our cybersecurity program.

Our processes also address cybersecurity threat risks associated with our use of third-party service providers, including our suppliers and manufacturers or who have access to patient and employee data or our systems. In addition, cybersecurity considerations affect the selection and oversight of our third-party service providers. We perform diligence on third parties that have access to our systems, data or facilities that house such systems or data.

We describe whether and how risks from identified cybersecurity threats, including as a result of any previous cybersecurity incidents, have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition, under the heading "*Failure in our information technology, telephone or other systems could significantly disrupt our operations and adversely affect our business and financial condition*," which disclosures are incorporated by reference herein.

Cybersecurity Governance; Management

Cybersecurity is an important part of our risk management processes and an area of focus for our board of directors and management. In general, our board of directors oversees risk management activities designed and implemented by our management, and considers specific risks, including, for example, risks associated with our strategic plan, business operations, and capital structure. Our board of directors executes its oversight responsibility for risk management both directly and through delegating oversight of certain of these risks to its committees, and our board of directors has authorized our Audit Committee to oversee risks from cybersecurity threats.

Upon detection of a material cybersecurity threat, our Audit Committee receives an update from management of the cybersecurity threat, risk management and strategy processes, as well as the steps management has taken to respond to such risks. In such sessions, our Audit Committee generally receives materials that include cybersecurity materials discussing current material cybersecurity threat risks, and describing our ability to mitigate those risks, and discusses such matters with our Chief Executive Officer. Our Audit Committee and board of directors receive prompt and timely information regarding any cybersecurity incident that meets established reporting thresholds.

Our cybersecurity risk management and strategy processes, which are discussed in greater detail above, are led by our Vice President of Information Services, with support from our entire Information Services department. Such individuals have collectively over 10 years of prior work experience in various roles involving managing information security, developing cybersecurity strategy, implementing effective information and cybersecurity programs, as well as several relevant degrees and certifications. These Information Services team members are informed about and monitor the prevention, mitigation, detection, and remediation of cybersecurity incidents through their management of, and participation in, the cybersecurity risk management and strategy processes described above, including the operation of our incident response plan. As discussed above, these Information Services team members report to our Chief Executive Officer, and ultimately to the Audit Committee of our board of directors about material cybersecurity threats.

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 also lease approximately 28,000 square feet of additional office space in Carlsbad, California, under a sublease that is co-terminus with our other lease expiring in 2027. We believe that our current facilities are adequate for our current needs and that suitable additional or alternative spaces will be available in the future on commercially reasonable terms, if required.

Item 3. 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.

In October 2023, we resolved an investigation with the U.S. Attorney's Office for the District of Massachusetts that was initiated by a *qui tam* lawsuit. Pursuant to a Settlement Agreement, we made a single lump-sum remittance to the government in the amount of $0.7 million plus interest in connection with specimen processing arrangements that we historically had with physicians. The U.S. Attorney's Office dismissed this "covered conduct" in the qui tam with prejudice, while non-covered conduct was dismissed without prejudice. In November 2023, the complaint was unsealed and served on us. We filed a motion to dismiss the complaint. In February 2024, the relator filed a motion for leave to amend the complaint. We opposed this motion, and all motions are still pending. The Company intends to vigorously defend against the claims being asserted in the complaint.

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 14, 2024, there were approximately 31 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.

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 exist to provide clarity in autoimmune disease decision making with the goal of improving patients' clinical outcomes. We have developed and are commercializing a portfolio of innovative testing products under our AVISE® brand, which allow for the differential diagnosis, prognosis and monitoring of complex autoimmune and autoimmune-related diseases. 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 in this market, particularly for potentially life-threatening diseases such as SLE.

Since inception we have devoted substantially all of our efforts to developing and marketing products for the diagnosis, prognosis and monitoring of autoimmune diseases. We commercially launched our lead testing product, AVISE® CTD, in 2012. Our proprietary AVISE® Lupus test is included as part of the AVISE® CTD panel and employs a patent-protected method for diagnosing patients with SLE based on levels of CB-CAPs (e.g. EC4d and BC4d), ANA, and ds-DNA. The AVISE® Lupus test also employs patent-protected algorithms used to generate risk scores to diagnose patients with SLE based on the levels of the biomarkers. These proprietary, patent-protected methods vastly improve the diagnostic sensitivity of our test compared to the current standard of care. AVISE® CTD enables differential diagnosis for patients presenting with symptoms indicative of a wide variety of CTDs and other related diseases with overlapping symptoms. Revenue from this product comprised 88% and 84% of our revenue for the years ended December 31, 2023 and 2022, respectively. For the years ended December 31, 2023 and 2022, we incurred net losses of $23.7 million and $47.4 million, respectively, and we expect to continue to incur operating losses in the near term. Our operations have been funded primarily through equity financings, debt financings and revenue from product sales. We have never been profitable and, as of December 31, 2023, we had $36.5 million of cash and cash equivalents and an accumulated deficit of $279.2 million.

Reimbursement for our testing services comes from several sources, including commercial payors (such as insurance companies and health maintenance organizations), government payors (such as Medicare and Medicaid), and patients. Reimbursement rates vary by product and payor.

All of our AVISE® tests are performed in our approximately 13,000 square foot laboratory located in Vista, California, which is certified under the CLIA and accredited by CAP. 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 typically reports all AVISE® testing product results within five business days.

We market our AVISE® testing products using our specialized sales force covering 40 territories in the United States. Many diagnostic sales forces are trained only to understand the comparative benefits of the tests they promote. In contrast, the specialized backgrounds of our sales personnel, coupled with our comprehensive training, enables our sales representatives to interpret results from our de-identified patient test reports and provide unique insights in a highly tailored discussion with rheumatologists. We believe our focus on and experience in the field of rheumatology, combined with our commitment to excellent customer service and support, position us very well to respond to the needs of rheumatologists and the patients they serve.

Factors Affecting Our Performance

We believe there are several important factors that have impacted, and that we expect will impact, our operating performance and results of operations, including:

- ***Reimbursement for Our Testing Products***. Our revenue depends on achieving broad coverage and reimbursement for our tests from third-party payors, including both commercial payors and government payors. Payment from third-party payors differs depending on whether we are considered a "participating provider" (have entered into a contract with the payors as a participating provider) or a "non-participating provider" (do not have a contract and are considered a "non-participating provider"). Payors will often

reimburse non-participating providers at a lower amount than participating providers, if at all. We have received a substantial portion of our revenue from a limited number of 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, changes in our estimated reimbursements for tests performed in prior periods can positively or negatively impact our revenue in the current period and cause our financial results to fluctuate. In addition, in connection with our revenue cycle management initiatives, we plan to hold claims in the first half of the year which will likely result in increases in our accounts receivable and an accelerated decrease in our cash in the first half of the year which we would expect to return to typical levels by the end of our fiscal year.

- ***Continued Growth of Our Testing Products.*** Since the launch of AVISE® CTD in 2012 and through December 31, 2023, we have delivered approximately 887,000 of these tests. 137,650 AVISE® CTD tests were delivered in the year ended December 31, 2023, representing approximately 2% growth over the same period in 2022. The number of ordering healthcare providers in the quarter ended December 31, 2023 was 2,383, representing an approximate 2% decrease over the same period in 2022. Revenue growth for our testing products will depend, in part, on our ability to continue to expand our base of ordering healthcare providers and increase our penetration with existing healthcare providers.

- ***Development of Additional Testing Products.*** We rely on sales of our AVISE® CTD test to generate the significant majority of our revenue. We expect to continue to invest in research and development in order to develop additional testing products. Our success in developing new testing products will be important in our efforts to grow our business by expanding the potential market for our products and diversifying our sources of revenue.

- ***Maintain Meaningful Margin***. We seek to maintain meaningful margin through a continued focus on increasing operating leverage through the implementation of certain internal initiatives, such as leveraging validation, utility and reimbursement oriented clinical studies to facilitate payor coverage of our testing products. We plan to center our efforts around long-term reimbursement and ASP growth and seek to improve our per test costs by focusing on profitable, core test offerings and limiting fixed costs and overhead.

- ***Timing of Our Research and Development Expenses***. We conduct clinical studies to validate our new testing products, as well as ongoing clinical and outcome studies to further expand the published evidence that supports our commercialized AVISE® testing products. We also expend funds to secure clinical samples that can be used in discovery, product development, clinical validation, utility and outcome studies. Our spending on experiments and clinical studies may vary substantially from quarter to quarter, and 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.

- ***How We Recognize Revenue***. We record revenue on an accrual basis, using an estimate of the amount that we will ultimately realize, as determined based on a historical analysis of amounts collected by test and by payor, among other factors. 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."

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 (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.

Inflationary Environment

The current inflationary environment has resulted in higher prices, which have impacted our costs incurred to generate revenue from our laboratory testing services, costs to attract and retain personnel, and other operating costs. The severity and duration of the current inflationary environment remains uncertain and may continue to impact our financial condition and results of operations.

Financial Overview

Revenue

We recognize revenue in accordance with the provisions of ASC Topic 606, *Revenue from Contracts with Customers.* We record revenue on an accrual basis, using an estimate of the amount we will ultimately receive, as determined based on a historical analysis of amounts collected by test and by payor, among other factors. These assessments require significant judgment by management.

To date, we have derived nearly all of our revenue from the sale of our testing products, most of which is attributable to our AVISE® CTD test. We primarily market our testing products to rheumatologists in the United States. The rheumatologists who order our testing products, and to whom results are reported, are generally not responsible for payment for these products. The parties that pay for these services (payors) consist of commercial payors (insurance companies, health maintenance organizations, etc.), government payors (primarily Medicare and Medicaid), client payors (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.

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.

