

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549  
**FORM 10-K**

(Mark One)

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

For the fiscal year ended December 31, 2020

OR

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

Commission File Number 001-39659

**Biodesix, Inc.**  
(Exact name of Registrant as specified in its Charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)  
**2970 Wilderness Place, Suite 100**  
**Boulder, CO**  
(Address of principal executive offices)

**20-3986492**  
(I.R.S. Employer  
Identification No.)

**80301**  
(Zip Code)

Registrant's telephone number, including area code: (303) 417-0500

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	BDSX	The NASDAQ Global Market

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

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

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

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

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). YES ☒ NO ☐

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

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

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

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

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

The aggregate market value of the Registrant's common stock, par value \$.001 per share (the "Common Stock") held by non-affiliates was approximately \$344,635,079 based upon the December 31, 2020, closing price of \$20.16 as reported by the Nasdaq Global Select Market. The Registrant has elected to use December 31, 2020 as the calculation date, which was the last trading date of the registrant's most recently completed fiscal year, because on June 30, 2020 (the last business day of the registrant's second fiscal quarter), the Registrant was a privately held company.

The number of shares of Registrant's Common Stock outstanding as of March 12, 2021 was 26,577,782.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Company's definitive Proxy Statement for its 2021 Annual Meeting of Shareholders are to be incorporated by reference into Part III, as specifically set forth in Part III.)

## Table of Contents

	<u>Page</u>
<b>PART I</b>	
Item 1. <a href="#"><u>Business</u></a>	3
Item 1A. <a href="#"><u>Risk Factors</u></a>	45
Item 1B. <a href="#"><u>Unresolved Staff Comments</u></a>	100
Item 2. <a href="#"><u>Properties</u></a>	100
Item 3. <a href="#"><u>Legal Proceedings</u></a>	100
Item 4. <a href="#"><u>Mine Safety Disclosures</u></a>	100
<b>PART II</b>	
Item 5. <a href="#"><u>Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u></a>	101
Item 6. <a href="#"><u>Selected Financial Data</u></a>	101
Item 7. <a href="#"><u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u></a>	102
Item 7A. <a href="#"><u>Quantitative and Qualitative Disclosures About Market Risk</u></a>	115
Item 8. <a href="#"><u>Financial Statements and Supplementary Data</u></a>	115
Item 9. <a href="#"><u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u></a>	115
Item 9A. <a href="#"><u>Controls and Procedures</u></a>	115
Item 9B. <a href="#"><u>Other Information</u></a>	115
<b>PART III</b>	
Item 10. <a href="#"><u>Directors, Executive Officers and Corporate Governance</u></a>	116
Item 11. <a href="#"><u>Executive Compensation</u></a>	116
Item 12. <a href="#"><u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u></a>	116
Item 13. <a href="#"><u>Certain Relationships and Related Transactions, and Director Independence</u></a>	116
Item 14. <a href="#"><u>Principal Accounting Fees and Services</u></a>	116
<b>PART IV</b>	
Item 15. <a href="#"><u>Exhibits, Financial Statement Schedules</u></a>	117
Item 16. <a href="#"><u>Form 10-K Summary</u></a>	117

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Annual Report on Form 10-K, including statements regarding our future financial condition, results of operations, business strategy and plans, and objectives of management for future operations, as well as statements regarding industry trends, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potentially,” “predict,” “should,” “will” or the negative of these terms or other similar expressions.

We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to a number of risks, uncertainties, factors, and assumptions described under the section titled “Risk Factors” and elsewhere in this annual Report on Form 10-K, regarding, among other things:

- our inability to achieve or sustain profitability;
- our ability to attain significant market acceptance among payers, providers, clinics, patients, and biopharmaceutical companies for our diagnostic tests;
- difficulties managing our growth, which could disrupt our operations;
- failure to retain sales and marketing personnel, and failure to increase our sales and marketing capabilities or develop broad awareness of our diagnostic tests to generate revenue growth;
- failure to maintain our current relationships, or enter into new relationships, with biopharmaceutical companies;
- significant fluctuation in our operating results, causing our operating results to fall below expectations or any guidance we provide;
- the demand for our COVID-19 and antibody testing program and our ability to meet such demand;
- product performance and reliability to maintain and grow our business;
- third-party suppliers, including courier services, contract manufacturers and single source suppliers; making us vulnerable to supply problems and price fluctuations;
- the impact of a pandemic, epidemic, or outbreak of an infectious disease in the United States or worldwide, including the COVID-19 pandemic on our business;
- natural or man-made disasters and other similar events, including the COVID-19 pandemic, negatively impacting our business, financial condition, and results of operations;
- failure to offer high-quality support for our diagnostic tests, which may adversely affect our relationships with providers and negatively impact our reputation among patients and providers;
- our inability to continue to innovate and improve our diagnostic tests and services we offer;
- security or data privacy breaches or other unauthorized or improper access;
- significant disruptions in our information technology systems;
- the incurrence of substantial liabilities and limiting or halting the marketing and sale of our diagnostic tests due to product liability lawsuits;
- our inability to compete successfully with competition from many sources, including larger companies;
- performance issues, service interruptions or price increases by our shipping carriers and warehousing providers;
- cost-containment efforts of our customers, purchasing groups and integrated delivery networks having a material adverse effect on our sales and profitability;
- potential effects of litigation and other proceedings;

- general economic and financial market conditions;
- our ability to attract and retain key personnel;
- current and future debt financing placing restrictions on our operating and financial flexibility;
- our need to raise additional capital to fund our existing operations, develop our platform, commercialize new diagnostic tests, or expand our operations;
- the acquisition of other businesses, which could require significant management attention;
- the uncertainty of the insurance coverage and reimbursement status of newly approved diagnostic tests;
- future healthcare reform measures that could hinder or prevent the commercial success of our diagnostic tests;
- compliance with anti-corruption, anti-bribery, anti-money laundering and similar laws;
- compliance with healthcare fraud and abuse laws;
- our ability to develop, receive regulatory clearance or approval or certification for, and introduce new diagnostic tests or enhancements to existing diagnostic tests that will be accepted by the market in a timely manner;
- failure to comply with ongoing FDA or other domestic and foreign regulatory authority requirements, or unanticipated problems with our diagnostic tests, causing them to be subject to restrictions or withdrawal from the market;
- future product recalls;
- legal proceedings initiated by third parties alleging that we are infringing, misappropriating, or otherwise violating their intellectual property rights, the outcome of which would be uncertain;
- the volatility of the trading price of our common stock;
- inaccurate estimates or judgments relating to our critical accounting policies, which could cause our operating results to fall below the expectations of securities analysts and investors; and
- other risks, uncertainties and factors, including those set forth under Risk Factors.

These risks are not exhaustive. Other sections of this Annual Report on Form 10-K may include additional factors that could harm our business and financial performance. New risk factors may emerge from time to time and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Annual Report on Form 10-K or to conform these statements to actual results or to changes in our expectations.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report on Form 10-K, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

You should read this Annual Report on Form 10-K and the documents that we reference and have filed as exhibits with the understanding that our actual future results, levels of activity, performance and achievements may be different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

**Item 1. Business.**

Our **mission** is to improve every patient’s lung disease care by empowering physicians with swift, comprehensive and actionable insights.

Our **vision** is to be a trusted business partner that the world relies on for data-driven diagnostics in lung disease and beyond.

**Business Overview**

Biodesix, Inc. (“Biodesix”, “we,” “us,” “our” or the “Company”) is a leading data-driven diagnostic solutions company leveraging state of the art technologies with our proprietary artificial intelligence (AI) platform to discover, develop, and commercialize solutions for clinical unmet needs, with a primary focus in lung disease. By combining a technology agnostic approach with a holistic view of the patient’s disease state, we believe our solutions provide physicians with greater insights to help personalize their patient’s care and meaningfully improve disease detection, evaluation, and treatment. Our unique approach to precision medicine provides timely and actionable clinical information, which we believe improves overall patient outcomes and lowers the overall healthcare cost by reducing the use of ineffective and unnecessary treatments and procedures. In addition to our diagnostic tests, we provide biopharmaceutical companies with services that include diagnostic research, clinical trial testing, and the discovery, development, and commercialization of companion diagnostics.

Our core belief is that no single technology will answer all clinical questions that we encounter. Therefore, we employ multiple technologies, including genomics, transcriptomics, proteomics, and radiomics, and leverage our proprietary AI platform, the Diagnostic Cortex®, to discover innovative diagnostic tests for clinical use. Because of this approach, we believe we are unique in the diagnostics market as this approach allows for a broader and more holistic understanding of each patient’s disease state. Our data-driven and technology agnostic approach is designed to enable us to discover diagnostic tests that answer critical clinical questions faced by physicians, researchers, and biopharmaceutical companies.

We operate in a single segment and derive our revenue from two sources: (i) providing diagnostic testing services associated with blood-based lung and Coronavirus Disease 2019 (COVID-19) tests (Diagnostic Tests); and (ii) providing biopharmaceutical companies with services that include diagnostic research, clinical research, development and testing services generally provided outside the clinical setting and governed by individual contracts with third parties as well as development and commercialization of companion diagnostics (Services). We derived 90% and 71% of our total revenues for fiscal 2020 and fiscal 2019, respectively, from our diagnostic testing business.

We are dedicated to continuously publishing and presenting new data on the clinical validation and utility of our diagnostic tests. Since our inception, we have performed over 285,000 tests and continue to generate a large and growing body of clinical evidence. We have participated in 27 clinical studies, five of which are ongoing, and have published over 275 peer-reviewed publications and presentations. We have over 140,000 samples and data in our biobank, including tumor profiles and immune profiles, which are used for both internal and external research and development (R&D) initiatives.

We have commercialized six diagnostic tests which are currently on market and we perform over 30 assays for research use as part of our laboratory services that have been used by over 50 biopharmaceutical customers and academic partners.

**Blood-Based Lung Tests**

We have four diagnostic blood-based tests across the lung cancer continuum of care, which generated \$12.6 million and \$17.3 million in revenue for fiscal 2020 and 2019, respectively.

- *Nodify XL2®* and *Nodify CDT™* tests, together marketed as part of our Nodify Lung™ Nodule Risk Assessment testing strategy, assess the risk of lung cancer to help identify the most appropriate treatment pathway. We believe we are the only company to offer two commercial blood-based tests to help physicians reclassify risk of malignancy in patients with suspicious lung nodules.

- *GeneStrat*® and *VeriStrat*® tests, together marketed as part of our Biodesix Lung Reflex® testing strategy, are used following diagnosis of lung cancer to measure the presence of mutations in the tumor and the state of the patient's immune system to establish the patient's prognosis and help guide treatment decisions. The GeneStrat tumor profiling test and the VeriStrat immune profiling test have a three-day average turnaround time, providing physicians with timely results to facilitate treatment decisions.

## **COVID-19 Tests**

In response to the COVID-19 pandemic, through our partnership with Bio-Rad, we commercialized the Biodesix WorkSafe™ testing program. We generated \$28.3 million in revenue from COVID-19 testing during fiscal 2020. Our scientific diagnostic expertise, technologies, and existing commercial infrastructure enabled us to rapidly commercialize two United States Food and Drug Administration (FDA) Emergency Use Authorization (EUA)-authorized tests, a part of our customizable WorkSafe™ program. Both diagnostic tests are owned and were developed by Bio-Rad and Bio-Rad has granted us permission to utilize both tests for commercial diagnostic services.

In February 2020, the U.S. Department of Health and Human Services Secretary declared a public health emergency for COVID-19 which justified the authorization of emergency use of diagnostic tests for the detection and/or diagnosis of COVID-19. The Bio-Rad SARS-CoV-2 Droplet Digital™ polymerase chain reaction (ddPCR) test and the Platelia SARS-CoV-2 Total Ab test have been granted FDA EUA pursuant to the current emergency declaration. The Bio-Rad SARS-CoV-2 ddPCR test was FDA EUA authorized on May 1, 2020, authorizing performance of the test in laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) to perform high complexity tests. The second test is the Platelia SARS-CoV-2 Total Ab test, which is an antibody test intended for detecting a B-cell immune response to SARS-CoV-2, indicating recent or prior infection. The Platelia SARS-CoV-2 Total Ab test was FDA EUA authorized on April 29, 2020. Medical products that are granted an EUA are only permitted to commercialize their products under the terms and conditions provided in the authorization. The FDA may revoke an EUA where it is determined that the underlying health emergency no longer exists or warrants such authorization, if the conditions for the issuance of the EUA are no longer met, or if other circumstances make revocation appropriate to protect the public health or safety, and we cannot predict how long the EUAs for the SARS-CoV-2 tests will remain in place. Using the Bio-Rad SARS-CoV-2 ddPCR test and the Platelia SARS-CoV-2 Total Ab tests, we operate and have commercialized the Biodesix WorkSafe testing program.

Prior to using the Bio-Rad tests as part of our WorkSafe testing program, we performed feasibility, verification, and validation studies, including developing software for process automation, sample accessioning, data management and reporting, all required to demonstrate the test operated as claimed by the manufacturer and as required by our certifying regulatory agencies for high complexity laboratory testing. We secured independent reference specimens run with EUA tests to validate these tests as fit for diagnostic use in our laboratories. Post-launch development support for these tests have included improvements in on-boarding new personnel, logistics of sample collection, sample receipt and data reporting, all required to support our testing program. Additional releases of the laboratory data management software are ongoing and planned for the foreseeable future.

These tests are utilized by healthcare providers, including hospitals and nursing homes, and are also offered to businesses and educational systems to assist in their back-to-work or back-to-school strategies, a crucial element of restarting economic activity. During 2020, we announced multiple partnerships for COVID-19 testing and have entered into an agreement with the State of Colorado to be one of the diagnostic companies to support widespread COVID-19 testing for the State. Additionally, we oversee and manage onsite testing and validating testing for the Big Ten Conference athletic competitions.

## **COVID-19 Pandemic**

The COVID-19 pandemic has disrupted, and we expect will continue to disrupt, our non-COVID-19 testing operations. To protect the health and well-being of our workforce, partners, vendors and customers, we provide voluntary COVID-19 testing for employees working on-site, implemented social distance and building entry policies at work, restricted travel and facility visits, and followed the States of Colorado and Kansas' public health orders and the guidance from the Centers for Disease Control and Prevention. Employees who can perform their duties remotely are asked to work from home and those on site are asked to follow our social distance guidelines. Our sales, marketing and business development efforts have also been constrained by our operational response to the COVID-19 pandemic due to travel restrictions. We expect to continue to adjust our operational norms in an effort to help slow the spread of COVID-19 in the coming months, including complying with government directives and guidelines as they are modified and supplemented.

The COVID-19 pandemic also has started to negatively affect, and we expect will continue to negatively affect, our non-COVID-19 testing- related revenue and our clinical studies. For example, cancer patients may have more limited access to hospitals, healthcare providers and medical resources as they take steps to control the spread of COVID-19. Our biopharmaceutical customers are facing challenges in recruiting patients and in conducting clinical trials to advance their pipelines, for which our tests could be utilized. As a result of the COVID-19 pandemic, beginning in the latter half of March 2020, we have been receiving fewer samples for non-COVID-19 testing on a daily average basis from our clinical and biopharmaceutical customers than before the outbreak of the COVID-19 pandemic. Further, our clinical studies, such as our ongoing INSIGHT study and our recently launched ALTITUDE study, as well as our arrangements with our biopharmaceutical customers, are expected to take longer to complete than what we originally expected before the outbreak of the COVID-19 pandemic.

Conversely, we are also experiencing an increase in revenues related to an increase in the demand for our Biodesix WorkSafe testing program which generated revenue of \$28.3 million during fiscal 2020 of which \$21.4 million is attributable to the fourth quarter 2020. As a result, our operating costs to expand capacity for COVID-19 testing also increased substantially during 2020 and we expect that trend to continue into the first quarter of 2021. There is no assurance that our COVID-19 testing program will continue to be accepted by the market or that other diagnostic tests will become more accepted, produce quicker results or are more accurate. Further, the longevity and extent of the COVID-19 pandemic is uncertain. If the pandemic were to dissipate, whether due to acquiring herd immunity based on previous natural infection, and the availability and rapid distribution of vaccines, the evolution of variant strains that impact diagnostic test performance, or otherwise, the need for a COVID-19 test could decrease significantly and this could have an adverse effect on our results of operations and profitability. As a result, the increase in revenue due to any increase in demand for these diagnostic tests may not be indicative of our future revenue. See “Risk Factors” for a description of how the COVID-19 pandemic may adversely affect our business, financial condition and results of operations.

### **Full Year Results for 2020**

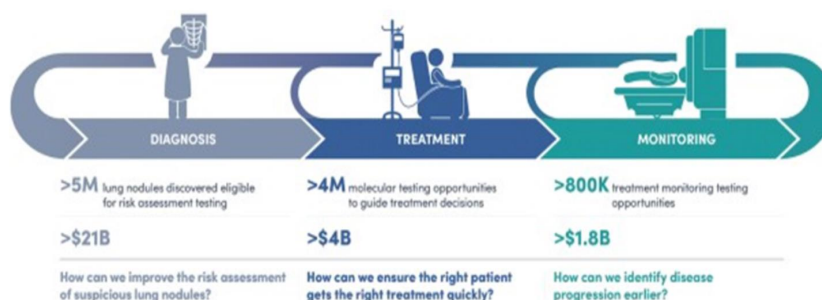
For the year ended December 31, 2020, compared to the prior year:

- *Total Revenue* was \$45.6 million, an increase of 86%;
- *Gross Margin* was \$23.6 million, an increase of 27%;
- *Operating Expenses, Excluding Cost of Revenue*, were \$46.5 million, an increase of 3%;
- *Net Loss and Comprehensive Loss* was \$31.4 million, an increase of 2%;
- *Basic and Diluted Net Loss Per Common Share* was \$6.48;
- *Net Cash Used by Operating Activities* was \$21.4 million, compared to \$21.7 million used; and
- *Cash and Cash Equivalents* was \$62.1 million at December 31, 2020, an increase of \$56.8 million primarily resulting from our successful initial public offering in October 2020.

## Our Market Opportunity

### Diagnostic Testing Market Size and Opportunity

Despite significant advances over the last decade, lung cancer is still the deadliest type of cancer in both men and women in the United States today. While diagnostic testing has become routinely used at certain points in the lung cancer continuum of care (diagnosis, treatment and monitoring), we believe there is a substantial need for novel, advanced testing to improve on the current standard of care. We estimate that in the United States, the lung cancer continuum of care currently represents over 10 million annual testing opportunities, and is over a \$27 billion market annually for testing alone.



Over the last two decades, the use of biomarker testing in clinical trials has increased, with 55% of oncology trials involving the use of biomarker testing in 2018 versus 15% in 2000. We believe the field of biomarker discovery and companion diagnostic development for biopharmaceutical therapeutics is set to continue growing as biopharmaceutical companies seek to de-risk their research and development pipelines and increase chances of drug development success. We estimate that the biopharmaceutical partnering and research opportunities represent over a \$2 billion market annually.

### Lung Cancer Continuum of Care – Clinical Unmet Needs

Standards of care in lung cancer have evolved rapidly over the past decade, along with our understanding of the disease. With the introduction of numerous treatment options, physicians need an ever-increasing amount of information in order to select the best treatment plan for each individual patient. We believe that the lung cancer continuum of care has a variety of clinical unmet needs ranging from initial diagnosis of lung cancer after discovery of a lung nodule to treatment guidance for early and advanced stage disease, and monitoring for disease progression.

- **Diagnosis:** We estimate approximately 1.6 million new incidental lung nodules and potentially 4 million lung nodules from the adoption of screening could be identified annually in the United States. Following initial discovery of a nodule, patients are typically evaluated by a pulmonologist for risk of lung cancer before an invasive procedure is carried out to obtain a tissue sample to confirm diagnosis. This risk assessment is based on clinical factors such as the patient's smoking history and age, and radiological features such as the size and location of the nodule, obtained from a computed tomography (CT) scan. On initial assessment, we estimate that approximately 80% of patients are identified as low to moderate risk (5-65%) where guideline recommendations for their care plan are unclear, often resulting in either *overtreatment* of patients with benign nodules or *undertreatment* in patients with cancer. An estimated 17% of patients with malignant nodules are initially sent to watchful waiting, where a follow-up CT scan is scheduled in three to six months, potentially delaying their diagnosis. Conversely, we estimate that 62% of biopsies and 35% of surgeries performed on lung nodules find benign disease, representing a significant overtreatment that incurs both risk and cost to the patient and their providers. We therefore believe that there is a clear clinical need for blood-based diagnostic testing to help improve the initial risk assessment of pulmonary nodules, helping direct patients to the relevant treatment pathway, and ultimately improving patient outcomes and saving costs to the system.



- **Treatment Guidance – Early Stage:** We estimate that there are over 700,000 testing opportunities annually in the United States in early-stage lung cancer to assess a patient’s risk of recurrence following curative-intent surgery, and to detect potential target mutations for therapeutics. Depending on a patient’s risk of recurrence, they may also receive chemotherapy, radiotherapy or chemoradiation post-surgery. The assessment of risk of recurrence is primarily based on the stage of cancer at diagnosis, with stage I patients typically receiving no additional treatment beyond surgery. However, 20 to 40% of patients with stage I disease do still recur within five years following surgery, representing a sub-group of patients who may have benefitted from more intensive treatment protocol. We believe there is a clear clinical need for blood-based diagnostic testing prior to surgery to identify stage I patients who may benefit from a more intensive treatment protocol and we also believe there is the need for identifying stage II and IIIA patients where low risk patients may benefit from a less intensive treatment protocol. There have also been recent advances in the use of targeted therapies in early-stage lung disease. These therapies typically target specific genomic mutations or alterations found in some tumors. We believe there is therefore an emerging need for testing designed specifically for mutation detection in early-stage disease.
- **Treatment Guidance – Advanced Stage:** We estimate that there are over 3 million diagnostic testing opportunities annually in the United States to guide advanced stage lung cancer treatment decisions. With nearly 50 FDA-approved systemic treatment regimens listed in national treatment guidelines for non-small cell lung cancer (NSCLC), there is an elevated need for personalized biomarkers to help physicians identify the right patient for the right treatment. Multiple tissue-based diagnostic tests have been approved to identify patients eligible for targeted therapies and immunotherapy; however, about 50% of patients do not have sufficient tissue collected following diagnosis to facilitate testing. To compound the issue, different molecular tests take varying amounts of time (days versus weeks) to report results back to the ordering physician, which often leads to treatment decisions being made on incomplete information. Therefore, we believe there is an imminent need for a blood-based testing solution that measures tumor mutations and the patient’s immune profile, to provide physicians with more comprehensive and timely information to assess the overall prognosis of the patient and personalize treatment.
- **Monitoring:** We estimate that there are over 800,000 testing opportunities in the United States for blood-based tumor and immune profiling to monitor for disease recurrence and progression in NSCLC patients. Unfortunately, advanced stage lung cancer is often terminal, so repeat tissue biopsy to assess the evolution of resistance mutations or to detect disease progression is not feasible from either a cost or risk perspective to the patient, which we believe demonstrates an important need for blood-based testing to help routinely monitor these patients. As a patient progresses through therapies, changes in their immune system occur and blood-based immune profiling could help physicians identify these changes prior to subsequent therapy selection.

### ***Current Limitations in Biomarker Discovery and Companion Diagnostics***

We estimate the biopharmaceutical biomarker testing and companion diagnostic market opportunity is \$2 billion annually. Over the last two decades, the use of biomarker testing in clinical trials has increased, with 55% of oncology trials involving the use of biomarker testing in 2018 versus 15% in 2000. From 2005 to 2015, a study identified that incorporating biomarkers into clinical development programs increased their probability of therapeutic success rate from phase 1 to FDA-approval by 570%, representing an increase from 1.6% without biomarkers to 10.7% with biomarkers. We believe the field of biomarker discovery and companion diagnostic development for biopharmaceutical therapeutics is set to continue growing as biopharmaceutical companies seek to de-risk their product development efforts and increase chances of drug development success. However, we believe as the market continues to advance, inherent limitations of both biomarker discovery and companion diagnostic development have become more apparent.

**Biomarker Discovery:** There are many limitations with biomarker discovery in biopharmaceutical drug development, including:

- Biomarkers with clinical utility are difficult to discover and validate in independent datasets.
- Classical statistical approaches to biomarker discovery are limited. Single-omic tests fail to see the whole biological picture.

- Tissue biopsies are limited by the amount of a sample that can be collected: longitudinal testing is difficult and the biology is only from the profile of the tumor (host response is not accounted for).
- Clinical trials are expensive and take a long period of time. It is often difficult to meet enrollment goals for clinical trials with slow diagnostic testing turnaround times.

**Companion Diagnostics (CDx):** While developing companion diagnostics is critical to precision medicine, the promise of companion diagnostics has not been fully realized and there are multiple limitations that still need resolution. The path to co-develop a successful companion diagnostic with a corresponding drug has several challenges, including:

- Traditional companion diagnostic agreements may fail to realize the full value of a testing opportunity, leading to difficulty in funding appropriate commercialization.
- Drug development is a lengthy, complex and costly process. There can be a financial impact to a pharmaceutical company to have a drug selected by a test.
- Current diagnostic reimbursement policies may not always support the coverage and payment of new companion diagnostics.
- Regulatory agencies continue to work on defining the co-development process, but the environment is continually changing.

### **The Diagnostic Cortex - Our Proprietary Artificial Intelligence (AI) Platform**

Our core belief is that no single technology will answer all clinical questions that we encounter. Therefore, we employ multiple technologies, including genomics, transcriptomics, proteomics, and radiomics, and leverage our proprietary AI platform, the Diagnostic Cortex, to discover innovative diagnostic tests for clinical use. We focus on developing technologies that are capable of single and multi-omic research and development.

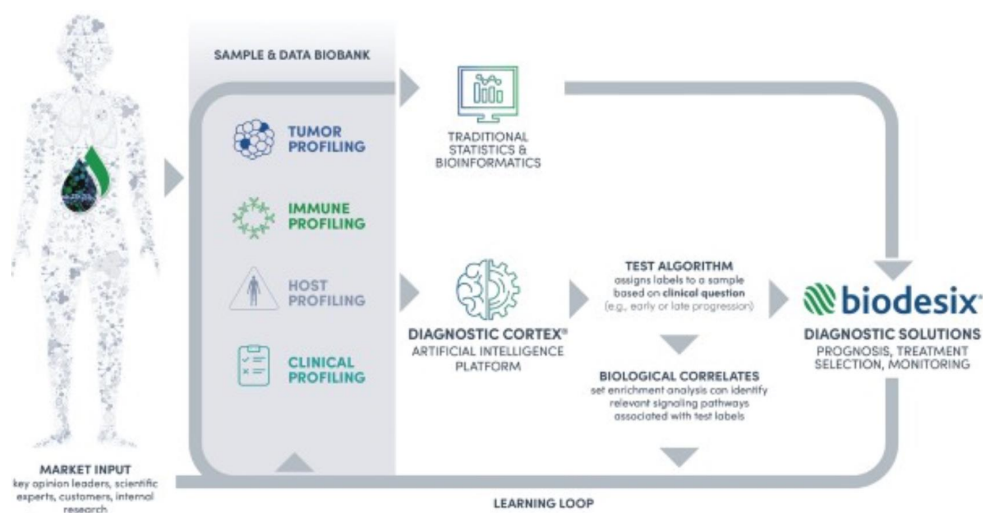
The Diagnostic Cortex is an extensively validated deep learning platform optimized for the discovery of clinical diagnostic tests, which we believe overcomes standard machine learning challenges faced in life sciences research. Researchers commonly encounter issues with machine learning-based biological discoveries that cannot be repeated or validated when assessed in additional specimen cohorts. This challenge, commonly referred to as overfitting, occurs when the machine identifies a perfect pattern in an initial training dataset but is unable to identify the same pattern in a new dataset. For over 15 years we have focused on developing our platform to overcome this challenge through proprietary computational techniques to ensure each diagnostic test that is discovered can be further developed to perform consistently in the clinical testing environment.

We are able to combine blood-based biological information related to the tumor, immune system, and host-status with clinical and radiomic data through our proprietary AI platform, which enables us to interpret the holistic disease state of each patient or clinical dataset we encounter.

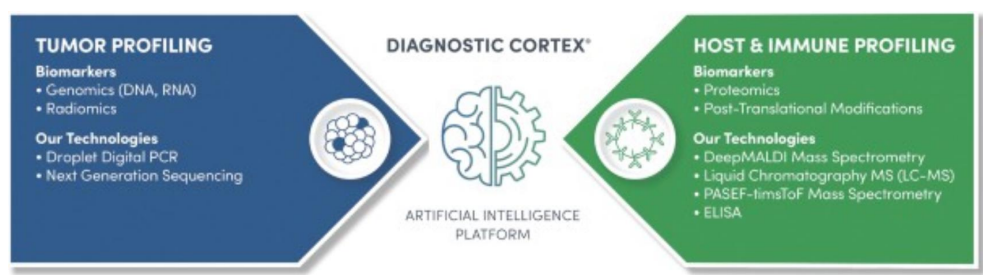
We continuously evolve and improve the Diagnostic Cortex platform. These improvements range from basic code optimization to complex improvements such as the incorporation of novel computational methods for the optimization of multi-omic diagnostic tests. Any AI platform is inherently limited without the highest quality data inputs. Therefore, all of the technologies that we employ have been chosen and developed to provide high-quality data to enable our Diagnostic Cortex platform. We feel that this level of data integrity is crucial for the development of diagnostic tests that require the advanced pattern matching abilities of deep learning algorithms.

We continuously incorporate new market insights and patient data to enhance our platform through a data-driven learning loop. We regularly engage our customers, key opinion leaders, and scientific experts to stay ahead of the rapidly evolving diagnostic and therapeutic landscape and learn about biological discoveries that are clinically meaningful. Additionally, we incorporate clinical and molecular profiling data aggregated through our commercial clinical testing, research studies, clinical trials, and biopharmaceutical customers or academic partnerships, into our platform. We have over 140,000 samples and data in our biobank, including tumor profiles and immune profiles, which are used for both internal and external development initiatives. With our data-driven and technology agnostic approach as data inputs into the Diagnostic Cortex, we are able to discover diagnostic tests that answer critical clinical questions faced by physicians, researchers, and biopharmaceutical companies.

The following is a diagram outlining our innovative diagnostic test discovery, development and commercialization infrastructure as outlined in the text above.



We employ multiple technologies, as illustrated below, including genomics, proteomics, transcriptomics, and radiomics, generated by different assay techniques, including ddPCR, NGS, LC-MS, ELISA, and our proprietary DeepMALDI mass spectrometry platform for the blood-based molecular analysis of the tumor, immune system, and host-status of each patient and/or clinical dataset. Through our learning loop, we continuously revisit our technology strategy and roadmap to integrate new technologies into our evolving platform, which ultimately support the addition of new service and product revenue offerings. We focus on developing technologies that are capable of single and multi-omic research and development.



Most diagnostic companies focus their strategy on using a single technology to discover biomarkers for a broad range of clinical questions. We believe that no single technology can interrogate the complexity of the human disease state to help solve all clinical questions. For that reason, we employ a technology agnostic approach to solving diagnostic challenges leveraging our proprietary AI platform. Because of this approach, we believe we are unique in the diagnostics market, allowing for a broader and more holistic understanding of each patient’s disease state.

We are experts in many technologies, but we are a true market leader with over 15 years of experience in the field of clinical proteomics. For over 10 years, we have been discovering and developing proteomic-based diagnostic tests and have a deep understanding of how to incorporate technologies that can be applied to blood samples in order to extract important protein-based biological information in the form of diagnostic tests, which can aid clinicians and scientists in understanding the dynamic biology of their system of interest, such as a patient with cancer.

Our suite of technologies that assist us in discovery, development and commercialization of novel diagnostic tests includes:

#### ***DeepMALDI Mass Spectrometry***

We have developed DeepMALDI, a proprietary high-density matrix-assisted laser desorption/ionization time-of-flight (MALDI-ToF) mass spectrometry (MS) technology, to produce blood-based proteomic data for disease diagnosis, personalized health care, precision medicine for direct treatment options, and disease screening in lung and other disease states. DeepMALDI overcomes the limitations of conventional MALDI and other mass spectrometry methods to produce highly sensitive, stable, and reproducible data by: (1) utilizing optimized signal-to-noise reduction and signal processing algorithms; and (2) novel batch correction methods and spectral alignment methods. The combination of these improvements yields substantially higher quality data content and is thereby much better suited for the discovery of biomarkers with clinical utility.

Our current DeepMALDI methods allow us to achieve finer mass resolution, greater sensitivity, and 20-times faster imaging speeds than other instruments. Additionally, we believe enhancements to our DeepMALDI methods and MALDI-ToF technology evolution will allow us to measure approximately 1,500 proteins, an improvement from the estimated 900 proteins we can measure today. We intend to maintain our leadership role in the discovery of proteomics-based diagnostic tests. We utilize our DeepMALDI and MALDI-ToF technologies in our discovery and development efforts and as part of our collaborations with our biopharmaceutical customers and academic partners.

#### ***Liquid Chromatography Mass Spectrometry MS***

We use Multiple Reaction Monitoring (MRM) MS with triple quadrupole mass spectrometers and up-front liquid chromatography (LC) sample injection in the Nodify XL2 test. This mass spectrometry method offers highly sensitive, specific, and cost-effective analysis for simultaneous quantitation of hundreds to several thousands of targeted peptides in a single experiment. We have since included the MRM technologies as part of our services for discovery and development with our biopharmaceutical customers and academic partners.

#### ***Enzyme-Linked Immunosorbent Assay***

ELISA is the most widely used ligand binding assay platform within and outside the pharmaceutical industry. Formats include direct, indirect and sandwich assays and are typically run in manually or semi-automated modes. We use a semi-automated implementation of ELISA in clinical testing for the Nodify CDT test and the Platelia SARS-CoV-2 Total Ab test for COVID-19. The acquisition of Oncimmune USA in 2019 expanded our ability to conduct very high throughput and cost-effective ELISAs in our clinical testing laboratory. We have now included the ELISA technologies for research and development both internally and externally with our biopharmaceutical customers and academic partners.

#### ***Droplet Digital PCR Platform***

We use the ddPCR technology for multiplexed, semi-automated nucleic acid detection. This allows high sensitivity, fast turn-around times, flexibility in our laboratory workflows, rapid scaling from low to moderate analyte complexity, and high-volume scalability. ddPCR is an absolute quantitation method based on the partitioning of circulating nucleic acids into up to 20,000 droplets per reaction and is used for the GeneStrat test and Bio-Rad SARS-CoV-2 ddPCR test for COVID-19. We have included the ddPCR technologies for research and development both internally and externally with our biopharmaceutical customers and academic partners.

#### ***Next Generation Sequencing Technology***

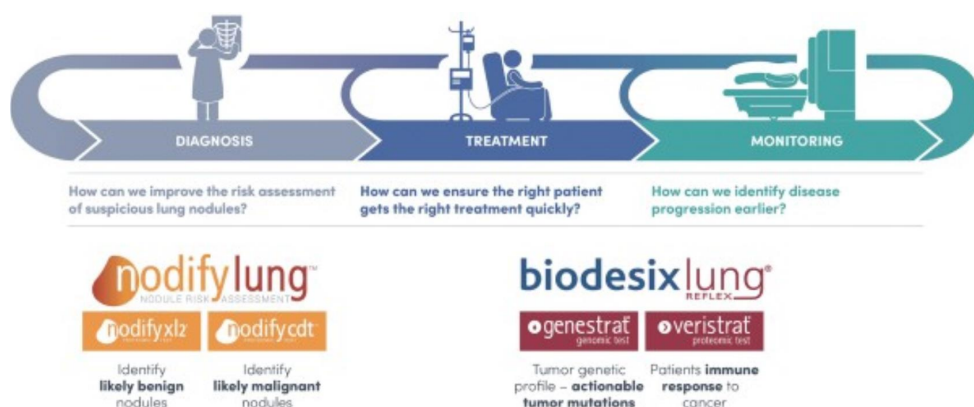
We use an NGS technology for broad genomic sequencing of clinical specimens. Our strategy with NGS relies on a menu of off-the-shelf and custom research use assays, which we develop and make available as a part of our biopharmaceutical test services. The NGS technology integrates automated systems to yield high sensitivity results with a rapid turnaround time. Since adoption of this technology, we have included the NGS technologies for research and development both internally and externally with our biopharmaceutical customers and academic partners.

## Our Solutions and Products

To help address the current limitations with standard of care in lung cancer diagnosis, treatment, and monitoring, we use combinations of tumor, immune and host profiling, radiological imaging, patient clinical profiling, and our proprietary AI platform to provide a holistic view of each patient's dynamic disease state.

We have four blood-based diagnostic tests across the lung cancer continuum of care to help address clinical unmet needs by physicians.

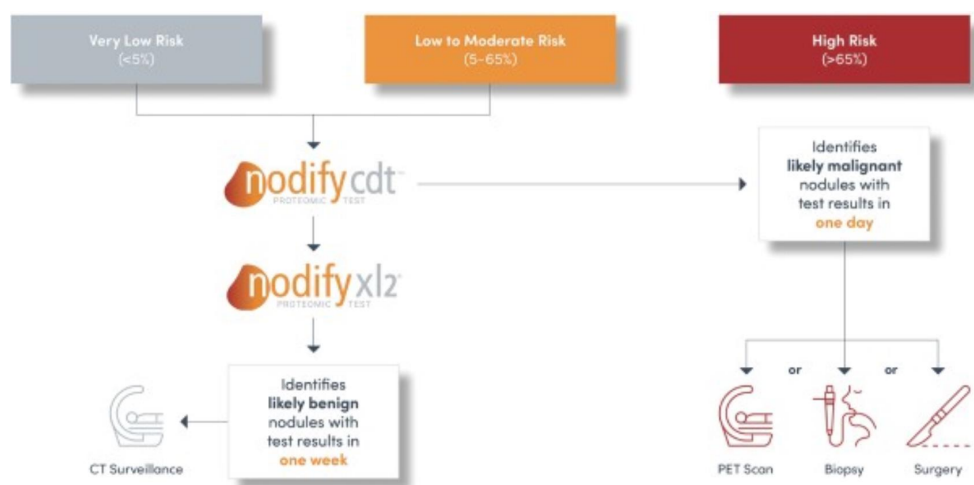
- **Diagnosis:** We believe there is a clinical need to help physicians reclassify risk of malignancy in patients presenting with suspicious lung nodules. We offer the blood-based Nodify Lung Nodule Risk Assessment testing strategy to aid physicians in stratifying patients into distinct nodule management treatment pathways: diagnostic procedure or imaging surveillance. Nodify Lung consists of two blood-based proteomic tests: the Nodify CDT test helps identify patients with lung nodules that are likely malignant and the Nodify XL2 test conversely helps identify those that are likely benign.
- **Treatment Guidance:** We believe there is an imminent need for a blood-based testing solution that measures tumor-specific mutations and the patient's immune profile to provide physicians with more comprehensive information to assess the overall prognosis of the patient and personalize treatment plans. We offer the blood-based Biodesix Lung Reflex testing strategy, which consists of the GeneStrat tumor profiling test and the VeriStrat immune profiling test for patients diagnosed with NSCLC. With a three-day turnaround time, we are able to quickly provide critical diagnostic information to physicians to facilitate personalized treatment decisions for their patients.
- **Monitoring:** We believe longitudinally monitoring advanced NSCLC patients for the dynamic evolution of their tumor and immune profile while on treatment can provide an earlier indication of treatment resistance and/or disease progression. We offer the Biodesix Lung Reflex testing strategy as a blood-based monitoring tool for physicians to track their patients' disease evolution.



### Diagnosis – Nodule Management

We believe we are the only company to offer two commercial blood-based tests to help physicians reclassify risk of malignancy in patients with suspicious lung nodules. Our blood-based nodule management offering, Nodify Lung Nodule Risk Assessment assists physicians in reclassifying a patient's risk of lung cancer by incorporating their protein biomarker results with radiographic imaging and clinical characteristics. Nodify Lung consists of the Nodify CDT and Nodify XL2 proteomic tests, which can be ordered separately or together from a single blood draw to help reclassify risk of cancer to aid physicians in stratifying patients into distinct nodule management pathways: intervention or surveillance.

The Nodify CDT test is used to help identify lung nodules that are likely malignant and the Nodify XL2 test helps identify lung nodules that are likely benign. Nodify Lung is available for patients 40 years or older, with nodules between 8 and 30mm, and less than 65% pre-test risk of lung cancer. The testing strategy starts with the Nodify CDT test to determine if a nodule is likely malignant or at a higher risk of lung cancer. The Nodify CDT test helps physicians identify cancer more quickly by prioritizing patients with a higher risk of malignancy for a diagnostic procedure, such as biopsy or surgery. If the nodule is not identified as having a high risk of malignancy by Nodify CDT, then the Nodify XL2 test is performed to help determine if the patient's nodule is likely benign or has a reduced risk of lung cancer and may be a candidate for CT imaging surveillance. The Nodify Lung testing strategy is represented graphically in the image below starting with the patient's pre-test risk of malignancy and ending with the guideline-recommended diagnostic procedure for each risk category.



We believe we are the only company to offer two commercial blood-based tests to help physicians reclassify risk of malignancy in patients with suspicious lung nodules. We launched the Nodify Lung combined offering of Nodify CDT and Nodify XL2 in March 2020. However, the Nodify XL2 test has been available to all physicians since September 2019 and has been available to a select group of physicians since October 2018. We acquired the Nodify XL2 test from Integrated Diagnostics in July 2018, and acquired the Nodify CDT from Oncimmune USA in October 2019.

#### *Nodify CDT*

Nodify CDT is a blood-based proteomic test that helps identify patients who have a suspicious lung nodule that is likely malignant or at a higher risk of being cancerous. Results allow physicians to identify patients who may be better candidates for timely invasive diagnostic procedures such as bronchoscopy, transthoracic needle biopsy, or surgical resection, with the hope of catching cancer earlier. Nodify CDT enhances lung nodule risk assessment to facilitate compliance with clinical treatment guidelines such as those of the American College of Chest Physicians (ACCP). Nodify CDT is intended for use in patients who are 40 years or older, have nodules between 8 and 30mm, and pre-test risk of lung cancer of less than 65%.

The test measures the levels of seven circulating autoantibodies (P53, NY-ESO-1, CAGE, GBU4-5, SOX2, HuD, and MAGE A4) associated with lung cancer, combined by an algorithm to report out three potential results: High Level, Moderate Level, or No Significant Levels of Antibodies Detected (NSLAD). The seven autoantibodies have shown to be elevated for all types of lung cancer, and from the earliest stage of the disease.

Unlike the tumor antigens themselves, the autoantibody levels can be measured accurately through a blood sample, based upon the signal amplification generated by the immune response to cancer. This mechanism of action likely reflects very early events in a tumor's evolution; as the immune system initiates a response to the cancer, it can also trigger an expansion of self-reactive antibodies that can be measured in circulation.

In addition to the test result of High Level, Moderate Level, or NSLAD, each test report includes the patient's pre-test risk of malignancy as calculated by the Solitary Pulmonary Nodule Risk Assessment calculator, and their post-test risk of cancer incorporating the result of the test. The Solitary Pulmonary Nodule Risk Assessment calculator was developed by Stephen Swensen, M.D., of the Mayo Clinic and is designed to provide a risk of malignancy for a patient with a newly discovered incidental nodule. The model incorporates six clinical and radiologic factors into the equation: age, nodule size, smoking status, nodule location, spiculation (nodule edge characteristic), and previous history of lung cancer. Incorporating the autoantibody levels with the risk model provides physicians with a more accurate assessment of risk. The test has been studied in 14 peer reviewed published studies and presentations.

#### *Nodify XL2*

Nodify XL2 is a blood-based proteomic test that helps identify patients who have a suspicious lung nodule that is likely benign or at a reduced risk of being cancerous. Results allow physicians to identify patients who may be better candidates for routine CT surveillance to monitor for growth or shrinkage of the nodule over time instead of an invasive diagnostic procedure. Nodify XL2 is used for patients who are 40 years or older, have nodules between 8 and 30mm, and have a pre-test risk of lung cancer of less than or equal to 50%.

Nodify XL2 integrates peptides measured by LC-MS with clinical and radiological characteristics that are combined by an algorithm to report out three potential results: Likely Benign, Reduced Risk, or Indeterminate. Specifically, the Nodify XL2 test measures the relative abundance of two peptides (LG3BP and C163A) in circulation in the patient's blood. The native proteins from which the peptides are derived, have been associated with an inflammatory response to cancer. The clinical factors are patient age and smoking status, and radiological factors are nodule size, location, and edge characteristics.

In addition to the test result of Likely Benign, Reduced Risk, or Indeterminate, each test report includes the patient's pre-test risk of lung cancer as calculated by the Solitary Pulmonary Nodule Risk Assessment calculator, and their post-Nodify XL2 risk of malignancy incorporating the result of the test. Incorporating the peptide levels with the risk model provides physicians with a revised assessment of risk incorporating the patient's biology.

In summary, the inclusion of the Nodify Lung testing strategy into clinical practice helps physicians reclassify risk of malignancy of low to moderate risk lung nodules by incorporating the patient's own biology into the assessment. The Nodify CDT test helps physicians identify patients with a high-risk lung nodule who may benefit from timely intervention, which can ultimately help identify lung cancer earlier. The Nodify XL2 test helps physicians identify patients with a very low risk lung nodule who may benefit from CT surveillance and could avoid unnecessary invasive procedures.

Blood samples for Nodify XL2 and Nodify CDT can be collected in the physician's office, laboratory, or at home through use of mobile phlebotomy. Mobile phlebotomy options facilitate testing for patients even if they are not seen in person by the physician and instead are seen through telehealth visits. This benefits the patient as scheduling can be conveniently fit to their needs and can keep them away from a physician's office or hospital for safety concerns, especially with the evolving coronavirus pandemic. Additionally, mobile phlebotomy benefits the physician as the logistics around a blood draw or tissue sampling are out of their hands. We have a national network of contracted Nurses and Phlebotomists to support at-home or mobile blood collection.

Both tests require a single blood sample shipped at ambient temperature to our certified, high-complexity clinical laboratory in De Soto, Kansas. Nodify CDT requires whole blood and Nodify XL2 requires whole blood spotted onto our proprietary Blood Collection Device (BCD). The introduction of the BCD as a qualified specimen collection method for use with the Nodify XL2 test alleviated the need for serum separation processing steps by phlebotomists at blood draw sites such as centrifugation, and cold chain (dry ice) shipments, which has increased the market access to our proteomic-based tests. Results for Nodify CDT alone are typically available within one day. If both tests are ordered for the patient and Nodify CDT returns a result of NSLAD, then both test results are typically available within 4 to 5 days. All results are available through a portal, fax, hard copy, or mobile device.

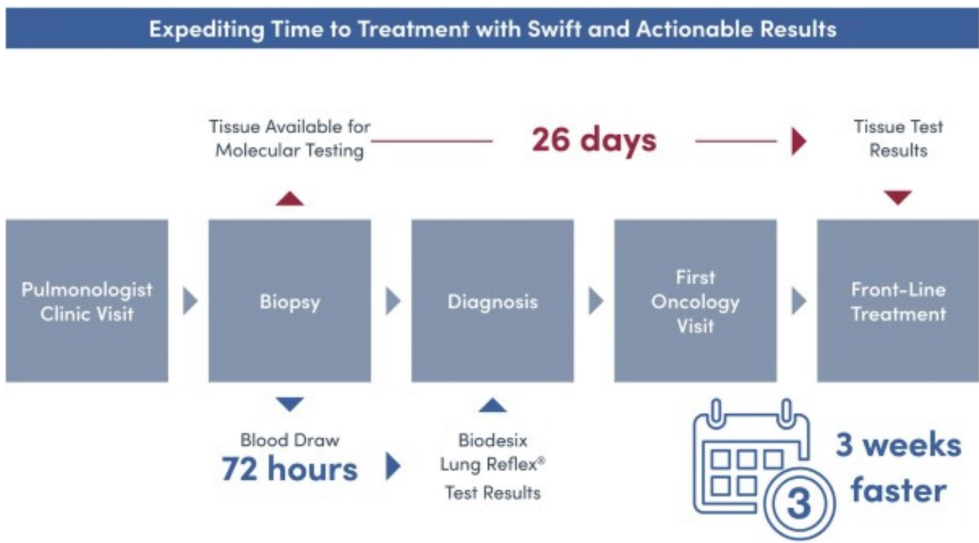
Treatment Guidance and Monitoring

Profiling the tumor through blood-based testing can help identify mutations in genes that may be driving growth of the tumor and may be targets for therapeutics. However, tumors also suppress intrinsic mechanisms that prevent the patient’s immune system from identifying and eliminating the cancer cells. Profiling the immune system can show if the patient’s immune system may have been subverted and therefore, is less likely to be responsive to immunotherapies. Our blood-based Biodesix Lung Reflex testing strategy consists of the GeneStrat tumor profiling test and the VeriStrat immune profiling test, which can be ordered together or separately for patients with NSCLC. Together, the tests typically have a 3-day turnaround time, providing physicians with timely results to facilitate treatment decisions.

GeneStrat

GeneStrat is a blood-based tumor profiling test that detects the guideline recommended, actionable mutations in lung cancer: *EGFR*, *KRAS*, *BRAF*, *EML4-ALK*, *ROS-1*, and *RET*. Physicians can order one or any combination of the gene tests, whichever they deem medically necessary for the individual patient. The presence of a mutation in one of the genes could indicate the patient is a candidate for the associated guideline-recommended targeted therapy. The GeneStrat test performance and potential clinical utility have been published in 3 peer reviewed studies.

GeneStrat test results are typically available within 72 hours from our receipt of the sample in our Boulder, Colorado clinical laboratory. In a study at Eastern Carolina University, it was observed that blood-based testing was up to three weeks faster than tissue-based testing, with tissue-based testing taking a median of 26 days from sample collection. With GeneStrat testing, results are typically available in time for the patient’s first oncology visit, allowing the patient to start front-line treatment as quickly as possible. In the same study, it was observed that only 4% of patients had tissue-based molecular test results prior to start of front-line treatment. Meanwhile, after integrating Biodesix Lung Reflex testing at the institution, 72% of patients had molecular test results available. Testing with the GeneStrat test can help physicians identify driver mutations quickly to help speed up time to treatment.



We believe that rapid, blood-based tumor profiling with the GeneStrat test is complementary to both targeted tissue-based testing (including PD-L1) and broad genomic sequencing. Testing with GeneStrat at diagnosis can help quickly identify patients who are eligible for targeted therapies. Additionally, blood-based testing upfront can help save valuable tissue for diagnostic evaluation, PD-L1 testing and broad genomic profiling for rare mutations to enroll in clinical trials.



## *VeriStrat*

VeriStrat is a blood-based proteomic test that provides a personalized view of each patient's immune response to their lung cancer. Results help inform physicians whether their patient has a more aggressive cancer and can help with treatment planning. VeriStrat profiles the patient's immune system by measuring eight protein features measured by mass spectrometry and interpreted by a proprietary machine learning-based algorithm to produce either a VeriStrat Good or VeriStrat Poor test result.

The presence of a VeriStrat Poor result indicates the presence of chronic inflammation and a chronic acute phase immune response. A chronic acute phase immune response can trigger the immune system to provide growth factors to the tumor to increase blood flow and tumor growth. The test has been studied in over 85 peer-reviewed and published clinical studies across many different types of therapies such as chemotherapy, targeted therapies, immune therapies, and combinations. The results consistently show the test to be predictive of outcomes, independent of other prognostic factors including PD-L1 expression and performance status. Patients who test as VeriStrat Poor, on average, have an overall survival that is less than half of those who test as VeriStrat Good, independent of treatment type, demonstrating that the test is strongly prognostic. Conversely, patients with a VeriStrat Good test result typically respond better to standard of care treatments than those patients that test as VeriStrat Poor. By using the VeriStrat test for immune profiling, physicians can help identify the patients with an immune status associated with generally poor prognosis who should be treated with alternate therapies or in clinical trials.

GeneStrat requires whole blood and VeriStrat requires a whole blood sample spotted onto our proprietary BCD. Both samples are shipped at ambient temperature and testing is performed in our certified, high-complexity clinical laboratory in Boulder, Colorado. GeneStrat is performed using the ddPCR technology, and the protein features in VeriStrat are measured using matrix-assisted laser desorption/ionization time of flight (MALDI-ToF) mass spectrometry. Results are typically available within 72 hours through a portal, fax, hard copy, or mobile device.

## **COVID-19**

### *Biodesix WorkSafe COVID-19 Testing Program*

In response to the COVID-19 pandemic, through our partnership with Bio-Rad, we commercialized the Biodesix WorkSafe testing program. Our scientific diagnostic expertise, technologies, and existing commercial infrastructure enabled us to rapidly commercialize two diagnostic tests for the SARS-CoV-2 virus that causes COVID-19. The first test is the Bio-Rad SARS-CoV-2 ddPCR test, which is a molecular test intended for detecting active SARS-CoV-2 infection. The test was FDA EUA authorized on May 1, 2020, authorizing performance of the test in laboratories certified under CLIA to perform high complexity tests. The second test is the Platelia SARS-CoV-2 Total Ab test, which is an antibody test intended for detecting a B-cell immune response to SARS-CoV-2, indicating recent or prior infection. The test was FDA EUA authorized on April 29, 2020.

Within a month of initiating our development collaboration with Bio-Rad, we were able to launch two tests for commercial use. We were able to bring these tests to market as fast as possible due to our scientific diagnostic expertise, technologies and existing commercial infrastructure. In addition to our launch agility, we have been able to rapidly scale our laboratory operations for high-volume testing. We remain committed to delivering rapid test results in 24 to 48 hours on average.

Using the Bio-Rad SARS-CoV-2 ddPCR test and the Platelia SARS-CoV-2 Total Ab tests, we operate and have commercialized the Biodesix WorkSafe testing program.

Prior to using the Bio-Rad tests as part of our testing program, we performed feasibility, verification, and validation studies, including developing software for process automation, sample accessioning, data management and reporting, all required to demonstrate the test operated as claimed by the manufacturer and as required by our certifying regulatory agencies for high complexity laboratory testing. We secured independent reference specimens run with EUA tests to validate these tests as fit for diagnostic use in our laboratories. Post-launch development support for these tests have included improvements in on-boarding new personnel, logistics of sample collection, sample receipt and data reporting, all required to support our testing program. Additional releases of the laboratory data management software are ongoing and planned for the foreseeable future.

Our tests are utilized by healthcare providers, including hospitals and nursing homes and are also offered to businesses and educational systems to assist in their back-to-work or back to school strategies. Recently, we announced multiple partnerships for COVID-19 testing, and Colorado Governor Jared Polis announced at a press conference on July 23, 2020 that we will now be supporting wide-spread COVID-19 testing for the State of Colorado. Additionally, we announced a partnership as the official COVID-19 testing partner for the Major League Lacrosse as they competed in their 2020 tournament. We also announced on September 30, 2020 that we will oversee and manage onsite testing and testing validation for the Big Ten Conference athletic competitions.

#### *Bio-Rad SARS-CoV-2 ddPCR test*

The Bio-Rad SARS-CoV-2 ddPCR test, also known as a molecular or viral test, is intended for the qualitative detection of nucleic acid from SARS-CoV-2, the virus that causes COVID-19. The test targets detection of the nucleic acid from SARS-CoV-2 (not from any other viruses or pathogens) in respiratory specimens to identify and isolate infected individuals. Recent studies have shown that ddPCR-based testing is more sensitive than qPCR for detecting SARS-CoV-2, specifically in the reduction of false negative results. In one study, the ddPCR test demonstrated 95% accuracy vs. 47% for other “bulk” RT-PCR technologies used in other molecular tests. Specimens are shipped at ambient temperature or dry ice depending on the viral transport media (VTM) used, and testing is performed using ddPCR in our certified, high-complexity clinical laboratory in Boulder, Colorado. Results are typically available through fax, hard copy, or encrypted email within 24 to 48 hours on average from receipt of the sample.

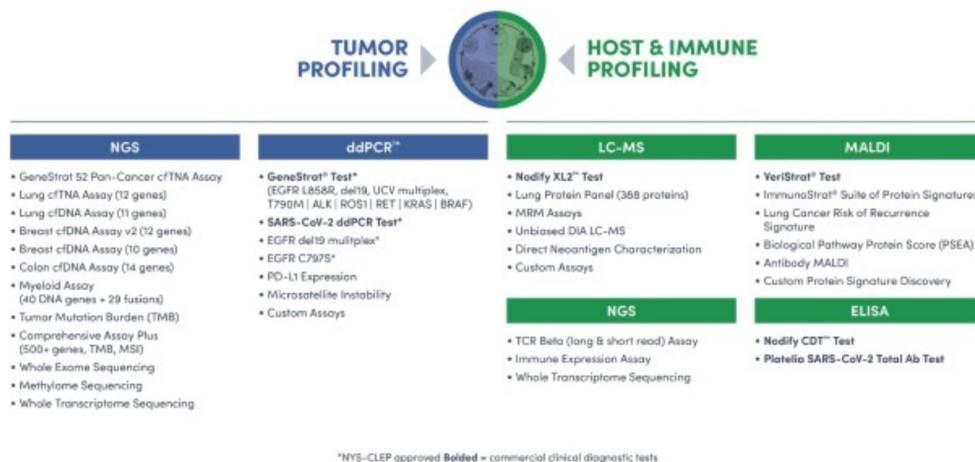
#### *Platelia SARS-CoV-2 Total Ab Test*

The Platelia SARS-CoV-2 Total Ab test (also known as a serology or antibody test) is intended for use as an aid in identifying individuals who have developed an adaptive immune response to the SARS-CoV-2 virus, indicating recent or prior infection. The test uses whole blood to detect circulating antibodies against the virus. The sensitivity is 98% and specificity is 99% eight days after the onset of symptoms. At this time, it is not known how long antibodies persist following infection and if the presence of antibodies confers protective immunity. The test is intended for the qualitative detection of total anti-SARS-CoV-2 nucleocapsid antibodies (IgG, IgM and IgA) in human serum or plasma specimens. The test requires a 3 mL blood draw, and samples are shipped at ambient temperature. Testing is conducted using semi-automated ELISA technology in our certified, high-complexity clinical laboratory in De Soto, Kansas. Results are typically available within 24 to 48 hours from receipt of the sample through fax, hard copy, or encrypted email.

### **Biopharmaceutical Diagnostic Discovery, Development and Testing Services Business**

We believe our leadership in clinical proteomics and our technology agnostic approach to probe the cancer disease state provides our customers with a clear and distinct advantage over other diagnostic service providers who solely focus on either genomics or proteomics. Similar to our commercial clinical testing business, our biopharmaceutical diagnostic discovery, development and testing services business leverages the Diagnostic Cortex to provide an extensively validated and deep learning approach to discovering new biomarkers, which in turn helps drive the clinical development of therapeutics. We recognize each clinical development program is complex, which is why we offer end-to-end diagnostic solutions, ranging from initial biomarker discovery and feasibility projects to commercialization of companion diagnostics.

To address the increasing complexity of disease biology and new drug mechanisms of action, we employ a technology agnostic approach to uncover insights about the tumor biology and patient’s immune response to cancer for therapeutics in clinical development. With our broad technology and service offering, including the performance of over 30 assays for research use as part of our laboratory services (see diagram below), we are able to provide the depth and breadth of biomarker tools for our partners for multi-omic analyses across their product development efforts. Although we recognize the importance of a multi-omic, technology agnostic approach in translational research, we are experts in discovering and developing proteomic-based diagnostic tests to help interrogate the immune profile and host disease state of patients on particular therapeutics. Traditionally, oncology biomarkers have been discovered from tumor tissue, but with the increased trend in the number of programs featuring immuno-oncology agents in therapeutic development, we believe there is a clinical unmet need for blood-based tumor markers and host/immune biomarkers to complement information obtained from tissue.



We believe we provide benefit to our biopharmaceutical customers as they integrate strategies for increasing the probability of success for pivotal clinical trials. Specifically, our diagnostic testing services may help enable quicker enrollment rates for patients in prospective clinical trials, ranging from phase 1 to phase 3, and could help identify patient populations who may experience the greatest benefit from new therapeutics. Ultimately, our goal is to help biopharmaceutical customers realize greater efficiency in their clinical development programs. Additionally, we have the ability to access and leverage our large sample and data biobank for our partners' data mining needs, including new test discovery.

While our biopharmaceutical discovery, diagnostic development and testing revenue continues to grow, it is important to note that we benefit greatly from these partnerships in many ways that expand beyond revenue. We are continuously expanding our knowledge and biological understanding of multiple diseases and the rapidly evolving treatment landscape, while our Diagnostic Cortex continues to be powered through these biomarker analyses. Additionally, our sample and data biobank continue to grow and can be further leveraged for internal test development and external partnering. Importantly, we look to supplement our product development efforts with companion diagnostics as they are developed.

To date, we have over 50 biopharmaceutical customers and academic partners who have utilized our diagnostic tests and services. The following are a few case studies of early-stage biomarker discovery and development with our biopharmaceutical customers.

- **AstraZeneca:** We provided services to AstraZeneca to retrospectively analyze samples from the FLAURA clinical trial (NCT02296125). The goal of this analysis was to interpret and establish the clinical utility of blood-based longitudinal monitoring of EGFR sensitizing and resistance mutations by ddPCR in advanced NSCLC patients treated with osimertinib. The data demonstrated that these circulating DNA mutations could be tracked in blood to interpret the patient's prognosis, and could help AstraZeneca to identify disease progression 3 months (median) in advance of standard imaging.
- **Genentech:** We partnered with Genentech to discover a novel proteomic classifier for advanced NSCLC patients treated with atezolizumab. The test was discovered on a small clinical cohort (n=77) and was independently validated on blinded samples (n=270) from the POPLAR clinical trial (NCT01903993). The validation revealed that the proteomic test was predictive of progression free survival and overall survival for atezolizumab versus the control arm docetaxel. Additionally, an analysis compared the correlation between our proteomic classifier with standard of care biomarkers (PD-L1 expression status and tumor mutation burden), which revealed there was no significant correlation. This implies that our classifier provides unique and valuable information in the treatment of patients with advanced NSCLC. It is our belief that Genentech could use this strategy to identify patients that could derive a longer progression free survival from atezolizumab.

- **Merck KGaA & Pfizer:** We announced the initiation of a clinical phase development program for the anti-PD-L1 checkpoint inhibitor, avelumab with Merck KGaA and Pfizer on February 12, 2020. The new proteomic test was developed through retrospective analysis of the circulating proteome combined with our proprietary AI platform. We have completed initial discovery of the test that identifies likely responders to avelumab and efforts are now focusing on transferring the test into our CLIA lab in Boulder, Colorado for clinical phase test validation.

## Our Competitive Advantages

We believe the following are our key competitive advantages:

- **Our proprietary extensively validated deep learning platform, which is tailored to discover diagnostic tests that address clinical unmet needs.** Our platform is an extensively validated deep learning platform optimized for discovery of diagnostic tests. By combining our data-driven and technology agnostic approach with deep learning techniques, we believe we have overcome many standard machine learning challenges. This has enabled us to develop commercial tests for clinical unmet needs and collaborate with our biopharmaceutical customers and academic partners.
- **Our data-driven approach to precision medicine combined with our biobank, which enables us to accelerate development of new tests.** We have over 140,000 samples and data in our biobank, including tumor profiles and immune profiles, used for both internal and external research and development initiatives. Our biobank, clinical trials, commercial testing and other partnerships provide an ongoing source of new data that further enhances our proprietary AI platform. We are continuously identifying and incorporating new market insights and input from our customers, key opinion leaders, and scientific experts to leverage this data in developing our diagnostic tests.
- **Our leadership in clinical proteomics, demonstrated research, development, and scientific expertise, combined with our intellectual property portfolio.** Our leadership in clinical proteomics and our technology agnostic approach, we believe provides us with a distinct advantage over our competitors, who focus on any single technology, such as genomics or proteomics. Our certified, high-complexity laboratories offer significant advantages in development of commercial tests.
- **Our proprietary technologies and processes are protected by a portfolio of approximately 87 issued patents in the United States and internationally, and 22 uniquely registered United States trademarks.** We take efforts to protect our proprietary position using a variety of methods, such as a pursuit of United States and foreign patent applications related to our proprietary technology, use of trade secrets, trademarks, know-how, continuing technological innovation and potential in-licensing and acquisition opportunities.
- **Our demonstrated success commercializing diagnostic tests in lung disease.** With six diagnostic tests launched and three currently in development, our commercial portfolio of blood-based solutions currently addresses clinical unmet needs within diagnosis, treatment and monitoring of lung cancer. Our diagnostic tests provide rapid, actionable, and holistic diagnostic information to help inform physicians on the next steps in a patient's care plan. We have displayed agility in our R&D and commercial launch efforts and within a month of initiating a development collaboration, launched two diagnostic tests for COVID-19 for commercial use.
- **Our depth and breadth of point of care access to physicians allows us to drive adoption of our diagnostic tests while incorporating real-life feedback to inform new product development.** Our commercial team's primary focus is to articulate the scientific and clinical evidence behind our tests, how they impact clinical care and can ultimately help to improve patient outcomes. Our demonstrated scientific expertise, leadership in clinical proteomics and breadth of data, including peer-reviewed publications, presentations and clinical studies, forms the basis of our relationships with major hospitals and physician networks across the United States.

- **Our commercial infrastructure, which includes our extensive knowledge and experience in sales, marketing, reimbursement and operations, provides us with the ability to launch, scale and drive revenue.** We believe our commitment to commercial excellence helps us to leverage insights, operational excellence and proven approaches to deliver revenue growth and enhance the brand of our company and products. We are able to deploy rapid clinical testing turnaround times and develop commercial tests at scale. Scaling of our test capacity to meet volumes is then achieved by adding instrumentation and qualified personnel to our quality systems.

## Our Strategy

We strive to provide swift, comprehensive and actionable insights to improve patient outcomes across lung disease and to help answer critical clinical questions faced by physicians, researchers, and biopharmaceutical companies. To achieve this, we intend to:

- **Drive increased awareness, adoption, and reimbursement coverage of our diagnostic tests by:**
  - continuously educating physicians, key opinion leaders, hospital systems, advocacy groups, patients, payers, academic research organizations, and technology assessment and guideline organizations on the clinical data and benefits of our tests;
  - utilizing our pulmonology-focused sales force and commercial reach with targeted awareness campaigns to employ highly targeted sales and marketing tactics in pulmonology clinics specializing in the management of lung nodules and the diagnosis of lung cancer;
  - continuing to invest in the expansion of our sales force and commercial support team;
  - incorporating our testing services into diagnostic pathways and protocols via a top-down strategy that introduces our diagnostic tests to the largest United States health systems; and
  - leveraging our clinical data to gain broad coverage from public and private payers for our tests.
- **Deepen our relationships with current biopharmaceutical customers and establish new customer opportunities by:**
  - selling our complete offering of tests and services to biopharmaceutical companies in the United States and internationally;
  - leveraging existing projects and relationships to expand sales with our current biopharmaceutical customers; and
  - targeting companies developing novel companion diagnostic strategies and drug development projects best suited to our platform for new test discovery, development and commercialization.
- **Further demonstrate the clinical utility and economic benefits of our diagnostic tests by:**
  - investing in commercial clinical testing, research studies and clinical trials to further demonstrate the clinical utility of our tests;
  - providing rapid, actionable, and holistic diagnostic information to help inform physicians on the next steps in a patient's care plan; and
  - providing timely and actionable clinical information to help improve overall patient outcomes and lower the overall healthcare cost.
- **Introduce new diagnostic tests in lung disease by:**
  - engaging with our customers, key opinion leaders, and scientific experts to stay ahead of the rapidly evolving diagnostic and therapeutic landscape and to identify additional clinical unmet needs;
  - entering strategic partnerships with biopharmaceutical companies, academic research organizations, technology providers, and other diagnostic companies; and

- developing companion diagnostic tests to support the therapeutics’ regulatory approval and adoption process for our biopharmaceutical customers.
- **Enhance our proprietary AI platform and expand our technology portfolio by:**
  - continuing to invest in R&D capabilities to foster innovation in test discovery and development;
  - identifying, acquiring technologies and integrating new data types into our proprietary AI platform; and
  - entering strategic partnerships across our commercial product portfolio and product development efforts in order to further our development capabilities, accelerate launch of commercial products, or expand our service offering.
- **Continue to expand and leverage our biobank by:**
  - expanding and enhancing the robustness of our samples and the data set, including through our collaborations and partnerships;
  - pursuing commercial opportunities with companies and researchers who are interested in utilizing our biobank for their own discovery and development efforts; and
  - monetizing these commercial opportunities.

## Our Diagnostic Tests in Development

With the goal of finding solutions for clinical unmet needs related to diagnosis, treatment and monitoring in lung disease, our diagnostic tests in development include the following:

### *Early-Stage NSCLC—Risk of Recurrence*

Currently, surgical resection of the tumor without systemic or radiation therapy is standard of care for stage I NSCLC patients. However, 20 to 40% of surgically treated patients will suffer a recurrence within 5 years after surgery. From market research with pulmonologists, thoracic surgeons, and medical oncologists, we identified a significant clinical unmet need for a blood-based test to help identify stage I NSCLC patients who are at a higher risk of recurrence and may benefit from neoadjuvant or adjuvant systemic treatment. With this information, we discovered the Risk of Recurrence (ROR) test, which is a pre-surgery blood-based proteomic test, designed with the Diagnostic Cortex to predict whether a stage I NSCLC patient has a higher risk of recurrence post-surgical resection. Knowing this information early and before surgery may support treatment decisions such as neoadjuvant or adjuvant therapy, which have the potential to reduce tumor volume and address micro-metastatic disease as early as possible. Our ROR test validated in an independent sample set, and we are currently working with major academic institutions across the United States to further validate the test.

### *Late-Stage NSCLC—Immunotherapy Treatment Guidance*

In 2015, the first immunotherapy-based treatment regimen was approved by the FDA for use in lung cancer. Currently, there are 9 immune checkpoint inhibitor (ICI) regimens (single agent or combinations) recommended by the NCCN guidelines for treatment of advanced NSCLC patients. For a portion of patients treated, these drugs can result in significant improvement in overall survival compared with platinum-based chemotherapy options.

The combination ICI regimens see some improvement in performance over single agent ICI, but side effect profiles are worse, and costs are higher than for single agent ICI. In addition, recent data have shown that a subset of patients experience more rapid disease progression on ICI compared with chemotherapy. We utilized the Diagnostic Cortex platform to discover our Primary Immune Response (PIR) test. PIR is a blood-based proteomic test designed to profile a patient’s immune response to their cancer and stratify by who is likely to respond to ICI treatment. Our PIR test has been validated in multiple independent sample sets for advanced stage NSCLC patients treated with single agent ICI, and we are currently working with major academic institutions across the United States to further validate the test in a prospective study called BEACON-Lung.

Blood-based monitoring with our ddPCR technology may offer a feasible method to non-invasively evaluate therapeutic mechanism of action, disease progression, and the emergence of resistance mutations in patients treated with targeted therapies. Our internal validation studies have shown the utility of the GeneStrat *EGFR* ddPCR test in all three of these indications. The test can identify disease progression up to 3 months (median) in advance of standard imaging. Using ddPCR for longitudinal blood-based monitoring of *EGFR* cell-free DNA mutations is a cost-effective testing method while patients are being treated with targeted therapies.

*COVID-19 Viral Infection – Risk of Severe Outcomes*

Despite significant medical advances in the prevention and treatment of COVID-19, the virus continues to place health systems under pressure, with COVID-19 hospitalization rates in the United States exceeding 417 hospitalizations per 100,000 population the week ending January 31, 2021. Better understanding of how to identify which patients are at greatest risk of developing severe lung disease, requiring intubation, or dying from COVID-19 would help inform physicians of the risks and benefits of treatments, target higher risk patients for clinical trials, compare outcomes between patients with similar risk, and prioritize resources in a time of shortage. In partnership with an academic institution, we have developed an artificial intelligence (AI)-based algorithm for clinical decision support to help stratify patients hospitalized with COVID-19 who are likely to require intervention, such as treatment with ventilators, admission to intensive care units, or those patients who may develop acute respiratory distress syndrome (ARDS), versus those who will likely not require intervention. Our COVID-19 AI-based algorithm validated in a blinded, independent study, and uses 26 easily obtainable variables from the emergency department at time of initial evaluation to classify patients, including patient characteristics, vital signs, and readily available laboratory test values. We are working with a United States and International COVID-19 consortia consisting of major academic institutions to perform additional large, blinded, independent validation testing of the classifier and we are currently exploring options for making the algorithm widely available to hospitals for future patient use.

**Clinical Trials**

We are dedicated to continuously publishing and presenting new data on the clinical validation and utility of our diagnostic tests. We have participated in 27 clinical studies, 5 of which are ongoing, and have published over 275 peer-reviewed publications and presentations. The following are our ongoing clinical studies for our diagnostic testing solutions.

*ORACLE Registry Study (NCT03766958)*

The ORACLE registry study was designed to develop real-world clinical utility data for Nodify XL2 and is titled “An Observational Registry Study to Evaluate the Performance of the Nodify XL2 Test”. The study objectives are to show a reduction in invasive procedures on patients with benign nodules compared to a historical control obtained from chart review. The first patient enrolled on October 16, 2018. As of May 1, 2020, 423 patients have been enrolled and are undergoing primary endpoint analysis, with 2-year follow-up estimated to be completed by the first half of 2022.

*ALTITUDE Clinical Utility Study (NCT04171492)*

The ALTITUDE clinical utility study is designed to evaluate the performance of Nodify Lung (Nodify XL2 and Nodify CDT) in a randomized controlled study (RCT). The study is titled “A Multicenter, Randomized Controlled Trial, Prospectively Evaluating the Clinical Utility of the Nodify XL2 Proteomic Test in Incidentally Discovered Low to Moderate Risk Lung Nodules”. We received central investigational review board (IRB) approval in December 2019 and have an enrollment goal of 2,000 patients. The study objectives are to evaluate how the addition of the Nodify Lung test result impacts the clinical decision making for patients with new, incidentally identified solid lung nodules assessed as low to moderate risk of lung cancer. The trial has an adaptive study design with a blinded standard of care arm and 2:1 randomization for open-label results for Nodify XL2. The study launched in December of 2020. Phase 1 of the study with only Nodify XL2 is expected to enroll 500 patients. Phase 2 of the adaptive study design will include an open-label arm for Nodify CDT, which is aligned with our commercial testing algorithm.

The INSIGHT observational study is designed to evaluate the real-world clinical utility and performance of the Biodesix Lung Reflex (GeneStrat and VeriStrat) testing strategy. The title is “Observational Study Assessing the Clinical Effectiveness of VeriStrat and Validating Immunotherapy Tests in Subjects with Non-Small Cell Lung Cancer (INSIGHT)” and the first patient enrolled was on May 11, 2016. To date, we have over 3,500 patients enrolled with a target 5,000 enrollment goal. Final analysis with 3-year follow-up is estimated to be completed by 2024. Results of an interim analysis were presented at ASCO 2020. The study rationale is to guide the adoption of VeriStrat and inform medical decision making, including treatment choice, and enable the validation of additional mass spectrometry-based proteomic tests. The primary study objective is to describe the impact of the VeriStrat test results on treatment decisions, including but not limited to the percentage change in treatment decision, differences in chosen treatments between patients classified as VeriStrat Good and those classified as VeriStrat Poor, and the percentage of patients receiving systemic therapy or supportive therapies only.

*BEACON-Lung Clinical Study (Trial in Progress)*

In partnership with ALCMI (Addario Lung Cancer Medical Institute), the BEACON-Lung clinical study is intended to evaluate the performance and utility of our proteomic product currently in development, PIR, in advanced stage NSCLC patients who express high PD-L1. The study title is “A Biomarker Analysis in High PD-L1 Expressing NSCLC Patients Treated With An Immune Checkpoint Inhibitor (ICI) With or Without Platinum-Based Chemotherapy.” The study design is an observational, multicenter, open-label study to assess biomarkers (serum, microbiome, radiomics and tissue) as predictive of early progression in 390 treatment-naïve patients with advanced stage NSCLC and PD-L1 greater than or equal to 50% treated with two standard of care regimens, triplet therapy (platinum-based chemotherapy plus ICI regimen) and ICI monotherapy (single agent ICI). The objectives are to collect biospecimens and evaluate candidate biomarkers, with a focus on PIR, to detect early progression on ICI monotherapy versus triplet therapy.