In the quarter ended March 31, 2022, CMS agreed, effective April 1, 2022, to recognize a new PLA code for our protein-based test, AVISE® Lupus. Noridian, our MAC, priced this PLA code at $1,085 per test. To determine pricing beyond 2022, CMS recommended crosswalking AVISE® Lupus (0312U) to Vectra (81490) at a rate of $840.65 per test. This pricing was finalized on the 2023 CLFS and is effective from January 1, 2023 through December 31, 2025. The process for obtaining and maintaining consistent reimbursement for new tests can be uncertain, lengthy and time consuming. A pricing determination is not synonymous with a coverage determination. Having a price associated with the PLA code for any particular test does not secure coverage or reimbursement for that PLA code from Medicare or any other third-party payor.

In an effort to improve transparency regarding Medicare support of AVISE® Lupus, on July 29, 2022, we submitted a formal request to Noridian for coverage of our AVISE® Lupus test under the new PLA Code. On September 27, 2022, we received notice that Noridian has deemed our application for an LCD to be valid. Ultimately receiving a favorable LCD is uncertain and may be time-consuming, resource intensive and require multiple quarterly or annual periods to complete. In the meantime, we have continued to submit Medicare claims for AVISE® Lupus, appeal denials and respond to requests for additional information. On January 31, 2024, CMS released a coverage article under which all multi-analyte proteomic testing will be considered within the scope of MolDX and reviewed through their technology assessment process. The article requires all laboratories furnishing multi-analyte proteomics testing in MolDX jurisdictions to register with the DEX® Diagnostics Exchange Registry and obtain a Z-Code® identifier. To determine if the submitted tests are compliant with relevant policy requirements, these tests will undergo technical assessment by Palmetto GBA as part of the MolDX program. The article listed several such tests, including the AVISE® Lupus test.

We face challenges relating to commercial payor claim processing and revenue. Now that we are billing under our PLA code, we are experiencing denials due to unfavorable medical policy with certain plans, and we expect this situation to persist.

During the year ended December 31, 2023, we implemented several revenue cycle management initiatives, including among others, withholding the submission of commercial payor claims for reimbursement until subsequent quarters, increasing appeals efforts and implementing increases to our patient payment rates. Additionally, in November 2023, we increased the list price billed for our tests. These ongoing revenue cycle management initiatives aim to optimize our appeals process and the potential for cash collections. We experienced moderate declines in test volume in the second half of 2023, as rheumatologists and patients adjust to these changes; however, we delivered 137,650 tests for our flagship product, AVISE® CTD, in the year ended December 31, 2023 as compared to 135,210 tests for the year ended December 31, 2022.

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, infrastructure expenses, shipping charges to transport specimens, blood specimen collections fees, royalties, depreciation and allocated overhead (including rent and utilities).

Each payor, whether commercial, 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. We expect that our costs of revenue will remain relatively consistent year-over-year in the near-term.

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 remain relatively consistent year-over-year in the near-term.

Research and Development Expenses

Research and development expenses include costs incurred to develop our technology, test products and product candidates, in addition to costs incurred to collect clinical specimens and conduct clinical studies to develop and support those products and product candidates. These costs consist of 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). 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 year-over-year in the near-term as a result of ongoing clinical studies.

Interest Expense

Interest expense consists of cash and non-cash interest expense associated with our financing arrangements, including the borrowings under our Amended Loan Agreement with Innovatus. We expect interest expense to remain relatively consistent in the year ending December 31, 2024 as compared to the year ended December 31, 2023.

Interest Income

Interest income consists of interest income earned on our cash and cash equivalents.

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, 2023 and 2022:

	Year Ended December 31,		
	2023	2022	Change
	(in thousands)		
Revenue	$ 52,548	$ 45,563	$ 6,985
Operating expenses:			
Costs of revenue	23,092	24,214	(1,122)
Selling, general and administrative expenses	47,428	52,018	(4,590)
Research and development expenses	4,865	9,876	(5,011)
Goodwill impairment	—	5,506	(5,506)
Total operating expenses	75,385	91,614	(16,229)
Loss from operations	(22,837)	(46,051)	23,214
Interest expense	(2,335)	(2,448)	113
Interest income	1,516	830	686
Loss before income taxes	(23,656)	(47,669)	24,013
Income tax (expense) benefit	(33)	282	(315)
Net loss	$ (23,689)	$ (47,387)	$ 23,698

Revenue

Revenue increased $7.0 million, or 15.3%, for the year ended December 31, 2023 compared to the year ended December 31, 2022, primarily due to improved commercial payor ASP, increased AVISE® CTD year-over-year volume and cash collections from tests performed in prior periods, partially offset by decreased Medicare ASP. The number of AVISE® CTD tests delivered increased to 137,650 in the year ended December 31, 2023 compared to 135,210 tests delivered in the same 2022 period. The AVISE® CTD test accounted for 88% and 84% of revenue for the years ended December 31, 2023 and 2022, respectively. The number of ordering healthcare providers decreased to 2,383 for the three months ended December 31, 2023 compared to 2,419 in the same 2022 period.

Costs of Revenue

Costs of revenue decreased $1.1 million, or 4.6%, for the year ended December 31, 2023 compared to the year ended December 31, 2022. This decrease was primarily due to decreases of $0.9 million in materials and supplies expenses resulting from price improvements related to transition of biomarkers to suppliers with favorable pricing, and $0.2 million in shipping and handling costs. Gross margin as a percentage of revenue increased to 56.1% for the year ended December 31, 2023 compared to 46.9% for the year ended December 31, 2022.

Selling, General and Administrative Expenses

Selling, general and administrative expenses decreased $4.6 million, or 8.8%, for the year ended December 31, 2023 compared to the year ended December 31, 2022. This decrease was primarily due to decreases of $6.1 million of personnel costs, including salaries, benefits, stock-based compensation, severance expenses and other reimbursable employee expenses, as a result of lower headcount, in addition to decreases of $1.5 million in marketing expenses related to advertising expenses, speaker programs and trade show expenses, $0.3 million in insurance expenses, $0.2 million in third-party billing expenses and $0.1 million in legal expenses. These decreases were partially offset by the recognition of a $1.5 million loss on the disposal of assets primarily related to an assignment of a lease, in addition to an increases in expenses related to bonuses of $1.3 million, facilities and allocated overhead expenses of $0.5 million and commissions of 0.3 million.

Research and Development Expenses

Research and development expenses decreased $5.0 million, or 50.7%, for the year ended December 31, 2023 compared to the year ended December 31, 2022. This decrease was primarily due to decreases of $2.7 million of personnel costs, including salaries, benefits and stock-based compensation, as a result of lower headcount, decreases related to lab supplies expenses of $1.0 million, collaboration expenses of $0.5 million, clinical study expenses of $0.3 million, and professional service fees of $0.2 million, in addition to a long-lived assets impairment charge of $0.4 million for the year ended December 31, 2022.

Goodwill Impairment

As part of our annual goodwill impairment assessment in the fourth quarter of 2022, we determined that the sustained decrease in our market capitalization constituted an indicator of impairment and as a result, a quantitative goodwill impairment test was completed as of December 31, 2022. This analysis identified an impairment of $5.5 million related to our goodwill.

Interest Expense

Interest expense decreased $0.1 million for the year ended December 31, 2023 compared to the year ended December 31, 2022 due to a lower principal balance on the company's Amended Loan Agreement.

Interest Income

Interest income increased $0.7 million for the year ended December 31, 2023 compared to the year ended December 31, 2022 due to higher money market and certificate of deposit interest rates in 2023 compared to 2022.

Income Tax (Expense) Benefit

Income tax benefit increased $0.3 million for the year ended December 31, 2023 compared to the year ended December 31, 2022, primarily due to the release of a valuation allowance.

Liquidity and Capital Resources

We have incurred net losses since our inception. For the years ended December 31, 2023 and 2022, we incurred a net loss of $23.7 million and $47.4 million, respectively, and we expect to incur additional losses in future periods. To date, we have generated only limited revenue, and we may never achieve revenue sufficient to offset our expenses. As of December 31, 2023, we had an accumulated deficit of $279.2 million and cash and cash equivalents of $36.5 million. 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, money market funds and certificates of deposit.

Since becoming a public company, our primary sources of capital have been cash inflows from product sales, sales of our common stock and, to a lesser extent, borrowings under our 2017 Term Loan. In April 2023, we further amended the 2017 Term Loan, pursuant to which we prepaid $10.0 million of principal and amended additional terms of the agreement. See Note 4, Borrowings, to our audited financial statements included in this Annual Report on Form 10-K for additional information.

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 minimum liquidity of $2.0 million, 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. Per the Amended Loan Agreement, we are not required to comply with the revenue covenant for any quarter during which we maintain a minimum aggregate cash balance equal to fifty percent of the aggregate principal amount of the 2017 Term Loan funded (excluding any capitalized interest paid-in-kind) at all times during such quarter. The consequences of failing to achieve the performance covenants, when applicable, will be cured if (i) within thirty days of failing to achieve the performance covenant, we submit a new Board approved financial plan to Innovatus under which we are expected to break even on a cash flow basis prior to the maturity date, and (ii) within thirty days of the submission of such financial plan, 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. As of December 31, 2023, we were in compliance with all covenants of the Amended Loan Agreement with Innovatus. 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.

On November 17, 2023, we filed a registration statement on Form S-3 (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, all of which remain available for sale at December 31, 2023.

On September 15, 2022, the Company entered into a sales agreement (the Sales Agreement) with TD Cowen as sales agent, pursuant to which the Company may offer and sell, from time to time, shares of Company common stock having an aggregate offering price of up to $50.0 million. The Sales Agreement was amended in November 2023 in connection with the filing of the Form S-3 discussed above. The Company is not obligated to sell any shares of Company common stock in the offering and, as of December 31, 2023, the Company had not sold any shares of its common stock pursuant to the Sales Agreement.