*DROPLET (Pending IRB Submission)*

Droplet is an exploratory direct to patient study to assess the utility a novel gene linkage phenomenon as measured by the Bio-Rad SARS-CoV-2 ddPCR test, on the correlative immune response in individuals previously infected with the COVID-19 virus. The primary objective of this study (titled “ddPCR Linkage, Viral Load and Immune Response in Individuals Infected with COVID-19”) is to evaluate the correlation between linkage, viral load and the immune responses in individuals who have had a natural infection with SARS-CoV-2. Fifty patients will be enrolled and serially tested for viral load and immune responses for up to 12 months.

## **Commercialization**

For our lung cancer and nodule management tests, commercial efforts are focused on the promotion of our testing strategies to healthcare professionals actively involved in the diagnosis and treatment of lung cancer. Primarily focusing on pulmonology, the commercial team, consisting of specialty sales representatives, medical affairs, marketing and customer care representatives, works to educate and inform the entire patient care group consisting of physicians, nurses, office staff, laboratory personnel, and administration as to the appropriate use and value provided by our testing. The team’s goal is to drive test adoption through articulating the scientific and clinical evidence behind our tests, how they impact the clinical care of a patient, and how the tests can ultimately help to improve patient outcomes.

Patients with pulmonary nodules are concentrated in this sub-specialty, where additional resources such as lung cancer screening and nodule management clinics may exist to provide an increased level of care. We are also engaging large hospital systems in a “top-down” approach, with a goal of incorporating our tests into system wide pathways and protocols.

After a physician orders our tests, blood is collected either in the physician office or laboratory, third-party “store front” patient service centers, or it can be collected in the patient’s home or workplace. We have contracted with a network of patient service centers and mobile phlebotomy services to be able collection of blood samples outside of the physician office, at home or work for patients across the United States.



For our Bidesix WorkSafe COVID-19 testing program, we have a dedicated outreach team that works with the State of Colorado healthcare providers and hospitals, and employers looking to safely return to work across many industries, including food services, oil and gas, biotechnology and pharmaceuticals, sports teams, universities, and many small businesses. We recognize everyone's COVID-19 situation is unique, which is why we provide end-to-end customized solutions to support testing for our different customers, such as risk assessment tools, physician ordering services, on-site testing, phlebotomy services, shipping logistics, and ongoing client support.

Our business development team is focused on selling our complete offering of tests and services to biopharmaceutical companies in the United States and internationally. Our team consists of customer facing business development associates that work with our biopharmaceutical customers to identify projects, draw up statements of work and negotiate service agreements. Alliance managers help to manage the contractual obligations and scope of the project, whereas our operations team assures the project is managed with adequate resources and delivers on time. We take a two-pronged approach generating business in this segment. Primarily, we leverage existing projects and relationships to expand sales in current accounts. We also actively map ongoing drug development projects in biopharmaceutical companies and target programs best suited to our platform for new test development.

## **Coverage and Reimbursement**

The primary source of reimbursement for our tests in the United States is from third-party payers including government payers, such as Medicare, and commercial payers, such as insurance companies. For our COVID-19 testing program, the primary source of reimbursement is through contracts with hospitals, companies providing wellness testing for their employees, or direct pay from patients. We believe that our lung cancer tests can both improve patient outcomes and help guide cost-effective treatment choices for patients with and at-risk of lung cancer. Achieving broad coverage and adequate reimbursement for each of our tests is a key component of our financial success and will continue to be important over time.

Under the Families First Coronavirus Response Act (FFCRA) and Coronavirus Aid, Relief, and Economic Security Act (CARES), Congress has imposed a broad requirement that Medicare fee-for-service, Medicare Advantage, Medicaid, and commercial payers generally cover clinical diagnostic laboratory tests administered during the Public Health Emergency for the detection of SARS-CoV-2 or the diagnosis of the virus that causes COVID-19. Where applicable, the FFCRA and CARES require payers to cover COVID-19 tests without cost sharing or medical management techniques like prior authorization. Medicare fee-for-service does not require cost sharing or prior authorization for any clinical diagnostic laboratory tests.

The Department of Health & Human Services (HHS) has indicated in guidance that the coverage requirements of the FFCRA and CARES can apply both to infection and serological testing, but that they are only applicable to testing that is "diagnostic," which "may include testing of individuals with signs or symptoms compatible with COVID-19, as well as asymptomatic individuals with known or suspected recent exposure to SARS-CoV-2." Testing that is "not primarily intended for individualized diagnosis or treatment of COVID-19 or another health condition," including "testing conducted to screen for general workplace health and safety," is beyond the scope of the statutory coverage requirements. We believe these coverage requirements apply to the Bio-Rad SARS-CoV-2 ddPCR test and the Platelia SARS-CoV-2 Total Ab test when performed for diagnostic purposes. In some cases, we submit claims to insurance payers for the Bio-Rad SARS-CoV-2 ddPCR test and/or the Platelia SARS-CoV-2 Total Ab test. In these cases, insurance payers may have a different position on the scope of mandatory coverage of our tests under the FFCRA and CARES. More commonly, we enter into arrangements with clients under which the client pays us directly for testing.

Compliance with applicable laws and regulations, as well as internal compliance policies and procedures adds complexity to the billing process. The Centers for Medicare & Medicaid Services (CMS) is responsible for overseeing the establishment of new Healthcare Common Procedure Coding System (HCPCS) codes for billing the Medicare program and other payers. CMS continuously evaluates and implements changes to the Medicare billing, coding, and reimbursement processes. To receive reimbursement from third-party payers, we bill our tests using a variety of HCPCS codes or Current Procedural Terminology (CPT) codes, as defined by the American Medical Association. For some of the tests we conduct, there may not be a specific CPT or HCPCS code, in which case the test may be billed under a miscellaneous code for an unlisted molecular pathology procedure or unlisted multiple analyte test with algorithmic analysis (MAAA) procedure. Because these miscellaneous codes do not describe a specific service, the third-party payer claim may be examined to determine the service provided, whether the service was appropriate and medically necessary and whether payment should be rendered. This process can result in a delay in processing the claim, a lower reimbursement amount, and/or denial of the claim.

## **Competitors**

We primarily face competition from lung cancer diagnostic solutions companies in the United States, Europe and Asia seeking to answer clinical questions in the space, all of whom provide cancer-focused diagnostic tests to hospitals, researchers, clinicians, laboratories and other medical facilities.

### ***Diagnosis—Nodule Management***

We are not aware of any other company that offers two commercial blood-based tests to help physicians reclassify risk of malignancy in patients with suspicious lung nodules. We are aware of efforts by Veracyte, Inc. to develop and validate a test that may be competitive to the Nodify XL2 and/or Nodify CDT tests in the future. Additionally, Veracyte currently markets a test that is used post-bronchoscopy that is not competitive with our pre-bronchoscopy nodule risk assessment tests.

### ***Prognosis, Treatment Guidance and Monitoring—NSCLC***

We are unaware of any other diagnostic test available, commercially or in development, that will compete with our VeriStrat immune profiling test. There is substantial interest and activity in tumor profiling through liquid biopsy. Our genomic test offering, GeneStrat, faces competition from academic hospital laboratories, and companies such as Guardant Health and Foundation Medicine. We believe that there are several companies and academic research institutions in the process of developing tests for monitoring patients on or following treatment for recurrence or progression of lung cancer.

### ***COVID-19 Testing***

We believe that our competitors include university and state laboratories, national reference laboratories such as Lab Corporation and Quest Diagnostics, in-hospital laboratories, and a number of other diagnostic providers. We are aware that a number of other companies have announced development efforts to develop COVID-19 tests.

### ***Biopharmaceutical Diagnostic Discovery, Development & Testing Services***

We are aware of a number of companies who compete with our diagnostic tests and services, including diagnostic research, clinical trial testing, and the discovery, development, and commercialization of companion diagnostics. From the perspective of tumor profiling, we believe Guardant Health and Foundation Medicine are our most significant competitors. Conversely, in the immune profiling market, we believe Adaptive Biotechnologies and Personalis are our most significant competitors.

## **Clinical Laboratory Operations**

We perform the VeriStrat, GeneStrat, and COVID-19 ddPCR tests in our Boulder, Colorado clinical laboratory. The laboratory is CAP-accredited, CLIA-certified, New York Department of Health (NYSDOH)—permitted and licensed, ISO 13485:2016 Quality Management Systems—Requirements for Regulatory Purposes for Medical Devices certified, along with all other states that require licensing: California, Maryland, Pennsylvania, and Rhode Island. All aspects of the testing process from receipt of the test requisition form through to delivery of test results are performed in the Boulder, Colorado facility. The proprietary testing methods use semi-automated workflows that facilitate the successful delivery of greater than 90% of our tests within 3 days, and we believe our existing workflows will continue to successfully deliver our tests within this timeframe.

The Nodify XL2, Nodify CDT, and COVID-19 total antibody tests are performed in our De Soto, Kansas clinical laboratory. This clinical laboratory is CLIA-certified, COLA-accredited, New York Department of Health—permitted and licensed, and licensed by California, Maryland, Pennsylvania, and Rhode Island. Efforts are underway with the NYSDOH to become permitted and licensed to perform Nodify XL2 and Nodify CDT testing for samples from the state of New York. Receipt of requisitions and testing is performed in our De Soto, Kansas clinical laboratory. Delivery of the test results is performed by personnel from our Boulder, Colorado headquarters. The proprietary testing methods use semi-automated workflows that facilitate the successful delivery of greater than 90% of our tests within 5 days, and we believe our existing workflows will continue to successfully deliver our tests within this timeframe.

Personnel in both facilities are responsible for quality assurance oversight, licensing, and regulation compliance and maintenance to ensure data integrity and consistent, validated processes.

## Supply Chain

We rely on third-party suppliers, including in some instances single source suppliers, to provide us with certain components of our diagnostic tests. The number of suppliers feeding into the production of our diagnostic tests is in excess of 65 worldwide. We consider a select few of these suppliers, located in the United States, Europe and China, as critical single source providers of components. Bio-Rad, as described below, is the sole source supplier for our GeneStrat test and COVID-19 and antibody testing program. Oncimmune is also the sole source supplier for our Nodify CDT tests but there are known secondary suppliers for these materials. We have initiated the second source qualification process for the majority of these critical components.

In addition, we purchase supplies through purchase orders without long-term supply agreements with, or guaranteed commitments from, many of our suppliers, including single source suppliers. Additionally, at present, we rely on contract manufacturers for the production of our diagnostic tests. We depend on our suppliers and contract manufacturers to provide us and our customers with materials in a timely manner that meet our and their quality, quantity and cost requirements.

We entered into a nonexclusive license and supply agreement with Bio-Rad in August 2019. We rely on Bio-Rad to supply equipment and reagents used to perform ddPCR testing, a service offered by us under a variety of fee for service agreements and the core technology powering the GeneStrat test, but these supplies are able to be supplied by known suppliers. A disruption to this supply would negatively impact our ability to perform the GeneStrat and SARS-CoV-2 tests until alternatives could be validated.

While we have initiated the second source qualification process for the majority of these critical components, we may not be successful in securing second sourcing for all of them at all or on a timely basis. A disruption to this supply would negatively impact our ability to perform these tests until an alternative supplier could be validated.

All materials for our VeriStrat test and Nodify XL2 tests have alternative suppliers readily available, and a disruption in any single supplier would not materially impact our ability to deliver the test.

The COVID-19 pandemic has allowed us to pressure-test our supply chain and logistics processes as we purchased additional manufacturing capacity above our normal run rates to ensure that supply to execute on tests for the foreseeable future was available in-stock and in-house. Our suppliers have been able to allocate sufficient capacity to meet this increased demand with reasonable lead times and therefore we believe sufficient capacity exists for all tests for the next 24 months.

## Intellectual Property

Our success depends, in part, on our ability to obtain and maintain intellectual property and proprietary protection for our products and other know-how, to operate our business without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of others, and to defend and enforce our intellectual property and proprietary rights. We take efforts to protect our proprietary position using a variety of methods, which include pursuit of United States and foreign patent applications related to our proprietary technology, inventions and improvements that we determine are important to our business. We also may rely on trade secrets, trademarks, know-how, continuing technological innovation and potential in-licensing and acquisition opportunities to develop and maintain our proprietary position. For more information regarding risks relating to intellectual property, please see “Risk Factors—Risks Related to Our Intellectual Property.”

We have invested heavily in the protection of our key assets, namely the VeriStrat® and GeneStrat® tests, and we acquired a patent portfolio relating to the Nodify XL2® and Nodify CDT™ tests in our acquisitions of Integrated Diagnostics in June 2018, and of Oncimmune USA in October 2019 from Oncimmune Limited (Oncimmune). We own patents and patent applications as well as trade secrets relating to our products currently in development, collection device for whole blood, business strategy, client lists and business methods. Further, we have expanded our access to key intellectual property through license and co-development agreements, including our Non-Exclusive License Agreement with Bio-Rad (the Bio-Rad License), which allows us to use the Droplet Digital PCR™ technology developed by Bio-Rad and which we employ in our GeneStrat test.

Our patent strategy has focused on creating and acquiring protection for our VeriStrat and Nodify XL2 proteomic tests, while utilizing trade secret and some methods patent protection for our genomic test (the GeneStrat test) and ELISA test (the Nodify CDT test). We have entered into a non-exclusive license agreement with Bio-Rad, without the right to grant sublicenses, to utilize certain of Bio-Rad's intellectual property, machinery, materials, reagents, supplies and know-how necessary for the performance of ddPCR in cancer detection testing for third parties in the United States. For more information regarding this license and supply agreement, please see "—Material Agreements—Agreements with Bio-Rad." Bio-Rad owns patents relating to ddPCR and to which we have a non-exclusive license to utilize for the performance of ddPCR in cancer detection testing for third parties as set forth in the Bio-Rad License Agreement. In addition, we have separately been granted permission by Bio-Rad to use the Bio-Rad SARS-CoV-2 ddPCR test and Platelia SARS-CoV-2 Total Ab test for commercial diagnostic services. For more information regarding the permission granted to us by Bio-Rad with respect to such tests, please see "Business—Material Agreements—Agreements with Bio-Rad." We are unaware of patents owned by Bio-Rad relating to its COVID-19 antibody test but acknowledge that Bio-Rad has know-how and trade secrets relating to this test. We have patent protection in the United States and other countries around the world for the primary use of the VeriStrat test for profiling of patients with NSCLC, and various other uses of the VeriStrat test, such as breast cancer, prostate cancer, head and neck cancer have received patent protection. We have also received patent protection relating to our core classifier development program, our Diagnostic Cortex® technologies and our approaches to using mass shot matrix-assisted laser desorption time of flight (MALDI-ToF) technology (DeepMALDI® techniques). Additionally, our first device patent was issued in 2019 for our internally designed blood collection device.

As of October 21, 2020, our patent portfolio includes approximately 49 issued United States patents, 38 issued foreign patents, which includes 3 European patents that were nationalized in multiple European countries, and 40 pending applications (including 23 foreign patent applications). With regard to our product development efforts, provisional applications have been filed around new developments relating to ARDS and COVID diagnostics, and national stage applications are now in active prosecution to protect our ROR and PIR tests.

The patent portfolio can be broken down into 5 categories:

- 1) Issued patents and patent applications relating to the VeriStrat and Nodify tests and uses of these tests;
- 2) Issued patents and patent applications relating to methods for developing classifiers using the Diagnostic Cortex and DeepMALDI technologies;
- 3) Issued patents and patent applications relating to tests currently in development;
- 4) Issued patents and patent applications relating to our novel blood collection device; and
- 5) Issued patents and patent applications relating to tests developed for our third-party partners.

The patents relating to the VeriStrat test are scheduled to expire between 2026 and 2032. The patents relating to the Nodify XL2 test are scheduled to expire beginning in 2031 (excluding any patent term extension granted by the USPTO), and the patents relating to the Nodify CDT test are scheduled to expire in 2027. The patent related to the blood collection device is scheduled to expire in 2039. Should our current patent applications in prosecution in the United States issue, the resulting patents would be scheduled to have expiration dates between 2036 and 2040 (excluding any patent term extension(s) granted by the USPTO).

While we do not currently have any pending PCT applications, we often convert provisional patent applications to PCT applications. PCT patent applications are not eligible to become issued patents until, among other things, we file such PCT applications as national stage patent application(s) within 30 months in the countries in which we seek patent protection. If we do not timely file any national stage patent applications, we may lose our priority date with respect to any such PCT patent applications and any patent protection on the inventions disclosed in such PCT patent applications. Provisional patent applications are not eligible to become issued patents but can become the basis of PCT foreign stage and United States non-provisional patent applications, if such applications are filed within 12 months of filing the related provisional patent application. If we do not timely file any non-provisional patent applications, we will lose our priority date and any patent protection on the inventions disclosed in any such provisional patent application.

In addition, the term of individual issued patents depends upon the legal term for patents in the countries in which they are obtained. In most countries in which we have filed, including the United States, the patent term is generally 20 years from the earliest filing date of a non-provisional patent application, assuming the patent has not been terminally disclaimed over a commonly-owned patent or a patent naming a common inventor, or over a patent not commonly owned but that was disqualified as prior art as the result of activities undertaken within the scope of a joint research agreement. The life of a patent, and the protection it affords, is therefore limited and once the patent lives of our issued patents have expired, we may face competition, including from other competing technologies. In the United States, the term of a patent may also be eligible for patent term adjustment for delays within the USPTO. The term of a patent that covers a biological product may also be eligible for patent term extension when FDA approval is granted for a portion of the term effectively lost as a result of the FDA regulatory review period, subject to certain limitations and provided statutory and regulatory requirements are met. Any such patent term extension can be for no more than five years, only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval, and only those claims covering the approved biological product, a method for using it or a method for manufacturing it may be extended. We may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. There can be no assurance that we will benefit from any patent term extension or favorable adjustment to the term of any of our patents. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Our ability to maintain and solidify our proprietary and intellectual property position will depend on our success in obtaining effective patent claims and maintaining and enforcing claims that are granted. However, our owned and licensed patents could be invalidated or narrowed or otherwise fail to adequately protect our proprietary and intellectual property position and our pending owned and licensed patent applications, and any patent applications that we may in the future file or license from third parties, may not result in the issuance of patents.

Because branding is as much a part of any intellectual property strategy as patent or trade secret protection we have a number of registered and pending trademarks relating to our company and products. We have received or filed for trademark protection in the United States for our tradename (Biodesix), the names of four of our commercial tests (namely the VeriStrat, GeneStrat, Nodify XL2 and Nodify CDT tests), and a suite of research tests (ImmunoStrat), as well as having trademark protection for our core development and methodological platforms, such as our Diagnostic Cortex and DeepMALDI technologies. In all, as of September 21, 2020, we have 22 uniquely registered United States trademarks 10 of which (including Biodesix, VeriStrat, and GeneStrat) have received foreign issuances as well. We will continue to pursue protection in the United States and abroad for our branded assets and will continue to use branding to protect products currently in development, key Biodesix developments and non-trade secret methodologies.

We also rely on trade secrets, including know how, confidential information, unpatented technologies and other proprietary information, to strengthen or enhance our competitive position, protect and maintain aspects of our business that are not amenable to, or that we do not presently consider appropriate for, patent protection, and prevent competitors from reverse engineering or copying our technologies. We have decided that some technologies, such as our laboratory methodologies (including sample preparation and assay development), and some information (such as client and billing information) are best kept as trade secrets. However, trade secrets and confidential know-how are difficult to protect. To avoid inadvertent and improper disclosure of trade secrets, and to avoid the risks of former employees using these trade secrets to future employment, it is our policy to require employees, consultants and independent contractors to assign all rights to intellectual property they develop in connection with their employment with or services for the Company to the Company. We also protect our existing and developing intellectual property expressly through confidentiality provisions in agreements with third parties. There can be no assurance, however, that these agreements will be self-executing or otherwise provide meaningful protection for our trade secrets or other intellectual property or proprietary information, or adequate remedies in the event of unauthorized use or disclosure of such trade secrets or other intellectual property or proprietary information.

We also seek to preserve the integrity and confidentiality of our trade secrets and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in the measures we take to protect and preserve our trade secrets, such measures can be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors.

We intend to pursue additional intellectual property protection to the extent we believe it would advance our business objectives, which may include objectives within and outside the United States. Despite our efforts to protect our intellectual property rights, and despite the breadth of protection that has issued around our key assets, these rights may not be respected in the future or may be circumvented or challenged (and potentially invalidated) in a legal proceeding in any jurisdiction where we have intellectual property rights. In addition, the laws of various foreign countries where we have received intellectual property protection and where we may eventually distribute our products may not afford the same protections or assurances to the same extent as the laws in the United States. See “Risk Factors—Risks Related to Our Intellectual Property” for additional information regarding these and other risks related to our intellectual property portfolio and their potential effect on us.

## Government Regulations

Clinical laboratory tests like our diagnostic tests are regulated under CLIA and State law. The FDA regulates medical devices pursuant to the FDCA, including many diagnostic test kits, such as IVDs. However, most LDTs are not currently subject to the FDA’s regulation (although reagents, instruments, software or components provided by third parties and used to perform LDTs may be subject to such regulation) because the FDA has historically exercised enforcement discretion over LDTs. LDTs are a subset of in vitro diagnostic (IVD) tests that are intended for clinical use and developed, validated, and offered within a single laboratory for use only in that laboratory. FDA’s authority to regulate LDTs has been contested for many years, and there have been several legislative and administrative proposals regarding LDT regulation seeking to end or limit enforcement discretion and to bring LDTs under new or existing FDA regulatory frameworks:

- On July 9, 2012, Congress passed legislation in the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA) requiring the agency to notify the Committee on Health, Education, Labor, and Pensions and the House Committee on Energy and Commerce of its intent to regulate LDTs. This law, though enacted, had a 5-year sunset provision, meaning that FDA is no longer subject to this notification requirement.
- In October 2014, the FDA issued two draft guidance documents: *Framework for Regulatory Oversight of Laboratory Developed Tests*, which provided an overview of how the FDA would regulate LDTs through a risk-based approach, and *FDA Notification and Medical Device Reporting for Laboratory Developed Tests*, which provided guidance on how the FDA intended to collect information on existing LDTs, including adverse event reports. In the Framework for Regulatory Oversight draft guidance, the FDA asserted that LDT manufacturers would be subject to medical device premarket submission, registration, listing, and adverse event reporting requirements phased in over several years based on which tests posed the highest risk to public health.
- On November 18, 2016, however, the FDA announced that it would not release the final guidance and would instead continue to work with stakeholders, the new administration, and Congress to determine the right approach.
- On January 13, 2017, the FDA released a discussion paper on possible approaches to regulate LDTs in which it described a policy wherein previously marketed LDTs would not be expected to comply with most or all FDA oversight requirements, except for adverse event and malfunction reporting. In addition, certain new and significantly modified LDTs would not be expected to comply with pre-market review unless the agency determines certain tests could lead to patient harm.
- In March 2017, the draft Diagnostic Accuracy and Innovation Act (DAIA) was introduced and outlined a risk-based regulatory approach for in vitro clinical tests (IVCT), i.e., all IVDs regardless of whether they are commercially distributed diagnostic kits or LDTs.
- In April 2017, the FDA issued a document describing 20 case studies of LDTs that raised concerns about the safety and efficacy of this category of tests.
- In August 2018, the FDA responded to the DAIA draft with its own proposal for IVCTs, including PMA, provisional approval, and precertification, in addition to authority to revoke approval, request raw data, and take corrective action against test developers to protect public health.

- On October 31, 2018, the FDA issued its Safety Communication entitled “The FDA Warns Against the Use of Many Genetic Tests with Unapproved Claims to Predict Patient Response to Specific Medications” alleging that the agency was “aware” of healthcare providers making “inappropriate changes to a patient’s antidepressant medication based on the results from genetic tests.” Following this Safety Alert, the FDA contacted several laboratories that offered tests that made claims regarding drug responses for specific medications. While most laboratories addressed the FDA’s concerns by removing specific medication names from their labeling, the FDA issued an enforcement letter against a laboratory for making such claims without first undergoing the FDA premarket review.
- In December 2018, a new draft bill which revised the DAIA and incorporated feedback from the FDA was released. The Verifying Accurate, Leading-edge, IVCT Development (VALID) Act creates a risk-based regulatory framework for IVCT regulation. Under the VALID Act framework, premarket review would be required for certain higher risk tests, while lower risk tests would be subject to a precertification pathway.
- On April 4, 2019, the FDA issued a warning letter to Inova Genomics Laboratory for its pharmacogenomics tests, i.e., tests that predict medication response, among other things. In this letter, the FDA rebutted Inova’s argument that it believed it was operating within the scope of FDA’s LDT exemption and not subject to the FDA’s premarket review or labeling requirements by noting that the FDA has not created a legal “carve-out” or exemption for LDTs and that it ultimately retains discretion to take action when appropriate.
- On March 5, 2020, identical versions of the VALID Act were introduced in both chambers of Congress. The same day, the House bill was referred to the House Committee on Energy and Commerce.
- On August 19, 2020, HHS announced a new policy determining that FDA must engage in notice-and-comment rulemaking before requiring premarket review of LDTs.
- On Nov. 16, 2020, HHS directed FDA to review voluntarily submitted EUAs for LDTs; if FDA’s review time exceeds 14 days, the submission would be referred to the National Institute of Health National Cancer Institute and also to other scientific government agencies, or to outside technical contractors if FDA remains unable to conduct the reviews.

We currently market our GeneStrat, VeriStrat, Nodify XL2 and Nodify CDT tests as LDTs in the United States. As a result, we believe our diagnostic services are not currently subject to the FDA’s enforcement of its medical device regulations and the applicable FDCA provisions. If the FDA disagrees with the LDT status of any of our tests, the FDA may consider the test to be an unapproved medical device and may subject us to FDA enforcement action, including, without limitation, requiring us to seek clearance, authorization or approval for the laboratory test. If the FDA were to begin enforcement with respect to our LDTs, we could incur substantial costs and delays associated with trying to obtain pre-market clearance or approval and costs associated with complying with post-market requirements.

To date, the FDA has not engaged in notice-and-comment rulemaking or released broad-sweeping guidance, but it could choose to do so in the future and if pre-market review is required, our business could be negatively impacted as a result of commercial delay that may be caused by the new requirements. The cost of conducting clinical trials and otherwise developing data and information to support pre-market applications may be significant. If we are required to submit applications for our currently marketed tests, we may be required to conduct additional studies, which may be time-consuming, costly and could result in our currently-marketed tests being withdrawn from the market. Continued compliance with the FDA’s regulations would increase the cost of conducting our business, and subject us to heightened regulation by the FDA including penalties for failure to comply with these requirements. Failure to comply with applicable regulatory requirements could result in an enforcement action by the FDA, such as fines, product suspensions, warning letters, recalls, injunctions and other civil and criminal sanctions. There are other regulatory and legislative proposals that would increase general FDA oversight of clinical laboratories and LDTs. Until the FDA finalizes its regulatory position regarding LDTs, or the VALID Act or other legislation is passed reforming the federal government’s regulation of LDTs, it is unknown how the FDA may regulate our tests in the future and what testing and data may be required to support any required clearance or approval. The outcome and ultimate impact of such proposals on the business is difficult to predict at this time and we are monitoring developments and anticipate that our products will be able to comply with requirements that may be imposed by the FDA. In the meantime, we maintain our CLIA accreditation, which permits the use of LDTs for diagnostics purposes.

## FDA Emergency Use Authorization

Section 564 of the FDCA allows the FDA to authorize the shipment of drugs, biological products, or medical devices that either lack required approval, licensure, or clearance (unapproved products), or are approved but are to be used for unapproved ways to diagnose, treat, or prevent serious diseases or conditions in the event of an emergency declaration by the HHS Secretary. 21 U.S.C. § 360bbb-3(a)(1)-(2).

On February 4, 2020, HHS Secretary Alex M. Azar II declared a public health emergency for COVID-19, under 21 U.S.C. § 360bbb-3(b)(1), justifying the authorization of emergency use of IVDs for detection and/or diagnosis of COVID-19. This determination was published in the Federal Register on February 7, 2020. 85 Fed. Reg. 7316 (Feb. 7, 2020).

While this emergency declaration is effective, the FDA may authorize the use of an unapproved product or an unapproved use of an approved product if it concludes that:

- an agent referred to in the emergency declaration could cause a serious or life-threatening disease or condition;
- it is reasonable to believe that the authorized product may be effective in diagnosing, treating, or preventing that disease or condition or a serious or life-threatening disease or condition caused by an approved product or a product marketed under an EUA;
- the known and potential benefits of the authorized product, when used for that disease or condition, outweigh known and potential risks, taking into consideration the material threat of agents identified in the emergency declaration;
- there is no adequate, approved, and available alternative to the authorized product for diagnosing, preventing, or treating the relevant disease or condition;
- any other criteria prescribed by the FDA is satisfied. *Id.* § 360bbb-3(c).

Medical products that are granted an EUA are only permitted to commercialize their products under the terms and conditions provided in the authorization. The FDA may revoke an EUA where it is determined that the underlying health emergency no longer exists or warrants such authorization, if the conditions for the issuance of the EUA are no longer met, or if other circumstances make revocation appropriate to protect the public health or safety, and we cannot predict how long the EUAs for the SARS-CoV-2 tests will remain in place.

The Bio-Rad SARS-CoV-2 ddPCR test and the Platelia SARS-CoV-2 Total Ab test have been granted FDA EUA pursuant to the current emergency declaration. We have completed all required performance verification studies to validate the use of the tests in our laboratories in accordance with the FDA Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency, CAP and New York State Clinical Laboratory Standards of Practice (NYS CLEP) requirements. The FDA Policy for COVID-19 tests is a guidance document that explains the FDA's current thinking on the topic, is subject to change, and does not establish any legally enforceable responsibilities. As stated in the FDA's Policy for COVID-19, the FDA does not expect a separate notification or EUA request from laboratories that are performing testing using EUA-authorized test kits purchased from commercial manufacturers or their distributors. According to the FDA Policy for COVID-19 tests, a laboratory may make certain modifications to an EUA-authorized test if the modified test is validated using a bridging study without submitting an EUA amendment or formal notification. A laboratory may modify an EUA authorized test for use of a new specimen through a bridging study when the new specimen type has been previously authorized for another test of the same technology without submitting an EUA amendment or formal notification.

## Federal and State Laboratory Licensing Requirements

The Biodesix Boulder, Colorado clinical laboratory is a College of American Pathology (CAP)-accredited clinical laboratory regulated by CMS pursuant to CLIA. CMS has granted CAP deeming authority under CLIA, which allows CAP to inspect laboratories in lieu of CMS. In addition to holding a CLIA Certificate and CAP laboratory accreditation, Biodesix's Quality Management System (QMS) holds an ISO 13485:2016 certificate. The Biodesix Boulder, Colorado clinical laboratory has received approval from The New York State Department of Health (NYSDOH), New York State Clinical Laboratory Evaluation Program (NYS CLEP) in Soluble Tumor Markers and Molecular, Cellular Tumor Markers as well as holding state permits and licenses in California, Maryland, New York, Pennsylvania, and Rhode Island.



CLIA regulations establish standards for proficiency testing; facility administration; general laboratory systems; pre-analytic, analytic systems, post-analytic systems; personnel qualifications and responsibilities; quality control, quality assessment; and specific provisions for laboratories performing moderate to high complexity tests. Our Boulder, Colorado clinical laboratory is inspected biennially as part of its ongoing certification under CLIA certificate of accreditation by CAP. The Boulder, Colorado clinical laboratory most recently passed its CAP inspection in February 2019.

Under CLIA, a laboratory is any facility that performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease, or the impairment of or assessment of health. CLIA requires that a laboratory hold a certificate applicable to the type of laboratory examinations it performs and that it complies with, among other things, standards covering operations, personnel, facilities administration, quality systems and proficiency testing, which are intended to ensure, among other things, that clinical laboratory testing services are accurate, reliable and timely.

The Biodesix De Soto, Kansas clinical laboratory is a COLA-accredited clinical laboratory regulated by CMS pursuant to CLIA. COLA Inc. (COLA) was founded in 1988 as a private alternative to help laboratories stay in compliance with CLIA. In 1993, the Health Care Financing Administration (now CMS) granted COLA deeming authority under CLIA, and in 1997 The Joint Commission also recognized COLA Inc.'s laboratory accreditation program. The De Soto, Kansas clinical laboratory is inspected biennially by COLA. The De Soto, Kansas clinical laboratory most recently passed inspection in August 2019. The De Soto, Kansas clinical laboratory also holds state permits and licenses in California, Maryland, New York, Pennsylvania, and Rhode Island.

The International Organization for Standardization (ISO) is an independent, non-governmental international organization that defines world-class specifications for products, services and systems, to ensure quality, safety and efficiency. ISO 13485:2016 is a harmonized, international regulatory benchmark for quality management systems that addresses most or all of the QMS requirements in markets including the United States, European Union, Australia, Japan and Canada. The ISO 13485:2016 certificate confirms that an organization operates a QMS that conforms to the standards established by ISO. The FDA has proposed a rule to harmonize and modernize its QSR, which would supplant the existing requirements with ISO 13485:2016 although this rule has been delayed several times spring 2018. In February 2021, we passed an ISO 13485:2016 inspection.

To renew our CLIA certificate, we are subject to survey and inspection every two years to assess compliance with program standards. Laboratories such as ours, which are performing high complexity testing, are required to meet more stringent CLIA requirements than laboratories performing less complex tests, and therefore our laboratories are also subject to random, unannounced survey and inspection at any time. In addition, a laboratory that is certified as "high complexity" under CLIA may develop, manufacture, validate and use proprietary LDTs. CLIA requires analytical validation including accuracy, precision, specificity, sensitivity and establishment of a reference range for any LDT used in clinical testing. 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.

CLIA provides that a state may adopt laboratory regulations that are more stringent than those under federal law, and a number of states have implemented their own more stringent laboratory regulatory requirements. State laws may require that out-of-state laboratories maintain an in-state laboratory license to perform tests on samples from patients who reside in that state. As a condition of licensure, certain states may require that laboratory personnel meet qualifications, quality control procedures, facility requirements, record maintenance requirements or other state-specific requirements.

Because our Boulder, Colorado clinical laboratory is located in the State of Colorado, we do not need a specific State of Colorado laboratory license, however, we maintain licenses to conduct testing in other states where nonresident laboratories are required to obtain state laboratory licenses. We maintain licenses for our Boulder, Colorado and De Soto, Kansas laboratories with the New York State Dept. of Health (NYSDOH). We also hold licenses in other states in which we operate, including California, Maryland, Pennsylvania and Rhode Island, that require licensing of out-of-state laboratories under certain circumstances. Other states may currently have or adopt similar licensure requirements in the future, which may require us to modify, delay or stop its operations in those states until such requirements are met.

Failure to comply with CLIA certification and state clinical laboratory licensure requirements may result in a range of enforcement actions, including certificate or license suspension, limitation, or revocation, directed plan of action, onsite monitoring, civil monetary penalties, criminal sanctions, and revocation of the laboratory's approval to receive Medicare and Medicaid payment for its services, as well as significant adverse publicity.

CLIA and state laws and regulations, operating together, sometimes limit the ability of laboratories to offer consumer-initiated testing, also known as direct access testing. We do not offer direct access testing and instead require that our tests be ordered by licensed healthcare providers.

Our Boulder, Colorado and De Soto, Kansas laboratories are certified and adhere to the New York State Clinical Laboratory Evaluation Program (NYS CLEP), based on New York State Public Health Law, Article 5 Title 5. New York State Clinical Laboratory Evaluation Program is exempt from CLIA and establishes their own method of laboratory certification and test validation approval. To process New York State patient specimens a laboratory must submit a robust analytical and clinical validation package to demonstrate clinical utility of the test and receive approval prior to offering the test in the state of New York. Our GeneStrat and VeriStrat tests have received New York State Clinical Laboratory Evaluation Program approval. New York State Clinical Laboratory Evaluation Program requires semi-annual inspections to ensure the laboratory meets all general and specialty standards. Biodesix passed New York State Clinical Laboratory Evaluation Program inspection in May 2019 and is currently scheduled for a routine re-inspection in May 2021.

### **Regulatory framework for medical devices in the United States**

Pursuant to its authority under the FDCA, the FDA has jurisdiction over medical devices, which are defined to include, among other things, IVDs. The FDA regulates the research, design, development, pre-clinical and clinical testing, manufacturing, safety, effectiveness, packaging, labeling, storage, recordkeeping, pre-market clearance or approval, adverse event reporting, marketing, promotion, sales, distribution and import and export of medical devices. It is possible that one of our current, or future, tests will be subject to FDA authority and oversight as either an IVD or a CDx pursuant to the FDA's authority to regulate medical devices under the FDCA.

Medical devices are subject to extensive regulation in the United States and elsewhere, including by the FDA and its foreign counterparts. Government regulations specific to medical devices are wide ranging and govern, among other things:

- product design, development, manufacture, and release;
- laboratory and clinical testing, labeling, packaging, storage and distribution;
- product safety and efficacy;
- premarketing clearance or approval;
- service operations;
- record keeping;
- product marketing, promotion and advertising, sales and distribution;
- post-marketing surveillance, including reporting of deaths or serious injuries and recalls and correction and removals;
- post-market approval studies; and
- product import and export

Market access, sales and marketing of medical devices in non-U.S. countries are subject to foreign regulatory requirements that vary widely from country to country. For example, in the European Economic

Area (EEA), a medical device must meet the Medical Devices Directive's (MDD)/In Vitro Medical Devices Directive's (IVDD) Essential Requirements or, applicable on May 26, 2021, the Medical Devices Regulation's (MDR) / applicable on May 26, 2022, In Vitro Medical Devices Regulation's (IVDR) General Safety and Performance Requirements which apply to it, taking into account its intended purpose as defined by the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or

statements and as specified by the manufacturer in the clinical evaluation. Before placing a medical device on the EEA market, the manufacturer must draw up a declaration of conformity, certifying that the device complies with the MDD/IVDD/MDR/IVDR, and must then affix the CE mark. For medium and high-risk devices as well as low risk devices that are placed on the market in sterile condition, have a measuring function, or are reusable surgical instruments, the manufacturer must obtain a CE Certificate from a notified body. The notified body typically audits and examines the device's technical documentation, including the clinical evaluation, and the quality system for the manufacture, design and final inspection of the relevant device before issuing a CE Certificate. Following the issuance of this CE Certificate, manufacturers may draw up the declaration of conformity and affix the CE mark to the devices covered by this CE Certificate.

Manufacturers of medical devices must document in a clinical evaluation report (CER) the evaluation of the clinical data related to the device. The CER is part of the device's technical file. The evaluation shall document that the applicable Essential Requirements/General Safety and Performance Requirements are met and document the evaluation of the undesirable side-effects and the acceptability of the benefit-risk- ratio. The CER must be updated based on information from the post-market surveillance and vigilance activities related to the device. The CER shall consist, inter alia, of analyzed clinical data collected from a clinical investigation of the device, or the results of other studies on substantially equivalent devices. Reliance on "substantially equivalent" devices is very restrictive and requires, inter alia, that the manufacturer has full access to the technical documentation of the equivalent device on an ongoing basis and, if the "equivalent device" is not its own, that the manufacturer has in place a contract with the manufacturer of the "equivalent device."

Similar requirements apply in the UK. For access to the UK market, manufacturers must obtain a UKCA Certificate and affix a UKCA mark to their medical devices. However, the CE mark will be accepted in the UK until July 1, 2023.

### **Device classification**

Under the FDCA, medical devices are classified into one of three classes: Class I, Class II or Class III, depending on the degree of risk to patients that is associated with each medical device and the amount of oversight needed to provide reasonable assurances with respect to safety and effectiveness of the medical device.

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

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

Class III devices include devices deemed by the FDA to pose the greatest risk: such as life-supporting or life-sustaining devices, implantable devices, or those deemed novel and not substantially equivalent to a predicate device following the 510(k) process. CDx tests are regularly considered Class III devices.

### **Premarket submission process**

Unless a statutory or regulatory exemption or enforcement discretion policy applies, before a new medical device, or a new intended use of, claim for, or significant modification to an existing device, can be marketed in the United States, the manufacturer must obtain the FDA's: (1) permission for commercial distribution under section 510(k) of the FDCA (510(k) clearance); or (2) approval of a PMA; or (3) de novo classification and authorization. These processes can be resource intensive, expensive, and lengthy, and require payment of significant user fees.

Under the 510(k) clearance process, the manufacturer must submit to the FDA a premarket notification, demonstrating that the device is “substantially equivalent” to a legally marketed predicate device. A predicate device is a legally marketed device that is not subject to a PMA, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and therefore a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was previously found substantially equivalent through the 510(k) process. To be “substantially equivalent,” the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Premarket notifications typically include bench, analytical, and preclinical data. Clinical data is sometimes required to support substantial equivalence. If a manufacturer obtains a 510(k) clearance for its device and then makes a modification that could significantly affect the device’s safety or effectiveness or constitutes a major change or modification in the intended use of the device, a new clearance, authorization or approval may be required.

By statute, the FDA is required to complete its review of a 510(k) notification within 90 days of receiving the 510(k) notification. As a practical matter, clearance often takes longer, and clearance is never assured. Although many 510(k) premarket notifications are cleared without clinical data, the FDA may require further information, including clinical data, to make a determination regarding substantial equivalence, which may significantly prolong the review process. If the FDA agrees that the device is substantially equivalent, it will grant clearance to commercially market the device. If the FDA determines that the device is not “substantially equivalent” to a predicate device, or if the device is automatically classified into Class III, the device sponsor must then fulfill the much more rigorous, costly, and time-consuming PMA approval process or seek reclassification of the device through the de novo process.

To obtain a PMA, the applicant must submit data and information demonstrating reasonable assurance of the safety and effectiveness of the device for its intended use to the FDA’s satisfaction. Accordingly, a PMA typically includes, but is not limited to, extensive technical information regarding device design and development, pre-clinical and clinical trial data, manufacturing information, labeling, and financial disclosure information for the clinical investigators in device studies. The PMA application must provide valid scientific evidence that demonstrates to the FDA’s satisfaction a reasonable assurance of the safety and effectiveness of the device for its intended use.

Once filed as a PMA, the FDA has 180 days to review the filed PMA application, although the review of an application more often occurs over a significantly longer period of time. During this review period, the FDA may request additional information or clarification of information already provided, and the FDA may issue a major deficiency letter to the applicant, requesting the applicant’s response to deficiencies communicated by the FDA.

Prior to approval of a PMA, the FDA may conduct inspections of any clinical trial data and clinical trial sites, as well as inspections of any manufacturing facility and processes. The FDA can delay, limit or deny approval of a PMA application for many reasons, including (1) the device may not be shown safe or effective to the FDA’s satisfaction; (2) the data from pre-clinical studies and/or clinical trials may be found unreliable or insufficient to support approval; (3) the manufacturing process or facilities may not meet applicable requirements; and (4) changes in FDA approval policies or adoption of new regulations may require additional data.

If the FDA evaluation of a PMA is favorable, the FDA will issue either an approval letter, or an approvable letter, the latter of which usually contains a number of conditions that must be met in order to secure final approval of the PMA. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA approval letter authorizing commercial marketing of the device, subject to the conditions of approval and the limitations established in the approval letter. The FDA also may determine that additional tests or clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and data is submitted in an amendment to the PMA, or the PMA is withdrawn and resubmitted when data is available. The PMA process can be expensive, uncertain and lengthy. A number of devices for which the FDA approval has been sought by other companies have never been approved by the FDA for marketing. New PMA applications or PMA supplements are required for any modifications to the manufacturing process, equipment or facility, quality control procedures, sterilization, packaging, expiration date, labeling, device specifications, ingredients, materials or design of a device that has been approved through the PMA process.

As a condition of PMA application approval, the FDA may also require some form of post-approval study or post-market surveillance, whereby the applicant conducts a follow-up study or follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional or longer-term safety and effectiveness data for the device. The FDA may also approve a PMA application with other post-approval conditions intended to ensure the safety and effectiveness of the device, such as, among other things, restrictions on labeling, promotion, sale, distribution and use.

Alternatively, the FDA also allows the submission of a direct de novo petition. This procedure allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA application. Prior to the enactment of FDASIA, a medical device could only be eligible for de novo classification if the manufacturer first submitted a 510(k) premarket notification and received a determination from the FDA that the device was not substantially equivalent. FDASIA streamlined the de novo classification pathway by permitting manufacturers to request de novo classification directly without first submitting a 510(k) premarket notification to the FDA and receiving a not substantially equivalent determination.

The 510(k), de-novo or PMA processes can be expensive, lengthy and unpredictable. The FDA's 510(k) clearance process usually takes from three to 12 months, but can last longer. The process of obtaining a PMA is much more costly and uncertain than the 510(k) clearance process and generally takes from one to three years, or even longer, from the time the application is filed with the FDA. In addition, a PMA generally requires the performance of one or more clinical trials. Despite the time, effort and cost, a device may not be approved or cleared by the FDA. Any delay or failure to obtain necessary regulatory clearances or approvals could harm our business. Furthermore, even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for the device, which may limit the market for the device.

### **Companion Diagnostics and the Premarket Process**

We believe that one of our future product candidates may include a companion diagnostic or complementary diagnostic (collectively CDx). CDx's can identify patients who are most likely to benefit from a particular therapeutic product; identify patients likely to be at increased risk for serious side effects as a result of treatment with a particular therapeutic product; or monitor response to treatment with a particular therapeutic product for the purpose of adjusting treatment to achieve improved safety or effectiveness. The use of the CDx will be stipulated in the labeling of both the CDx and the therapeutic product. The FDA may require an application for the CDx separate from the drug approval process, and this could potentially delay the approval of any new drug application or the CDx, or complicate the review process. CDx's are generally regulated as Class III medical devices by the FDA and are therefore most often subject to the PMA approval process.

The FDA issued guidance in July 2016 for the co-development of CDx tests with a therapeutic product and issued another draft guidance in December 2018 specific to oncology CDx tests. The FDA finalized this draft guidance in April 2020 in "Developing and Labeling In vitro Companion Diagnostic Devices for a Specific Group of Oncology Therapeutic Products." The guidance is meant to guide the development of CDx products, which are defined as IVDs that provide information that is essential for the safe and effective use of the therapeutic product. A CDx is often developed and approved or cleared contemporaneously with the therapeutic, and the use of the CDx is stipulated in the labeling of both the CDx and the corresponding therapeutic product. While it supports contemporaneous marketing authorizations, if there are any deficiencies in the submissions, the FDA may place a PMA review of a CDx on hold or request additional testing, which could potentially delay the approval of the corresponding new drug application or the marketing authorization of the CDx, or otherwise complicate the review process. Some oncology CDx tests can be developed in a way that results in labeling for a specific group of oncology therapeutic products, rather than a single therapeutic product.

## **Post-Market FDA Regulation**

Even if regulatory clearance, authorization or approval of a device is granted, the FDA may impose limitations on the uses and indications for which the device may be labeled and promoted, and the device remains subject to significant regulatory requirements. Medical devices may be marketed only for the uses and indications for which they are cleared, authorized or approved. After a device, including a device exempt from FDA premarket review, is placed on the market, numerous post-market regulatory requirements apply, and the FDA has broad authority to enforce these requirements. Medical device manufacturers are subject to unannounced inspections by the FDA and other state, local and foreign regulatory authorities to assess compliance with the QSR and other applicable regulations, and these inspections may include the manufacturing facilities of any suppliers. Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include sanctions such as: warning letters, fines, injunctions, consent decrees and civil penalties; unanticipated expenditures, including requirements to repair, replace, and/or refund the cost of the devices, recall or seizure of our products; operating restrictions, partial suspension or total shutdown of production; the FDA's refusal of our requests for 510(k) clearance, de novo classification, or PMA of new products, new intended uses or modifications to existing products; the FDA's refusal to issue certificates to foreign governments needed to export products for sale in other countries; and withdrawing 510(k) clearance or PMAs that have already been granted and criminal prosecution. In the event that a supplier fails to maintain compliance with the FDA's or our quality requirements, we may have to qualify a new supplier and could experience manufacturing delays as a result.

## **Federal and State Fraud and Abuse Laws**

We are subject to federal fraud and abuse laws such as the federal Anti-Kickback Statute (AKS), the federal prohibition against physician self-referral (Stark Law), the Eliminating Kickbacks in Recovery Act (EKRA), and the federal False Claims Act (FCA). We are also subject to similar state and foreign fraud and abuse laws.

The AKS prohibits knowingly and willfully offering, paying, soliciting, or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for or to induce such person to refer an individual, or to purchase, lease, order, arrange for, or recommend purchasing, leasing or ordering, any item or service that may be reimbursable, in whole or in part, under a federal healthcare program, such as Medicare or Medicaid. There are a number of statutory exceptions and regulatory safe harbors to the AKS that provide protection from AKS liability to arrangements that fully satisfy the applicable requirements.

EKRA prohibits knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in return for the referral of a patient to, or in exchange for an individual using the services of certain entities, including laboratories, if the services are covered by a health care benefit program. The term "health care benefit program" is broadly defined such that EKRA extends to referrals reimbursed by both governmental and commercial third-party payers. EKRA includes a number of statutory exceptions that provide protection from EKRA liability if the applicable requirements are met.

The Stark Law generally prohibits, among other things, clinical laboratories and other so-called "designated health services" entities from billing Medicare for any services when the physician ordering the service, or any member of such physician's immediate family, has a financial relationship, such as a direct or indirect investment interest in or compensation arrangement with the billing entity, unless the arrangement meets an exception to the prohibition. The Stark Law also prohibits physicians from making such referrals to a designated health services entity. There are also similar state laws that apply where Medicaid and/or commercial payers are billed.

The FCA imposes civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment to the government that are false or fraudulent, or knowingly making, using or causing to be made or used a false record or statement material to such a false or fraudulent claim, or knowingly concealing or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government. This statute also permits a private individual acting as a "qui tam" whistleblower to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. FCA liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties of \$11,665 to \$23,331 per false claim or statement for penalties assessed after June 19, 2020, with respect to violations occurring after November 2, 2015.

Other federal statutes pertaining to healthcare fraud and abuse include the civil monetary penalties statute, which prohibits, among other things, the offer or payment of remuneration to a Medicaid or Medicare beneficiary that the offeror or payer knows or should know is likely to influence the beneficiary to order or receive a reimbursable item or service from a particular provider, practitioner, or supplier, and contracting with an individual or entity that the person knows or should know is excluded from participation in a federal health care program. In addition, federal criminal statutes created by HIPAA prohibit, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program or obtain by means of false or fraudulent pretenses, representations or promises any money or property owned by or under the control of any healthcare benefit program in connection with the delivery of or payment for healthcare benefits, items or services.

In addition to these federal laws, there are often similar state anti-kickback and false claims laws that typically apply to arrangements involving reimbursement by a state-funded Medicaid or other health care program. Often, these laws closely follow the language of their federal law counterparts, although they do not always have the same exceptions or safe harbors. In some states, these anti-kickback laws apply with respect to all payers, including commercial payers.

A number of states have enacted laws that require pharmaceutical and medical device companies to monitor and report payments, gifts and other remuneration made to physicians and other healthcare providers, and, in some states, marketing expenditures. In addition, some state statutes impose outright bans on certain manufacturer gifts to physicians or other health care professionals. Some of these laws, referred to as “aggregate spend” or “gift” laws, carry substantial fines if they are violated.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs and extensive annual trainings for all of our employees and contractors. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from participation in government-funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with the law, 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. If any of the physicians or other healthcare providers or entities with whom we do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

## **Anti-Corruption**

The FCPA and similar international bribery laws make it unlawful for entities to make payments to foreign government officials to assist in obtaining and maintaining business. Specifically, the anti-bribery provisions of the FCPA prohibit any offer, payment, promise to pay, or authorizing the payment of money or anything of value to any person, while knowing that all or a portion of such money or thing of value will be offered, given or promised, directly or indirectly, to a foreign official to do or omit to do an act in violation of his or her duty, or to secure any improper advantage in order to assist in obtaining or retaining business for or with, or directing business, to any person. In addition to the anti-bribery provisions of the FCPA, the statute also contains accounting requirements designed to operate in tandem with the anti-bribery provisions. Covered companies are required to make and keep books and records that accurately and fairly reflect the transactions of the company and devise and maintain an adequate system of internal accounting controls. With our international operations through our third-party partnerships, we could incur significant fines and penalties, as well as criminal liability, if we fail to comply with either the anti-bribery or accounting requirements of the FCPA, or similar international bribery laws. Even an unsuccessful challenge of our compliance with these laws could cause us to incur adverse publicity and significant legal and related costs.

## Privacy and Data Protection Laws

Numerous federal and state laws and regulations, including HIPAA, as amended by the HITECH, govern the collection, dissemination, security, use and confidentiality of protected health information (PHI) and personal information. In the course of performing our business we obtain personal information, including PHI. Laws and regulations relating to privacy, data protection, and consumer protection are evolving and subject to potentially differing interpretations. Under HIPAA and HITECH, the HHS, issues regulations that establish uniform standards governing the conduct of certain electronic healthcare transactions and requirements for protecting the privacy and security of PHI, used or disclosed by covered entities (CEs) and their authorized business associates (BAs). Because we are a health care provider that electronically transmits health care information, we are at times either a CE or a BA, as defined by HIPAA. Our subcontractors that create, receive, maintain, transmit or otherwise process PHI on our behalf are HIPAA BAs and must also comply with HIPAA, as applicable.

HIPAA and HITECH include the privacy and security rules, breach notification requirements and electronic transaction standards. The privacy rule governs the use and disclosure of PHI by CEs and BAs. The privacy rule generally prohibits the use or disclosure of PHI except as permitted under the rule. The rule also sets forth individual patient rights, such as the right to access or amend certain records containing such individual's PHI, or to request restrictions on the use or disclosure of such individual's PHI. The security rule requires CEs and BAs to safeguard the confidentiality, integrity, and availability of electronically transmitted or stored PHI (also referred to as ePHI) by implementing administrative, physical and technical safeguards. Under HITECH's breach notification rule, a CE must notify individuals, the Secretary of HHS, and in some circumstances, the media of certain breaches of unsecured PHI or ePHI.

Penalties for failure to comply with a requirement of HIPAA and HITECH vary depending on the number and nature of the violations and any history of prior violations, but can be significant and include civil monetary or criminal penalties. HIPAA is enforced by the Department of Health and Human Services, Office for Civil Rights, and HIPAA also authorizes state attorneys general to file suit on behalf of their residents for violations. Courts are able to award damages, costs and attorneys' fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to file suit 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 resulting in improper access to PHI. In addition, HIPAA mandates that the Secretary of HHS conduct periodic compliance audits of HIPAA CEs, such as us, and their BAs for compliance with the HIPAA privacy and security standards. It also tasks HHS with establishing a methodology whereby harmed individuals who were the victims of breaches of unsecured PHI may receive a percentage of the civil monetary penalty paid by the violator.

In addition, we may be subject to state privacy, cybersecurity, and data breach notification laws, which may govern the collection, use, disclosure and protection of health-related and other personal information. California, for example, has enacted the Confidentiality of Medical Information Act, which, in addition to HIPAA and HITECH, sets forth standards with which all California health care providers must abide. State laws may be more stringent, broader in scope or offer greater individual rights with respect to PHI than HIPAA, and state laws may differ from each other, which may complicate compliance efforts. For instance, the CCPA became effective on January 1, 2020. The CCPA, among other things, 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 by requiring covered companies to provide new disclosures to California consumers (as that term is broadly defined) and provide such consumers new ways to opt-out of certain sales of 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. The CCPA has been amended from time to time, and it remains unclear what, if any, further modifications will be made to this legislation or how it will be interpreted. Although there are certain exemptions for PHI and clinical trial data, the CCPA's implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future and the CCPA may increase our compliance costs and potential liability. Additionally, a California ballot initiative, the California Privacy Rights Act (CPRA) was adopted by California voters. The CPRA will impose additional data protection obligations on companies doing business in California, including additional consumer rights processes and opt outs for certain uses of sensitive data. It would also create a new California data protection agency specifically tasked to enforce the law, which would likely result in increased regulatory scrutiny of California businesses in the areas of data protection and security. Similar laws have been proposed in other states and at the federal level, and if passed, such laws may have potentially conflicting requirements that could continue to make compliance challenging and costly.



Additionally, the Federal Trade Commission (FTC) and state attorneys general enforce consumer protection laws that prohibit unfair and deceptive acts and practices, including Section 5 of the FTC Act, which creates standards for the collection, use, dissemination and security of health-related and other personal information. Claims of unfair or deceptive trade practices regarding privacy and security can lead to significant liabilities and consequences, including regulatory investigations, penalties, fines and orders as well as civil claims, which could impact our data practices and operations or cause reputational damage.

We may also be subject to laws and regulations in foreign countries covering data privacy and other protection of health and employee information that may add additional compliance burden and complexity. For example, in the EEA, the collection and use of personal data is governed by the GDPR. In the United Kingdom, the GDPR will be adopted in substantially the same form. The GDPR, together with national legislation, regulations and guidelines of the EU member states and the United Kingdom governing the processing of personal data, impose strict obligations and restrictions on the ability to collect, analyze, store, transfer and otherwise process personal data. European and United Kingdom data protection authorities may interpret the GDPR and national laws differently and impose additional requirements, which adds to the complexity of processing personal data in or from the EEA or United Kingdom. Guidance on implementation and compliance practices are often updated or otherwise revised. GDPR applies extra-territorially under certain circumstances and imposes stringent requirements on controllers and processors of personal data, including, for example, requirements to ensure a legal bases to process personal information, provide robust disclosures to individuals, facilitate data subject rights, provide data security breach notifications within 72 hours after discovering a breach in certain circumstances, limit retention of personal information and apply enhanced protections to health data and other categories of sensitive personal information. The GDPR also has requirements around international transfers of personal data. Requirements around transfers to the United States and other jurisdictions have increased since a July 2020 decision by the Court of Justice of the European Union invalidated the Privacy Shield as a basis to transfer personal data from Europe to the United States, and added requirements for reliance on Standard Contractual Clauses. Regulatory guidance on requirements for international transfers, and other GDPR compliance matters, continues to evolve. Failure to comply with the requirements of the GDPR may result in fines of up to €20 million or up to 4% of the total worldwide annual turnover of our preceding fiscal year, whichever is higher, and other administrative penalties. To comply with the GDPR and other applicable international data protection laws and regulations, we may be required to put in place additional mechanisms ensuring compliance, which may result in other substantial expenditures.

## **Cybersecurity**

Our business relies on secure and continuous processing of information and the availability of our IT networks and IT resources, as well as critical IT vendors that support our technology, research and other data processing operations. While we take steps to protect our systems and data, security incidents, data breaches, computer malware and computer hacking attacks have become more prevalent across industries, including the life sciences sector, and may occur on our systems or those of our third-party service providers. Unauthorized persons may in the future be able to exploit weaknesses in the security systems of our (or our third-party service providers) IT networks and gain access to PHI and other personal information, or sensitive trade secrets or other proprietary information. Any wrongful use or disclosure of PHI, other personal information, trade secrets or other proprietary information by us or our third-party service providers could subject us to regulatory fines or penalties, third-party claims or otherwise could adversely affect our business and results of operations. Although HIPAA and the regulations promulgated thereunder do not provide for a private right of action, failures to adequately protect PHI or our IT systems could be viewed as violations of the HIPAA security rule or violations of other applicable information security laws, regulations, contractual obligations or industry standards, and could further result in costly data breach notification obligations that negatively impact our reputation.

Moreover, data security incidents or data breaches, as well as attacks on our IT systems, could result in operational disruptions or data loss or corruption that could adversely impact our business and operations, result in substantial investment of resources to investigate, recover and remediate and subject us to heightened regulatory scrutiny.

## International Regulations

Many countries in which we may offer any of our diagnostic tests in the future have anti-kickback regulations prohibiting providers from offering, paying, soliciting or receiving remuneration, directly or indirectly, in order to induce business that is reimbursable under any national health care program. In situations involving physicians employed by state-funded institutions or national health care agencies, violation of the local anti-kickback law may also constitute a violation of the FCPA.

The FCPA prohibits any United States individual, business entity or employee of a United States business entity to offer or provide, directly or through a third party, including any potential distributors we may rely on in certain markets, anything of value to a foreign government 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, its books and records provisions and its anti-bribery provisions.

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

When marketing our diagnostic tests 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 diagnostic tests 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.

Market access, sales and marketing of medical devices in non-U.S. countries are subject to foreign regulatory requirements that vary widely from country to country. For example, in the European Economic Area (EEA), a medical device must meet MDDs/ IVDD Essential Requirements or, applicable on May 26, 2021, the MDR applicable on May 26, 2022, IVDR General Safety and Performance Requirements which apply to it, taking into account its intended purpose as defined by the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation. Before placing a medical device on the EEA market, the manufacturer must draw up a declaration of conformity, certifying that the device complies with the MDD/IVDD/MDR/IVDR, and must then affix the CE mark. For medium and high-risk devices as well as low risk devices that are placed on the market in sterile condition, have a measuring function, or are reusable surgical instruments, the manufacturer must obtain a CE Certificate from a notified body. The notified body typically audits and examines the device's technical documentation, including the clinical evaluation, and the quality system for the manufacture, design and final inspection of the relevant device before issuing a CE Certificate. Following the issuance of this CE Certificate, manufacturers may draw up the declaration of conformity and affix the CE mark to the devices covered by this CE Certificate.

Manufacturers of medical devices must document in a CER the evaluation of the clinical data related to the device. The CER is part of the device's technical file. The evaluation shall document that the applicable Essential Requirements/General Safety and Performance Requirements are met and document the evaluation of the undesirable side-effects and the acceptability of the benefit-risk- ratio. The CER must be updated based on information from the post-market surveillance and vigilance activities related to the device. The CER shall consist, *inter alia*, of analyzed clinical data collected from a clinical investigation of the device, or the results of other studies on substantially equivalent devices. Reliance on "substantially equivalent" devices is very restrictive and requires, *inter alia*, that the manufacturer has full access to the technical documentation of the equivalent device on an ongoing basis and, if the "equivalent device" is not its own, that the manufacture has in place a contract with the manufacturer of the "equivalent device."

Similar requirements apply in the UK. For access to the UK market, manufacturers must obtain a UKCA Certificate and affix a UKCA mark to their medical devices. However, the CE mark will be accepted in the UK until July 1, 2023.

## Healthcare Reform

In March 2010, the Patient Protection and Affordable Care Act (ACA) was enacted in the United States. The ACA made a number of substantial changes to the way healthcare is financed both by governmental and private insurers. For example, the ACA requires each medical device manufacturer to pay a sales tax equal to 2.3% of the price for which such manufacturer sells its medical devices. The medical device tax was permanently repealed at the end of 2019. The ACA also contains a number of other provisions, including provisions governing enrollment in federal and state healthcare programs, reimbursement matters, and fraud and abuse, which we expect will impact our industry and our operations in ways that we cannot currently predict.

While the Biden administration has recently signaled its intent to pursue policies strengthening the ACA, the Trump administration and Congress sought to modify, repeal, or otherwise invalidate all, or certain provisions of, the ACA. The Trump administration issued three executive orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. For example, on December 20, 2019, President Trump signed appropriations legislation for fiscal year 2020 that repealed certain ACA-mandated fees, including the so-called “Cadillac” tax on certain high-cost employer-sponsored insurance plans, for tax years beginning after December 31, 2019; the annual fee imposed on certain health insurance providers based on market share, for calendar years beginning December 31, 2020; and the medical device excise tax on non-exempt medical devices, for sales after December 31, 2019. While Congress has not passed comprehensive legislation that would repeal all or part of the ACA, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017 (TCJA) among other things, included a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment, or penalty, imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” In December 2018, a federal district court in Texas ruled that the ACA’s individual mandate, without the penalty that was repealed effective January 1, 2019, was unconstitutional and could not be severed from the ACA. As a result, the court ruled the remaining provisions of the ACA were also invalid. The Fifth Circuit Court of Appeals affirmed the district court’s ruling that the individual mandate was unconstitutional, but it remanded the case back to the district court for further analysis of whether the mandate could be severed from the ACA; that is, whether the entire ACA was therefore also unconstitutional. The United States Supreme Court granted certiorari on March 2, 2020 and heard oral argument on November 10, 2020; the case is expected to be decided in 2021.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted to reduce healthcare expenditures. These changes include the Budget Control Act of 2011, which, among other things, led to aggregate reductions of Medicare payments to providers of up to 2% per fiscal year that started in 2013 and, due to subsequent statutory amendments, will remain in effect through 2030 unless additional Congressional action is taken. In 2020, the CARES Act temporarily suspended the 2% cut in Medicare payments from May 1, 2020 through December 31, 2020, and it extended the sequestrian reductions through FY 2030 to offset the cost of such temporary suspension. The Consolidated Appropriations Act, 2021 further extended the temporary suspension through March 31, 2021. The American Taxpayer Relief Act of 2012 made other changes, including reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. If federal spending is further reduced, anticipated budgetary shortfalls may also impact the ability of relevant agencies, such as the FDA or the National Institutes of Health to continue to function at current levels. Amounts allocated to federal grants and contracts may be reduced or eliminated. These reductions may also impact the ability of relevant agencies to timely review and approve R&D, manufacturing, and marketing activities, which may delay our ability to develop, market and sell any products we may develop. Additionally, the Biden administration has already indicated a shift in direction from Trump administration policies by issuing orders and other documents rolling back regulations and Executive Orders from the Trump administration, and as noted, indicating that it will pursue policies strengthening the ACA. The recent change in presidential administration could materially impact our business in ways that are difficult to predict.

In December 2020, in its enactment of the Consolidated Appropriations Act, Congress enacted the No Surprises Act. This law, which takes effect January 1, 2022, bars an out-of-network providers from billing patients in excess of the in-network cost sharing for services furnished with respect to a visit at certain in-network health care facilities. The law establishes an independent dispute resolution process between the provider and the payer to determine the appropriate payment rate to the provider. As written, the No Surprises Act may apply to laboratory tests furnished by an independent laboratory with respect to a hospital visit. The law establishes a notice and consent exception that generally does not apply to laboratory tests, although it allows HHS to apply this exception to certain advanced tests. Additional information on the applicability of the No Surprises Act, any applicability of the notice and consent exception to advanced tests, and the rules governing the independent dispute resolution process may be determined in rulemaking and subregulatory guidance from HHS, the Department of Labor, and the Department of the Treasury in 2021.

### **Coverage and Reimbursement**

Reimbursement for laboratory tests in the United States is determined by various payers, including private third-party payers, managed care organizations, and state and federal health care programs, such as Medicare and Medicaid. In Medicare, coverage of an item or service depends on whether it is “reasonable and necessary” under the section 1862(a)(1)(A) of the Social Security Act (SSA). For single-source laboratory tests, this determination is typically made by the Medicare Administrative Contractor (MAC) with jurisdiction over the laboratory where the test is performed. Our Boulder, Colorado laboratory is currently under the jurisdiction of Novitas Solutions, Inc. Our De Soto, Kansas laboratory is under the jurisdiction of Wisconsin Physicians Service Insurance Corporation, which participates in the MolDX program (administered by another MAC, Palmetto GBA) to set coverage policy for molecular diagnostic tests.

Medicare pays for clinical diagnostic laboratory tests (CDLTs), on the Clinical Laboratory Fee Schedule (CLFS). Section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA), added section 1834A to the SSA, which established the current CLFS rate setting processes and coding provisions for CDLTs, and created a new subcategory of CDLTs called Advanced Diagnostic Laboratory Tests (ADLTs), with separate reporting and payment requirements.

Under section 1834A and its implementing regulations, clinical laboratories that receive the majority of their Medicare revenues from payments made under the CLFS and the Physician Fee Schedule report on a triennial basis (or annually for ADLTs), private payer rates and volumes for their tests with specific billing codes based on final payments made during a set data collection period. The payment rate for a test for the ensuing three-year period (or one year for ADLTs) is set at the weighted median of the rates reported under the specific billing code for that test. Newly established codes for CDLTs are priced until the next private payer rate reporting cycle either based on the payment rate of a comparable code on the CLFS (as determined by CMS) or at the median of rates submitted by the individual MACs based on statutory and regulatory factors. New ADLTs are initially priced at “actual list charge” for a nine-month period, after which they are priced based on private payer rates, with a recoupment provision if actual list charge is more than 130% of the weighted median of private payer rates reported.

The various payers in the United States also determine their own billing rules. In December 2020, Medicare revised its billing rules for clinical laboratory tests to require cancer-related protein-based Multianalyte Assays with Algorithmic Analyses to be billed directly to Medicare by the performing laboratory in most cases when performed on a specimen collected from a hospital outpatient. Molecular pathology tests and most ADLTs are also generally required to be billed directly to Medicare by the laboratory under these circumstances.

### **Environmental, Health and Safety Regulations**

We are subject to various federal, state, local, and foreign environmental, health and safety laws and regulations and permitting and licensing requirements. Such laws include those governing laboratory practices, the generation, storage, use, manufacture, handling, transportation, treatment, remediation, release and disposal of, and exposure to, hazardous materials and wastes and worker health and safety. Our operations involve the generation, use, storage and disposal of hazardous materials, and the risk of injury, contamination or non-compliance with environmental, health and safety laws and regulations or permitting or licensing requirements cannot be eliminated. In particular, the introduction of our Bio-Rad SARS-CoV-2 ddPCR and Platelia SARS-CoV-2 Total Ab tests requires that we maintain compliance with applicable and evolving federal and state laws and regulations relating to COVID-19, including the generation, use, storage, and disposal of testing materials and agents. Compliance with environmental laws and regulations has not had a material effect on our capital expenditures, earning or competitive position.

## Corporate Information

We were incorporated in Delaware in 2005 as Elston Technologies, Inc. Our principal executive offices are located at 2970 Wilderness Place, Suite 100, Boulder, Colorado 80301, and our telephone number is (303) 417-0500. On June 20, 2006, we changed our name to Biondesix, Inc.

## Implications of Being an Emerging Growth Company and Smaller Reporting Company

We are an “emerging growth company” within the meaning of the Jumpstart Our Business Startups Act (JOBS Act). As an emerging growth company, we may take advantage of certain exemptions from various public company reporting requirements, including the requirement that our internal control over financial reporting be audited by our independent registered public accounting firm pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, certain requirements related to the disclosure of executive compensation in our periodic reports and proxy statements, the requirement that we hold a nonbinding advisory vote on executive compensation and any golden parachute payments. We may take advantage of these exemptions until we are no longer an emerging growth company. Section 107 of the JOBS Act provides that an “emerging growth company” can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended (the Securities Act), for complying with new or revised accounting standards. In other words, an “emerging growth company” can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies.

We have elected to take advantage of the extended transition period to comply with new or revised accounting standards and to adopt certain of the reduced disclosure requirements available to emerging growth companies. As a result of the accounting standards election, we will 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. Additionally, because we have taken advantage of certain reduced reporting requirements, the information contained herein may be different from the information you receive from other public companies in which you hold stock.

We will remain an emerging growth company until the earliest to occur of (i) the last day of the fiscal year in which we have more than \$1.07 billion in annual revenue; (ii) the date we qualify as a “large accelerated filer,” with at least \$700 million of equity securities held by non-affiliates; (iii) the date on which we have issued, in any three-year period, more than \$1.0 billion in non-convertible debt securities; and (iv) the last day of the fiscal year ending after the fifth anniversary of the completion of our initial public offering.

Additionally, we are a “smaller reporting company” as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the last day of the fiscal year in which (i) the market value of our common stock held by non-affiliates exceeds \$250 million as of the end of that year’s second fiscal quarter, or (ii) our annual revenues exceeded \$100 million during such completed fiscal year and the market value of our common stock held by non-affiliates exceeds \$700 million as of the end of that year’s second fiscal quarter. To the extent we take advantage of such reduced disclosure obligations, it may also make comparison of our financial statements with other public companies difficult or impossible.

For certain risks related to our status as an emerging growth company, see “Risk Factors—Risks Related to our Common Stock—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.”

## Human Capital Resources

Our culture is underpinned by our cultural beliefs including an unwavering commitment to inclusion and diversity. We are committed to fostering a diverse and inclusive workplace that attracts and retains exceptional talent offering opportunities for our team members to grow and develop in their careers, supported by strong compensation, benefits and health and wellness programs. We regularly engage our team members in monthly all-hands meetings to align and focus on the current state of affairs of our business, our partnerships, new products, clinical trials, and other pertinent information about our business. We engage our team members in programs such as peer recognition, recruitment and our newly introduced Diversity, Equity and Inclusion Council that focus on recognizing outstanding individual contributions to company performance, cultural fit of new team members and acknowledging the diversity of our team to ensure our team members feel valued and can do their best work. We have a national annual community service initiative, “Biondesix Gives Back” that allows each team member to invest ten hours of paid community service to organizations of their choosing.

As of December 31, 2020, we had approximately 200 full-time and part-time employees with more than 95% located in the United States. Of our 200 full-time and part-time team members, the majority of our team member base is located in proximity to our corporate office and testing facilities located in Boulder, Colorado and our laboratory in De Soto, Kansas.

### ***Diversity, Equity and Inclusion***

We believe that a diverse employee population, including across background, gender, ethnicity, sexual orientation and lived experiences, is critical to our success. Our employees are encouraged to leverage their personal strengths and experiences to continually innovate and contribute to the development of new ideas and process improvements that drive better experiences for our partners.

### ***Employee Engagement***

Our company culture emphasizes the satisfaction and well-being of our team members and a diverse, engaged workforce. We solicit the opinion and views of our team members through surveys and peer focus groups. We have an established and valued Peer Recognition Culture. Teammates recognize other teammates publicly for their support and contributions fostering engagement and retention. We are reviewing feedback we received on our current cultural beliefs to determine if any modifications are needed. Additionally, the Company celebrates our top sales performers through the President's Club and other top company performers as nominated by fellow team members through our four (4) Performance Excellence Awards that recognize creativity and innovation, an entrepreneurial spirit, a strategic impact on the success of the Company and lastly, embodying the Biodesix cultural beliefs and goes "above and beyond" daily.

### ***Training and Development***

We invest in our team members career growth and provide team members with a wide range of development opportunities, including face-to-face, virtual, and self-directed learning, mentoring, coaching, and external development.

### ***Health, Safety and Wellness***

The physical health, financial stability, life balance and mental health of each of our team members is vital to our success. We sponsor several cancer awareness activities in our local communities to bring engagement and awareness of health, safety and wellness to positively impact lives. We provide an Employee Assistance Program through our professional employer organization (PEO) to enhance physical, financial, and mental well-being for all our team members. Since the onset of the COVID-19 pandemic, we have successfully transitioned a significant portion of our workforce to a remote working environment and implemented several safety and social distancing measures in our sites to protect the health and safety of our team members. We also have provided extraordinary safety protocols and standards for all of "essential" team members who work in our Laboratories and our field sales organization including regularly scheduled serial testing for COVID-19. We also have an active "Friends and Family" COVID-19 testing program for our team members, their families and close friends.

### ***Pay Equity***

The main objective of our compensation program is to provide a compensation package that will attract, retain, motivate, and reward superior team members who operate in a highly competitive and technologically challenging environment. We emphasize overall Company performance and provide equity incentives for all team members to align their financial interests with the interests of shareholders. In addition, we offer an employee stock purchase plan to all employees in which participants are eligible to purchase shares at a discount to market. We think like customers and act like owners.

Biodesix seeks fairness in total compensation. We benchmark with external comparisons, internal comparisons and look at the relationship between team member roles within the organization. We also review our compensation practices, both in terms of our overall workforce and individual team members, to ensure our pay is fair and equitable. We have no pay disparities based on gender, race, or ethnicity.

## Available Information

We file with, or furnish to, the SEC reports including our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended. These reports are available free of charge on our corporate website ([www.biodesix.com](http://www.biodesix.com)) as soon as reasonably practicable after they are electronically filed with or furnished to the SEC. Copies of any materials we file with the SEC can be obtained at [www.sec.gov](http://www.sec.gov). The foregoing website addresses are provided as inactive textual references only. The information provided on our website (or any other website referred to in this report) is not part of this report and is not incorporated by reference as part of this Annual Report on Form 10-K.

## Item 1A. Risk Factors

### Risk Factors Summary

The following is a summary of the principal risks that could adversely affect our business, operations and financial results. This summary does not address all of the risk that we face and should be read in conjunction with the entire Risk Factors section below beginning at “Risks Related to Our Business and Industry” within this Item 1A. Risk Factors.