Our ability to utilize the $150 million of capacity remaining under our Shelf Registration Statement, including the $50.0 million of capacity remaining under our at the market offering sales agreement is limited by our compliance with the baby shelf rules (as defined below). As of the filing of this Annual Report on Form 10-K, our public float is less than $75 million, and under SEC regulations, for so long as our public float remains less than $75 million, the amount we can raise through primary public offerings of securities in any twelve-month period using shelf registration statements subject to Instruction I.B.6. to Form S-3 is limited to an aggregate of one-third of our public float, which is referred to as the "baby shelf rules." As of February 15, 2024, our public float was approximately $29.7 million, based on 12,916,064 shares of outstanding common stock held by non-affiliates and at a price of $2.30 per share, which was the last reported sale price of our common stock on the Nasdaq Capital Market on January 30, 2024.

Funding Requirements

Our primary use of cash is to fund our operations as we continue to grow our business. We expect to continue to incur operating losses in the near term. In the short-term, we expect costs of revenue and selling, general and administrative expenses to remain relatively consistent. We expect research and development expenses to increase in the short-term as a result of ongoing clinical studies. We believe we have sufficient laboratory capacity to support increased test volume. 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 finance leases related to our laboratory equipment (see Note 4, Borrowings, and Note 6, Commitments and Contingencies, to our 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. Actual results could vary as a result of a number of factors, including:

- 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;
- 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;
- 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; and
- 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.

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:

	Year Ended December 31,	
	2023	2022
(in thousands)		
Net cash provided by (used in):		
Operating activities	$ (14,462)	$ (32,144)
Investing activities	(804)	(4,318)
Financing activities	(10,632)	(489)
Net change in cash, cash equivalents and restricted cash	$ (25,898)	$ (36,951)

Cash Flows from Operating Activities

Net cash used in operating activities for the year ended December 31, 2023 was $14.5 million and primarily resulted from (i) our net loss of $23.7 million adjusted for non-cash charges of $8.9 million primarily related to stock-based compensation, depreciation, amortization, loss on disposal of assets primarily related to the assignment of a lease, non-cash lease expenses and non-cash interest and (ii) changes in our net operating assets of $0.3 million primarily related to net increases in prepaid expenses and other current assets and accounts receivable, and net decreases in operating lease liabilities, partially offset by net increases in accrued and other current liabilities.

Net cash used in operating activities for the year ended December 31, 2022 was $32.1 million and primarily resulted from (i) our net loss of $47.4 million adjusted for non-cash charges of $13.6 million related to stock-based compensation, depreciation, amortization, non-cash interest and deferred income taxes and (ii) changes in our net operating assets of $1.7 million primarily related to net increases in accounts receivable 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.

Cash Flows from Investing Activities

Net cash used in investing activities for the year ended December 31, 2023 and 2022 was $0.8 million and $4.3 million, respectively, and was primarily due to net purchases of property and equipment.

Cash Flows from Financing Activities

Net cash used in financing activities for the year ended December 31, 2023 was $10.6 million, primarily consisting of principal payments on the Amended Loan Agreement, finance lease obligations and notes payable, partially offset by the proceeds from the Exagen Inc. 2019 Employee Stock Purchase Plan (the ESPP) purchases.

Critical Accounting 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 (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 the following accounting estimates are the most critical to us, in that they require our most difficult, subjective or complex judgments in the preparation of our financial statements. For further information, see Note 2, Summary of Significant Accounting Policies, to our Financial Statements, which outlines our application of significant accounting policies.

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 commercial payors, government payors (primarily Medicare and Medicaid), client payors (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, are recorded upon settlement. The transaction price is estimated using an expected value method on a portfolio basis. Our portfolios are grouped per payor (each individual third-party insurance, Medicare, Medicaid, 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. Included in revenues for the years ended December 31, 2023 and 2022 was a net revenue increase of $3.4 million and a net revenue decrease of $2.4 million, respectively, associated with changes in estimated variable consideration related to performance obligations satisfied in previous periods.

Stock-Based Compensation

We recorded stock-based compensation expense of approximately $3.6 million and $4.7 million for the years ended December 31, 2023 and 2022, respectively. We expect to continue to grant stock options, restricted stock units (RSUs) 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. For stock options and purchase rights granted under the ESPP, we estimate the grant date fair value using the Black-Scholes option-pricing valuation model. For RSUs, we use the closing price of our common stock on the date of grant to determine the fair value.

The Black-Scholes option pricing model requires the use of 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 Note 2, Summary of Significant Accounting Policies, and Note 9, Stock Option Plan, to our audited financial statements 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, 2023 and 2022.

Recent Accounting Pronouncements

See 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" like 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 $1.235 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.

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, 2023, 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, 2023, 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 (2013 framework). Based on this assessment, our management concluded that, as of December 31, 2023, our internal control over financial reporting was effective.

Remediation of Previously Disclosed Material Weaknesses

On November 13, 2022, management and the Audit Committee determined that we made certain errors in revenue resulting from erroneous and duplicate billings related to changes in billing practices. The errors were due to the inadequate design, implementation and precision of internal controls and procedures to evaluate and monitor the accounting for revenue recognition. As a result, revenue and accounts receivable were overstated and other liabilities was understated for the quarter and year to date periods ended June 30, 2022.

We concluded that these were material errors in the financial statements requiring a restatement of the Form 10-Q for the three and six months ended June 30, 2022. Accordingly, management determined that this control deficiency constituted a material weakness as of December 31, 2022.

In response to the material weaknesses, and as previously disclosed in Item 9A of our annual report on Form 10-K for the year ended December 31, 2022, we implemented a remediation plan which included, but was not limited to, evaluating the staffing level, skills and qualification of accounting department personnel, enhancement of our existing control structure and processes for revenue recognition and improving the detailed review process of our revenue recognition models. The enhancements made to our control environment were in place as of December 31, 2023, and based on the evaluation of relevant internal controls, management has concluded that the material weaknesses previously identified have been remediated as of December 31, 2023.

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

Other than the remediation of the material weakness discussed above, there have been no changes in our internal control over financial reporting during the three months ended December 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls and Procedures

Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. 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 judgment in evaluating the cost-benefit relationship of possible controls and procedures.

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 2023 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 2023 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 2023 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 2023 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 registered public accounting firm is BDO USA, P.C., 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 2023 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) Exhibits

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

(2) All financial statements

The financial statements of Exagen Inc., together with the report thereon of BDO USA, P.C., an independent registered public accounting firm, are included in this Annual Report on Form 10-K beginning on page F-2.

(3) 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.

Item 16. Form 10-K Summary.

None.

Index to Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed/Furnished Herewith
		Form	File No.	Exhibit	Exhibit Filing Date	
3.1	Amended and Restated Certificate of Incorporation.	8-K	001-39049	3.1	9/23/2019	
3.2	Amended and Restated Bylaws.	8-K	001-39049	3.1	3/22/2021	
3.3	Amendment to Amended and Restated Bylaws, dated January 19, 2023.	8-K	001-39049	3.1	1/23/2023	
4.1	Specimen stock certificate evidencing the shares of common stock.	S-1/A	333-233446	4.1	9/9/2019	
4.2	Amended and Restated Investors' Rights Agreement, dated July 12, 2019, by and among the Company and certain of its stockholders.	S-1/A	333-233446	4.2	9/9/2019	
4.3	Amended and Restated Stockholders' Agreement, dated July 12, 2019, by and among the Company and certain of its stockholders.	S-1/A	333-233446	4.3	9/9/2019	
4.4	Form of Common Stock Purchase Warrant issued to investors by the Company in connection with private placement financings.	S-1/A	333-233446	4.4	9/9/2019	
4.5	Form of Common Stock Purchase Warrant to purchase common stock issued to investors by the Company in 2016.	S-1/A	333-233446	4.8	9/9/2019	
4.6	Form of Warrant to Purchase Stock issued to Innovatus Life Sciences Lending Fund I, LP in connection with the Company's 2018 loan agreement.	S-1/A	333-233446	4.9	9/9/2019	
4.7	Form of Exchange Warrant.	10-Q	001-39049	4.5	8/9/2021	
4.8	Description of Securities.					X
10.1#	Exagen Corporation 2002 Stock Option Plan, as amended, and form of option agreement thereunder.	S-1/A	333-233446	10.1	9/9/2019	
10.2#	Exagen Diagnostics, Inc. 2013 Stock Option Plan, as amended, and form of option agreement thereunder.	S-1/A	333-233446	10.2	9/9/2019	
10.3#	Exagen Inc. 2019 Incentive Award Plan.	S-1/A	333-233446	10.3	9/9/2019	
10.4#	Form of Option Agreement under Exagen Inc. 2019 Incentive Award Plan.	S-1/A	333-233446	10.4	9/9/2019	
10.5#	Form of Restricted Stock Unit Agreement under Exagen Inc. 2019 Incentive Award Plan.	10-K	001-39049	10.5	3/16/2021	
10.6#	Exagen Inc. 2019 Employee Stock Purchase Plan.	S-1/A	333-233446	10.5	9/9/2019	
10.7 †	Asset Purchase Agreement, dated October 8, 2010, by and between Cypress Bioscience, Inc., Proprius, Inc. and the Company.	S-1/A	333-233446	10.11	9/9/2019	
10.8†	Amendment No. One to Asset Purchase Agreement, dated March 10, 2011, by and between Cypress Bioscience, Inc., Proprius, Inc. and the Company.	S-1/A	333-233446	10.12	9/9/2019	
10.9	Amendment No. Two to Asset Purchase Agreement, dated August 21, 2012, by and between Royalty Pharma Collection Trust, Proprius, Inc. and the Company.	S-1/A	333-233446	10.13	9/9/2019	
10.10†	Amendment No. Three to Asset Purchase Agreement, dated February 6, 2013, by and between Royalty Pharma Collection Trust, Proprius, Inc. and the Company.	S-1/A	333-233446	10.14	9/9/2019	

10.11	Amendment No. Four to Asset Purchase Agreement, dated October 8, 2013, by and between Royalty Pharma Collection Trust, Proprius, Inc. and the Company.	S-1/A	333-233446	10.15	9/9/2019
10.12	Amendment No. Five to Asset Purchase Agreement, dated January 26, 2016, by and between Royalty Pharma Collection Trust, Proprius, Inc. and the Company.	S-1/A	333-233446	10.16	9/9/2019
10.13†	Amendment No. Six to Asset Purchase Agreement, dated February 16, 2017, by and between Royalty Pharma Collection Trust, Proprius, Inc. and the Company.	S-1/A	333-233446	10.17	9/9/2019
10.14†	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.	S-1/A	333-233446	10.18	9/9/2019
10.15†	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.	S-1/A	333-233446	10.19	9/9/2019
10.16†	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.	S-1/A	333-233446	10.20	9/9/2019
10.17	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.	S-1/A	333-233446	10.21	9/9/2019
10.18†	Exclusive License Agreement, dated September 30, 2013, by and between the University of Pittsburgh-Of the Commonwealth System of Higher Education and the Company.	S-1/A	333-233446	10.22	9/9/2019
10.19†	Exclusive License Agreement, dated September 5, 2011, by and between Thierry Dervieux, Ph.D. and the Company.	S-1/A	333-233446	10.23	9/9/2019
10.20	Standard Industrial/Commercial Multi-Tenant Lease, dated January 13, 2012, by and between RGS Properties and the Company.	10-Q	001-39049	10.1	7/28/2020
10.21	First Amendment to Standard Industrial/ Commercial Multi-Tenant Lease, dated December 1, 2013, by and between RGS Properties and the Company.	10-Q	001-39049	10.2	7/28/2020
10.22	Second Amendment to Standard Industrial/Commercial Multi-Tenant Lease, dated April 29, 2016, by and between RGS Properties and the Company.	10-K	001-39049	10.27	3/25/2020
10.23	Third Amendment to Standard Industrial/ Commercial Multi-Tenant Lease, dated June 16, 2017, by and between RGS Properties and the Company.	10-K	001-39049	10.28	3/25/2020
10.24	Fourth Amendment to Standard Industrial/ Commercial Multi-Tenant Lease, dated March 16, 2020, by and between RGS Properties and the Company.	10-K	001-39049	10.29	3/25/2020
10.25	Fifth Amendment to Standard Industrial/ Commercial Multi-Tenant Lease, dated October 19, 2021, by and between RGS Properties and the Company.	10-Q	001-39049	10.3	11/10/2021
10.26	Standard Industrial/Commercial Single-Tenant Lease, dated September 4, 2014, by and between Geiger Court, LLC and the Company.	S-1/A	333-233446	10.31	9/9/2019

10.27	First Amendment to Standard Industrial/ Commercial Single-Tenant Lease, dated August 2, 2017, by and between Geiger Court, LLC and the Company.	10-K	001-39049	10.31	3/25/2020
10.28	Extension of Lease to Standard Industrial/ Commercial Single-Tenant Lease, dated March 12, 2020, by and between Liberty Vista and the Company.	10-K	001-39049	10.32	3/25/2020
10.29	First Amendment to Standard Industrial/ Commercial Single-Tenant Lease, dated January 6, 2021, by and between Liberty Vista and the Company.	10-K	001-39049	10.34	3/16/2021
10.30	Second Amendment to Standard Industrial/Commercial Single-Tenant Lease, dated October 11, 2021, by and between Liberty Vista and the Company.	10-Q	001-39049	10.2	11/10/2021
10.31	Standard Industrial/Commercial Multi-Tenant Lease, dated March 17, 2020 by and between RGS Properties and the Company.	10-K	001-39049	10.33	3/25/2020
10.32	First Amendment to Standard Industrial/ Commercial Multi-Tenant Lease, dated October 19, 2021, by and between RGS Properties and the Company.	10-Q	001-39049	10.4	11/10/2021
10.33†	Sublease Agreement, dated August 19, 2021, by and between Plum Healthcare Group, LLC and the Company.	10-Q	001-39049	10.1	11/10/2021
10.34	Master Lease Agreement, dated February 1, 2018, by and between Celtic Commercial Finance, a division of MB Equipment Finance, LLC and the Company.	S-1/A	333-233446	10.32	9/9/2019
10.35	Loan and Security Agreement, dated September 7, 2017, by and between Innovatus Life Sciences Lending Fund I, LP and the Company.	S-1/A	333-233446	10.33	9/9/2019
10.36	First Amendment to Loan and Security Agreement, dated November 19, 2019, by and between Innovatus Life Sciences Lending I, LP and the Company.	10-K	001-39049	10.36	3/25/2020
10.37	Acknowledgement Letter to Loan and Security Agreement, dated October 7, 2020, by and between Innovatus Life Sciences Lending Fund I, LP and the Company.	10-Q	001-39049	10.1	11/10/2020
10.38	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.	10-Q	001-39049	10.5	11/10/2021
10.39#	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.	S-1/A	333-233446	10.34	9/9/2019
10.40	Form of Indemnification Agreement for Directors and Officers.	S-1/A	333-233446	10.35	9/9/2019
10.41#	Offer Letter, dated October 7, 2011, by and between Fortunato Ron Rocca and the Company, as amended on September 4, 2019.	S-1/A	333-233446	10.36	9/9/2019
10.42#	Offer Letter, dated May 16, 2017, by and between Kamal Adawi and the Company, as amended on September 4, 2019.	S-1/A	333-233446	10.37	9/9/2019
10.43#	Offer Letter dated February 21, 2020, by and between Debra Zack, MD Ph.D. and the Company.	10-K	001-39049	10.41	3/25/2020
10.44#	Non-Employee Director Compensation Program.	S-1/A	333-233446	10.38	9/9/2019
10.45#	Executive Change in Control Severance Plan.	10-K	001-39049	10.46	3/16/2021
10.46#	Employment Agreement, dated as of October 16, 2022, by and between the Company and John Aballi	8-K	001-39049	10.1	10/16/2022

10.47#	Severance Agreement, dated as of October 14, 2022, by and between the Company and Ron Rocca	8-K	001-39049	10.2	10/16/2022	
10.48	Sales Agreement, dated as of September 15, 2022, by and between the Company and Cowen and Company, LLC	8-K	001-39049	1.1	9/15/2022	
10.49	Consulting Agreement, dated as of December 5, 2022, by and between the Company and Debra Zack, M.D., Ph.D.	8-K	001-39049	10.1	12/5/2022	
10.50^	Third Amendment to Loan and Security Agreement dated April 28, 2023, by and among Innovatus Life Sciences Lending I, LP, other lenders and the Company.	8-K	001-39049	10.1	5/4/2023	
10.51	Assignment and Assumption Agreement, by and among Liberty Vista, L.P., Mindera Corporation and the Company.	10-Q	001-39049	10.1	11/13/2023	
10.52	Consulting Agreement, dated as of December 6, 2023, by and between the Company and Mark Hazeltine.	8-K	001-39049	10.1	12/11/2023	
23.1	Consent of Independent Registered Public Accounting Firm.					X
24.1	Power of Attorney (included on signature page).					X
31.1	Certificate of Principal Executive Officer, pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certificate of Principal Financial Officer, pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1*	Certifications Pursuant to U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Public Company Accounting Reform and Investor Protection Act of 2002.					X
97.1#	Exagen Inc. Clawback Policy.	10-Q	001-39049	10.2	11/13/2023	
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.

^ Certain schedules to this exhibit have been omitted pursuant to Item 601(a)(5) of Regulation S-K. Copies of the omitted schedules will be furnished to the SEC upon request.

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 18, 2024

by: /s/ John Aballi

John Aballi

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 John Aballi and Kamal Adawi as his or her true and lawful attorneys-in-fact, and each of them, with full power of substitution, for him or her in any and all capacities, to sign any amendments to this Annual Report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact, and either of them, or his or their substitute or substitutes may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ John Aballi John Aballi	President, Chief Executive Officer and Director (Principal Executive Officer)	March 18, 2024
/s/ Kamal Adawi Kamal Adawi	Chief Financial Officer and Corporate Secretary (Principal Financial and Accounting Officer)	March 18, 2024
/s/ Tina S. Nova, Ph.D. Tina S. Nova, Ph.D.	Executive Chairman of the Board	March 18, 2024
/s/ Brian Birk Brian Birk	Director	March 18, 2024
/s/ Ana Hooker Ana Hooker	Director	March 18, 2024
/s/ Wendy S. Johnson Wendy S. Johnson	Director	March 18, 2024
/s/ Paul Kim Paul Kim	Director	March 18, 2024
/s/ Ebetuel Pallares, Ph.D. Ebetuel Pallares, Ph.D.	Director	March 18, 2024
/s/ Bruce C. Robertson, Ph.D. Bruce C. Robertson, Ph.D.	Director	March 18, 2024
/s/ Frank Stokes Frank Stokes	Director	March 18, 2024

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Exagen Inc.

Index to Financial Statements

Report of Independent Registered Public Accounting Firm

Shareholders 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, 2023 and 2022, 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, 2023 and 2022, 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, P.C.

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

San Diego, California

March 18, 2024

Exagen Inc.