- We have a history of net losses, and we expect to continue to incur losses for the foreseeable future. If we achieve profitability, we may not be able to sustain it.
- The commercial success of our current and future diagnostic tests and services depends upon attaining significant market acceptance among payers, providers, clinics, patients, and biopharmaceutical companies.
- We may encounter difficulties in managing our growth, which could disrupt our operations.
- If we fail to retain sales and marketing personnel and, as we grow, fail to increase our sales and marketing capabilities or develop broad awareness of our diagnostic tests in a cost-effective manner, we may not be able to generate revenue growth.
- If we cannot maintain our current relationships, or enter into new relationships, with biopharmaceutical companies, our revenue prospects could be reduced.
- Our commercial success and revenue growth are highly dependent on the demand for, and increased adoption of, our diagnostic tests, including our COVID-19 testing program, which are subject to a number of risks and uncertainty.
- We need to ensure strong product performance and reliability to maintain and grow our business.
- We depend upon third-party suppliers, including contract manufacturers and single source suppliers, making us vulnerable to supply problems and price fluctuations.
- Natural or man-made disasters, pandemics, outbreaks, or other similar events, including a sustained outbreak or second wave of the novel strain of coronavirus disease, COVID-19, could significantly disrupt our business, and negatively impact our business, financial condition and results of operations.
- Our industry is highly competitive and subject to rapid change, which could make our diagnostic tests and services obsolete. If we are unable to continue to innovate and expand and enhance our diagnostic tests and service offerings, we could lose customers or market share.
- Any failure to offer high-quality support for our diagnostic tests and services may adversely affect our relationships with providers and negatively impact our reputation among patients and providers, which may adversely affect our business, financial condition and results of operations.
- We may face additional costs, loss of revenue, significant liabilities, harm to our brand, decreased use of our products or services and business disruption if there are disruptions in our information technology systems, including any security or data privacy breaches or other unauthorized or improper access.

## Risk Factors

*Our operations and financial results are subject to various risks and uncertainties that could adversely affect our business, financial condition, and results of operations and cash flows. All of the risks described below should be carefully considered together with the other information contained and incorporated by reference in this report.*

### Risks Related to our Business and Industry

***We have a history of net losses, and we expect to continue to incur losses for the foreseeable future. If we achieve profitability, we may not be able to sustain it.***

We have incurred losses since our inception, and expect to continue to incur losses for the foreseeable future. We have reported net losses of \$31.4 million and \$30.7 million the years ended December 31, 2020 and 2019, respectively. As a result of these losses, as of December 31, 2020, we had an accumulated deficit of approximately \$258.8 million. Our cash and cash equivalents were \$62.1 million as of December 31, 2020 and we expect our cash and cash equivalents will enable us to fund our operating expenses for at least the next twelve months. We have based this estimate on assumptions that in the future may prove to be wrong, and we could use our capital resources sooner than we currently expect.

We expect that our sales and marketing, research and development, regulatory and other expenses will continue to increase as we expand our marketing efforts for our diagnostic tests and services, expand existing relationships with our customers, obtain regulatory clearances or approvals or certifications for future enhancements to our existing diagnostic tests and services and conduct further clinical trials. In addition, we expect our general and administrative expenses to increase due to the additional costs associated with scaling our business operations and testing capacity, particularly with respect to our COVID-19 testing capacity, as well as being a public company, including due to legal, accounting, insurance, exchange listing and compliance, investor relations and other expenses. As a result, we expect to continue to incur operating losses and may never achieve profitability. We will need to generate significant additional revenue in order to achieve and sustain profitability. Even if we achieve profitability, we cannot be sure that we will remain profitable for any substantial period of time. If we do not achieve or sustain profitability, it will be more difficult for us to finance our business and accomplish our strategic objectives, either of which would have a material adverse effect on our business, financial condition and results of operations.

***The commercial success of our current and future diagnostic tests and services and our revenue growth depends upon attaining significant market acceptance among payers, providers, clinics, patients, and biopharmaceutical companies.***

Our commercial success depends, in part, on the acceptance of our diagnostic tests and services as being safe and relatively simple for medical personnel to learn and use, clinically flexible, operationally versatile and, with respect to providers and payers, cost effective. We cannot predict how quickly, if at all, payers, providers, clinics and patients will accept future diagnostic tests and services or, if accepted, how frequently they will be used. These constituents must believe that our diagnostic tests offer benefits over other available alternatives.

The degree of market acceptance of our current and future diagnostic tests and services depends on a number of factors, including:

- whether there is adequate utilization of our tests by clinicians, biopharmaceutical companies and other target groups based on the potential and perceived advantages of our diagnostic tests over those of our competitors;
- the convenience and ease of use of our diagnostic tests relative to those currently on the market;
- the effectiveness of our sales and marketing efforts;
- our ability to provide incremental data that show the clinical benefits and cost effectiveness, and operational benefits, of our diagnostic tests;
- the coverage and reimbursement acceptance of our products and services;
- pricing pressure, including from group purchasing organizations (GPOs), seeking to obtain discounts on our diagnostic tests based on the collective bargaining power of the GPO members;



- negative publicity regarding our or our competitors' diagnostic tests resulting from defects or errors;
- the accuracy of our tests relative to those of our competitors;
- product labeling or product insert requirements by the FDA or other regulatory authorities or conformity assessment bodies; and
- limitations or warnings contained in the labeling cleared or approved by the FDA or other regulatory authorities or conformity assessment bodies.

Additionally, even if our diagnostic tests achieve widespread market acceptance, they may not maintain that market acceptance over time if competing diagnostic tests or technologies, which are more cost effective or are received more favorably, are introduced. Failure to achieve or maintain market acceptance and/or market share would limit our ability to generate revenue and would have a material adverse effect on our business, financial condition and results of operations.

There is no assurance that our COVID-19 and antibody testing program will continue to be accepted by the market or that other diagnostic tests will become more accepted, produce quicker results or are more accurate. Further, the longevity and extent of the COVID-19 pandemic is uncertain. If the pandemic were to dissipate, whether due to a significant decrease in new infections, due to the availability of vaccines, or otherwise, the need for a COVID-19 test could decrease significantly and this could have an adverse effect on our results of operation and profitability.

***We may encounter difficulties in managing our growth, which could disrupt our operations.***

As of December 31, 2020, we had approximately 200 full and part-time employees. Over the next several years, we expect to increase significantly the number of our employees and the scope of our operations, particularly in the areas of sales, marketing and reimbursement, product development, regulatory affairs and other functional areas, including finance, accounting, quality and legal. Additionally, we expect to expand our testing capacity as we commercialize additional diagnostic tests. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational quality and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources, we may not be able to manage the expansion of our operations or recruit and train additional qualified personnel in an effective manner. Any inability to manage growth could delay the execution of our business plans or disrupt our operations and have a material and adverse effect on our prospects.

Since our inception, we have experienced multiple cycles of growth and anticipate further growth in our business operations. This future growth could create strain on our organizational, administrative and operational infrastructure, including laboratory operations, quality control, customer service and sales organization management. We expect to continue to increase headcount and to hire more specialized personnel in the future as we grow our business. We will need to continue to hire, train and manage additional qualified scientists, laboratory personnel, client and account services personnel, and sales and marketing staff and improve and maintain our technology to properly manage our growth. If our new hires perform poorly, if we are unsuccessful in hiring, training, managing and integrating these new employees or if we are not successful in retaining our existing employees, our business may be harmed.

We may not be able to maintain the quality or expected turnaround times of our diagnostic tests and services, or satisfy customer demand as it grows. We may not be able to expand our COVID-19 testing capacity rapidly enough to meet the current and anticipated demand. Our ability to manage our growth properly will require us to continue to improve our operational, financial and management controls, as well as our reporting systems and procedures. The time and resources required to implement these new systems and procedures is uncertain, and failure to complete this in a timely and efficient manner could materially adversely affect our operations.

***If we fail to retain sales and marketing personnel and, as we grow, fail to increase our sales and marketing capabilities or develop broad awareness of our diagnostic tests in a cost-effective manner, we may not be able to generate revenue growth.***

We have limited experience marketing and selling our diagnostic tests. We currently rely on our direct sales force to sell our diagnostic tests in the United States, and any failure to maintain and grow our direct sales force will negatively affect our business, financial condition and results of operations. The members of our direct sales force are highly trained and possess substantial technical expertise, which we believe is critical in increasing adoption of our diagnostic tests. The members of our United States sales force are at-will employees. The loss of these personnel to competitors, or otherwise, will negatively affect our business, financial condition and results of operations. If we are unable to retain our direct sales force personnel or replace them with individuals of equivalent technical expertise and qualifications, or if we are unable to successfully instill such technical expertise in replacement personnel, it may negatively affect our business, financial condition and results of operations.

In order to generate future growth, we plan to continue to expand and leverage our sales and marketing infrastructure. Identifying and recruiting qualified sales and marketing personnel and training them on how to promote our diagnostic tests, on applicable federal and state laws and regulations and on our internal policies and procedures requires significant time, expense and attention. It often takes several months or more before a sales representative is fully trained and productive. Our sales force may subject us to higher fixed costs than those of companies with competing techniques or diagnostic tests that utilize independent third parties, which could place us at a competitive disadvantage. It will negatively affect our business, financial condition and results of operations if our efforts to expand and train our sales force do not generate a corresponding increase in revenue, and our higher fixed costs may slow our ability to reduce costs in the face of a sudden decline in demand for our diagnostic tests. Any failure to hire, develop and retain talented sales personnel, to achieve desired productivity levels in a reasonable period of time, or timely reduce fixed costs, could negatively affect our business, financial condition and results of operations. Our ability to increase our customer base and achieve broader market acceptance of our diagnostic tests will depend to a significant extent on our ability to expand our marketing efforts. We plan to dedicate significant resources to our marketing programs. It will negatively affect our business, financial condition and results of operations if our marketing efforts and expenditures do not generate a corresponding increase in revenue. In addition, we believe that developing and maintaining broad awareness of our diagnostic tests in a cost-effective manner is critical to achieving broad acceptance of our diagnostic tests. Promotion activities may not generate patient or physician awareness or increase revenue, and even if they do, any increase in revenue may not offset the costs and expenses we incur in building our brand. If we fail to successfully promote, maintain and protect our brand, we may fail to attract or retain the physician acceptance necessary to realize a sufficient return on our brand building efforts, or to achieve the level of brand awareness that is critical for broad use of our diagnostic tests, which in turn could have a material adverse effect on our business, financial condition and results of operations.

***If we cannot maintain our current relationships, or enter into new relationships, with biopharmaceutical companies, our revenue prospects could be reduced.***

We collaborate with biopharmaceutical companies to analyze patient samples for multiple applications primarily to support clinical trials, including patient identification, companion or complementary diagnostics and retrospective testing. For fiscal years 2020 and 2019, revenue from our top biopharmaceutical customer accounted for 3% and 21% of our total revenue, respectively. The revenue attributable to our biopharmaceutical customers may also fluctuate in the future, which could have a material adverse effect on our financial condition and results of operations. In addition, the termination of these relationships could result in a temporary or permanent loss of revenue.

Our future success depends in part on our ability to maintain these relationships and to establish new relationships. Many factors have the potential to impact such collaborations, including the type of biomarker support required and our ability to deliver it and our biopharmaceutical customers' satisfaction with our tests or services and other factors that may be beyond our control. Furthermore, our biopharmaceutical customers may decide to decrease or discontinue their use of our tests due to changes in research and product development plans, failures in their clinical trials, financial constraints, or utilization of internal testing resources or tests performed by other parties, or other circumstances outside of our control. In addition to reducing our revenue, the loss of one or more of these relationships may reduce our exposure to research and clinical trials that facilitate the collection and incorporation of new information into our biobank and proprietary AI platform.

We engage in conversations with biopharmaceutical companies regarding potential commercial opportunities on an ongoing basis. There is no assurance that any of these conversations will result in a commercial agreement, or if an agreement is reached, that the resulting relationship will be successful or that clinical or research studies conducted as part of the engagement will produce successful outcomes. Speculation in the industry about our existing or potential relationships with biopharmaceutical companies can also be a catalyst for adverse speculation about us, our tests and our technology, which can adversely affect our reputation and our business.

***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 revenue and operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. Our quarterly and annual operating results may fluctuate as a result of a variety of factors, many of which are outside our control and, as a result, may not fully reflect the underlying performance of our business. These fluctuations may occur due to a variety of factors, including, but not limited to:

- the level of demand for our diagnostic tests, which may vary significantly;
- the timing and cost of manufacturing our diagnostic tests, 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 tests and technologies;
- unanticipated pricing pressures;
- the rate at which we grow our sales force and the speed at which newly hired salespeople become effective, and the cost and level of investment therein;
- the degree of competition in our industry and any change in the competitive landscape of our industry, including consolidation among our competitors or future partners;
- coverage and reimbursement policies with respect to lung cancer treatment equipment, and potential future diagnostic tests that compete with our diagnostic tests;
- the timing and success or failure of clinical trials for our diagnostic tests or any enhancements to such tests we develop or competing diagnostic tests;
- positive or negative coverage, or public perception, of our diagnostic tests or those of our competitors or broader industry trends;
- the impact, if any, of the spread of COVID-19 and any newly discovered variants, and the resulting effects on the number of patients treated or the demand for our non-COVID-19 tests;
- the timing and cost of, and level of investment in, research, development, licenses, regulatory approval, conformity certification, commercialization activities, acquisitions and other strategic transactions, or other significant events relating to our diagnostic tests, which may change from time to time;
- the timing and cost of obtaining regulatory approvals, conformity certifications or clearances for planned or future improvements or enhancements to our diagnostic tests;
- changes in regulatory requirements or in the status of regulatory approvals or applications or conformity certifications;
- pricing, discounts, and incentives for our diagnostic tests;
- future accounting pronouncements or changes in our accounting policies; and
- general market conditions.

In addition, we can provide no assurances that the demand for our COVID-19 and antibody testing program will be sustained, and even if it is, the period of time for which it would be sustained. As vaccines for COVID-19 become more available and widespread in the future, we expect the demand for our COVID-19 diagnostic and antibody tests will decrease. As a result, the increase in revenue due to any increase in demand for our COVID-19 and antibody testing program is not indicative of results expected for any future period.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual financial results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Further, our historical results are not necessarily indicative of results expected for any future period, and quarterly results are not necessarily indicative of the results to be expected for the full year or any other period, and accordingly should not be relied upon as indicative of 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 guidance we may provide, or if the guidance we provide is below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any publicly stated guidance we may provide, and could in turn negatively impact our business, financial condition and results of operations.

***We need to ensure strong product performance and reliability to maintain and grow our business.***

We need to maintain and continuously improve the performance and reliability of our diagnostic tests, including our Biodesix WorkSafe testing program, the Nodify XL2 and Nodify CDT tests, and the GeneStrat and VeriStrat tests, to achieve our profitability objectives. Poor product performance and reliability could lead to customer dissatisfaction, adversely affect our reputation and revenues, and increase our service and distribution costs and working capital requirements. Our diagnostic tests may contain errors or defects, and while we have made efforts to test them extensively, we cannot assure that our current diagnostic tests, or those developed in the future, will not have performance problems. Performance issues with our diagnostic tests will increase our costs in the near-term and accordingly adversely affect our business, financial condition and results of operations.

***We depend upon third-party suppliers, including contract manufacturers and single source suppliers, making us vulnerable to supply problems and price fluctuations.***

We rely on third-party suppliers, including in some instances single source suppliers, to provide us with certain components of our diagnostic tests. The number of suppliers feeding into the production of our diagnostic tests is in excess of 65 worldwide. We consider a select few of these suppliers, located in the United States, Europe and China, as critical single source providers of components. Bio-Rad Laboratories, as described below, is the sole source supplier for our GeneStrat tests and COVID-19 diagnostic and antibody testing program. Oncimmune is also the sole source supplier for our Nodify CDT tests. While we have initiated the second source qualification process for the majority of these critical components, we may not be successful in securing second sourcing for all of them at all or on a timely basis.

In addition, we may purchase supplies through purchase orders and may not have long-term supply agreements with, or guaranteed commitments from, many of our suppliers, including single source suppliers. Additionally, at present, we rely on contract manufacturers for the production of our supplies for our diagnostic test. Many of our suppliers and contract manufacturers are not obligated to perform services or supply diagnostic testing materials for any specific period, in any specific quantity or at any specific price, except as may be provided in a particular purchase order. We depend on our suppliers and contract manufacturers to provide us and our customers with materials in a timely manner that meet our and their quality, quantity and cost requirements. These suppliers and contract manufacturers may encounter problems during manufacturing for a variety of reasons, any of which could delay or impede their ability to meet our demand. These suppliers and contract manufacturers may cease producing the components we purchase from them or otherwise decide to cease doing business with us. Further, we maintain limited volumes of inventory from most of our suppliers and contract manufacturers. If we inaccurately forecast demand for finished goods, we may be unable to meet customer demand which could harm our competitive position and reputation. In addition, if we fail to effectively manage our relationships with our suppliers and contract manufacturers, we may be required to change suppliers or contract manufacturers. While we believe replacement suppliers exist for all materials, components and services necessary to manufacture our diagnostic tests, establishing additional or replacement suppliers for any of these materials, components or services, if required, could be time-consuming and expensive, may result in interruptions in our operations and product delivery, may affect the performance of our diagnostic tests or could require that we modify their processes. Even if we are able to find replacement suppliers, we will be required to verify that the new supplier maintains facilities, procedures and operations that comply with our quality expectations and applicable regulatory requirements. Any of these events could require that we obtain a new regulatory authority approval before we implement the change, which we may not obtain on a timely basis or at all.

If our third-party suppliers fail to deliver the required commercial quantities of materials on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement suppliers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality on a timely basis, the continued commercialization of our diagnostic tests, the supply of our diagnostic tests to customers and the development of any future diagnostic tests will be delayed, limited or prevented, which could have material adverse effect on our business, financial condition and results of operations.

We entered into a nonexclusive license and supply agreement with Bio-Rad in August 2019. We rely on Bio-Rad to supply equipment and reagents used to perform ddPCR testing, a service offered by us under a variety of fee for service agreements and the core technology powering the GeneStrat test. Under the terms of this arrangement, we were granted non-exclusive rights to utilize the intellectual property, machinery, materials, reagents, supplies and know-how necessary for the performance of ddPCR in cancer detection testing for third parties in the United States. We agreed to purchase all of the necessary supplies and reagents for such testing exclusively from Bio-Rad. As further consideration for the non-exclusive license, we agreed to pay a royalty of two and one half percent (2.5%) on net service fees (such fees are defined in the Non-Exclusive License Agreement with Bio-Rad) collected from contracted third parties who receive ddPCR services from us. In addition, we have separately been granted permission by Bio-Rad to use the Bio-Rad SARS-CoV-2 ddPCR test and Platelia SARS-CoV-2 Total Ab test for commercial diagnostic services. For more information regarding this license and supply agreement and the permission granted to us by Bio-Rad with respect to such tests, please see “Business—Material Agreements—Agreements with Bio-Rad.”

This relationship may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. We cannot be certain that, following the realization of this relationship, we will achieve the revenue or specific net income that justifies our entry into it. Any termination of this relationship, or delays in entering into new strategic partnership agreements with Bio-Rad, could delay our sales and marketing efforts, which would harm our business prospects, financial condition and results of operations.

***We may not be able to sufficiently reduce costs in the performance, manufacturing and production of our diagnostic tests to achieve sustainable gross margins.***

We partner with contract manufacturers in the development and production of supplies for our diagnostic tests. While we are undertaking a number of initiatives designed to reduce the cost of performing our diagnostic tests, including reducing the costs of supplies, there is no guarantee that we will be able to achieve planned cost reductions from our various cost savings initiatives. There may also be unforeseen occurrences that increase our costs, such as increased prices of the components of our diagnostic tests, changes to labor costs or less favorable terms with third-party suppliers or contract manufacturing partners. If we are unable to reduce our costs, or if cost reductions are less significant or less timely than projected, we will not be able to achieve sustainable gross margins, which would adversely affect our ability to invest in and grow our business and adversely impact our business, financial condition and results of operations.

***A pandemic, epidemic or outbreak of an infectious disease in the United States or worldwide, including the outbreak of the novel strain of coronavirus disease, COVID-19, and its variants could adversely affect our business.***

If a pandemic, epidemic or outbreak of an infectious disease occurs in the United States or worldwide, our business may be adversely affected. COVID-19 has spread throughout the United States and to most countries globally. Numerous U.S. state and local jurisdictions have imposed, and others in the future may impose, “shelter-in-place” orders, quarantines, executive orders and similar government orders and restrictions for their residents to control the spread of COVID-19. In March 2020, the Governor of Colorado, where our headquarters are located, issued “stay at home” orders limiting non-essential activities, travel and business operations. Such orders or restrictions have resulted in reduced operations at our headquarters, work stoppages, slowdowns and delays, travel restrictions and cancellation of events. Other disruptions or potential disruptions include the inability of our suppliers to manufacture components and parts and to deliver these to us on a timely basis, or at all; disruptions in our production schedule and ability to assemble diagnostic tests; inventory shortages or obsolescence; delays in actions of regulatory bodies; diversion of or limitations on employee resources that would otherwise be focused on the operations of our business; delays in growing or reductions in our sales organization, including through delays in hiring, lay-offs, furloughs or other losses of sales representatives; business adjustments or disruptions of certain third parties, including suppliers, medical institutions and clinical investigators with whom we conduct business; and additional government requirements or other incremental mitigation efforts that may further impact our or our suppliers’ capacity to manufacture our diagnostic tests.

The COVID-19 pandemic also has negatively affected our non-COVID-19 testing-related revenue and our clinical studies. For example, cancer patients may have more limited access to hospitals, healthcare providers and medical resources as they take steps to control the spread of COVID-19. Our biopharmaceutical customers are facing challenges in recruiting patients and in conducting clinical trials to advance their pipelines, for which our tests could be utilized. As a result of the COVID-19 pandemic, beginning in the latter half of March 2020, we have been receiving fewer samples for non-COVID-19 testing on a daily average basis from our clinical and biopharmaceutical customers than before the outbreak of the COVID-19 pandemic. Further, our clinical studies, such as our ongoing INSIGHT study and our recently launched ALTITUDE study, as well as our arrangements with our biopharmaceutical customers, are expected to take longer to complete than what we expected before the outbreak of the COVID-19 pandemic.

The COVID-19 pandemic has also created an opportunity for our diagnostic tests and we have commercialized two diagnostic tests to test for the presence of COVID-19 and antibodies. We are expecting to increase our testing capacity for our COVID-19 diagnostic and antibody testing program in the near term to meet the rising demand for rapid and accurate testing. We expect that the revenue we generate from this expansion will comprise a significant portion of our revenue for the first quarter of 2021. However, there is no assurance that our COVID-19 diagnostic and antibody testing program will continue to be accepted by the market or that other diagnostic tests will become more accepted, produce quicker results or be accurate. Further, the longevity and extent of the COVID-19 pandemic is uncertain. If the pandemic were to dissipate, whether due to a significant decrease in new infections, due to the availability of vaccines, or otherwise, the need for a COVID-19 test could decrease significantly and this could have an adverse effect on our results of operations and profitability. As a result, the increase in revenue due to any increase in demand for these diagnostic tests may not be indicative of our future revenue.

The extent to which the COVID-19 pandemic impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity and spread of COVID-19 and the actions to contain COVID-19 or treat its impact, among others. Furthermore, there is no assurance that our diagnostic tests will continue to be effective against the virus in the future.

While the potential economic impact brought by, and the duration of, any pandemic, epidemic or outbreak of an infectious disease, including COVID-19, may be difficult to assess or predict, the widespread COVID-19 pandemic has resulted in, and may continue to result in, significant disruption of global financial markets and a reduction in our ability to access capital, which could adversely affect our liquidity. In addition, a recession or market correction resulting from the spread of an infectious disease, including COVID-19, could materially affect our business. Such economic recession could have a material adverse effect on our long-term business. To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this “Risk Factors” section.

***Natural or man-made disasters and other similar events, including the COVID-19 pandemic, may significantly disrupt our business, and negatively impact our business, financial condition and results of operations.***

A significant portion of our employee base, operating facilities and infrastructure are centralized in Boulder, Colorado and we operate a laboratory facility in De Soto, Kansas. Any of our facilities may be harmed or rendered inoperable by natural or man-made disasters, including earthquakes, wildfires, floods, nuclear disasters, riots, acts of terrorism or other criminal activities, infectious disease outbreaks or pandemic events, including the COVID-19 pandemic, power outages and other infrastructure failures, which may render it difficult or impossible for us to operate our business for some period of time. Our facilities would likely be costly to repair or replace, and any such efforts would likely require substantial time. Any disruptions in our operations could adversely affect our business, financial condition and results of operations and harm our reputation. Moreover, although we have disaster recovery plans, they may prove inadequate. We may not carry sufficient business insurance to compensate for losses that may occur. Any such losses or damages could have a material adverse effect on our business, financial condition and results of operations. In addition, the facilities of our suppliers and manufacturers may be harmed or rendered inoperable by such natural or man-made disasters, which may cause disruptions, difficulties or otherwise materially and adversely affect our business.

***Any failure to offer high-quality support for our diagnostic tests and services may adversely affect our relationships with providers and negatively impact our reputation among patients and providers, which may adversely affect our business, financial condition and results of operations.***

In implementing and using our diagnostic tests and services, providers depend on our support to resolve issues in a timely manner. We may be unable to respond quickly enough to accommodate short-term increases in demand for customer support. Increased customer demand for support could increase costs and adversely affect our business, financial condition and results of operations. Our sales are highly dependent on our reputation and on positive recommendations from our existing patients, care partners, providers and clinics. Any failure to maintain high-quality customer support, or a market perception that we do not maintain high-quality customer support, could adversely affect our reputation, our ability to sell our diagnostic tests and services, and in turn our business, financial condition and results of operations.

***The sizes of the markets for our diagnostic tests and services and any future diagnostic tests and services may be smaller than we estimate and may decline.***

Our estimates of the annual total addressable market for our diagnostic tests and services are based on a number of internal and third-party estimates and assumptions, including, without limitation, the assumed prices at which we can sell our diagnostic tests and services in the market. 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 diagnostic tests and services in different market segments may prove to be incorrect. If the actual number of patients who would benefit from our diagnostic tests, the price at which we can sell them or the annual total addressable market for them is smaller than we have estimated, it may impair our sales growth and negatively affect our business, financial condition and results of operations.

***Our industry is subject to rapid change, which could make our solutions and the diagnostic tests we develop and services we offer, obsolete. If we are unable to continue to innovate and improve our diagnostic tests and services we offer, we could lose customers or market share.***

Our industry is characterized by rapid changes, including technological and scientific breakthroughs, frequent new product introductions and enhancements and evolving industry standards, all of which could make our current diagnostic tests and others we are developing obsolete. Our future success will depend on our ability to keep pace with the evolving needs of our customers on a timely and cost-effective basis and to pursue new market opportunities that develop as a result of scientific and technological advances. In recent years, there have been numerous advances in technologies relating to the diagnosis and treatment of cancer. There have also been advances in methods used to analyze very large amounts of molecular information. We must continuously enhance our offerings and develop new and improved diagnostic tests to keep pace with evolving standards of care. If we do not leverage or scale our sample and data biobank to discover new diagnostic tests or applications or update our diagnostic tests to reflect new scientific knowledge, including about lung cancer biology, information about new cancer therapies or relevant clinical trials, our diagnostic tests could become obsolete and sales of our current diagnostic tests and any new tests we develop could decline or fail to grow as expected. This failure to make continuous improvements to our diagnostic tests to keep ahead of those of our competitors could result in the loss of customers or market share that would adversely affect our business, financial condition and results of operations.

***We may face additional costs, loss of revenue, significant liabilities, harm to our brand, decreased use of our products or services and business disruption if there are any security or data privacy breaches or other unauthorized or improper access.***

In connection with various facets of our business, we collect and use a variety of personal data, such as names, mailing addresses, email addresses, mobile phone numbers, location information, prescription information and other medical information. Any failure to prevent or mitigate security breaches or improper access to, use, disclosure or other misappropriation of our data or consumers' personal data could result in significant liability under state (e.g., state breach notification and privacy laws such as the California Consumer Privacy Act (CCPA) federal (e.g., the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Health Information Technology for Economic and Clinical Health Act (HITECH Act) and laws in other jurisdictions (e.g., the EU General Data Protection Regulation (GDPR)). Such an incident may also cause a material loss of revenue from the potential adverse impact to our reputation and brand, affect our ability to retain or attract new users of our diagnostic tests and services and potentially disrupt our business.

Unauthorized disclosure of sensitive or confidential patient or employee data, including personally identifiable information, whether through a breach of computer systems, systems failure, employee negligence, fraud or misappropriation, or otherwise, or unauthorized access to or through our information systems and networks, whether by our employees or third parties, could result in negative publicity, legal liability and damage to our reputation. Unauthorized disclosure of personally identifiable information could also expose us to sanctions for violations of data privacy laws and regulations around the world. To the extent that any disruption or security breach resulted in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed. For example, the loss of or damage to clinical trial data, such as from completed or ongoing clinical trials, for any of our product candidates would likely result in delays in our marketing approval efforts and significantly increased costs in an effort to recover or reproduce the data.

As we become more dependent on information technologies to conduct our operations, cyber incidents, including deliberate attacks and attempts to gain unauthorized access to computer systems and networks, may increase in frequency and sophistication. These threats pose a risk to the security of our systems and networks, the confidentiality and the availability and integrity of our data and these risks apply both to us, and to third parties on whose systems we rely for the conduct of our business. Because the techniques used to obtain unauthorized access, disable or degrade service or sabotage systems change frequently and often are not recognized until launched against a target, we and our partners may be unable to anticipate these techniques or to implement adequate preventative measures. We have in the past experienced, and may in the future, experience security incidents. While no security incidents in the past have had a material adverse effect on our business, financial condition and results of operations, we cannot predict the impact of any such future events. Further, we do not have any control over the operations of the facilities or technology of our cloud and service providers, including any third-party vendors that collect, process and store personal data on our behalf. Our systems, servers and platforms and those of our service providers may be vulnerable to computer viruses or physical or electronic break-ins that our or their security measures may not detect. Individuals able to circumvent such security measures may misappropriate our confidential or proprietary information, disrupt our operations, damage our computers or otherwise impair our reputation and business. We may need to expend significant resources and make significant capital investments to protect against security breaches or to mitigate the impact of any such breaches. In addition, to the extent that our cloud and other service providers, experience security breaches that result in the unauthorized or improper use of confidential data, employee data or personal data, we may not be indemnified for any losses resulting from such breaches. There can be no assurance that we or our third-party providers will be successful in preventing cyber-attacks or successfully mitigating their effects. If we are unable to prevent or mitigate the impact of such security breaches, our ability to attract and retain new customers, patients and other partners could be harmed as they may be reluctant to entrust their data to us, and we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our business or other adverse consequences.

***We have significant payer concentration, with a limited number of customers accounting for a substantial portion of our revenues.***

For year ended December 31, 2020, Medicare reimbursed to us 18% of our diagnostic test revenue and two healthcare providers accounted for 47% of our total revenue. For the year ended December 31, 2019, Medicare reimbursed to us 60% of our diagnostic test revenue and one biopharmaceutical customer accounted for 21% of our total revenue and 71% of our service revenue. There are risks whenever a large percentage of total revenues are concentrated with a limited number of payers and customers. It is not possible for us to predict the level of demand for our diagnostic tests and services that will be generated by any of these customers in the future. In addition, revenues from these larger customers may fluctuate from time to time based on these customers' business needs, the timing of which may be affected by market conditions or other factors outside of our control. These payers and customers could also potentially pressure us to reduce the prices we charge for our diagnostic tests and services, which could have an adverse effect on our margins and financial position and could negatively affect our revenues and results of operations. If any of our largest payers terminates its relationship with us or our tests are no longer reimbursable by such payer, such termination could negatively affect our revenues and results of operations.



***Our results of operations will be materially harmed if we are unable to accurately forecast customer demand for, and utilization of, our diagnostic tests and manage our inventory.***

To ensure adequate inventory supply, we must forecast inventory needs and manufacture our diagnostic tests based on our estimates of future demand for our diagnostic tests. Our ability to accurately forecast demand for them could be negatively affected by many factors, including our failure to accurately manage our expansion strategy, product introductions by competitors, an increase or decrease in customer demand for our diagnostic tests or for those of our competitors, our failure to accurately forecast customer acceptance of new diagnostic tests, unanticipated changes in general market conditions or regulatory matters and weakening of economic conditions or consumer confidence in future economic conditions. Inventory levels in excess of customer demand may result in inventory write-downs or write-offs, which would cause our gross margin to be adversely affected and could impair the strength of our brand. Conversely, if we underestimate customer demand for our diagnostic tests, our supply chain, manufacturing partners and/or internal manufacturing team may not be able to deliver components and diagnostic tests to meet our requirements, and this could result in damage to our reputation, sales growth and customer relationships. In addition, if we experience a significant increase in demand, such as we are currently experiencing with respect to our COVID-19 and antibody testing program, additional supplies of raw materials or additional manufacturing capacity may not be available when required on terms that are acceptable to us, or at all, or suppliers may not be able to allocate sufficient capacity in order to meet our increased requirements, which will adversely affect our business, financial condition and results of operations.

***If we experience significant disruptions in our information technology systems, our business may be adversely affected.***

We depend on our information technology systems for the efficient functioning of our business, including the performance, distribution and maintenance of our diagnostic tests and services, as well as for accounting, data storage, compliance, purchasing and inventory management. We do not have redundant information technology in all aspects of our systems at this time. Our information technology systems may be subject to computer viruses, ransomware or other malware, attacks by computer hackers, failures during the process of upgrading or replacing software, databases or components thereof, power outages, damage or interruption from fires or other natural disasters, hardware failures, telecommunication failures and user errors, among other malfunctions. We could be subject to an unintentional event that involves a third party gaining unauthorized access to our systems, which could disrupt our operations, corrupt our data or result in release of our confidential information. Technological interruptions would disrupt our operations, including our ability to timely ship and track diagnostic test orders and results, project inventory requirements, manage our supply chain and otherwise adequately service our customers or disrupt our customers' ability to use our diagnostic tests. In the event we experience significant disruptions, we may be unable to repair our systems in an efficient and timely manner. Accordingly, such events may disrupt or reduce the efficiency of our entire operation and have a material adverse effect on our business, financial condition and results of operations.

Currently, we carry business interruption coverage to mitigate certain potential losses but this insurance is limited in amount, and we cannot be certain that such potential losses will not exceed our policy limits. The successful assertion of one or more large claims against us that exceed or are not covered by our insurance coverage or changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, could have a material adverse effect on our business, financial condition and results of operations. We are increasingly dependent on complex information technology to manage our infrastructure. Our information systems require an ongoing commitment of significant resources to maintain, protect and enhance our existing systems. Failure to maintain or protect our information systems and data integrity effectively could have a material adverse effect on our business, financial condition and results of operations.

***If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit or halt the marketing and sale of our diagnostic tests and services. The expense and potential unavailability of insurance coverage for liabilities resulting from issues with our diagnostic tests and services could harm us and negatively impact sales.***

We face an inherent risk of product liability as a result of the marketing and sale of our diagnostic tests and services. For example, we may be sued if our diagnostic tests or services cause or are perceived to cause injury or are found to be otherwise unsuitable during manufacturing, marketing or sale. Any such product liability claim may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. In addition, we may be subject to claims against us even if the apparent injury is due to the actions of others or the pre-existing health of the patient. For example, medical personnel, care partners and patients collect samples for our diagnostic tests. If these medical personnel, care partners or patients are not properly trained, are negligent or use our diagnostic tests incorrectly, the capabilities of such tests may be diminished or the patient may suffer critical injury. We may also be subject to claims that are caused by the activities of our suppliers, such as those who provide us with components and sub-assemblies for our diagnostic tests.

If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or halt the marketing and sale of our diagnostic tests and services. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our diagnostic tests and services;
- harm to our reputation;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals, or labeling, marketing, or promotional restrictions;
- loss of revenue;
- adverse impact on the market price of our common stock; and
- exhaustion of any available insurance and our capital resources.

We believe we have adequate product liability insurance, but it may not prove to be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain or obtain insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Our insurance policy contains various exclusions, and we may be subject to a product liability claim for which we have no coverage. The potential inability to obtain sufficient product liability insurance at an acceptable cost to protect against product liability claims could prevent or inhibit the marketing and sale of our diagnostic tests and services. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts, which would have a material adverse effect on our business, financial condition and results of operations. In addition, any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, harm our reputation in the industry, significantly increase our expenses and reduce product sales.

***We face competition from many sources, including larger companies, and we may be unable to compete successfully.***

There are a number of lung cancer diagnostic solutions companies in the United States, Europe and Asia. Notable competitors in the United States include Veracyte, Inc., Guardant Health, Inc., and Foundation Medicine, Inc. These competitors all provide cancer-focused diagnostic tests to hospitals, researchers, clinicians, laboratories and other medical facilities. Many of these organizations are significantly larger with greater financial and personnel resources than us, and enjoy significantly greater market share and have greater resources than we do. As a consequence, they may be able to spend more on product development, marketing, sales and other product initiatives than we can. Some of our competitors have:

- substantially greater name recognition;
- broader, deeper, or longer-term relations with healthcare professionals, customers, and third-party payers;
- more established distribution networks;
- additional lines of diagnostic tests and the ability to offer rebates or bundle them to offer greater discounts or other incentives to gain a competitive advantage;
- greater experience in conducting research and development, manufacturing, clinical trials, marketing and obtaining regulatory clearance or approval or certification for diagnostic tests; and
- greater financial and human resources for product development, sales and marketing and patent litigation.

Our continued success depends on our ability to:

- further penetrate the lung disease diagnostic solutions market and increase utilization of our diagnostic tests;
- maintain and widen our technology lead over competitors by continuing to innovate and deliver new product enhancements on a continuous basis; and
- cost-effectively manufacture our diagnostic tests and their component parts as well as drive down the cost of service.

In addition, competitors with greater financial resources than ours could acquire other companies to gain enhanced name recognition and market share, as well as new technologies or diagnostic tests that could effectively compete with our existing diagnostic tests, which may cause our revenue to decline and would harm our business.

Our competitors also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, as well as in acquiring technologies complementary to, or necessary for, development of our diagnostic tests. Because of the complex and technical nature of diagnostic testing and the dynamic market in which we compete, any failure to attract and retain a sufficient number of qualified employees could materially harm our ability to develop and commercialize our diagnostic tests, which would have a material adverse effect on our business, financial condition and results of operations.