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

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 36,493	$ 62,391
Accounts receivable, net	6,551	6,077
Prepaid expenses and other current assets	4,797	4,143
Total current assets	47,841	72,611
Property and equipment, net	5,201	8,197
Operating lease right-of-use assets	3,286	4,885
Other assets	616	528
Total assets	$ 56,944	$ 86,221
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,131	$ 3,046
Operating lease liabilities	976	1,040
Borrowings-current portion	264	190
Accrued and other current liabilities	7,531	5,347
Total current liabilities	11,902	9,623
Borrowings-non-current portion, net of discounts and debt issuance costs	19,231	28,778
Non-current operating lease liabilities	2,760	4,493
Other non-current liabilities	357	867
Total liabilities	34,250	43,761
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, $0.001 par value per share; 10,000,000 shares authorized, no shares issued or outstanding at December 31, 2023 and December 31, 2022	—	—
Common stock, $0.001 par value per share; 200,000,000 shares authorized at December 31, 2023 and December 31, 2022; 17,045,954 and 16,549,984 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively	17	17
Additional paid-in capital	301,893	297,970
Accumulated deficit	(279,216)	(255,527)
Total stockholders' equity	22,694	42,460
Total liabilities and stockholders' equity	$ 56,944	$ 86,221

The accompanying notes are an integral part of these financial statements

Exagen Inc.

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

	Year Ended December 31,	
	2023	2022
Revenue	$ 52,548	$ 45,563
Operating expenses:		
Costs of revenue	23,092	24,214
Selling, general and administrative expenses	47,428	52,018
Research and development expenses	4,865	9,876
Goodwill impairment	—	5,506
Total operating expenses	75,385	91,614
Loss from operations	(22,837)	(46,051)
Interest expense	(2,335)	(2,448)
Interest income	1,516	830
Loss before income taxes	(23,656)	(47,669)
Income tax (expense) benefit	(33)	282
Net loss	$ (23,689)	$ (47,387)
Net loss per share, basic and diluted (Note 2)	$ (1.34)	$ (2.77)
Weighted-average number of shares used to compute net loss per share, basic and diluted (Note 2)	17,679,467	17,082,348

The accompanying notes are an integral part of these financial statements

Exagen Inc.

Statements of Stockholders' Equity
(in thousands, except share amounts)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balances at December 31, 2021	16,164,994	$ 16	$ 293,060	$ (208,140)	$ 84,936
Issuance of stock from vested restricted stock units and payment of employees' taxes	64,064	—	(239)	—	(239)
Exercise of stock options	245,186	1	60	—	61
Issuance of stock under Employee Stock Purchase Plan	75,740	—	385	—	385
Stock-based compensation	—	—	4,704	—	4,704
Net loss	—	—	—	(47,387)	(47,387)
Balances at December 31, 2022	16,549,984	17	297,970	(255,527)	42,460
Issuance of stock from vested restricted stock units	273,042	—	—	—	—
Exercise of stock options	93,335	—	27	—	27
Issuance of stock under Employee Stock Purchase Plan	129,593	—	279	—	279
Stock-based compensation	—	—	3,617	—	3,617
Net loss	—	—	—	(23,689)	(23,689)
Balances at December 31, 2023	17,045,954	$ 17	$ 301,893	$ (279,216)	$ 22,694

The accompanying notes are an integral part of these financial statements

Exagen Inc.

Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2023	2022
Cash flows from operating activities:		
Net loss	$ (23,689)	$ (47,387)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,168	1,557
Amortization of debt discount and debt issuance costs	156	161
Non-cash interest expense	363	551
Deferred income taxes	—	(306)
Loss on disposal of assets	189	—
Loss on lease assignment	1,470	—
Non-cash lease expense	939	967
Long-lived assets impairment	—	397
Goodwill impairment	—	5,506
Stock-based compensation	3,617	4,704
Other	—	36
Changes in assets and liabilities:		
Accounts receivable, net	(474)	3,577
Prepaid expenses and other current assets	(654)	(505)
Other assets	(101)	(47)
Operating lease liabilities	(1,010)	(854)
Accounts payable	67	901
Accrued and other current liabilities	2,497	(1,402)
Net cash used in operating activities	(14,462)	(32,144)
Cash flows from investing activities:		
Purchases of property and equipment	(828)	(4,318)
Proceeds from disposal of property and equipment	24	—
Net cash used in investing activities	(804)	(4,318)
Cash flows from financing activities:		
Proceeds from exercise of stock options	27	61
Payments of taxes withheld on vested restricted stock units	—	(239)
Proceeds from common stock issued under Employee Stock Purchase Plan	279	385
Principal payment on finance lease obligations	(697)	(667)
Principal payment on note payable obligations	(241)	(29)
Principal payment on long-term debt	(10,000)	—
Net cash used in financing activities	(10,632)	(489)
Net change in cash, cash equivalents and restricted cash	(25,898)	(36,951)
Cash, cash equivalents and restricted cash, beginning of year	62,591	99,542
Cash, cash equivalents and restricted cash, end of year	$ 36,693	$ 62,591
Supplemental disclosure of cash flow information:		
Cash paid for interest expense	$ 1,737	$ 1,732
Supplemental disclosure of non-cash items:		
Equipment purchased under finance lease obligations	$ —	$ 741
Equipment purchased under notes payable obligations	$ 250	$ 807
Costs incurred, but not paid, in connection with capital expenditures	$ 66	$ 182

The accompanying notes are an integral part of these financial statements

Exagen Inc.

Notes to Financial Statements

Note 1. Organization

Description of Business

Exagen Inc. (the Company) is a commercial-stage diagnostics company which exists to provide clarity in autoimmune disease decision making with the goal of improving patients' clinical outcomes.

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, 2023, the Company had cash and cash equivalents of $36.5 million and had an accumulated deficit of $279.2 million. Since inception, the Company has financed its operations primarily through a combination of equity financings, 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 estimated incremental borrowing rate for the determination of the Company's operating lease right-of-use (ROU) assets and the recoverability of its long-lived assets 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. The Company has not experienced any losses on its cash or cash equivalents.

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	
	Year Ended December 31,	
	2023	2022
Medicare	34 %	39 %
Medicare Advantage	17 %	15 %

	Accounts Receivable	
	December 31,	
	2023	2022
Medicare	42 %	21 %
Medicare Advantage	16 %	13 %

For the years ended December 31, 2023 and 2022, approximately 88% and 84%, respectively, of the Company's revenue was related to the AVISE® CTD test.

The Company is dependent on key suppliers for certain laboratory materials. For each of the years ended December 31, 2023 and 2022, approximately 96% 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):

	Year Ended December 31,	
	2023	2022
Revenue:		
Commercial	$ 23,985	$ 18,975
Government	18,002	17,687
Client(1)	9,949	7,928
Other(2)	612	973
Total revenue	$ 52,548	$ 45,563

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

Cash, Cash Equivalents and Restricted Cash

The Company considers all highly-liquid investments purchased with a remaining maturity date of three months or less upon acquisition to be cash equivalents. These investments 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 certificate of deposit with this financial institution in the amount of $0.2 million as collateral for the balances borrowed on these cards. The Company has classified the value of this certificate of deposit (including all interest earned thereon) within other assets in the accompanying balance sheets. The Company has the right to terminate the credit card program at any time. Upon termination of the credit card program and repayment of all outstanding balances owed, the Company may redeem the certificate of deposit (and all interest earned thereon).

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

	December 31,	
	2023	2022
Cash and cash equivalents	$ 36,493	$ 62,391
Restricted cash	200	200
	$ 36,693	$ 62,591

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 operating expenses 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 and operating lease assets. The Company amortizes all finite lived intangible assets over their respective estimated useful lives. Operating lease assets are amortized over the term of the leases. In considering whether long-lived assets are impaired, the Company combines its intangible assets and other long-lived assets into groupings, a determination which is made principally on the basis of whether the assets are specific to a particular test offered or technology being developed. If the Company identifies a change in the circumstances related to its long-lived assets that indicates the carrying value of any such asset may not be recoverable, the Company will perform an impairment analysis. A long-lived asset 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. Management's estimates of future cash flows are impacted by projected test volume and levels of reimbursement, as well as expectations related to the future cost structure of the entity. 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

The Company operates in a single operating segment and reporting unit for the measurement of goodwill. Goodwill was reviewed for impairment annually (during the fourth quarter) or more frequently if indicators of impairment existed. The Company would first assess qualitative factors to determine whether it was more likely than not that the fair value of the reporting unit was less than its carrying amount as a basis for determining whether it was necessary to perform a quantitative assessment. If, after assessing qualitative factors, the Company determined it was not more likely than not that the fair value of a reporting unit was less than its carrying amount, then performing a quantitative assessment was unnecessary. If deemed necessary, a quantitative assessment compared the fair value of the reporting unit with its carrying amount, including goodwill. If the fair value of the reporting unit exceeded its carrying amount, goodwill was not considered impaired; otherwise, an impairment loss was recorded.

Leases

The Company categorizes leases at their commencement as either operating or finance leases. The Company recognizes operating lease ROU assets and operating lease liabilities for each lease arrangement identified. Lease liabilities are recorded at the present value of future lease payments discounted using the Company's incremental borrowing rate for the lease established at the commencement date. The incremental borrowing rate is the rate of interest the Company would have to pay to borrow, on a collateralized basis over a similar term and in a similar economic environment, an amount equal to the total lease payments. The Company primarily considers industry data, its credit rating and the lease term to determine its incremental borrowing rate. ROU assets are measured at the amount of the lease liability plus any initial direct costs, less any lease incentives received before commencement. Lease expense is recognized as a single lease cost over the lease term on a straight-line basis. The Company has elected not to apply the recognition requirements to short-term leases and not to separate non-lease components from lease components for its leases.