As we attain greater commercial success, our competitors are likely to develop diagnostic tests that offer features and functionality similar to our diagnostic tests that are currently on the market. Improvements in existing competitive diagnostic tests or the introduction of new competitive diagnostic tests may make it more difficult for us to compete for sales, particularly if those competitive diagnostic tests demonstrate better reliability, convenience or effectiveness or are offered at lower prices.

***Performance issues, service interruptions or price increases by our shipping carriers and warehousing providers could adversely affect our business and harm our reputation and ability to provide our services on a timely basis.***

Expedited, reliable shipping and delivery services and secure warehousing are essential to our operations. We rely heavily on providers of transport services for reliable and secure point-to-point transport of our diagnostic tests to our customers and for tracking of these shipments, and from time to time require warehousing for our diagnostic tests, sample collection kits and supplies. Should a carrier encounter delivery performance issues such as loss, damage or destruction of any systems, it would be costly to replace such systems in a timely manner and such occurrences may damage our reputation and lead to decreased demand for our diagnostic tests and increased cost and expense to our business. In addition, any significant increase in shipping or warehousing rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters, civil unrest and disturbances or other service interruptions affecting delivery or warehousing services we use would adversely affect our ability to process orders for our diagnostic tests on a timely basis.

We rely on commercial courier delivery services to transport samples to our laboratory facility in a timely and cost-efficient manner and if these delivery services are disrupted, our business will be harmed. Our business depends on our ability to quickly and reliably deliver test results to our customers. Blood samples are typically received within days from the United States and outside the United States for analysis at our Boulder, Colorado and De Soto, Kansas facilities. Disruptions in delivery service, whether due to labor disruptions, bad weather, natural disaster, civil unrest or disturbances, terrorist acts or threats or for other reasons could adversely affect specimen integrity and our ability to process samples in a timely manner and to service our customers, and ultimately our reputation and our business. In addition, if we are unable to continue to obtain expedited delivery services on commercially reasonable terms, our operating results may be adversely affected.

***Cost-containment efforts of our customers, purchasing groups and governmental purchasing organizations could have a material adverse effect on our sales and profitability.***

In an effort to reduce costs, many hospitals in the United States have become members of GPOs and Integrated Delivery Networks (IDNs). GPOs and IDNs negotiate pricing arrangements with medical device companies and distributors on behalf of their members, which may include hospitals and other providers. GPOs and IDNs typically award contracts on a category-by-category basis through a competitive bidding process. Bids are generally solicited from multiple providers with the intention of driving down pricing or reducing the number of vendors. Due to the highly competitive nature of the GPO and IDN contracting processes, we may not be able to obtain new, or maintain existing, contract positions with major GPOs and IDNs. Furthermore, the increasing leverage of organized buying groups may reduce market prices for our diagnostic tests, thereby reducing our revenue and margins.

While having a contract with a GPO or IDN for a given product category can facilitate sales to members of that GPO or IDN, such contract positions can offer no assurance that any level of sales will be achieved, as sales are typically made pursuant to individual purchase orders. Even when a provider is the sole contracted supplier of a GPO or IDN for a certain product category, members of the GPO or IDN are generally free to purchase from other suppliers. Furthermore, GPO and IDN contracts typically are terminable without cause by the GPO or IDN upon 60 to 90 days' notice. Accordingly, the members of such groups may choose to purchase alternative diagnostic tests due to the price or quality offered by other companies, which could result in a decline in our revenue.

Pricing and reimbursement of medical devices is not harmonized at European level, but is the exclusive competence of the EU Member States. In Europe, pricing and reimbursement decisions are generally made by regional or centralized bodies based on an assessment of the efficacy and clinical effectiveness of the devices or broad device types or procedures. There is a general trend for EU Member States to adopt cost containment measures to control public spend on medical devices. Due to the competitive nature of product offers and prices, we may not be able to obtain new, or maintain existing, contract positions with the EU Member States.

***Litigation and other legal proceedings may adversely affect our business.***

From time to time we may become involved in legal proceedings relating to patent and other intellectual property matters, product liability claims, employee claims, tort or contract claims, federal regulatory investigations, securities class action and other legal proceedings or investigations, which could have an adverse impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business. Litigation is inherently unpredictable and can result in excessive or unanticipated verdicts and/or injunctive relief that affect how we operate our business. We could incur judgments or enter into settlements of claims for monetary damages or for agreements to change the way we operate our business, or both. There may be an increase in the scope of these matters or there may be additional lawsuits, claims, proceedings or investigations in the future, which could have a material adverse effect on our business, financial condition and results of operations. Adverse publicity about regulatory or legal action against us could damage our reputation and brand image, undermine our customers' confidence and reduce long-term demand for our diagnostic tests and services, even if the regulatory or legal action is unfounded or not material to our operations.

We maintain product and professional liability insurance, but this insurance may not fully protect us from the financial impact of defending against product liability or professional liability claims. Any product liability or professional liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future.

***General economic and financial market conditions may exacerbate our business risks.***

Global macroeconomic conditions and the world's financial markets remain susceptible to significant stresses, resulting in reductions in available credit and government spending, economic downturn or stagnation, foreign currency fluctuations and volatility in the valuations of securities generally. As a result of uncertainties with respect to financial institutions and the global credit markets and other macroeconomic challenges currently or potentially affecting the economy of the United States and other parts of the world, customers and distributors may experience serious cash flow problems and other financial difficulties, decreasing demand for our products. Our customers and distributors may respond to such economic pressures by reducing or deferring their capital spending or reducing staff.

In addition, events in the United States or foreign markets, such as the United Kingdom's exit from the European Union, the worldwide effects from the spread of COVID-19 and political and social unrest in various countries around the world, can impact the global economy and capital markets. Additionally, if our customers and distributors are not successful in generating sufficient revenue or are precluded from securing financing, their businesses will suffer, which may materially and adversely affect our business, financial condition and results of operations.

***We may not realize the benefits or costs of our Co-Development and Collaboration Agreement with AVEO Oncology.***

In 2014, we entered into a Co-Development and Collaboration Agreement with AVEO Oncology (formerly known as AVEO Pharmaceuticals, Inc.) (AVEO) whereby the two parties agreed to various terms and conditions necessary for the co-development of AVEO's compound ficlatuzumab (the Collaboration Agreement).

We were granted a limited legal interest in ficlatuzumab and may not have the right to control the development and exploitation of ficlatuzumab. As consideration for the grant, we agreed to cover the first \$15.0 million of ficlatuzumab's clinical development costs, with both parties then sharing all costs equally after the cap was reached.

In October of 2016, the Collaboration Agreement was amended to eliminate the requirement that we cover all of the initial costs. Under the amended terms, we agreed to allow AVEO to recapture its cost that it otherwise would not have been responsible for said recapture to occur out of any royalties or revenues eventually derived from the Collaboration Agreement. As part of the Collaboration Agreement, unless we or AVEO exercise our right to opt-out of co-development, we equally share in any income received from licensing rights to ficlatuzumab to any third parties. In September 2020, we exercised our opt-out right for the payment of half of the development and regulatory costs for ficlatuzumab. This opt-out was effective as of December 2, 2020 with remaining obligations estimated to be \$0.3 million. Following the effective date, we will be entitled to a 10% royalty of net sales of ficlatuzumab and 25% of license income generated from the licensing of ficlatuzumab. Ficlatuzumab is currently being evaluated in squamous cell carcinoma of the head and neck (SCCHN), metastatic pancreatic ductal cancer (PDAC), and acute myeloid leukemia (AML). For more information regarding this Collaboration Agreement, please see "Business —Drug Co-Development."

Our relationship with AVEO may require us to incur non-recurring and other charges, increase our near and long-term expenditures, or disrupt our management and business. We cannot be certain that, following the realization of this relationship, we will achieve the revenue or specific net income that justifies our entry into it. Any termination of this relationship, or delays in entering into new strategic partnership agreements with AVEO, could delay our sales and marketing efforts, which would harm our business prospects, financial condition and results of operations.

***We are exposed to significant future payments and other obligations associated with our acquisitions of Integrated Diagnostics and Oncimmune, U.S.A., and may not realize the advantages we expect from these acquisitions.***

We purchased select assets and liabilities from Integrated Diagnostics, Inc. and IND Funding, LLC (collectively, the Seller) which included the Clinical Laboratory Improvement Amendments (CLIA) lab in Seattle, Washington, and all rights to the Nodify XL2 test and intellectual property rights related to that test. The purchase was made for total consideration of \$27.6 million, consisting of \$8.0 million (10,649,604 shares) of our Series G Preferred Stock and contingent consideration with an initial fair market value of \$19.6 million.

The acquisition of Integrated Diagnostics included a contingent consideration arrangement that requires additional consideration to be paid by us to the Seller based on the milestone of the attainment of a three consecutive month gross margin target of \$2 million within a seven-year period. If the gross margin target is met, the Company is required to issue 2,520,108 shares of common stock. For the 6 months following the achievement of the milestone, the Seller has the option to require us to redeem the common shares for \$37 million in cash over 8 equal installments due each calendar quarter. If the Seller elects not to exercise this option, we have 12 months to repurchase the common stock in two equal quarterly cash installments totaling \$37 million. As of December 31, 2020, we have not made any payments in connection with the contingent consideration.

In addition, on October 31, 2019 we completed an acquisition of United Kingdom-based Oncimmune, Ltd.'s (Oncimmune) United States operations including its CLIA lab in De Soto, Kansas and its incidental pulmonary nodule (IPN) malignancy test, then marketed in the United States as the EarlyCDT®-Lung. We renamed the test and relaunched the test on February 28, 2020 as the Nodify CDT test and the De Soto, Kansas lab will be the sole United States provider of the Nodify CDT test.

As part of the acquisition, we and Oncimmune entered into several agreements to govern the relationship between the parties and to allow us to provide the Nodify CDT test. The overarching umbrella Purchase and Commercialization Agreement (PCA) defines the general relationship between the parties. Included under the PCA was (a) an APA whereby we acquired all of the United States assets associated with the De Soto, Kansas clinical laboratory, as well as the trademarks and patent application associated with the test; (b) an intellectual property license granting us the rights necessary under Oncimmune's background intellectual property rights to perform the Nodify CDT test; (c) a supply agreement for supplying us with the necessary materials and reagents needed to run the Nodify CDT test; and (d) a development agreement where Oncimmune agrees to assist us in further developing the Nodify CDT test. We were also granted an option through December 31, 2020 to acquire the rights to expand the field of use of the Nodify CDT test to include lung cancer screening, which we elected to not exercise.

As consideration for the rights granted to us, we agreed to payments of \$1.2 million and further agreed to an option fee for the screening option of \$9.0 million due within 30 days of exercising the option. As of December 31, 2020, we have paid \$1.2 million of the agreed upon payments. We also agreed to a revenue share payment of 8% of recognized revenue for non-screening tests up to an annual minimum volume and 5% thereafter, with an escalating minimum through the first four years of sales. An insignificant amount of royalty payments was paid for the year ended December 31, 2020. In September 2020, we notified Oncimmune that we would not exercise this option for expansion of the field of use.

Our acquisitions may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. We cannot be certain that, following the realization of these acquisitions, we will achieve the revenue or specific net income that justifies our entry into them. This could delay our sales and marketing efforts, which would harm our business prospects, financial condition and results of operations.

***We are highly dependent on our senior management team and key personnel, and our business could be harmed if we are unable to attract and retain personnel necessary for our success.***

We are highly dependent on our senior management and other key personnel. Our success will depend on our ability to retain senior management and to attract and retain qualified personnel in the future, including sales and marketing professionals, scientists, clinical specialists, and other highly skilled personnel and to integrate current and additional personnel in all departments. The loss of members of our senior management, sales and marketing professionals, scientists, clinical and regulatory specialists could result in delays in product development and harm our business. If we are not successful in attracting and retaining highly qualified personnel, it would have a material adverse effect on our business, financial condition and results of operations.

***Our research and development programs and laboratory operations depend on our ability to attract and retain highly skilled scientists and technicians.***

We may not be able to attract or retain qualified scientists and technicians in the future due to the competition for qualified personnel among life science businesses, particularly near our headquarters in Boulder, Colorado and our laboratory facility in De Soto, Kansas. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified scientific personnel. We may have difficulties locating, recruiting, or retaining qualified salespeople. Recruiting and retention difficulties can limit our ability to support our research and development and sales programs. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have issued and may continue to issue equity awards that vest over time. The value to employees of equity awards that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Our employment arrangements with our employees provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We also do not maintain “key man” insurance policies on the lives of these individuals or the lives of any of our other employees.

***Our corporate culture has contributed to our success, and if we cannot maintain this culture as we grow, we could lose the innovation, creativity and teamwork fostered by our culture and our business may be harmed.***

We believe that our culture has been and will continue to be a critical contributor to our success. We expect to continue to hire aggressively as we expand, and we believe our corporate culture has been crucial in our success and our ability to attract highly skilled personnel. If we do not continue to develop our corporate culture or maintain and preserve our core values as we grow and evolve, we may be unable to foster the innovation, curiosity, creativity, focus on execution, teamwork and the facilitation of critical knowledge transfer and knowledge sharing we believe we need to support our growth. Moreover, liquidity available to our employee securityholders could lead to disparities of wealth among our employees, which could adversely impact relations among employees and our culture in general. Our anticipated headcount growth and our transition from a private company to a public company may result in a change to our corporate culture, which could harm our business.

***Our ability to utilize our net operating loss carryforwards and research and development credit may be limited.***

In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Code) a corporation that undergoes an ownership change, generally defined as a greater than 50% change by value in its equity ownership by certain shareholders over a three-year period, is subject to limitations on its ability to utilize its pre-change net operating losses (NOLs) and its research and development credit carryforwards to offset future taxable income. The applicable rules generally operate by focusing on changes in ownership among stockholders considered by the rules as owning, directly or indirectly, 5% or more of the stock of a company, as well as changes in ownership arising from new issuances of stock by the company. We believe that our NOLs are currently not subject to limitation under these rules. However, if we undergo an ownership change now or in the future, our ability to utilize NOLs and research and development credit carryforwards could be limited by Sections 382 and 383 of the Code. Future changes in stock ownership may be beyond our control. In addition, our ability to deduct net interest expense may be limited if we have insufficient taxable income for the year during which the interest is incurred, and any carryovers of such disallowed interest would be subject to the limitation rules similar to those applicable to NOLs and other attributes. For these reasons, in the event we experience a change of control, we may not be able to utilize a material portion of the NOLs, research and development credit carryforwards or disallowed interest expense carryovers, even if we attain profitability.

***The terms of our secured credit agreement require us to meet certain operating and financial covenants and place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.***

In February 2018, we entered into an agreement with Innovatus Life Sciences Lending Fund to refinance long-term debt carried over from earlier loan agreements (the 2018 Notes). The initial amount borrowed under the 2018 Notes was \$23 million and the maturity date is February 2023. We are required to make quarterly interest payments that began in June 2018 and outstanding principal is due in 24 equal installments commencing in March 2021. The agreement has been amended multiple times to adjust terms to account for our acquisitions and growth. Further, we granted the lender a security interest in all of our assets through a pledge and security agreement, patent security agreement and trademark security agreement, each between us and the lender.

The loan may be prepaid by us at any time, subject to a prepayment penalty of up to 3% of the principal amount, depending on the date of prepayment. Upon payment of the 2018 Notes at maturity or prepayment on any earlier date, unless waived, a 2% back-end facility fee will apply to the amounts paid or prepaid. The 2% fee is being recorded as additional interest expense over the term of the 2018 Notes.

The 2018 Notes contain customary affirmative and negative covenants for a loan, requires us to comply with a minimum daily liquidity covenant, and has a rolling monthly revenue requirement. Failure to comply with the covenants and loan requirements may result in early amortization of the loan in a 24- or 36-month payment schedule.

The 2018 Notes also contain certain covenants that prevent us from making acquisitions, incurring additional indebtedness, or making or terminating any agreement valued above a certain dollar threshold without the prior written consent of the lender. These covenants may restrict our ability to pursue new business opportunities and access additional capital.

In the event of a default, including, among other things, our failure to make any payment when due or our failure to comply with any covenant under the 2018 Notes, the lender could elect to declare all amounts outstanding to be immediately due and payable, and could proceed against the collateral granted to them to secure such indebtedness, including all of our intellectual property, which could have a material adverse effect on our business, financial condition, and results of operations.

***We will need to raise additional capital to fund our existing operations, develop our platform, commercialize new diagnostic tests or expand our operations.***

We will need to raise additional capital in the future to expand our business, to pursue strategic investments, to take advantage of financing opportunities or for other reasons, including to:

- increase our sales and marketing efforts to drive market adoption of and address competitive developments;
- fund development and marketing efforts of our diagnostic tests or any other future diagnostic tests;
- expand our technologies into other types of cancer management and lung disease detection diagnostic tests;
- acquire, license, or invest in technologies;
- acquire or invest in complementary businesses or assets; and
- finance capital expenditures and general and administrative expenses.

Our present and future funding requirements will depend on many factors, including:

- our ability to achieve revenue growth;
- our rate of progress in establishing payer coverage and reimbursement arrangements with domestic and international commercial third-party payers and government payers;
- the cost of expanding our laboratory operations and offerings, including our sales and marketing efforts;
- our rate of progress in, and cost of the sales and marketing activities associated with, establishing adoption of and reimbursement for our diagnostic tests;
- our rate of progress in, and cost of research and development activities associated with, diagnostic tests in research and early development;
- the effect of competing technological and market developments;
- costs related to international expansion; and
- the potential cost of and delays in product development as a result of any regulatory oversight applicable to our diagnostic tests.



The various ways we could raise additional capital carry potential risks. If we raise funds by issuing equity securities, our stockholders could experience dilution. Any preferred equity securities issued also could provide for rights, preferences or privileges senior to those of holders of our common stock. If we raise funds by issuing debt securities, those debt securities would have rights, preferences and privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings pursuant to a credit agreement could impose significant restrictions on our operations. If we raise funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our platform technologies or diagnostic tests, pay a portion of our royalties, or grant licenses on terms that are not favorable to us.

***We may acquire other businesses, which could require significant management attention, disrupt our business, dilute stockholder value and adversely affect our results of operations.***

As part of our business strategy, we may in the future make additional acquisitions or investments in complementary companies, diagnostic tests or technologies that we believe fit within our business model and can address the needs of our customers and potential customers. In the future, we may not be able to acquire and integrate other companies, diagnostic tests or technologies in a successful manner. We may not be able to find suitable acquisition candidates, and we may not be able to complete such acquisitions on favorable terms, if at all. In addition, the pursuit of potential acquisitions may divert the attention of management and cause us to incur additional expenses in identifying, investigating, and pursuing suitable acquisitions, whether or not they are consummated. If we do complete acquisitions, we may not ultimately strengthen our competitive position or achieve our goals, including increases in revenue, and any acquisitions we complete could be viewed negatively by our customers, investors and industry analysts.

Future acquisitions may reduce our cash available for operations and other uses and could result in amortization expense related to identifiable assets acquired. We may have to pay cash, incur debt or issue equity securities to pay for any such acquisition, each of which could adversely affect our financial condition or the value of our common stock. The sale or issuance of equity to finance any such acquisitions would result in dilution to our stockholders. The incurrence of indebtedness to finance any such acquisition would result in fixed obligations and could also include covenants or other restrictions that could impede our ability to manage our operations. In addition, our future results of operations may be adversely affected by the dilutive effect of an acquisition, performance earn-outs or contingent bonuses associated with an acquisition. Furthermore, acquisitions may require large, onetime charges and can result in increased debt or contingent liabilities, adverse tax consequences, additional stock-based compensation expenses and the recording and subsequent amortization of amounts related to certain purchased intangible assets, any of which items could negatively affect our future results of operations. We may also incur goodwill impairment charges in the future if we do not realize the expected value of any such acquisitions.

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. For example, our 2018 Notes restrict 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.

#### **Risks Related to our Governmental Regulation**

***The insurance coverage and reimbursement status of newly approved diagnostic tests, particularly in a new category of diagnostics and therapeutics, is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for current or future diagnostic tests could limit our ability, and that of our collaborators, to fully commercialize our diagnostic tests and decrease our ability to generate revenue.***

The availability and extent of reimbursement by governmental and private payers is essential for most patients to be able to afford the clinical diagnostic tests and cellular therapeutics that we and our collaborators currently or in the future plan to develop and sell. In addition, because our clinical diagnostics and diagnostic tests represent new approaches to the research, diagnosis, detection and treatment of diseases, we cannot accurately estimate how our diagnostic tests, and those jointly created with our collaborators, would be priced, whether reimbursement could be obtained or any potential revenue generated. Sales of our diagnostic tests will depend substantially, both domestically and internationally, on the extent to which the costs of our diagnostic tests are paid by health

maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payers. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize some of our diagnostic tests or services. Even if coverage is provided, the available reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize an adequate return on our investment in any of our diagnostic tests or services. Changes in the reimbursement landscape may occur, which are outside of our control, and may impact the commercial viability of our diagnostic tests.

There is significant uncertainty related to the insurance coverage and reimbursement of newly launched, cleared, authorized or approved diagnostic tests. In the United States, many significant decisions about reimbursement for new diagnostics and medicines are typically made by the Centers for Medicare and Medicaid Services (CMS), an agency within the Department of Health and Human Services (HHS). CMS decides whether and to what extent a new diagnostic or medicine will be covered and reimbursed under Medicare, although it frequently delegates this authority to local Medicare Administrative Contractors (MACs). Private payers tend to follow Medicare to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for novel diagnostic tests such as ours. Additionally, reimbursement authorities or bodies in Europe may be more conservative than CMS. For example, a number of cancer drugs have been approved for reimbursement in the United States and have not been approved for reimbursement, or have been approved under restricted conditions, in certain European countries.

Outside the United States, the reimbursement process and timelines vary significantly. In Europe, pricing and reimbursement of medical devices is the exclusive competence of the EU Member States. However, the European Commission is facilitating a voluntary corporation between the EU Member States on health technology assessments (HTA) which consists of a network of the EU Member States' national authorities and bodies responsible for HTA and a joint action to support cooperation at scientific and technical level between the HTA bodies. We cannot be sure that such prices and reimbursement decisions will be acceptable to us or our collaborators. If the regulatory authorities in these foreign jurisdictions set prices or make reimbursement criteria that are not commercially attractive for us or our collaborators, our revenues and the potential profitability of our products in those countries would be negatively affected. An increasing number of countries are taking initiatives to control the healthcare budget by focusing cost-cutting efforts on medicinal products, and to a lesser extent, medical devices, provided under their state-run healthcare systems. These price control efforts have impacted all regions of the world, but have been most prominent in the EU. Additionally, some countries require approval of the sale price of a product before it can be marketed or mandatory discounts or profit caps may be applied. Further, after the sale price is approved, it remains subject to review during the product lifecycle. In many countries, the pricing review period begins after marketing or product licensing approval is granted or the CE mark is obtained. As a result, we or our collaborators might obtain marketing approval for a product or service in a particular country, but then may experience delays in the reimbursement approval or be subject to price regulations that would delay the commercial launch of our product or service, possibly for lengthy time periods, which could negatively impact the revenues we are able to generate from the sale of that product or service in that particular country.

Moreover, increasing efforts by governmental and third-party payers, in the United States and abroad, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for newly cleared, authorized, certified or approved devices and medicines and, as a result, they may not cover or provide adequate payment for our clinical diagnostics to be sold by us or our collaborators. For example, in May 2018 the United States government released a "blueprint," or plan, to reduce the cost of drugs. This blueprint contains certain measures that HHS has been working to implement, although it is possible that HHS's regulatory priorities may change under the new Biden administration. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, which are, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect to experience pricing pressures on our clinical diagnostics sold by us and our collaborators due to the trend toward value-based pricing and coverage, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs, surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new diagnostic tests.

***Measures to reduce healthcare costs may hurt our business.***

The majority of our customers are healthcare providers who depend upon reimbursement by government and commercial insurance payers for lung cancer diagnostic solutions services. With a majority of United States patients with lung cancer covered by Medicare, the Medicare reimbursement rate is an important factor in a customer's decision to use our diagnostic tests and limits the prices we may charge for them. Commercial insurance payers may also exert downward pressure on payment rates for lung cancer treatment services. A reduction in reimbursement rates for lung cancer treatments may adversely affect our customers' businesses and cause them to enact cost reduction measures that may include reducing the scope of their programs, thereby potentially reducing demand for our diagnostic tests.

***Healthcare reform measures could hinder or prevent the commercial success of our diagnostic tests.***

In the United States, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system in ways that may harm our future revenues and profitability and the demand for our diagnostic tests. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. Current and future legislative proposals to further reform healthcare or reduce healthcare costs may limit coverage of or lower reimbursement for the procedures associated with the use of our diagnostic tests. The effect of any healthcare reform initiative implemented in the future could impact our revenue from the sale of our diagnostic tests. For example, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the ACA), contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which will impact existing government healthcare programs and will result in the development of new programs.

There have been judicial challenges to certain aspects of the ACA, as well as efforts by the Trump administration and Congress to repeal, replace or alter the implementation of certain aspects of the ACA. For example, as part of the Tax Cuts and Jobs Act of 2017 (TCJA), Congress eliminated the tax penalty, starting January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance. The Further Consolidated Appropriations Act of 2020, Pub. L. No. 116-94, signed into law December 20, 2019, fully repealed the ACA's "Cadillac Tax" on certain high-cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share (repeal effective in 2021), and the medical device excise tax on non-exempt medical devices. On December 14, 2018, a Texas District Court Judge invalidated the ACA in its entirety because he concluded that the individual mandate, which was repealed by Congress as noted above, is unconstitutional and cannot be severed from the remainder of the ACA. The Fifth Circuit Court of Appeals affirmed the district court's ruling that the individual mandate was unconstitutional, but it remanded the case back to the district court for further analysis of whether the mandate could be severed from the ACA; that is, whether the entire ACA was therefore also invalid. The Supreme Court of the United States granted certiorari on March 2, 2020 and heard oral argument on November 10, 2020; the case is expected to be decided by mid-2021. It is unclear how this decision, subsequent appeals, and other efforts to challenge, repeal, or replace, or alter the implementation of the ACA will affect our business, financial condition and results of operations.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011, among other things, included reductions to CMS payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030 unless additional Congressional action is taken, with the exception of a temporary suspension of the 2% cut in Medicare payments from May 1, 2020 through March 31, 2021. Additionally, the American Taxpayer Relief Act of 2012, among other things, reduced CMS payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover Medicare overpayments to providers from three to five years.

The Biden administration and Congress may continue to pursue significant changes to the current healthcare laws, and the Biden administration has indicated its intent to strengthen the ACA and focus on reducing the cost of healthcare. We face uncertainties that might result from modifications or repeal of any of the provisions of the ACA, including as a result of current and future executive orders and legislative actions. The impact of those changes on us and potential effect on the medical device industry as a whole is currently unknown. Any changes to the ACA are likely to have an impact on our results of operations, and may negatively affect our business, financial condition and results of operations. We cannot predict what other healthcare programs and regulations will ultimately be implemented at the federal or state level or the effect of any future legislation or regulation in the United States on our business, financial condition and results of operations.

The continuing efforts of the government, insurance companies, managed care organizations and other payers of healthcare services to contain or reduce costs of healthcare may harm:

- our ability to set a price that we believe is fair for our diagnostic tests;
- our ability to generate revenue and achieve or maintain profitability; and
- the availability of capital.

The ACA substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts our industry. Future changes in healthcare policy could increase our costs and subject us to additional regulatory requirements that may interrupt commercialization of our current and future solutions. Future changes in healthcare policy could also decrease our revenue and impact sales of and reimbursement for our current and future diagnostic tests.

***We must comply with anti-corruption, anti-bribery, anti-money laundering and similar laws.***

We are subject to the Foreign Corrupt Practices Act of 1977 (FCPA), which generally prohibits companies in the United States from engaging in bribery or other prohibited payments to foreign officials for the purpose of obtaining or retaining business and requires companies to maintain accurate books and records and internal controls. We are also subject to requirements under the United States Treasury Department's Office of Foreign Assets Control, United States domestic bribery laws and other anti-corruption, anti-bribery and anti-money laundering laws. While we have policies and procedures in place designed to promote compliance with such laws, our employees or other agents may nonetheless engage in prohibited conduct under these laws for which we or our executives might be held responsible. If our employees or other agents are found to have engaged in such practices, we could suffer severe penalties and other consequences that may have an adverse effect on our business, financial condition and results of operations.

Furthermore, international customers may currently order our diagnostic tests, either directly from us or through a potential joint venture, and we are subject to the FCPA, which prohibits companies and their intermediaries from making payments in violation of law to non-United States government officials for the purpose of obtaining or retaining business or securing any other improper advantage. Our reliance on independent distributors to sell our diagnostic tests internationally demands a high degree of vigilance in maintaining our policy against participation in corrupt activity, because these distributors could be deemed to be our agents and we could be held responsible for their actions. Other United States companies in the medical device and biopharmaceutical field have faced criminal penalties under the FCPA for allowing their agents to deviate from appropriate practices in doing business with these individuals. We are also subject to similar anti-bribery laws in the jurisdictions in which we operate, including laws promulgated by OECD countries in which we operate, such as Israel. These laws are complex and far-reaching in nature, and, as a result, we cannot assure you that we would not be required in the future to alter one or more of our practices to be in compliance with these laws or any changes in these laws or the interpretation thereof. Any violations of these laws, or allegations of such violations, could disrupt our operations, involve significant management distraction, involve significant costs and expenses, including legal fees and could result in a material adverse effect on our business, prospects, financial condition and results of operations. We could also suffer severe penalties, including criminal and civil penalties, disgorgement and other remedial measures.

***We must comply with healthcare fraud and abuse laws.***

Various federal and state laws, as well as the laws of foreign countries, prohibit payments to induce the referral, purchase, order or use of healthcare products or services and require medical device companies to limit prevent, and/or monitor, and report certain payments to third-party payers, health care professionals, and other individuals. These healthcare fraud and abuse, anti-kickback, public reporting and aggregate spend laws affect our sales, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with lung cancer treatment providers, hospitals, physicians or other potential purchasers or users, including patients, of medical devices and services. They also impose additional administrative and compliance burdens on us. In particular, these laws influence, among other things, how we structure our sales offerings, including discount practices, customer support, education and training programs and physician consulting and other service arrangements. These laws prohibit certain marketing initiatives that are commonplace in other industries. If we were to offer or pay inappropriate inducements for the purchase, order or use of our diagnostic tests or our services, or our arrangements are perceived as inappropriate inducements, we could be subject to claims under various healthcare fraud and abuse laws.

Restrictions under applicable United States federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute, a criminal law, prohibits, among other things, persons and entities from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, in cash or in kind, to induce or reward purchasing, leasing, ordering, or arranging for, referring, or recommending the purchase, lease, order of any good or service for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid;
- the Eliminating Kickbacks in Recovery Act, which prohibits knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in return for the referral of a patient to, or in exchange for an individual using the services of certain entities, including laboratories, if the services are covered by a health care benefit program;
- the Beneficiary Inducement Statute, which prohibits any person, organization, or entity from giving anything of value to a federal health care program beneficiary that is likely to induce or influence the beneficiary's choice of provider, practitioner, or supplier for covered services;
- the federal civil False Claims Act, which may be enforced through civil whistleblower or *qui tam* actions and is often used to enforce the federal Anti-Kickback Statute and other healthcare laws and regulations, imposes civil penalties and potential exclusion from federal healthcare programs, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or for making a false record or statement material to an obligation to pay the federal government or for knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the federal government;
- federal criminal statutes created by HIPAA impose criminal liability for, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program, including private insurance plans, or, in any matter involving a healthcare benefit program, for knowingly and willfully making materially false, fictitious, or fraudulent statements in connection with the delivery of or payment for health care benefits; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payers, including private insurers.

Other federal and state laws, as well as the laws of foreign countries, generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payments to government or commercial payers that are false or fraudulent, or for items or services that were not provided as claimed. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of product candidates and medical devices from government-funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations. Moreover, any investigation into our practices could cause adverse publicity and require a costly and time-consuming response. If any physicians or other healthcare providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

Manufacturers can also be held liable under these laws if they are deemed to “cause” the submission of false or fraudulent claims by providing inaccurate billing or coding information to customers, by providing improper financial inducements, or through certain other activities. We attempt to ensure that any billing and coding information we provide for our diagnostic tests emphasizes the need for physicians and other providers to make independent judgments, use accurate and appropriate billing and coding that complies with all applicable payer policies, and document the medical need for their patients as appropriate. Nevertheless, the government may not regard any billing errors that may be made by our customers as inadvertent and may examine our role in providing information to our customers, physicians and patients concerning the benefits and potential coverage of more frequent therapy.

***FDA regulation of our industry generally or our tests specifically could be disruptive to our business.***

Our operations are subject to extensive federal, state, local and foreign laws and regulations, including FDA laws and regulations, all of which are subject to change. These laws and regulations are complex and are subject to interpretation by the courts and by government agencies. We believe that we are in material compliance with all statutory and regulatory requirements applicable to us, but there is a risk that one or more government agencies could take a contrary position, or that a private party could file suit under the qui tam provisions of the federal False Claims Act or a similar state law. Such occurrences, regardless of their outcome, could damage our reputation and adversely affect important business relationships with third parties, including managed care organizations, and other private third-party payers.

The FDA has recently increased its attention to marketing of pharmacogenetic tests. For example, in late 2018, the FDA issued a safety communication regarding genetic laboratory tests with claims to predict a patient's response to specific medications that have not been reviewed by the FDA and may not be supported by clinical evidence. Among other tests, the FDA notice cited genetic tests that claim results can be used to help physicians identify which antidepressant medication would have increased effectiveness or side effects compared to other antidepressant medications. As explained by the FDA in its update to this safety communication, the FDA sent notices to several firms marketing such pharmacogenetic tests where the FDA believes the relationship between genetic variations and the medication's effects has not been established, including a warning letter sent to a laboratory, in part, for failing to obtain premarket review of its test. HHS recently issued an announcement stating that the FDA cannot require premarket review of any LDT without engaging in formal notice-and-comment rulemaking, as opposed to through guidance documents, compliance manuals, website statements, or other informal issuances.

The HHS announcement was made on the Department's website and we can provide no assurances that the HHS statement will not be rescinded or revised or that it would preclude the FDA from renewing its attention on diagnostic tests, including those that we provide. If this were to happen, it may impact our marketing practices relating to the relevant tests, which in turn may have an adverse impact on our business, financial condition and results of operations.

The SARS-CoV-2 tests we perform are currently the subject of EUAs, which permit the use of unapproved medical products or unapproved uses of medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when there are no adequate, approved, and available alternatives, as provided under section 564 for the Federal Food, Drug, and Cosmetic Act (FDCA). EUAs are temporary authorizations that are revoked at the end of the public health emergency, when there is an adequate, approved, or available alternative, or when there are performance or safety concerns. These EUAs also set out conditions for laboratories who are authorized to perform the particular test. The HHS statement mentioned above did not affect EUAs for COVID-19 laboratory-developed tests that were already in effect at the time the statement was released. The HHS statement did not affect EUAs issued for commercially developed COVID-19 IVD tests, which apply to test developers and authorized laboratories.

The EUA for Bio-Rad's SARS-CoV-2 Droplet Digital PCR™ test provides several conditions for authorized laboratories, including that the test result reports will include Fact Sheets that are authorized as part of the EUA, deviations from the authorized procedures, including specimen types, are not permitted, notification of public health authorities of intent to run the test prior to initiating testing, collection and reporting of performance data to the FDA, including false positives, false negatives, and significant deviations from the established performance characteristics, and appropriate training and protective equipment for laboratory staff. This EUA also states that authorized laboratories must maintain records associated with the EUA and be made available to the FDA for inspection upon request. Printed materials, advertising, and promotion related to use of the test must be consistent with the authorized labeling and Fact Sheets, as well as other terms set forth in the EUA and any applicable requirements under the FDCA and its implementing regulations, and conspicuously bear the following statements:

- This test has not been FDA cleared or approved;
- This test has been authorized by the FDA under an EUA for use by authorized laboratories;
- This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and

- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Other statements that appear in advertising and promotional materials must not represent or suggest that this test is safe or effective for the detection of SARS-CoV-2.

The EUA for Bio-Rad's serological test for the antibodies associated with SARS-CoV-2, also sets out several conditions for authorized laboratories that mirror the conditions for the PCR test described above, except that the printed materials, advertising, and promotion of the test must conspicuously bear the following statements:

- This test has not been FDA cleared or approved;
- This test has been authorized by the FDA under an EUA for use by authorized laboratories;
- This test has been authorized only for the detection of total antibodies, including IgM/IgG/IgA, against SARS-CoV-2, not for any other viruses or pathogens; and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

***Failure to comply with federal, state and foreign laboratory licensing requirements and the applicable requirements of the FDA or any other regulatory authority, could cause us to lose the ability to perform our tests, experience disruptions to our business, or become subject to administrative or judicial sanctions.***

The diagnostic testing industry is subject to extensive laws and regulations, many of which have not been interpreted by the courts, including the application of the FDA's EUA authority. As noted above, the EUAs for the COVID-19 tests that are part of our Biodesix WorkSafe testing program set out certain conditions for authorized laboratories using the tests, which have not received premarket clearance, approval, or a de novo from the FDA. If we fail to meet these conditions, the FDA may take enforcement action, such as issuing a warning letter, seeking an injunction, seizure, fines, or criminal penalties. Pursuant to the August 19, 2020 statement by HHS, the FDA cannot require any LDT to undergo premarket approval until it has engaged in notice-and-comment rulemaking. Laboratory tests that have already received an EUA to detect the COVID-19 virus were "unaffected" by the announcement. Tests without FDA clearance, approval, or authorization would not be considered covered countermeasures under the Public Readiness and Emergency Preparedness Act (PREP Act). The HHS statement also did not affect EUAs issued for commercially developed COVID-19 IVD tests, which apply to test developers and authorized laboratories.

We are also 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 requires virtually all laboratories to be certified by the federal government and mandates compliance with various operational, personnel, facilities administration, quality and proficiency testing requirements intended to ensure that testing services are accurate, reliable and timely. CLIA certification is also a prerequisite to be eligible to bill state and federal health care programs, as well as many private third-party payers, for laboratory testing services. As a condition of CLIA certification, each of our laboratories is subject to survey and inspection every other year, in addition to being subject to additional random inspections. The biennial survey is conducted by CMS, a CMS agent (typically a state agency), or, if the laboratory holds a CLIA certificate of accreditation, a CMS-approved accreditation organization.