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 based on estimated progress of services performed, including actual level of subjects enrolled and progress of the clinical studies. Payments made prior to the completion of clinical study services are capitalized as a prepaid expense. The prepaid amounts are expensed as the related goods are delivered or the services are performed, or when it is no longer expected that the goods will be delivered or the

services 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 commercial payors (healthcare insurers), government payors (primarily Medicare and Medicaid), client payors (i.e., hospitals, other laboratories, etc.) and patient self-pay.

The Company recognizes revenue in accordance with Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers* (ASC 606) and follows a five-step process to determine the amount and timing of revenue recognized: (1) identify the contract with the customer, (2) identify the performance obligations in the contract, (3) determine the transaction price, (4) allocate the transaction price to performance obligations in the contract, and (5) recognize revenue when (or as) the performance obligation is satisfied. 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 generally billed at the Company's list price, unless a separate pricing contract is in place. 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. Adjustments are recorded in the current period as changes in estimates occur. Further adjustments to the allowances, based on actual receipts, are recorded upon settlement. Included in revenues for the years ended December 31, 2023 and 2022 was a net revenue increase of $3.4 million and a net revenue decrease of $2.4 million, respectively, associated with changes in estimated variable consideration related to performance obligations satisfied in previous periods. The transaction price is estimated using an expected value method on a portfolio basis.

Variable consideration is included in the transaction price only to the extent it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainties with respect to the amount are resolved. The Company's portfolios are grouped per payor (i.e. each individual commercial payor, Medicare, Medicaid, client payors, patient self-pay, etc.) and per test. Consideration may be constrained and excluded from the transaction price in situations where there is no contractually agreed upon reimbursement coverage or in absence of a predictable pattern and history of collectability with a payor. Accordingly, in such situations revenues are recognized on the basis of actual cash collections. Additionally, from time to time, the Company may issue refunds to payors for overpayments or amounts billed in error. Any refunds are accounted for as reductions in revenues in the statement of operations as an element of variable consideration. The estimated expected refunds are accrued as a liability on the Company’s balance sheet.

Collection of the Company's net revenues from payors is normally a function of providing complete and correct billing information, along with any requested medical or other claims-related information to the healthcare insurers. This generally occurs within 30 to 90 days of billing, however, the amount and timing of any reimbursements or collections for our billed tests may vary by payor and other circumstances. Contracts do not contain significant financing components based on the typical period of time between performance of services and collection of consideration.

Accounts Receivable and Allowance for Credit Losses

We accrue an allowance for credit losses against our accounts receivable based on management’s current estimate of amounts that will not be collected. Management’s estimates are typically based on historical loss information adjusted for current conditions. We generally do not perform evaluations of the financial condition of our customers and generally do not require collateral. The allowance for credit losses was zero as of December 31, 2023. There was no allowance for credit losses recognized as of December 31, 2022. Adjustments for implicit price concessions attributable to variable consideration, as discussed above, are incorporated into the measurement of the accounts receivable balances and are not part of the allowance for credit losses. Accounts receivable was $6.6 million, $6.1 million, $9.7 million for the years ended December 31, 2023, 2022 and 2021, respectively.

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; depreciation; amortization 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 $1.5 million and $3.0 million for the years ended December 31, 2023 and 2022, 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 were approximately $2.5 million and $2.7 million for the years ended December 31, 2023 and 2022, 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 inputs, including the fair value of the Company's common stock, expected volatility, expected term and risk-free interest rates. Volatility is based on the Company's historical calculated volatility since being publicly traded. The weighted-average expected term of options was calculated using the simplified method, as we have concluded that our stock option exercise history does not provide a reasonable basis upon which to estimate the expected term. 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 is 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 (RSU) is determined on the grant date using the closing price of the Company's common stock on that date. The Company's RSUs generally vest in equal annual installments over four years from the date of grant or, for grants to new hires, date of hire. Vesting of RSUs is subject to the holder's continued service with the Company. The Company issues new shares to satisfy RSUs upon vesting.

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 as an expense 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 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, stock options, RSUs 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 each of the years ended December 31, 2023 and 2022, 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):

	Year Ended December 31,	
	2023	2022
Warrants to purchase common stock	409,108	409,108
Common stock options	986,819	1,421,235
Restricted stock units	1,387,459	1,036,208
Employee stock purchase plan	44,700	58,711
Total	2,828,086	2,925,262

Segment Reporting

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

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (FASB), or other standard setting bodies and adopted by the Company as of the specified effective date. Under the Jumpstart Our Business Startups Act of 2012 (JOBS Act), the Company meets the definition of an emerging growth company. The Company has elected to use the extended transition period for complying with new or revised accounting standards pursuant to Section 107(b) of the JOBS Act. Unless otherwise discussed, Accounting Standards Updates (ASU) not included in the Company’s disclosures were assessed and determined to be either not applicable or are not expected to have a material impact on the Company’s financial statements or disclosures.

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* (ASU 2023-07), which requires public entities to disclose significant segment expenses that are regularly provided to the Chief Operating Decision Maker (CODM) and details of how the CODM uses financial reporting to assess the performance of a segment. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. This ASU will likely result in additional required disclosure when adopted. The Company is currently evaluating the provisions of this ASU and the impact on its financial statements and related disclosures.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* (ASU 2023-09), which requires additional income tax disclosures in the rate reconciliation table for federal, state and foreign income taxes, in addition to more details about the reconciling items in some categories

when items meet a certain quantitative threshold. ASU 2023-09 is effective for annual periods beginning after December 15, 2024 with early adoption permitted. The Company is currently evaluating the impact of this standard, but does not expect that it will have a material impact on its financial statements.

Recently Adopted Accounting Standards

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which requires the measurement of expected credit losses (based on historical experience, current conditions and reasonable forecasts) for financial instruments (such as accounts receivable) held at the reporting date which are carried at amortized cost. The main objective of this ASU is to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. In November 2018, the FASB issued ASU 2018-19, *Codification Improvements to Topic 326, Financing Instruments-Credit Losses*, which included an amendment of the effective date for nonpublic entities. The Company adopted this pronouncement on January 1, 2023. The adoption did not have material impact on its financial statements.

In August 2020, the FASB issued ASU 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40)*. ASU 2020-06 eliminates the beneficial conversion and cash conversion accounting models for convertible instruments. It also amends the accounting for certain contracts in an entity's own equity that are currently accounted for as derivatives because of specific settlement provisions. In addition, ASU 2020-06 modifies how particular convertible instruments and certain contracts that may be settled in cash or shares impact the diluted EPS computation. The amendments in ASU 2020-06 are effective for smaller reporting companies as defined by the SEC for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. The Company early adopted ASU 2020-06 as of January 1, 2023. The adoption did not have an impact on its financial statements.

Note 3. Other Financial Information

Prepaid Expenses and Other Current Assets

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

	December 31,	
	2023	2022
Diagnostic testing supplies	$ 2,871	$ 1,795
Prepaid product royalties	35	40
Prepaid maintenance and insurance contracts	1,860	2,072
Other prepaid expenses and other current assets	31	236
Prepaid expenses and other current assets	$ 4,797	$ 4,143

Property and Equipment

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

	December 31,	
	2023	2022
Furniture and fixtures	$ 98	$ 98
Laboratory equipment	5,312	5,136
Computer equipment and software	2,185	1,482
Leasehold improvements	3,316	5,223
Construction in progress	59	1,382
Total property and equipment	10,970	13,321
Less: accumulated depreciation and amortization	(5,769)	(5,124)
Property and equipment, net	$ 5,201	$ 8,197

Depreciation and amortization expense for the years ended December 31, 2023 and 2022, was approximately $2.2 million and $1.6 million, respectively. At December 31, 2023 and 2022, the gross book value of assets under finance leases was $2.5 million and $2.8 million, respectively, and is classified in "Laboratory equipment" in the table above.

Loss on Lease Assignment

On October 24, 2023, the Company entered into an assignment and assumption (the Assignment and Assumption Agreement) of the Company's previously executed lease agreement with Liberty Vista, LP (formerly known as Geiger Court, LLC) and Mindera Corporation (Mindera), pursuant to which the Company assigned to Mindera the lease of a building located adjacent to the Company's headquarters in Vista, CA. Under the terms of the Assignment and Assumption Agreement, Mindera assumed all obligations under the lease, effective October 31, 2023. As a result of the lease assignment, the Company derecognized the remaining balances related to the associated operating lease ROU asset of $0.7 million, operating lease liability of $0.8 million and leasehold improvements of $1.6 million, resulting in a $1.5 million loss on lease assignment. The loss was classified within selling, general and administrative expenses in the accompanying statements of operations.

Impairment of Long-Lived Assets and Goodwill

During the year ended December 31, 2022, the Company recorded an impairment charge of $0.4 million related to previously capitalized equipment used in research and development activities that were halted in the fourth quarter of 2022. The impairment charge was classified within research and development expenses in the accompanying statements of operations.

During the year ended December 31, 2022, the Company also determined that a sustained decrease in its market capitalization constituted an indicator of impairment of goodwill and as a result, instead of performing a qualitative test, the Company chose to proceed directly to performing a quantitative test during the fourth quarter. The Company determined the fair value of the reporting unit using the discounted cash flow (DCF) method, which is considered a Level 3 measurement. In applying the DCF method, cash flows are estimated for a five-year financial forecast developed by management. A terminal value, which represents the value of additional cash flows into perpetuity, is also calculated. Cash flows are then discounted to present value at a discount rate commensurate with their risk. Based on this analysis, the carrying value of the reporting unit was in excess of the fair value and the goodwill was fully impaired. During the year ended December 31, 2022, the Company recorded a goodwill impairment charge of $5.5 million.

The following table presents details of the Company's goodwill for the year ended December 31, 2022 (in thousands):

	Total
Balance as of December 31, 2021	$ 5,506
Goodwill impairment	(5,506)
Balance as of December 31, 2022	$ —

Accrued and Other Current Liabilities

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

	December 31,	
	2023	2022
Accrued payroll and related expenses	$ 4,738	$ 2,355
Accrued interest	139	142
Accrued purchases of goods and services	720	803
Accrued royalties	463	514
Accrued clinical study activity	118	162
Finance lease obligations, current portion	490	700
Refund liability	302	445
Other accrued liabilities	561	226
Accrued and other current liabilities	$ 7,531	$ 5,347

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), as amended (the Amended Loan Agreement), pursuant to which the Company borrowed $25.0 million. At December 31, 2023, no additional amounts remained available to borrow under the Amended Loan Agreement.

On April 28, 2023, the Company entered into the Amended Loan Agreement. The Amended Loan Agreement was treated as a modification. In connection with the Amended Loan Agreement, the Company repaid $10.0 million of the principal balance outstanding, for which the prepayment premium was waived. Pursuant to the Amended Loan Agreement, the interest rate on all borrowings under the Amended Loan Agreement is the sum (the Basic Rate) of (a) the greater of 8.0% or The Wall Street Journal prime rate (the Prime Rate), plus (b) 2.0%, which is paid-in-kind in the form of additional term loans (PIK Loans). Under the Amended Loan Agreement, an amount equal to 1.5% of the Basic Rate will be payable in-kind and capitalized to the principal amount of the outstanding term loan on a monthly basis until April 1, 2026, after which interest is scheduled to accrue at the Basic Rate. The maturity date of the loan was extended to December 31, 2026. The Company estimated the effective interest rate of this loan to be approximately 11.0% and 8.5% as of December 31, 2023 and 2022, respectively. Accrued interest is due and payable monthly, unless the Company elects to pay paid-in-kind interest. The outstanding principal and accrued interest under the Amended Loan Agreement is to be repaid in ten equal monthly installments commencing in April 2026. Upon repayment of the final installment under the Amended Loan Agreement, 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 the loan using the effective interest method. For the years ended December 31, 2023 and 2022, the Company issued PIK Loans totaling $0.4 million and $0.6 million, respectively. At December 31, 2023, $18.2 million in principal and PIK loans are outstanding, all of which is included in borrowings-non-current portion on the accompanying balance sheet.

The Amended Loan Agreement currently requires a prepayment premium of 1% of the aggregate outstanding principal for any prepayments made prior to November 1, 2024.

The Amended Loan Agreement is collateralized by a first priority security interest in substantially all of the Company's assets, including intellectual property. The affirmative covenants of the Amended Loan Agreement 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, however the Company is not required to comply with the revenue covenant for any quarter during which it maintains a minimum aggregate cash balance equal to fifty percent of the aggregate principal amount of the Amended Loan Agreement (excluding any capitalized interest paid-in-kind) at all times during such quarter. The consequences of failing to achieve the performance covenants, when applicable, will be cured if, (i) within thirty days of failing to achieve the performance covenant, the Company submits a new Board approved financial plan to Innovatus under which the Company is expected to break even on a cash flow basis prior to the maturity date, and (ii) within thirty days of the submission of such financial plan, the Company issues additional equity securities or subordinated debt with net proceeds sufficient to fund any cash flow deficiency generated from operations, as defined in the Amended Loan Agreement. The Amended Loan Agreement 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 Amended Loan 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, 2023, the Company was in compliance with all covenants of the Amended Loan Agreement.

Upon an event of default in any of the Amended Loan Agreement covenants, the repayment of the 2017 Term Loan may be accelerated, and the applicable interest rate will be increased by 4.0% until the default is cured. Although repayment of the 2017 Term Loan 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 Third Loan Amendment due beyond twelve months of the balance sheet date as non-current.

2022 Equipment Notes Payable

In May 2022, the Company purchased laboratory equipment using notes payable. At December 31, 2023, the total notes payable balance related to this financed equipment was $0.8 million, with $0.3 million classified within borrowings-current portion and $0.5 million within borrowings-non-current portion, net of discounts and debt issuance costs in the accompanying balance sheets. At December 31, 2022, the total notes payable balance related to this financed equipment was $0.8 million, with $0.2 million classified within borrowings-current portion and $0.6 million within borrowings-non-current portion, net of discounts and debt issuance costs in the accompanying balance sheets. The financed equipment is subject to a 5.28% effective interest rate and will mature on October 1, 2026.

Future Minimum Payments on Outstanding Borrowings

As of December 31, 2023, future minimum aggregate payments, including interest, for outstanding borrowings are as follows (in thousands):

	Years Ending December 31,
2024	1,949
2025	1,974
2026	21,243
Total	25,166
Less:	
Unamortized debt discount and issuance costs	(113)
Interest	(5,558)
Total borrowings, net of discounts and debt issuance costs	19,495
Less: Borrowings-current portion	(264)
Borrowings-non-current portion, net of discounts and debt issuance costs	$ 19,231

Note 5. Leases

Leases

Operating Leases

The Company leases office and laboratory space located in Vista, California. The lease expires in April 2027, with an option to extend portions of the lease for additional 5-year periods. The Company has not included the optional renewal periods in the measurement of the lease liability, because it is not reasonably certain that the Company will exercise these renewal options. The Company's payments under the lease are subject to escalation clauses.

The Company leases additional office space in Carlsbad, California, under a sub-lease which commenced in October 2021 and expires in April 2027. Monthly base rent under the sub-lease agreement is $70,042. The monthly base rent increases by approximately 3% annually, each October 1, through the remainder of the lease term.

Finance Leases

The Company has entered into various finance lease agreements to obtain laboratory equipment. The terms of the Company's finance leases generally range from three to five years and are typically secured by the underlying equipment. The portion of the future payments designated as principal repayments were classified as finance lease liabilities on the Company's balance sheet.

Operating and Finance Leases Balances and Costs

Operating and finance leases consist of the following (in thousands):

Lease Balance	Classification	December 31, 2023	December 31, 2022
Lease Assets			
Operating	Operating lease right-of-use assets	$ 3,286	$ 4,885
Finance	Property and equipment, net	$ 810	$ 1,427
Lease Liabilities			
Current			
Operating	Operating lease liabilities	$ 976	$ 1,040
Finance	Accrued and other current liabilities	$ 490	$ 700
Non-current			
Operating	Non-current operating lease liabilities	$ 2,760	$ 4,493
Finance	Other non-current liabilities	$ 358	$ 848

Costs associated with the Company's leases were included in the statements of operations as follows (in thousands):

Lease Cost	Year Ended December 31, 2023	Year Ended December 31, 2022
Operating leases		
Operating lease cost[(1)]	$ 1,463	$ 1,540
Finance lease cost		
Amortization of lease assets	556	679
Interest on finance lease liabilities	128	80
Total lease cost	$ 2,147	$ 2,299

(1) Includes variable lease cost of $129,000 and $165,000 for the years ended December 31, 2023 and 2022, respectively.

Supplemental cash flow information on leases is as follows (in thousands):

Cash paid for amounts included in the measurement of lease liabilities	Year Ended December 31, 2023	Year Ended December 31, 2022
Operating cash out flows from operating leases	$ 1,405	$ 1,262
Operating cash out flows from interest paid on finance leases	$ 128	$ 80
Financing cash out flows from finance leases	$ 697	$ 667

Information regarding the weighted-average lease term and weighted average discount rate are as follows:

	Year Ended December 31, 2023	Year Ended December 31, 2022
Weighted-average remaining lease term (years)		
Operating leases	3.3	4.3
Finance leases	2.06	1.94
Weighted-average discount rate		
Operating leases	8.0 %	8.0 %
Finance leases	12.2 %	4.8 %

Future payments under operating and finance leases as of December 31, 2023 are as follows (in thousands):

	Operating Leases	Finance Leases
2024	$ 1,240	$ 574
2025	1,277	248
2026	1,315	147
2027	445	28
Total minimum lease payments	4,277	997
Less: imputed interest	(541)	(149)
Total lease liabilities	3,736	848
Less: current portion	(976)	(490)
Lease obligations, net of current portion	$ 2,760	$ 358

Note 6. Commitments and Contingencies

Acquisition-related liabilities

In connection with the acquisition of the medical diagnostics division of Royalty Pharma Collection Trust (Royalty Pharma) (formerly known as Cypress Bioscience, Inc.) in 2010, the Company had royalty payment obligations of 2.5% on net sales of products which incorporate certain acquired technologies through December 31, 2023. These obligations no longer exist for products sold after December 31, 2023.

Licensing Agreements

The Company has licensed technology for use in its diagnostic tests. In addition to the milestone payments required by these agreements, 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 incurred and recorded in costs of revenue in the accompanying statements of operations.

Supply Agreements

In December 2021, the Company amended a supply agreement with one supplier for reagents which includes minimum annual purchase commitments of $8.0 million and $9.2 million for the years ended December 31, 2024 and 2025, respectively.

Collaboration Obligations

In May 2021, the Company entered into a master research collaboration agreement with Allegheny Health Network Research Institute (AHN), pursuant to which the Company is required to pay AHN a collaboration fee of $0.4 million per year. Collaboration expenses under the master research collaboration agreement were $0.3 million for each of the years ended December 31, 2023 and 2022. Collaboration expenses under the AHN collaboration are included in research and development expenses in the accompanying statements of operations.

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 for subpoenas and other civil investigative demands, from governmental agencies, Medicare or Medicaid 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. The Company does not believe the outcome of any such matters as of December 31, 2023 will have a material effect on its financial position or results of operations.