Sanctions for failure to comply with CLIA requirements, including proficiency testing violations, may include suspension, revocation, or limitation of a laboratory's CLIA certificate, which is necessary to conduct our business, as well as the imposition of significant fines or criminal penalties.

Any sanction imposed under CLIA, its implementing regulations, or state or foreign laws or regulations governing licensure, or our failure to renew a CLIA certificate, a state or foreign license, or accreditation, could have a material adverse effect on our business. If the CLIA certificate of any one of our laboratories is revoked, CMS could seek revocation of the CLIA certificates of our other laboratories based on their common ownership or operation, even though they are separately certified.

In addition, we are subject to state laws and regulations governing laboratory licensure. Some states have enacted state licensure laws that are more stringent than CLIA. 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.

We may also be subject to regulation in foreign jurisdictions as we seek to expand international utilization of our tests or such jurisdictions adopt new licensure requirements, which may require review of our tests in order to offer them or may have other limitations that may limit our ability to make our tests available outside of the United States. Complying with licensure requirements in new jurisdictions may be expensive, time-consuming and subject us to significant and unanticipated delays. Changes in state or foreign licensure laws that affect our ability to offer and provide diagnostic services across state or foreign country lines could materially and adversely affect our business. In addition, state and foreign requirements for laboratory certification may be costly or difficult to meet and could affect our ability to receive specimens from certain states or foreign countries.

Failure to comply with applicable clinical laboratory licensure requirements may result in a range of enforcement actions, including suspension, limitation or revocation of our CLIA certificate and/or state licenses, imposition of a directed plan of action, onsite monitoring, civil monetary penalties, criminal sanctions and revocation of the laboratory's approval to receive Medicare and Medicaid payment for its services, as well as significant adverse publicity. Any sanction imposed under CLIA, its implementing regulations, or state or foreign laws or regulations governing clinical laboratory licensure or our failure to renew our CLIA certificate, a state or foreign license or accreditation, could have a material adverse effect on our business, financial condition and results of operations. Even if we were able to bring our laboratory back into compliance, we could incur significant expenses and potentially lose revenue in doing so.

Our Boulder, Colorado and De Soto, Kansas laboratories are College of American Pathologists (CAP)-accredited (Boulder) or COLA-accredited (De Soto) clinical laboratories regulated by CMS pursuant to CLIA. We also have a current CLIA certificate for each facility. To maintain these certificates, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may make random inspections of our laboratory from time to time. Furthermore, our diagnostic tests are categorized as Laboratory Developed Tests (LDTs) and are not currently subject to FDA regulation, although certain components provided by third parties and used to create and/or administer the test may be. LDTs are a subset of in vitro diagnostics (IVDs) that are intended for clinical use and developed, validated, and offered within a single laboratory for use only in that laboratory. The FDA's authority to regulate LDTs has been frequently contested, and HHS recently issued a public statement purporting to rescind the FDA's policies regarding the premarket review of LDTs. According to the HHS statement, the FDA will not require premarket review of LDTs unless it engages in notice-and-comment rulemaking. There is no guarantee, however, that the HHS statement will not be revised or rescinded, that legislation reforming the federal government's regulation of LDTs will not be passed, or that LDTs will otherwise continue to be able to operate without first receiving FDA premarket review. Failure to adhere to any new FDA regulation would result in fines, product suspensions, warning letters, recalls, injunctions and other civil and criminal penalties.

***Changes in the way that the FDA regulates tests performed by laboratories like ours could result in delay or additional expense in offering our tests and tests that we may develop in the future.***

Historically, the FDA has exercised enforcement discretion with respect to most LDTs and has not required laboratories that furnish LDTs to comply with the agency's requirements for medical devices (e.g., establishment registration, device listing, quality systems regulations, premarket clearance or premarket approval, and post-market controls). In recent years, however, the FDA publicly announced its intention to regulate certain LDTs and issued two draft guidance documents that set forth a proposed phased-in risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs. However, these guidance documents were withdrawn at the end of the Obama administration and replaced by an informal discussion paper reflecting some of the feedback that the FDA had received on LDT regulation. The FDA acknowledged that the discussion paper in January 2017 does not represent the formal position of the FDA and is not enforceable. Nevertheless, the FDA wanted to share its synthesis of the feedback that it had received in the hope that it might advance public discussion on future LDT oversight. HHS has since issued a statement purporting to rescind FDA's policies regarding the premarket review of LDTs, stating that FDA must engage in notice and comment rulemaking (as opposed to through guidance documents, compliance manuals, website statements, or other informal issuances) prior to requiring premarket review of LDTs. HHS issued this statement on its website and it may be subject to change. Also, it is possible that Congress will pass legislation to reform the federal government's regulation of LDTs or that FDA will engage in notice-and-comment rulemaking to require premarket review of LDTs, which could result in delay or additional expense in offering our tests and tests that we may develop in the future.



***Our current line of diagnostic tests is covered under CLIA and CMS, although our COVID testing program and select partnerships we may enter may cause us to be subject to additional FDA requirements.***

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. Pursuant to its authority under the FDCA, the FDA has jurisdiction over medical devices, including in vitro diagnostics and, therefore, potentially our clinical laboratory tests.

Pursuant to the FDCA and its implementing regulations, the FDA regulates the research, testing, manufacturing, safety, labeling, storage, recordkeeping, premarket clearance or approval, marketing and promotion, and sales and distribution of medical devices in the United States to ensure that medical products distributed domestically are safe and effective for their intended uses. Although the FDA has asserted that it has authority to regulate the development and use of LDTs, such as our and many other laboratories' tests, as medical devices, it has generally exercised enforcement discretion and is not otherwise regulating most tests developed and performed within a single high complexity CLIA-certified laboratory. On August 19, 2020, HHS issued a statement purporting to rescind the FDA's policies regarding the premarket review of LDTs, absent notice-and-comment rulemaking. The FDA's policies to date have been articulated through guidance documents, compliance manuals, website statements, and other informal issuances. The FDA could, at any time, engage in notice-and-comment rulemaking, or Congress could take action to amend the law to change the current regulatory framework for in vitro diagnostics and LDTs. Further, the HHS statement was issued on its website and may be subject to change, particularly given the reasoning that additional flexibility is needed due to the COVID-19 pandemic.

We believe that our tests, as utilized in our clinical laboratory, are and would be considered LDTs and that as a result, the FDA does not require that we obtain regulatory clearances or approvals for our LDTs or their components pursuant to the FDA's current policies and guidance. Although we believe that our tests and test components are either exempt from FDA medical device regulations or are subject to an enforcement discretion policy, it is possible that the FDA would not agree with our determinations or that the FDA will change its regulations and policies such that our products become regulated as medical devices.

In contrast with our LDTs, the FDA has regulatory jurisdiction over the two FDA EUA-authorized COVID-19 tests that were developed by Bio-Rad, which we offer as part of our Biodesix WorkSafe testing programs.

Our operations, therefore, are or may become subject to extensive regulation by the FDA in the United States. Government regulations specific to medical devices are wide ranging and govern, among other things:

- test design, development, manufacture, and release;
- laboratory and clinical testing, labeling, packaging, storage, and distribution;
- product safety and efficacy;
- premarketing clearance or approval;
- service operations;
- record keeping;
- product marketing, promotion and advertising, sales, and distribution;
- post-marketing surveillance, including reporting of deaths or serious injuries and recalls and correction and removals;
- post-market approval studies; and
- product import and export.

The FDA classifies medical devices into one of three classes on the basis of the intended use of the device, the risk associated with the use of the device for that indication, as determined by the FDA, and on the controls deemed by the FDA to be necessary to reasonably ensure their safety and effectiveness. Class I devices, which have the lowest level of risk associated with them, are subject to general controls. Class II devices are subject to general controls and special controls, including performance standards. Class III devices, which have the highest level of risk associated with them, are subject to general controls and premarket approval.

Before a new medical device or service, or a new intended use for an existing product or service, can be marketed in the United States, a company must first submit and receive either 510(k) clearance, de-novo authorization, or premarket approval (PMA) from the FDA, unless an exemption applies. Most Class I devices and some Class II devices are exempt from these requirements. In the 510(k) clearance process, before a device may be marketed, the FDA must determine that a proposed device is substantially equivalent to a legally-marketed predicate device, which includes a device that has been previously cleared through the 510(k) process, a device that was legally marketed prior to May 28, 1976 (preamendments device), a device that was originally on the United States market pursuant to an approved PMA and later down-classified, or a 510(k)-exempt device. To be substantially equivalent, the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data are sometimes required to support substantial equivalence.

In the process of obtaining PMA approval, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices.

The FDA also allows the submission of a direct de-novo petition. This procedure allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA application. Prior to the enactment of the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), a medical device could only be eligible for de novo classification if the manufacturer first submitted a 510(k) premarket notification and received a determination from the FDA that the device was not substantially equivalent. FDASIA streamlined the de novo classification pathway by permitting manufacturers to request de novo classification directly without first submitting a 510(k) premarket notification to the FDA and receiving a not substantially equivalent determination.

The 510(k), de-novo or PMA process can be expensive, lengthy and unpredictable. The FDA can delay, limit, or deny clearance or approval of a device for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or conformity assessment body that the diagnostic tests are safe or effective for their proposed intended uses;
- the disagreement of the FDA with the design or implementation of our clinical trials or the interpretation of data from clinical trials;
- serious and unexpected adverse device effects experienced by participants in our clinical trials;
- the data from our clinical trials may be insufficient to support clearance or approval, where required;
- our inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- the manufacturing process or facilities we use may not meet applicable requirements; and
- the potential for approval policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data or regulatory filings insufficient for clearance or approval.

The FDA and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by any such agency, which may include any of the following sanctions:

- adverse publicity, warning letters, untitled letters, it has come to our attention letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recall or seizure of our diagnostic tests;
- operating restrictions, partial suspension, or total shutdown of production;
- denial of our requests for regulatory clearance or premarket approval of new diagnostic tests or services, new intended uses, or modifications to existing diagnostic tests or services;

- withdrawal of regulatory clearance or premarket approvals that have already been granted; or
- criminal prosecution.

As discussed above, we believe that our current line of diagnostic tests and their components are LDTs, subject to state licensing requirements and federal regulation by CMS under CLIA, although our COVID-19 testing program and select partnerships we may enter may cause us to be subject to additional FDA regulations discussed above.

While we believe that we are currently in material compliance with applicable laws and regulations, it is possible that the FDA, or other regulatory agencies, would not agree with our determinations. If our products became subject to 510(k) or other similar FDA regulations, we would need to comply with the applicable regulations or face significant civil and criminal penalties. In addition, IVDs and CDx tests are widely considered to be Class III devices, and it is possible that in the future, we may develop tests that fall into this category. CDx tests in particular may require further administrative procedures in the PMA process. Exposure to these additional regulatory requirements would also affect our business, financial condition and results of operations.

***Our future success depends on our ability to develop, receive regulatory clearance or approval or certification for, and introduce new diagnostic tests or enhancements to existing diagnostic tests that will be accepted by the market in a timely manner. There is no guarantee that the FDA will grant 510(k) clearance or PMA approval of our future diagnostic tests and failure to obtain necessary clearances or approvals for our future diagnostic tests would adversely affect our ability to grow our business.***

It is important to our business that we build a pipeline of diagnostic test offerings that address limitations of current lung disease diagnostic tests. As such, our success will depend in part on our ability to develop and introduce new diagnostic tests. However, we may not be able to successfully develop and obtain regulatory clearance or approval or certification for enhancements to our existing diagnostic tests, or new diagnostic tests for any number of reasons, including due to the cost associated with certain regulatory approval requirements, or these diagnostic tests may not be accepted by physicians or users.

The success of any new diagnostic test or enhancement to an existing diagnostic test will depend on a number of factors, including our ability to, among others:

- identify and anticipate physician and patient needs properly;
- develop and introduce new diagnostic tests or enhancements to our existing diagnostic tests in a timely manner;
- avoid infringing upon, misappropriating, or violating the intellectual property rights of third parties;
- demonstrate, if required, the safety and efficacy of new diagnostic tests with data from clinical studies;
- obtain the necessary regulatory clearances or approvals or certifications for new diagnostic tests or enhancements to existing diagnostic tests;
- comply fully with FDA and foreign regulations on marketing of new diagnostic tests or modified diagnostic tests; and
- provide adequate training to potential users of our diagnostic tests.

If we do not develop new diagnostic tests or enhancements to our existing diagnostic tests in time to meet market demand or if there is insufficient demand for these diagnostic tests or enhancements, or if our competitors introduce new diagnostic tests with functionalities that are superior to ours, our results of operations will suffer.

Some of our future diagnostic tests may require FDA clearance of a 510(k) submission. Other diagnostic tests may require the approval of a PMA. In addition, some of our future diagnostic tests may require clinical trials to support regulatory approval and we may not successfully complete these clinical trials. The FDA may not approve or clear these diagnostic tests for the indications that are necessary or desirable for successful commercialization. Indeed, the FDA may refuse our requests for 510(k) clearance or premarket approval of new diagnostic tests. Failure to receive clearance or approval for our new diagnostic tests would have an adverse effect on our ability to expand our business.

***Modifications to our marketed tests may require new 510(k) clearances or PMA approvals, or may require us to cease marketing or recall the modified tests until clearances or approvals are obtained.***

Modifications to our diagnostic tests may require new regulatory approvals or clearances, including 510(k) clearances or premarket approvals, or require us to recall or cease marketing the modified systems until these clearances or approvals are obtained. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance. A manufacturer may determine that a modification could not significantly affect safety or efficacy and does not represent a major change in its intended use, so that no new 510(k) clearance is necessary. However, the FDA can review a manufacturer's decision and may disagree. The FDA may also on its own initiative determine that a new clearance or approval is required. We have made modifications to our diagnostic tests in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing our diagnostic tests as modified, which could require us to redesign our diagnostic tests and harm our operating results. In these circumstances, we may be subject to significant enforcement actions.

If a manufacturer determines that a modification to an FDA-cleared device could significantly affect its safety or efficacy, or would constitute a major change in its intended use, then the manufacturer must file for a new 510(k) clearance or possibly a premarket approval application. Where we determine that modifications to our diagnostic tests require a new 510(k) clearance or premarket approval application, we may not be able to obtain those additional clearances or approvals for the modifications or additional indications in a timely manner, or at all. Obtaining clearances and approvals can be a time-consuming process, and delays in obtaining required future clearances or approvals would adversely affect our ability to introduce new or enhanced diagnostic tests in a timely manner, which in turn would harm our future growth.

***If we or our suppliers fail to comply with ongoing FDA or other domestic and foreign regulatory authority or conformity assessment body requirements, or if we experience unanticipated problems with our diagnostic tests, they could be subject to restrictions or withdrawal from the market.***

Any medical device that we manufacture, including those for which we obtain regulatory clearance or approval or certification, and the manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for such diagnostic test, will be subject to continued regulatory review, oversight, and periodic inspections by the FDA and other domestic and foreign regulatory bodies or conformity assessment bodies. In particular, we and our suppliers may be required to comply with FDA's Quality System Regulations (QSR codified at 21 C.F.R. § 820) for medical devices and International Standards Organization (ISO) regulations for the manufacture of our diagnostic tests and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any diagnostic test for which we obtain clearance or approval. Regulatory bodies, such as the FDA, and conformity assessment bodies enforce the QSR and other regulations through periodic inspections and audits. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies or conformity assessment bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, one or more of the following enforcement actions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications for repair, replacement, or refunds;
- recall, detention, or seizure of our diagnostic tests;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance or premarket approval of new diagnostic tests or modified versions of current diagnostic tests;
- operating restrictions;
- withdrawing 510(k) clearances on PMA approvals that have already been granted;
- revocation of EUAs that have been authorized previously;
- refusal to grant export approval for our diagnostic tests; and
- criminal prosecution.

If any of these actions were to occur it would harm our reputation and cause our diagnostic test sales and profitability to suffer and may prevent us from generating revenue. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements which could result in our failure to produce our diagnostic tests on a timely basis and in the required quantities, if at all.

In addition, we are required to conduct surveillance to monitor the safety or effectiveness of our diagnostic tests, and we must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our diagnostic tests. Later discovery of previously unknown problems with our diagnostic tests, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR, may result in changes to labeling, restrictions on such diagnostic tests or manufacturing processes, withdrawal of the diagnostic tests from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

***Our diagnostic tests and services may in the future be subject to product recalls that could harm our reputation, business and financial results.***

Medical devices can experience performance problems in the field that require review and possible corrective action. The occurrence of component failures, manufacturing errors, software errors, design defects or labeling inadequacies affecting a medical device could lead to a government-mandated or voluntary recall by the device manufacturer, in particular when such deficiencies may endanger health. The FDA requires that certain classifications of recalls be reported to the FDA within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our diagnostic tests and services in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. Product recalls may divert management attention and financial resources, expose us to product liability or other claims, harm our reputation with customers and adversely impact our business, financial condition and results of operations. Other jurisdictions have similar recall requirements.

***Legislative or regulatory reforms may make it more difficult and costly for us to obtain regulatory clearance or approval or certification of any future diagnostic tests and to manufacture, market and distribute our diagnostic tests after clearance or approval is obtained.***

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacture and marketing of regulated products or the reimbursement thereof. For example, the Verifying Accurate, Leading-edge IVCT Development (VALID) Act recently introduced in Congress would codify into law the term “in vitro clinical test” in order to create a new medical product category separate from medical devices that would include products currently regulated as in vitro diagnostics as well as LDTs.

In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our diagnostic tests. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of planned or future diagnostic tests. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

Any change in the laws or regulations that govern the clearance and approval processes relating to our current, planned and future diagnostic tests could make it more difficult and costly to obtain clearance or approval for new diagnostic tests or to produce, market and distribute existing diagnostic tests. Significant delays in receiving clearance or approval or the failure to receive clearance or approval for any new diagnostic tests would have an adverse effect on our ability to expand our business.

***Clinical trials may be necessary to support future product submissions to FDA. These clinical trials are expensive and will require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Delays or failures in our clinical trials will prevent us from commercializing any modified or new diagnostic tests and will adversely affect our business, operating results and prospects.***

Initiating and completing clinical trials necessary to support any future PMA applications, and additional safety and efficacy data beyond that typically required for a 510(k) clearance, for our possible future product candidates, will be time consuming and expensive and the outcome uncertain. Moreover, the results of early clinical trials are not necessarily predictive of future results, and any product we advance into clinical trials may not have favorable results in later clinical trials.

Conducting successful clinical studies will require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Patient enrollment in clinical trials and completion of patient participation and follow-up depends on many factors, including the size of the patient population, the nature of the trial protocol, the attractiveness of, or the discomforts and risks associated with, the treatments received by enrolled subjects, the availability of appropriate clinical trial investigators, support staff, and proximity of patients to clinical sites and ability to comply with the eligibility and exclusion criteria for participation in the clinical trial and patient compliance. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and effectiveness of our diagnostic tests or if they determine that the treatments received under the trial protocols are not attractive or involve unacceptable risks or discomforts.

Development of sufficient and appropriate clinical protocols to demonstrate safety and efficacy are required and we may not adequately develop such protocols to support clearance and approval. Further, the FDA may require us to submit data on a greater number of patients than we originally anticipated and/or for a longer follow-up period or change the data collection requirements or data analysis applicable to our clinical trials. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may cause an increase in costs and delays in the approval and attempted commercialization of our diagnostic tests or result in the failure of the clinical trial. In addition, despite considerable time and expense invested in our clinical trials, the FDA may not consider our data adequate to demonstrate safety and efficacy. Such increased costs and delays or failures could adversely affect our business, operating results and prospects.

***If the third parties on which we rely to conduct our clinical trials and to assist us with pre-clinical development do not perform as contractually required or expected, we may not be able to obtain regulatory clearance or approval or certification for or commercialize our diagnostic tests and services.***

We may not have the ability to independently conduct our pre-clinical and clinical trials for our future diagnostic tests and services and we must rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct such trials. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, our diagnostic tests and services on a timely basis, if at all, and our business, operating results and prospects may be adversely affected. Furthermore, our third-party clinical trial investigators may be delayed in conducting our clinical trials for reasons outside of their control.

***Our use, disclosure, and other processing of personally identifiable information, including health information, is subject to HIPAA and other federal, state, and foreign privacy and security regulations, and our failure to comply with those regulations or to adequately secure the information we hold could result in significant liability or reputational harm and, in turn, a material adverse effect on our business, operating results and prospects.***

We maintain and process, and our third-party vendors, collaborators, contractors and consultants maintain and process on our behalf, a large quantity of sensitive information, including confidential business, personal and patient health information in connection with our clinical studies and our employees, and are subject to data privacy and protection laws and regulations that apply to the collection, transmission, storage and use of personally identifying information, which among other things, impose certain requirements relating to the privacy, security and

transmission of personal information. Failure by us or our third-party vendors, collaborators, contractors and consultants to comply with any of these laws and regulations could result in notification obligations or enforcement actions against us, which could result in fines, imprisonment of company officials and public censure, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects. These laws, rules and regulations evolve frequently and their scope may continually change, through new legislation, amendments to existing legislation and changes in enforcement, and may be inconsistent from one jurisdiction to another. The interpretation and application of consumer, health-related and data protection laws, especially with respect to genetic samples and data, in the United States, the European Union (EU) and elsewhere, are often uncertain, contradictory and in flux. As a result, implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future.

In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators.

Domestic laws in this area are complex and developing rapidly. Many state legislatures have adopted legislation relating to privacy, data security and data breaches. Laws in all 50 states require businesses to provide notice to customers whose personally identifiable information has been disclosed as a result of a data breach. The laws are not consistent, and compliance in the event of a widespread data breach is costly. States are also frequently amending existing laws, requiring attention to frequently changing regulatory requirements. For example, California recently enacted the CCPA, which became effective on January 1, 2020. The CCPA, among other things, requires new disclosures to California consumers and affords such consumers new abilities to access and delete their personal information, opt-out of certain sales of personal information and receive detailed information about how their personal information is used. The CCPA provides for fines of up to \$7,500 per violation, as well as a private right of action for data breaches that is expected to increase the frequency of data breach litigation. While the CCPA has already been amended multiple times, it is unclear how this legislation will be further modified or how it will be interpreted. Interpretations of the CCPA may continue to evolve with regulatory guidance and the CCPA continue to be amended, including through a ballot initiative, the California Privacy Rights Act (the CPRA). That passed in November 2020. The CPRA will impose additional data protection obligations on companies doing business in California, including additional consumer rights, including regarding certain uses of sensitive data. It also creates a new California data protection agency specifically tasked to enforce the law, which may likely result in increased regulatory scrutiny of California businesses in the areas of data protection and security. The effects of this legislation potentially are far-reaching, however, and may require us to modify our data processing practices and policies and incur substantial compliance-related costs and expenses. The CCPA and other changes in state and federal laws or regulations relating to privacy, data protection and information security, particularly any new or modified laws or regulations that require enhanced protection of certain types of data or new obligations with regard to data retention, transfer or disclosure, could increase the cost of providing our offerings, require significant changes to our operations or even prevent us from providing certain offerings in jurisdictions in which we currently operate and in which we may operate in the future.

Because of the breadth of these data protection laws and the narrowness of their exceptions and safe harbors, it is possible that our business or data protection policies could be subject to challenge under one or more of such laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of heightened regulatory focus on data privacy and security issues. Although we endeavor to comply with our published policies and documentation and ensure their compliance with current laws, rules and regulations, we may at times fail to do so or be alleged to have failed to do so. The publication of our privacy policy and other documentation that provide promises and assurances about privacy and security can subject us to potential state and federal action in the United States if they are found to be deceptive, unfair, or misrepresentative of our actual practices. Any failure by us or other parties with whom we do business to comply with this documentation or with federal, state, local or international regulations could result in proceedings against us by governmental entities, private parties or others. In many jurisdictions, enforcement actions and consequences for noncompliance are rising.

If our operations are found to be in violation of any of the data protection laws described above or any other laws that apply to us, we may be subject to penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in government healthcare programs, injunctions, private qui tam actions brought by individual whistleblowers in the name of the government, class action litigation and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corrective action plan or other agreement to resolve allegations of non-compliance with these laws, any of which could adversely affect our ability to operate our business and our results of operations.

In addition, numerous state and federal laws and regulations govern the collection, dissemination, use, privacy, confidentiality, security, availability, integrity, and other processing of PHI and PII. These laws and regulations include HIPAA. HIPAA establishes a set of national privacy and security standards for the protection of protected health information (as defined in HIPAA, PHI) by health plans, healthcare clearinghouses and certain healthcare providers, referred to as covered entities, and the business associates with whom such covered entities contract for services. We are a covered entity under HIPAA when we are conducting our clinical trials. We are a covered entity with regard to our observational studies and clinical trials, and also a business associate under HIPAA for certain other business activities, and we execute business associate agreements with our clients.

HIPAA requires covered entities and business associates, such as us, to develop and maintain policies with respect to the protection of, use and disclosure of electronic PHI, including the adoption of administrative, physical and technical safeguards to protect such information, and certain notification requirements in the event of a data breach.

HIPAA imposes mandatory penalties for certain violations. Penalties for violations of HIPAA and its implementing regulations start at \$119 per violation and are subject to a cap of \$1,785,651 for violations of the same standard in a single calendar year. However, a single breach incident can result in violations of multiple standards. HIPAA also authorizes state attorneys general to file suit on behalf of their residents. Courts may 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 violations of HIPAA, its standards have been used as the basis for duty of care in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI.

In addition, HIPAA mandates that the Secretary of HHS conduct periodic compliance audits of HIPAA covered entities and business associates. With regard to business associates, those audits assess the business associate's compliance with the HIPAA Privacy and Security Standards. Such audits are conducted randomly and after an entity experiences a breach affecting more than 500 individuals' data. Undergoing an audit can be costly, can result in fines or onerous obligations, and can damage a business associate's reputation.

In addition to HIPAA, numerous other federal, state, and foreign laws and regulations protect the confidentiality, privacy, availability, integrity and security of PHI and other types of PII. Some of these laws and regulations may be preempted by HIPAA with respect to PHI, or may exclude PHI from their scope but impose obligations with regard to PII that is not PHI, and in some cases, can impose additional obligations with regard to PHI. These laws and regulations are often uncertain, contradictory, and subject to changing or differing interpretations, and we expect new laws, rules and regulations regarding privacy, data protection, and information security to be proposed and enacted in the future. HHS is also proposing amendments to the HIPAA Privacy Rule to modernize certain data sharing provisions and enhance patient access to their information. This complex, dynamic legal landscape regarding privacy, data protection, and information security creates significant compliance issues for us and our clients and potentially exposes us to additional expense, adverse publicity and liability. While we have implemented data privacy and security measures in an effort to comply with applicable laws and regulations relating to privacy and data protection, some PHI and other PII or confidential information is transmitted to us by third parties, who may not implement adequate security and privacy measures, but it is possible that laws, rules and regulations relating to privacy, data protection, or information security may be interpreted and applied in a manner that is inconsistent with our practices or those of third parties who transmit PHI and other PII or confidential information to us. If we or these third parties are found to have violated such laws, rules or regulations, it could result in government-imposed fines, orders requiring that we or these third parties change our or their practices, or criminal charges, which could adversely affect our business.



Complying with these various laws and regulations 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.

We may eventually operate in a number of countries outside of the United States whose laws, including data privacy laws, may in some cases be more stringent than the requirements in the United States. For example, EU and UK data privacy laws have specific requirements relating to cross-border transfers of personal data to certain jurisdictions, including to the United States, have strict requirements relating to personal data collection, use or sharing, and have more stringent requirements relating to organizations' privacy programs and provide stronger individual rights. Moreover, we may also be subject to evolving international privacy and data security regulations which could result in greater compliance costs and in turn lead to penalties, where such compliance programs are not implemented correctly.

Certain of our processing activities are subject to the EU General Data Protection Regulation and the UK General Data Protection Regulation (collectively, the "GDPR") – including, those involving pseudonymised / key-coded data - as the GDPR applies extra-territorially. The GDPR imposes strict requirements on controllers and processors processing personal data, including, for example, requirements to: (i) identify a legal basis for the processing of personal data, (ii) provide robust disclosures to individuals, (iii) respond to requests from individuals to exercise their data subject rights, (iv) provide personal data breach notifications within 72 hours after discovering the breach, (v) limit the collection and retention of personal data, (vi) impose specific contractual obligations on processors engaged to process personal data on the instructions of the controller, and (vii) apply enhanced protections to health data and other special categories of personal data.

The EU GDPR also provides that EU Member States may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data, which could limit our ability to use and share such personal data and cause our costs to increase and harm our financial condition.

Failure to comply with the requirements of the GDPR may result in fines of up to €20 million (£17.5 million in the case of the UK GDPR) or up to 4% of the total worldwide annual turnover of our preceding fiscal year, whichever is higher, and other administrative penalties. GDPR compliance may require us to put in place additional mechanisms, which may result in compliance costs and other substantial expenditures. This may be onerous and adversely affect our business, financial condition, results of operations and the profitability of our platform of diagnostic tests. Failure to comply with the GDPR and other countries' privacy or data security-related laws, rules or regulations could result in material penalties imposed by regulators, affect our compliance with contracts entered into with our collaborators and other third-party payers, and have an adverse effect on our business and financial condition. Currently, the GDPR is only applicable to us as a processor, but as we continue to expand into the European market, the GDPR will have direct applicability to us as a controller.

The GDPR also prohibits the transfer of personal data from the EEA/UK to a country outside of the EEA/UK (e.g., the United States) unless made to a country deemed to have adequate data privacy laws by the European Commission (or UK Government in case of the UK GDPR) or a data transfer mechanism has been put in place. Until recently, one such data transfer mechanism was the EU-US Privacy Shield. However, in July 2020 the Court of Justice of the European Union (CJEU) declared the Privacy Shield to be invalid. The CJEU upheld the validity of standard contractual clauses (SCCs) as a legal mechanism to transfer personal data but companies relying on SCCs will need to carry out a transfer privacy impact assessment, which among other things, assesses laws governing access to personal data in the recipient country and considers whether supplementary measures that provide privacy protections additional to those provided under SCCs will need to be implemented to ensure an essentially equivalent level of data protection to that afforded in the EEA. In turn, the findings of the CJEU will have significant implications for cross-border data flows and may lead to increased transaction, compliance, and technological costs to support international data transfers.

Organizations operating in Canada and covered by the Personal Information Protection and Electronic Documents Act (PIPEDA), or equivalent Canadian provincial laws, must obtain an individual's consent when they collect, use or disclose that individual's personal information. Individuals have the right to access and challenge the accuracy of their personal information held by an organization, and personal information may only be used for the purposes for which it was collected. If an organization intends to use personal information for another purpose, it must again obtain that individual's consent.

We regularly monitor, defend against and respond to attacks to our networks and other information security incidents. Despite our information security efforts, our facilities, systems, and data, as well as those of our third-party service providers, may be vulnerable to privacy and information security incidents such as data breaches, viruses or other malicious code, coordinated attacks, data loss, phishing attacks, ransomware, denial of service attacks, or other security or IT incidents caused by threat actors, technological vulnerabilities or human error. If we, or any of our vendors that support our IT or have access to our data, including any third-party vendors that collect, process and store personal data on our behalf, fail to comply with laws requiring the protection of personal information, or fail to safeguard and defend personal information or other critical data assets or IT systems, we may be subject to regulatory enforcement and fines as well as private civil actions. We may be required to expend significant resources in the response, containment, mitigation of cybersecurity incidents as well as in defense against claims that our information security was unreasonable or otherwise violated applicable laws or contractual obligations.

***Our employees, collaborators, independent contractors and consultants may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.***

We are exposed to the risk that our employees, collaborators, independent contractors and consultants may engage in fraudulent or other illegal activity with respect to our business. Misconduct by these employees could include intentional, reckless and/or negligent conduct or unauthorized activity that violates:

- FDA regulations, including those laws requiring the reporting of true, complete, and accurate information to the FDA authorities;
- federal and state healthcare fraud and abuse laws and regulations; or
- laws that require the true, complete and accurate reporting of financial information or data.

In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve individually identifiable information, including, without limitation, the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Any incidents or any other conduct that leads to an employee, contractor, or other agent, or our company, receiving an FDA debarment or exclusion by the HHS Office of Inspector General (OIG) could result in penalties, a loss of business from third parties, and severe reputational harm.

We have adopted a Code of Business Conduct and Ethics and compliance policies to govern and deter such behaviors, but it is not always possible to identify and deter misconduct by our employees and other agents, 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 governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, treble damages, monetary fines, disgorgement, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations.

***Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.***

Our ongoing research and development and clinical trial activities are subject to extensive regulation and review by numerous governmental authorities both in the United States and abroad. We are currently conducting pre-and post-market clinical studies of some of our tests. In the future we may conduct clinical trials to support approval of new diagnostic tests and services, or new indications. Clinical studies may need to be conducted in compliance with FDA regulations or the FDA may take enforcement action. The data collected from these clinical studies may ultimately be used to support marketing authorization for these diagnostic tests and services. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product candidate claims or that the FDA or foreign authorities and conformity assessment bodies will agree with our conclusions

regarding them. Success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and pre-clinical studies. The clinical trial process may fail to demonstrate that our tests are safe and effective for the proposed indicated uses, which could cause us to abandon development of our tests and may delay development of others. Any delay or termination of our clinical trials will delay the filing of our product submissions and, ultimately, may impact our ability to commercialize our tests and generate revenues.

Many of the factors that may cause or lead to a delay in the commencement or completion of clinical trials may also ultimately lead to delay or denial of regulatory clearance or approval or certification. The commencement of clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites and the eligibility criteria for the clinical trial.

We may find it necessary to engage contract research organizations to perform data collection and analysis and other aspects of our clinical trials, which might increase the cost and complexity of our trials. We may also depend on clinical investigators, medical institutions, and contract research organizations to perform the trials, and would control only certain aspects of their activities. Nevertheless, we would be responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on these third parties would not relieve us of our regulatory responsibilities. We and our third-party contractors are required to comply with good clinical practices (GCPs) which are regulations and guidelines enforced by the FDA, and comparable regulations enforced by foreign regulatory authorities for products in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any third-party contractor fails to comply with applicable GCPs, the clinical data generated in clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities or conformity assessment bodies may require us to perform additional clinical trials before clearing or approving our marketing applications. A failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory clearance or approval or certification process. In addition, if these parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality, completeness or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or for other reasons, our clinical trials may have to be extended, delayed or terminated.

Many of these factors could be beyond our control. We may not be able to undertake additional trials, repeat trials or enter into new arrangements with third parties without undue delays or considerable expenditures. If there are delays in testing or clearances or approvals as a result of the failure to perform by third parties, our research and development costs would increase and we may not be able to obtain regulatory clearance or approval or certification for our tests. In addition, we may not be able to establish or maintain relationships with these parties on favorable terms, if at all. Each of these outcomes would harm our ability to market our tests, or to achieve sustained profitability.

***The results of our clinical trials may not support our product candidate claims or may result in the discovery of adverse side effects.***

We cannot be certain that the results of our future clinical trials will support our future product claims or that the FDA or comparable foreign regulatory authorities or conformity assessment bodies will agree with our conclusions regarding them. Success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and pre-clinical studies. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses, which could cause us to abandon a product candidate and may delay development of others. Any delay or termination of our clinical trials will delay the filing of our product submissions and, ultimately, our ability to commercialize our product candidates and generate revenues. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of the future product's profile.

***Our billing, collections and claims processing activities are complex and time-consuming, and any delay in transmitting and collecting claims or failure to comply with applicable billing requirements, could have an adverse effect on our future revenue.***

Billing for our tests is complex, time-consuming and expensive. Depending on the billing arrangement and applicable law, we bill various payers, such as government payers, insurance companies and patients, all of which may have different billing requirements. We may face increased risk in our collection efforts, including long collection cycles and the risk that we may never collect at all, either of which could adversely affect our business, financial condition and results of operations. Several factors make the billing process complex, including:

- differences between the list price for our tests and the reimbursement rates of payers;
- compliance with complex federal and state regulations related to billing government healthcare programs, including Medicare and Medicaid, to the extent our tests are covered by such programs;
- differences in coverage among payers and the effect of patient co-payments or co-insurance;
- differences in information and billing requirements among payers;
- changes to codes and coding instructions governing our tests;
- incorrect or missing billing information; and
- the resources required to manage the billing and claims appeals process.

These billing complexities and the related uncertainty in obtaining payment for our tests could negatively affect our revenue and cash flow, our ability to achieve profitability and the consistency and comparability of our results of operations. In addition, if claims for our tests are not submitted to payers on a timely basis, or if we fail to comply with applicable billing requirements, it could have an adverse effect on our revenue and our business.

Third-party payers require us to identify the test for which we are seeking reimbursement using a Current Procedural Terminology (CPT) code. The CPT code set is maintained by the American Medical Association (AMA). In cases where there is not a specific CPT code to describe a test, such as with Nodify CDT and GeneStrat, the test may be billed under an unlisted molecular pathology procedure code or through the use of a combination of single gene CPT codes, depending on the payer. The Protecting Access to Medicare Act of 2014 (PAMA) authorized the adoption of new, temporary billing codes and unique test identifiers for FDA-cleared or approved tests as well as advanced diagnostic laboratory tests. The AMA has created a new section of CPT codes, Proprietary Laboratory Analyses codes to facilitate implementation of this section of PAMA. In addition, CMS may assign unique level II Healthcare Common Procedure Coding System codes to tests that are not already described by a unique CPT code. VeriStrat and Nodify XL2 both have test specific CPT codes, but GeneStrat and Nodify CDT do not at this time.

In the instance where a code used does not describe a specific test, the insurance claim must be examined to determine what test was provided, whether the test was appropriate and medically necessary, and whether payment should be rendered, which may require a letter of medical necessity from the ordering physician. This process can result in a delay in processing the claim, a lower reimbursement amount or denial of the claim. As a result, obtaining approvals from third-party payers to cover our tests and establishing adequate reimbursement levels is an unpredictable, challenging, time-consuming and costly process and we may never be successful.

***We and our third-party manufacturers and suppliers must comply with environmental, health and safety laws and regulations, which can be expensive and restrict how we do, or interrupt our, business.***

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the generation, use, storage and disposal of hazardous materials. We work with materials, including chemicals, biological agents and compounds and samples that could be hazardous to human health and safety or the environment. Our operations also produce hazardous and biological waste products. Accordingly, we and our third-party manufacturers and suppliers are subject to federal, state, local and foreign environmental, health and safety laws and regulations, and permitting and licensing requirements, including those governing the generation, use, manufacture, storage, handling, transportation, release and disposal of, and exposure to, these materials, and worker health and safety.