In October 2023, the Company resolved an investigation with the U.S. Attorney's Office for the District of Massachusetts that was initiated by a *qui tam* lawsuit. Pursuant to a Settlement Agreement, the Company made a single lump-sum remittance to the government in the amount of $0.7 million in connection with specimen processing arrangements that Exagen historically had with physicians. The U.S. Attorney's Office dismissed this "covered conduct" in the *qui tam* lawsuit with prejudice, while non-covered conduct was dismissed without prejudice. In November 2023 the complaint was unsealed and served on Exagen. Exagen filed a motion to dismiss the complaint. In December 2023, the Company's insurance carrier provided reimbursement for certain defense costs the Company incurred in the October 2023 *qui tam* lawsuit. In February 2024, the relator filed a motion for leave to amend the complaint. Exagen opposed this motion, and all motions are still pending. The Company intends to vigorously defend against the claims being asserted in the complaint.

The Company's participation in federal healthcare programs is not affected by the Settlement Agreement.

Note 7. Fair Value Measurements

The carrying values of the Company's cash, cash equivalents and restricted cash, accounts receivable, prepaid expenses and other current assets, accounts payable and accrued and other current liabilities approximate their fair values due to their short-term nature and are considered to be Level 1 measurements. The estimated fair value of the Company's long-term borrowings is determined by Level 2 inputs and based primarily on quoted market prices for the same or similar issues. As of December 31, 2023, the Amended Loan Agreement had a carrying value of $18.7 million and a fair value of $19.7 million. As of December 31, 2022, the 2017 Term Loan had a carrying value of $28.3 million and a fair value of $26.9 million. The estimated fair value of the Amended Loan Agreement was determined based on a discounted cash flow approach using available market information on discount and borrowing rates with similar terms, maturities, and credit ratings. The carrying value of the Company's other long-term borrowing as of December 31, 2023 was $0.8 million, which approximated its fair value.

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. Techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.

The three-levels of the valuation hierarchy for disclosure of fair value measurements are defined 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.

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, 2023			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds, included in cash and cash equivalents	$ 14,386	$ 14,386	$ —	$ —

	December 31, 2022			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds, included in cash and cash equivalents	$ 29,438	$ 29,438	$ —	$ —
Certificate of deposit, included in cash and cash equivalents	30,100	30,100	—	—
Total	$ 59,538	$ 59,538	$ —	$ —

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

Note 8. Stockholders' Equity

Common Stock

Shelf Registration Statement

On November 17, 2023, the Company filed a registration statement on Form S-3, as amended (the 2023 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. The 2023 Shelf Registration Statement became effective on November 29, 2023, and all $150.0 million remain available for sale as of December 31, 2023.

At The Market Sales Agreement

On September 15, 2022, the Company entered into a sales agreement, as amended on November 17, 2023 (the Sales Agreement) with Cowen and Company, LLC as sales agent, pursuant to which the Company may offer and sell, from time to time, shares of Company common stock having an aggregate offering price of up to $50.0 million. The Company is not obligated to sell any shares of Company common stock in the offering. As of December 31, 2023, the Company has not sold any shares of its common stock pursuant to the Sales Agreement.

Outstanding Warrants

The following equity classified warrants to purchase common stock were outstanding as of December 31, 2023:

	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			

No warrants to purchase common stock were exercised during the years ended December 31, 2023 and 2022.

Note 9. 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, RSUs 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 Company's board of directors and is generally four years from the date of grant or, for grants to new hires, date of hire. 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 Company's board of directors. As of December 31, 2023, 1,831,107 shares of common stock remained available for future awards.

Pursuant to the evergreen provision, on January 1, 2024, an additional 681,838 shares of common stock became available for issuance under the 2019 Plan.

Restricted Stock Units

RSU 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, 2022	1,036,208	$ 7.28	$ 2,487
Awards granted	857,300	$ 2.39	
Awards released	(273,319)	$ 7.80	
Awards canceled	(232,730)	$ 6.80	
Outstanding, December 31, 2023	1,387,459	$ 4.24	$ 2,761

As of December 31, 2023, all of the outstanding RSUs are unvested. The fair value of RSUs vested in the years ended December 31, 2023 and 2022 was $0.6 million and $0.7 million, respectively. The weighted average grant date fair value for RSUs granted during the years ended December 31, 2023 and 2022 was $2.39 and $5.89, respectively. As of December 31, 2023, total unrecognized compensation cost related to RSUs was $4.4 million, which is expected to be recognized over a remaining weighted-average vesting period of 2.8 years.

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, 2022	1,421,235	$ 12.94	7.09	$ 483
Granted	73,500	$ 3.04		
Exercised	(93,335)	$ 0.26		
Forfeited	(43,895)	$ 13.83		
Expired	(370,686)	$ 16.88		
Outstanding, December 31, 2023	986,819	$ 11.87	6.44	$ 228
Vested and expected to vest, December 31, 2023	986,819	$ 11.87	6.44	$ 228
Options exercisable, December 31, 2023	877,937	$ 12.46	6.18	$ 228

The weighted-average grant date fair value per share of options granted during the years ended December 31, 2023 and 2022 was $2.17 and $2.74, respectively. The aggregate intrinsic value of options exercised during the years ended December 31, 2023 and 2022 was $0.2 million and $0.6 million, 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 was $1.99 and $2.40 per share at December 31, 2023 and 2022, respectively. As of December 31, 2023, total unrecognized compensation cost related to option awards was $0.3 million, which is expected to be recognized over a remaining weighted-average vesting period of 0.8 years.

2019 Employee Stock Purchase Plan

In September 2019, the Company's 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 Company's board of directors. During the year ended December 31, 2023, the Company issued 129,593 shares of common stock pursuant to scheduled purchases under the ESPP. As of December 31, 2023, 449,332 shares of common stock remained available for issuance. Pursuant to the evergreen provision, on January 1, 2024, an additional 170,460 shares became available for issuance under the ESPP.

Stock-based compensation expense related to the ESPP for each of the years ended December 31, 2023 and 2022 was less than $0.1 million. As of December 31, 2023, 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.

Stock-Based Compensation Expense

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

	Year Ended December 31,	
	2023	2022
Cost of revenue	$ 191	$ 213
Selling, general and administrative	3,174	3,860
Research and development	252	631
Total	$ 3,617	$ 4,704

Common stock reserved for future issuance consists of the following at December 31, 2023:

Warrants to purchase common stock	1,214,059
Common stock option grants issued and outstanding	986,819
Common stock reserved for issuance upon vesting of outstanding restricted stock units	1,387,459
Common shares available for grant under the 2019 Plan	1,831,107
Common shares available for future issuance under ESPP	449,332
Total	5,868,776

Note 10. Income Taxes

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

	Year Ended December 31,	
	2023	2022
Current:		
Federal	$ —	$ —
State	(33)	(24)
Total current	(33)	(24)
Deferred:		
Federal	—	137
State	—	169
Total deferred	—	306
Income tax (expense) benefit	$ (33)	$ 282

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

	Year Ended December 31,	
	2023	2022
Federal statutory tax rate	21.0 %	21.0 %
State income taxes, net of federal tax benefits	2.2 %	4.3 %
Research and development tax credits	0.1 %	1.5 %
Stock compensation	(3.4)%	(1.4)%
Non-deductible expenses	(1.4)%	(0.9)%
Change in valuation allowance	(18.5)%	(23.9)%
Other	(0.1)%	— %
Effective tax rate	(0.1)%	0.6 %

Significant components of the Company's deferred tax assets at December 31, 2023 and 2022 are shown below (in thousands). 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.

	December 31,	
	2023	2022
Deferred tax assets:		
Net operating loss carryforwards	$ 32,479	$ 29,789
Research and development tax credits	2,353	2,216
Accruals, reserves and other	1,119	349
Interest expense	2,547	2,236
Indefinite lived assets	300	362
Stock compensation	1,391	1,606
Lease liability	925	1,374
Capitalization of research and experimentation costs	2,929	2,047
Total gross deferred tax assets	44,043	39,979
Less: valuation allowance	(42,942)	(38,567)
Deferred tax assets, net	1,101	1,412
Deferred tax liabilities:		
Right of use assets	(814)	(1,206)
Basis differences in fixed and intangible assets	(287)	(206)
Deferred tax liabilities	(1,101)	(1,412)
Net deferred tax assets	$ —	$ —

Changes in the valuation allowance for deferred tax assets during the years ended December 31, 2023 and 2022, which related primarily to increases in net operating loss (NOL) carryforwards, research and development tax credits, capitalization of research and experimentation costs, and impairment of goodwill were as follows (in thousands):

	December 31,	
	2023	2022
Valuation allowance at the beginning of the year	$ 38,567	$ 27,158
Increases recorded to income tax provision	4,375	11,409
Valuation allowance at the end of the year	$ 42,942	$ 38,567

At December 31, 2023 and 2022, the Company had federal NOL carryforwards of approximately $129.8 million and $118.4 million, respectively. At December 31, 2023 and 2022, the Company had state NOL carryforwards of $91.0 million and $87.0 million, respectively. Approximately $43.5 million of the federal tax loss carryforwards will begin to expire in 2024, unless previously utilized. The federal NOL carryforwards generated after December 31, 2017 of $86.3 million will carryforward indefinitely. The Company's state tax loss carryforwards will begin to expire in 2030, unless previously utilized.

At December 31, 2023, 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, $61.1 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 2004 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 material accruals for, and did not recognize any, material interest or penalties in these financial statements in any period presented.

Uncertain Tax Positions

At December 31, 2023 and 2022, the Company had no unrecognized tax benefits.

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

Note 11. 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, 2023 and 2022, the Company made contributions to the 401(k) Plan at 4% of qualified employee compensation. For the years ended December 31, 2023 and 2022, these contributions totaled approximately $0.8 million and $0.9 million, respectively.

Shareholder Information

Exchange

Our common stock is traded on the Nasdaq Global Market under the ticker symbol "XGN".

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