We cannot eliminate the risk of contamination or injury resulting from such hazardous materials. We also cannot guarantee that the procedures utilized by our third-party manufacturers for handling and disposing of hazardous materials and wastes comply with all applicable environmental, health and safety laws and regulations. As a result, we may be held liable for any resulting damages, costs or liabilities, including cleanup costs and liabilities, which could be significant, or our commercialization, research and development efforts and business operations may be restricted or interrupted.

Environmental, health and safety laws and regulations are complex, change frequently and have tended to become more stringent. Compliance with such laws and regulations is expensive, and current or future environmental, health and safety laws and regulations may restrict our operations. If we do not comply with applicable environmental health and safety laws and regulations, and permitting and licensing requirements, we may be subject to fines, penalties, a suspension of our business or other sanctions.

## **Risks Related to our Intellectual Property**

### ***Our success may be impaired if we are unable to obtain, maintain and protect our intellectual property rights.***

Our commercial success will depend in part on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our diagnostic tests, products and services and technology. We rely on patent protection, as well as a combination of copyright, trade secret and trademark laws, to protect our proprietary technology and prevent others from duplicating our suite of diagnostic tests and products. However, these means may afford only limited protection and may not:

- prevent our competitors from duplicating our diagnostic tests and products, including our COVID-19 testing program and Nodify XL2, Nodify CDT, GeneStrat and VeriStrat tests;
- prevent our competitors from gaining access to our proprietary information and technology, including the Diagnostic Cortex platform, tech platforms such as the DeepMALDI analysis and intellectual property covering technologies that allow us to develop “test algorithms”; or
- allow us to gain or maintain a competitive advantage.

Any of our patents, including those we may license, may be challenged, invalidated, rendered unenforceable or circumvented. Consequently, we do not know whether any of our diagnostic tests, products and services will be protectable or remain protected by valid and enforceable patents. We may not prevail if our patents are challenged by competitors or other third parties. The United States federal courts or equivalent national courts or patent offices elsewhere may invalidate our patents, find them unenforceable, or narrow their scope. Furthermore, competitors may be able to design around our patents by developing similar or alternative technologies or products in a non-infringing manner, or obtain patent protection for more effective technologies, designs or methods, including for treating lung cancer. If these developments were to occur, our diagnostic tests and products may become less competitive and sales may decline.

We have filed numerous patent applications seeking protection of diagnostic tests and other inventions originating from our research and development. Our patent applications may not result in issued patents, and any patents that are issued may not provide meaningful protection against competitors or competitive technologies. Further, the examination process may require us to narrow the claims for our pending patent applications, which may limit the scope of patent protection that may be obtained if these applications issue. The scope of a patent may also be reinterpreted and significantly reduced after issuance. Even if patent applications we license or own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with the protection or competitive advantages we are seeking.

Moreover, some of our owned and in-licensed patents and patent applications are, and may in the future be, co-owned with third parties. If we are unable to obtain or maintain an exclusive license to any such third-party co-owners’ interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

The patent position of biotechnology companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. In addition, the determination of patent rights with respect to pharmaceutical compounds and technologies commonly involves complex legal and factual questions, which has in recent years been the subject of much litigation. Various courts, including the United States Supreme Court have rendered decisions that affect the scope of patentability of certain inventions or discoveries relating to biotechnology. These decisions state, among other things, that a patent claim that recites an abstract idea, natural phenomenon, or law of nature (for example, the relationship between particular genetic variants and cancer) are not themselves patentable. Precisely what constitutes a law of nature or abstract idea is uncertain, and it is possible that certain aspects of our technology could be considered unpatentable under applicable law. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Depending on decisions by the United States Congress, the federal courts and the United States Patent and Trademark Office (USPTO), the laws and regulations governing patents could change in unpredictable ways that would weaken our and our licensors' ability to obtain new patents or to enforce our existing owned or in-licensed patents and patents that we might obtain or in-license in the future. Additionally, our pending and future patent applications may not result in patents being issued which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. The scope of patent protection outside of the United States is also uncertain. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property rights or narrow the scope of our owned and licensed patents.

If we are unable to obtain and maintain patent protection for our technology, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize diagnostic tests, products and services similar or superior to ours, and our competitive position may be adversely affected. It is also possible that we will fail to identify patentable aspects of inventions made in the course of our 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. In addition, the patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

Additionally, while software and other of our proprietary works may be protected under copyright law, we have chosen not to register any copyrights in these works, and instead, primarily rely on protecting our software as a trade secret. In order to bring a copyright infringement lawsuit in the United States, the copyright must be registered. Accordingly, the remedies and damages available to us for unauthorized use of our copyrights may be limited.

***If we are unable to protect the confidentiality of our trade secrets, our business and competitive position may be harmed.***

In addition to seeking patent protection for the patents underlying our diagnostic tests, products and services, we also rely upon unpatented trade secrets, know-how and continuing technological innovation to develop and maintain a competitive position. Trade secrets and know-how can be difficult to protect. We seek to protect such proprietary information, in part, through confidentiality agreements with our employees, collaborators, contractors, advisors, consultants and other third parties and invention assignment agreements with our employees. We also have agreements with some of our consultants that require them to assign to us any inventions created as a result of their working with us. The confidentiality agreements are designed to protect our proprietary information and, in the case of agreements or clauses containing invention assignment, to grant us ownership of technologies that are developed through a relationship with employees or third parties.

We cannot guarantee that we have entered into such agreements with each party that has or may have had access to our trade secrets or proprietary information. Additionally, despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to, or independently developed by, a competitor or other third party, our competitive position would be materially and adversely harmed. Furthermore, we expect these trade secrets, know-how and proprietary information to over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology and the movement of personnel from academic to industry scientific positions. Consequently, we may be unable to prevent our proprietary technology from being exploited in the United States and abroad, which could affect our ability to expand in domestic and international markets or require costly efforts to protect our technology.

We also seek to preserve the integrity and confidentiality of our data and trade secrets 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 breach. In addition, our trade secrets may otherwise become known, or be independently discovered by, competitors. To the extent that our employees, consultants, contractors or collaborators use intellectual property rights owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions, which could have a material adverse effect on our business, financial condition and results of operations.

***We may be subject to claims that we or our employees have misappropriated the intellectual property rights of a third party, including trade secrets or know-how, or are in breach of non-competition or non-solicitation agreements with our competitors, and third parties may claim an ownership interest in intellectual property we regard as our own.***

Many of our employees and consultants were previously employed at or engaged by universities or other medical device, diagnostic, biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants and contractors, may have executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees, consultants and independent contractors do not use the intellectual property rights, proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we or these individuals have, inadvertently or otherwise, used, infringed, misappropriated or otherwise violated the intellectual property rights or disclosed the alleged trade secrets or other proprietary information, of these former employers, competitors or other third parties, or to claims that we have improperly used or obtained such trade secrets. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Any litigation or the threat of litigation may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize potential diagnostic tests, products and services, which could harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management and other employees.

Additionally, we may be subject to claims from third parties challenging our ownership interest in intellectual property rights we regard as our own, based on claims that our employees or consultants have breached an obligation to assign inventions to another employer, to a former employer, or to another person or entity. Litigation may be necessary to defend against any other claims, and it may be necessary or we may desire to enter into a license to settle any such claim; however, there can be no assurance that we would be able to obtain a license on commercially reasonable terms, if at all. If our defense to those claims fails, in addition to paying monetary damages, a court could prohibit us from using technologies or features that are essential to our diagnostic tests or products, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers.

An inability to incorporate technologies or features that are important or essential to our diagnostic tests or products could have a material adverse effect on our business, financial condition and results of operations, and may prevent us from selling our rights to our COVID-19 testing program, either of the Nodify XL2 and Nodify CDT tests, or the VeriStrat and GeneStrat tests.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property rights to execute agreements assigning such intellectual property rights to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property rights that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property rights. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

***Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our existing and future diagnostic tests, products and services.***

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. In 2011, the Leahy-Smith America Invents Act (Leahy-Smith Act) was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and also may affect patent litigation. These also include provisions that switched the United States from a first-to-invent system to a first-inventor-to-file system, allow third-party submission of prior art to the USPTO during patent prosecution and set forth additional procedures to attack the validity of a patent by the USPTO administered post grant proceedings, including post-grant review, *inter partes* review and derivation proceedings. Under a first-inventor-to-file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor was the first to invent the claimed invention. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective in 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition and results of operations.

In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and applications. Furthermore, the United States Supreme Court and the United States Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Recent United States Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by United States and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future.

***If our trademarks and tradenames are not adequately protected, then we may not be able to build name recognition in our markets and our business may be adversely affected.***

Our trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be violating or infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these trademarks or trade names, which we need to build name recognition among potential partners and customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement or dilution claims brought by owners of other trademarks. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected.



We have not yet registered certain of our trademarks in all of our potential markets, although we have registered several connected to our diagnostic tests, products and services in the United States. If we apply to register these and trademarks in the United States and other countries, our applications may not be allowed for registration in a timely fashion or at all, and our registered trademarks may not be maintained or enforced. During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademark applications and registrations, and our trademarks may not survive such proceedings. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would.

Our efforts to enforce or protect our rights related to trademarks, trade secrets, domain names or other intellectual property rights may be ineffective, could result in substantial costs and diversion of resources and could adversely affect our business, financial condition and results of operations.

***We may become involved in lawsuits to protect or enforce our patents, the patents of our licensors or other intellectual property rights, which could be expensive, time consuming and unsuccessful.***

Competitors or other third parties may infringe, misappropriate or otherwise violate our patents, the patents of our licensors or other intellectual property rights, or we may be required to defend against claims of infringement, misappropriation or other violations. In addition, our patents also may become involved in inventorship, priority or validity disputes. To counter or defend against such claims can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke those parties to assert counterclaims against us alleging that we infringe their patents or other intellectual property. In any such proceeding, a court or other administrative body may decide that a patent or other intellectual property right owned by us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover such technology. Grounds for a validity challenge could include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description, non-enablement or failure to claim patent-eligible subject matter. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld information material to patentability from the USPTO, or made a misleading statement, during prosecution. Third parties also may raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include reexamination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions, including opposition proceedings. Such proceedings could result in the revocation or cancellation of or amendment to our patents in such a way that they no longer cover our diagnostic tests, products and services or prevent third parties from competing with our diagnostic tests, products and services. 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 the patent examiner and we or our licensing partners were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we could lose at least part, and perhaps all, of the patent protection on our diagnostic tests, products and services. An adverse result in any litigation or other proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. 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 litigation.

Moreover, some of our owned and in-licensed patents and patent applications are, and may in the future be, co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing diagnostic tests, products, services or technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

Even if resolved in our favor, litigation or other proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our management and other personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on our common stock price. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

***Third parties may initiate legal proceedings alleging that we are infringing, misappropriating, or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.***

The intellectual property landscape in the field of precision oncology is in flux, and it may remain uncertain for the coming years. There may be significant intellectual property related litigation and proceedings relating to our owned and in-licensed, and other third party, intellectual property and proprietary rights in the future. As we move into new markets and applications for our diagnostic tests, products or services, incumbent participants in such markets may assert their patents and other intellectual property rights against us as a means of slowing our entry into such markets or as a means to extract substantial license and royalty payments from us. Our competitors and others may now and, in the future, have significantly larger and more mature patent portfolios than we currently have. In addition, future litigation may involve patent holding companies or other adverse patent owners who have no relevant product or service revenue and against whom our own patents may provide little or no deterrence or protection. Therefore, our commercial success depends in part on our non-infringement of the patents or other intellectual property rights of third parties.

However, we may in the future be subject to claims that we, or other parties we have agreed to indemnify, infringe, misappropriate or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Because patent applications are published sometime after filing, and because applications can take several years to issue, there may be additional currently pending third-party patent applications that are unknown to us, which may later result in issued patents. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. We may not have sufficient resources to bring these actions to a successful conclusion.

There is a substantial amount of litigation and other patent challenges, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology industry, including patent infringement lawsuits, interferences, oppositions and *inter partes* review proceedings before the USPTO, and corresponding foreign patent offices. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, including our competitors, exist in the fields in which we are developing diagnostic tests and in which we may develop future diagnostic tests, products and services. As the precision oncology industry expands and more patents are issued, the risk increases that our diagnostic tests may be subject to claims of infringement of the patent rights of third parties. Numerous significant intellectual property issues have been litigated, are being litigated and will likely continue to be litigated, between existing and new participants in our existing and targeted markets, and competitors have and may assert that our diagnostic tests or services infringe their intellectual property rights as part of a business strategy to impede our successful entry into or growth in those markets.

We could incur substantial costs and divert the attention of our management and technical personnel in defending against any of these claims. Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources.

Because of the inevitable uncertainty in intellectual property litigation, we could lose a patent infringement or other action asserted against us regardless of our perception of the merits of the case. There is no assurance that a court would find in our favor on questions of infringement, validity, enforceability, or priority. A court of competent jurisdiction could hold that these third-party patents are valid, enforceable, and infringed, which could materially and adversely affect our ability to commercialize any product candidates we may develop and any other product candidates or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such United States patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such United States patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such United States patent.

Parties making claims against us may be able to obtain injunctive or other relief, which could block our ability to develop, commercialize and sell diagnostic tests, products or services, and could result in the award of substantial damages against us, including treble damages, attorney's fees, costs, and expenses if we are found to have willfully infringed. In the event of a successful claim of infringement against us, we may be required to pay damages and ongoing royalties, which could be significant, and obtain one or more licenses from third parties, or be prohibited from selling certain diagnostic tests, products or services. We may not be able to obtain these licenses on acceptable or commercially reasonable terms, if at all, or these licenses may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we could encounter delays in diagnostic test introductions while we attempt to develop alternative diagnostic tests, products or services to avoid infringing third-party patents or intellectual property rights. Defense of any lawsuit or failure to obtain any of these licenses could prevent us from commercializing diagnostic tests, products or services, and the prohibition of sale of any of our diagnostic tests, products or services could materially affect our business and our ability to gain market acceptance for our diagnostic tests, products and services.

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, during the course of this kind of litigation, 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.

In addition, our agreements with some of our customers, suppliers or other entities with whom we do business require us to defend or indemnify these parties to the extent they become involved in infringement claims, including the types of claims described above. We could also voluntarily agree to defend or indemnify third parties in instances where we are not obligated to do so if we determine it would be important to our business relationships. If we are required or agree to defend or indemnify third parties in connection with any infringement claims, we could incur significant costs and expenses that could adversely affect our business, operating results or financial condition.

***We may be subject to claims challenging the priority or inventorship of our patents and other intellectual property rights.***

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets or other intellectual property rights as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' ownership of our owned or in-licensed patents, trade secrets or other intellectual property rights. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property rights that are important to our product candidates.

If we or our licensors are unsuccessful in any interference proceeding or other priority or inventorship dispute, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture, and commercialization of one or more of our diagnostic tests, products or services. The loss of exclusivity or the narrowing of our owned and licensed patent

claims could limit our ability to stop others from using or commercializing similar or identical technology and products. Any of the foregoing could result in a material adverse effect on our business, financial condition, results of operations, or prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

***Obtaining and maintaining our patent protection depends on compliance with various required procedures, document submissions, fee payments and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States at several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees due to non-United States patent agencies. We are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property rights. The USPTO and various non-US governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance 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 may be able to enter the market without infringing our patents and this circumstance would have a material adverse effect on our business.

***Issued patents covering our diagnostic tests and any other or future diagnostic tests, products or services could be found invalid or unenforceable if challenged.***

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability and some of our patents or patent applications, including licensed patents, may be challenged, in courts or patent offices in the United States and abroad, in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference. Additionally, if we and our licensing partners initiate or become involved in legal proceedings against a third party to enforce a patent covering one of our diagnostic tests, products, services or technologies, the defendant could counterclaim that the patent covering our diagnostic tests, products or services is invalid or unenforceable. In patent litigation in the United States, counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including patent eligible subject matter, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement during prosecution. In addition, the United States now awards patent priority to the first party to file a patent application, and others may submit patent claims covering our inventions prior to us. 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 third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our diagnostic tests or any diagnostic tests, products and services that we may develop.

A successful third-party challenge to our patents could result in the unenforceability or invalidity of such patents, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights, which could have a material adverse impact on our business. Furthermore, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future diagnostic tests, products or services.

We may not be aware of all third-party intellectual property rights potentially relating to our current or future diagnostic tests, products or services.

Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until approximately 18 months after filing or, in some cases, not until such patent applications issue as patents. We, or our current or future license partners or collaborators, 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. The outcome of such proceedings is uncertain, and other patent applications may have priority over our patent applications. Such proceedings could also result in substantial costs to us and divert our management's attention and resources.

***We rely on licenses from third parties in relation to certain diagnostic tests, products and services and if we lose these licenses then we may be subjected to future litigation.***

We are a party to license agreements that grant us rights to use certain intellectual property rights, including patents and patent applications, typically in certain specified fields of use, in connection with our diagnostic tests, products and services. Some of those licensed rights could provide us with freedom to operate for aspects of our diagnostic tests, products and services. We may need to obtain additional licenses from others to advance our research, development and commercialization activities.

The in-licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to in-license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

Furthermore, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. In addition, we expect that competition for the in-licensing or acquisition of third-party intellectual property rights for product candidates that are attractive to us may increase in the future, which may mean fewer suitable opportunities for us as well as higher acquisition or licensing costs. We may be unable to in-license or acquire the third-party intellectual property rights for product candidates on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to suitable product candidates, our business, financial condition, results of operations and prospects for growth could suffer.

Our existing license agreements impose, and we expect that our future license agreements will impose, various diligence, royalty payment, milestone payment, insurance and other obligations on us. If we fail to comply with these obligations or other obligations in our license agreements, our licensors may have the right to terminate these agreements, in which event we may not be able to develop and market any product or use any technology that is covered by these agreements. If our license agreements terminate, or we experience a reduction or elimination of licensed rights under these agreements, we may have to negotiate new or reinstated licenses with less favorable terms or we may not have sufficient intellectual property rights to operate our business. The occurrence of such events could materially harm our business.

Our success may depend in part on the ability of our licensors to obtain, maintain and enforce patent protection for our licensed intellectual property rights. Our licensors may not successfully prosecute the patent applications we license. Even if patents issue in respect of these patent applications, our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents or may pursue such litigation less aggressively than we would. Without protection for the intellectual property rights we license, other companies might be able to offer substantially identical diagnostic tests for sale, which could adversely affect our competitive business position and harm our business prospects.

Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Moreover, disputes may also arise between us and our current or future licensors regarding intellectual property rights subject to a license agreement, including those relating to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether, and the extent to which, our diagnostic tests, products, services, technology, and processes infringe on intellectual property rights of the licensor that is not subject to the licensing agreement;
- whether our licensor or its licensor had the right to grant the license agreement;
- whether third parties are entitled to compensation or equitable relief, such as an injunction, for our use of the intellectual property rights without their authorization;
- our involvement in the prosecution of licensed patents and our licensors' overall patent enforcement strategy;
- the amounts of royalties, milestones, or other payments due under the license agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property rights by our licensors and us and our collaborators; and
- the priority of invention of patented technology.

If we do not prevail in such disputes, we may lose any or all of our rights under such license agreements.

In addition, the agreements under which we currently license intellectual property rights or technology from third parties are complex and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property rights or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, or are insufficient to provide us the necessary rights to use the intellectual property rights, we may be unable to successfully develop and commercialize any affected diagnostic tests, products or services, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

Absent the license agreements, we may infringe patents subject to those agreements, and if the license agreements are terminated, we may be subject to litigation by the licensor. Litigation could result in substantial costs to us and distract our management. If we do not prevail, we may be required to pay damages, including treble damages, attorneys' fees, costs and expenses and royalties or be enjoined from selling our diagnostic tests, products or services, which could adversely affect our ability to offer diagnostic tests, products or services, our ability to continue operations and our financial condition.

***Some intellectual property that we in-license may have been developed through government funded programs and thus may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for companies based in the United States. Compliance with such regulations may limit our exclusive rights, and limit our ability to contract with manufacturers that are not based in the United States.***

Certain of the intellectual property that we license may have been developed through the use of United States government funding and therefore may be subject to certain federal regulations. As a result, the United States government may have certain rights to intellectual property embodied in our diagnostic tests, products and services pursuant to the Bayh-Dole Act of 1980 (Bayh-Dole Act). These United States government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the United States government has

the right 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; 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”). To date, none of our commercialized products are subject to march-in rights. The United States government also has the right to take title to these inventions if we, or the applicable licensor, fail to disclose the invention to the government and fail 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 or the applicable licensor to expend substantial resources. In addition, the United States government requires that any products of the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner 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 United States manufacturers may limit our ability to contract with product manufacturers outside of the United States for products covered by such intellectual property. To the extent any of our current or future owned or licensed intellectual property is generated through the use of United States government funding, the provisions of the Bayh-Dole Act may similarly apply. Any failure by us to comply with federal regulations regarding intellectual property rights that were developed through the use of United States government funding could have a material adverse effect on our business, financial condition, results of operations, and prospects.

***Patent terms may be inadequate to protect our competitive position on our diagnostic tests, products and services for an adequate amount of time.***

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest United States non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited.

Even if patents covering our diagnostic tests, products and services are obtained, once the patent life has expired, we may be open to competition from competitive diagnostic tests, products and services. Given the amount of time required for the development, testing and regulatory review of potential new diagnostic tests, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing diagnostic tests, products or services similar or identical to ours.

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

Third parties may attempt to commercialize competitive diagnostic tests, products or services in foreign countries where we do not have any patents or patent applications and/or where legal recourse may be limited. This may have a significant commercial impact on our foreign business operations.

Filing, prosecuting and defending patents on our diagnostic tests, products and services in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing diagnostic tests or products made using our inventions in and into the United States or other jurisdictions. Competitors may use our diagnostic tests, products, services and technologies in jurisdictions where we have not obtained patent protection to develop their own diagnostic tests and, further, may export otherwise infringing diagnostic tests or products to territories where we have patent protection but enforcement is not as strong as that in the United States. These diagnostic tests and products may compete with our diagnostic tests, products or services 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, which could make it difficult for us to stop the infringement of our patents or marketing of competing diagnostic tests, products and services in violation of our intellectual property rights generally. Proceedings to enforce our intellectual property 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, could put our patent applications at risk of not issuing 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.

Many countries, including India, China, and certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our current or future licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition and results of operations may be adversely affected.

***Intellectual property rights do not necessarily address all potential threats.***

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make diagnostic tests or products that are similar to our Nodify XL2, Nodify CDT, GeneStrat or VeriStrat tests or the COVID-19 tests that we use in our COVID-19 testing program or utilize similar technology that is not covered by the claims of our patents or that incorporates certain technology in our Nodify XL2, Nodify CDT, GeneStrat or VeriStrat tests or such COVID-19 tests that is in the public domain;
- we, or our current or future licensors or collaborators, might not have been the first to make the inventions covered by the applicable issued patent or pending patent application that we own or license now or may own or license in the future;
- we, or our current or future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our current or future pending patent applications will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive diagnostic tests, products and services for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property rights.

Any of the foregoing could have a material adverse effect on our business, financial condition and results of operations.



## General Risk Factors

***There has been no prior public market for our common stock and an active trading market may not develop.***

We completed our initial public offering in October 2020. Prior to that time, there had not been a public market for our common stock. An active trading market may not develop or may not be sustained. The lack of an active trading market may impair the value of your shares and your ability to sell your shares at the time you wish to sell them. An inactive trading market may also impair our ability to both raise capital by selling shares of common stock and acquire other complementary diagnostic tests, technologies or businesses by using our shares of common stock as consideration.

If we fail to satisfy the continued listing standards of the Nasdaq Global Market, we could be de-listed, which would negatively impact the price of our common stock.

***We expect that the price of our common stock will fluctuate substantially and you may not be able to sell your shares at or above the price you paid for them.***

The market price of our common stock is likely to be highly volatile and may fluctuate substantially due to many factors, including:

- volume and customer mix for our COVID-19, Nodify XL2, Nodify CDT, GeneStrat and VeriStrat testing;
- the introduction of new diagnostic tests or enhancements to such tests by us or others in our industry;
- disputes or other developments with respect to our or others' intellectual property rights;
- our ability to develop, obtain regulatory clearance or approval or certification for, and market new and enhanced diagnostic tests on a timely basis;
- product liability claims or other litigation;
- quarterly variations in our results of operations or those of others in our industry;
- media exposure of our diagnostic tests or of those of others in our industry;
- changes in governmental regulations or in the status of our regulatory approvals or applications;
- changes in earnings estimates or recommendations by securities analysts; and
- general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

In recent years, the stock markets generally have 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 may significantly affect the market price of our common stock, regardless of our actual operating performance, and 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, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Securities litigation brought against us following volatility in our stock price, regardless of the merit or ultimate results of such litigation, could result in substantial costs, which would hurt our financial condition and operating results and divert management's attention and resources from our business.

***Securities analysts may not publish favorable research or reports about our business or may publish no information at all, which could cause our stock price or trading volume to decline.***

If a trading market for our common stock develops, the trading market will be influenced to some extent by the research and reports that industry or financial analysts publish about us and our business. We do not control these analysts. As a newly public company, we may be slow to attract research coverage and the analysts who publish information about our common stock will have had relatively little experience with us, which could affect their ability to accurately forecast our results and could make it more likely that we fail to meet their estimates. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us provide inaccurate or unfavorable research or issue an adverse opinion regarding our stock price, our stock price could decline. If one or more of these analysts cease coverage of us or fail to publish reports covering us regularly, we could lose visibility in the market, which in turn could cause our stock price or trading volume to decline.

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

We are an “emerging growth company,” as defined in the JOBS Act. We may take advantage of certain exemptions and relief from various public reporting requirements, including the requirement that our internal control over financial reporting be audited by our independent registered public accounting firm pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 (the Sarbanes-Oxley Act). We will be exempt from any rules that could be adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotations or a supplement to the auditor’s report on financial statements; we will be subject to reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements; and we will not be required to hold nonbinding advisory votes on executive compensation or stockholder approval of any golden parachute payments not previously approved.

Section 7(a)(2)(B) of the Securities Act, for complying with new or revised accounting standards. In other words, an “emerging growth company” can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies.

We have elected to take advantage of the extended transition period to comply with new or revised accounting standards and to adopt certain of the reduced disclosure requirements available to emerging growth companies. As a result of the accounting standards election, we will 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. Additionally, because we have taken advantage of certain reduced reporting requirements, the information contained herein may be different from the information you receive from other public companies in which you hold stock.

We will remain an “emerging growth company” until the earliest to occur of (i) the last day of the fiscal year in which we have more than \$1.07 billion in annual revenue; (ii) the date we qualify as a “large accelerated filer,” with at least \$700 million of equity securities held by non-affiliates; the date on which we have issued, in any three-year period, more than \$1.0 billion in non-convertible debt securities; and (iv) the last day of the fiscal year ending after the fifth anniversary of the completion of our initial public offering.

We are also a “smaller reporting company” as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the last day of the fiscal year in which (1) the market value of our common shares held by non-affiliates exceeds \$250 million as of the end of that year’s second fiscal quarter, or (2) our annual revenues exceeded \$100 million during such completed fiscal year and the market value of our common shares held by nonaffiliates exceeds \$700 million as of the end of that year’s second fiscal quarter. To the extent we take advantage of such reduced disclosure obligations, it may also make comparison of our financial statements with other public companies difficult or impossible.

Investors may find our common stock less attractive to the extent we rely on the exemptions and relief granted by the JOBS Act. 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 decline or become more volatile.

***If our estimates or judgments relating to our critical accounting policies are based on assumptions that change or prove to be incorrect, our operating results could fall below the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.***

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity, revenue and expenses that are not readily apparent from other sources. It is possible that interpretation, industry practice and guidance may evolve over time. If our assumptions change or if actual circumstances differ from our assumptions, our operating results may be adversely affected and could fall below the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

***A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.***

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell their shares, could result in a decrease in the market price of our common stock.

We have 26,561,504 outstanding shares of common stock based on the number of shares outstanding as of December 31, 2020. This includes the 4,000,000 shares that we sold in our initial public offering in October 2020, which may be resold in the public market immediately without restriction, unless purchased by our affiliates. Of the remaining shares, 22,561,504 shares are currently restricted as a result of securities laws or Section 107 of the JOBS Act provides that an “emerging growth company” can take advantage of the extended transition period provided in 180-day lock-up agreements but will be able to be sold after the offering. Moreover, holders of an aggregate of 20,090,745 shares of our common stock that were issued upon conversion of our convertible preferred stock have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We also intend to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market, subject to volume limitations applicable to affiliates lock-up agreements.

***Our directors, officers and principal stockholders have significant voting power and may take actions that may not be in the best interests of our other stockholders.***

Our officers, directors and principal stockholders each holding more than 5% of our common stock collectively control approximately 60.7% of our outstanding common stock. As a result, these stockholders, if they act together, will be able to control the management and affairs of our company and most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change of control and might adversely affect the market price of our common stock. This concentration of ownership may not be in the best interests of our other stockholders.

***We expect to incur significant additional costs as a result of being a public company, which may adversely affect our business, financial condition and results of operations.***

As a result of our initial public offering completed in October 2020, we expect to incur costs associated with corporate governance requirements that are applicable to us as a public company, including rules and regulations of the SEC, under the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, and the Securities Exchange Act of 1934, as amended (the Exchange Act), as well as the rules of Nasdaq. These rules and regulations are expected to significantly increase our accounting, legal and financial compliance costs and make some activities more time-consuming. We also expect these rules and regulations to make it more expensive for us to maintain directors’ and officers’ liability insurance. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our Board of Directors or as executive officers. Accordingly, increases in costs incurred as a result of becoming a publicly traded company may adversely affect our business, financial condition and results of operations.

***If we experience material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.***

As a result of becoming a public company, we will be required, under Section 404 of the Sarbanes-Oxley Act to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting beginning with our Annual Report on Form 10-K for the year ended December 31, 2021. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company’s annual and interim financial statements will not be detected or prevented on a timely basis.

We are further enhancing internal controls, processes and related documentation necessary to perform the evaluation needed to comply with Section 404. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are effective. The effectiveness of our controls and procedures may be limited by a variety of factors, including:

- faulty human judgment and simple errors, omissions, or mistakes;
- fraudulent action of an individual or collusion of two or more people;
- inappropriate management override of procedures; and
- the possibility that any enhancements to controls and procedures may still not be adequate to assure timely and accurate financial control.

When we cease to be an “emerging growth company” under the federal securities laws, our auditors will be required to express an opinion on the effectiveness of our internal controls. If we are unable to confirm that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion on the effectiveness of our internal controls, we could lose investor confidence in the accuracy and completeness of our financial reports, which could cause the price of our common stock to decline.

***Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.***

We are subject to the periodic reporting requirements of the Exchange Act. We have designed our disclosure controls and procedures to provide reasonable assurance that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

***Provisions in our corporate charter documents and under Delaware law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our current management.***

Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board of Directors. Because our Board of Directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

***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 specifies that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions involving actions brought against us by stockholders. Notwithstanding the foregoing, the exclusive forum provision will not apply to any claim to enforce any liability or duty created by the Exchange Act or the Securities Act and for which the federal courts have exclusive jurisdiction. We believe this exclusive forum provision benefits us by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, the provision may have the effect of discouraging lawsuits against our directors and officers. 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, in connection with any applicable action brought against us, a court could find the choice of forum provisions contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in such action.

***Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.***

Our amended and restated articles of incorporation provide that we will indemnify our directors and officers to the fullest extent permitted by Section 145 of the Delaware General Corporate Law.

In addition, as permitted by the Delaware General Corporate Law, our amended and restated articles of incorporation and our indemnification agreements that we have entered into with our directors and officers provide that:

- we will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by applicable law. Such law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to our best interests and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful;
- we may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law;
- we are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification;
- the rights conferred in our amended and restated articles of incorporation are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons; and
- we may not retroactively amend our amended and restated articles of incorporation provisions to reduce our indemnification obligations to directors, officers, employees and agents.

**1B. Unresolved Staff Comments.**

None.

**Item 2. Properties.**

Our headquarters is located in Boulder, Colorado, where we office and laboratory space, under a lease that expires in January 2023. We also lease laboratory space located in De Soto, Kansas, under a lease that expires in October 2023. A portion of our employees are located outside of Colorado and Kansas, and others work from home. We believe our existing facilities meet our current needs. We will need additional office space in the future as we continue to build our development, commercial and support teams. We believe we can find suitable additional space in the future on commercially reasonable terms.

<b>Location</b>	<b>Use</b>	<b>Square Feet</b>	<b>Expiration</b>
Boulder, Colorado	Office and laboratory	29,722	January 14, 2023
De Soto, Kansas	Laboratory	9,066	October 31, 2023

**Item 3. Legal Proceedings.**

From time to time we may become involved in legal proceedings or investigations which could have an adverse impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business. We are not presently a party to any legal proceedings that, if determined adversely to us, would individually or taken together have a material adverse effect on our business, results of operations, financial condition, or cash flows.

**Item 4. Mine Safety Disclosures.**

None.

## PART II

### Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

#### Market Information

Our common stock is traded on The NASDAQ Global Market under the symbol "BDSX." The high and low closing prices for our common stock on The NASDAQ Global Market for the period from October 28, 2020 (the date our common stock began trading following our initial public offering) to December 31, 2020 were \$20.16 and \$10.89, respectively.

#### Holders of our Common Stock

As of March 12, 2021, there were approximately 172 holders of our common stock.

#### Dividend Policy

We have never declared or paid dividends on our common stock and do not expect to pay dividends on our common stock for the foreseeable future. Instead, we anticipate that all of our earnings in the foreseeable future will be used for the operation and growth of our business. Any future determination to declare dividends will be subject to the discretion of our Board of Directors and will depend on various factors, including applicable laws, our results of operations, financial condition, future prospects, and any other factors deemed relevant by our Board of Directors. In addition, the terms of our credit agreement restrict our ability to pay dividends on our common stock, and we may also enter into credit agreements or other borrowing arrangements in the future that will further restrict our ability to declare or pay dividends on our common stock.

#### Use of Proceeds

On October 28, 2020 we completed an initial public offering of our common stock. In connection with our initial public offering, we issued and sold 4,000,000 shares of common stock at a price to the public of \$18.00 per share. As a result of the initial public offering, we received approximately \$63.8 million in net proceeds, after deducting underwriting discounts and commissions of \$5.0 million and offering expenses of approximately \$3.2 million paid by us. The offering was completed in October 2020.

We registered the shares under the Securities Act on a Registration Statement on Form S-1 (Registration No. 333-249260), which was filed on October 29, 2020 and declared effective on October 27, 2020. From the date of the initial closing of the initial public offering through December 31, 2020, we have used a portion of the net proceeds from the sale of these securities to fund our operations, to make capital expenditures, for working capital and for other general corporate purposes.

#### Recent Sales of Unregistered Securities

From January 1, 2019 through December 31, 2020, we granted stock options under our 2016 and 2006 Stock Plans to purchase 1.7 million shares of our common stock at exercise prices ranging from \$0.77 to \$6.83 per share, and issued an aggregate of 0.4 million shares of common stock pursuant to the exercise of stock options with aggregate proceeds of approximately \$1.4 million. These issuances were undertaken in reliance upon an exemption from registration under Rule 701 of the Securities Act of 1933.

### Item 6. Selected Financial Data.

None.

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

*The following discussion of our financial condition and results of operations should be read together with our audited financial statements and related notes and other financial information included elsewhere in this Annual Report on Form 10-K and our audited financial statements and notes thereto and the related Management’s Discussion and Analysis of Financial Condition and Results of Operations included in our final prospectus dated October 29, 2020 that forms a part of our Registration Statement on Form S-1 (File No. 333-249260), as filed with the Securities and Exchange Commission (SEC) pursuant to Rule 424(b) under the Securities Act of 1933, as amended (the “Securities Act”), on October 29, 2020 (Prospectus).*

*In addition to historical financial information, this discussion and other parts of this report contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, based upon current expectations that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth in the section titled “Risk Factors” under Part II, Item 1A below. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results and events to differ from those anticipated.*

*These statements are based upon information available to us as of the date of this Annual Report on Form 10-K, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements, like all statements in this report, speak only as of their date, and we undertake no obligation to update or revise these statements in light of future developments. These statements are inherently uncertain, and investors are cautioned not to unduly rely upon these statements.*

The following Management’s Discussion and Analysis of Financial Condition and Results of Operations (MD&A), is provided to supplement the financial statements and the related notes in Part II - Item 8 of this Annual Report on Form 10-K. We intend for this discussion to provide you with information that will assist you in understanding our financial statements, the changes in key items in those financial statements from year to year and the primary factors that accounted for those changes. Data for the years ended December 31, 2020 and 2019 has been derived from our audited financial statements included in this Annual Report on Form 10-K.

### Overview

We are a leading data-driven diagnostic solutions company leveraging state of the art technologies with our proprietary AI platform to discover, develop, and commercialize solutions for clinical unmet needs, with a primary focus in lung disease. By combining a technology agnostic approach with a holistic view of the patient’s disease state, we believe our solutions provide physicians with greater insights to help personalize their patient’s care and meaningfully improve disease detection, evaluation, and treatment. Our unique approach to precision medicine provides timely and actionable clinical information, which we believe helps improve overall patient outcomes and lowers the overall healthcare cost by reducing the use of ineffective and unnecessary treatments and procedures. In addition to our diagnostic tests, we provide biopharmaceutical companies with services that include diagnostic research, clinical trial testing, and the discovery, development, and commercialization of companion diagnostics.

Our core belief is that no single technology will answer all clinical questions that we encounter. Therefore, we employ multiple technologies, including genomics, transcriptomics, proteomics, and radiomics, and leverage our proprietary AI platform, the Diagnostic Cortex, to discover innovative diagnostic tests for clinical use. The Diagnostic Cortex is an extensively validated deep learning platform optimized for the discovery of diagnostic tests, which we believe overcomes standard machine learning challenges faced in life sciences research. Our data-driven and technology agnostic approach is designed to enable us to discover diagnostic tests that answer critical clinical questions faced by physicians, researchers, and biopharmaceutical companies.



We continuously incorporate new market insights and patient data to enhance our platform through a data-driven learning loop. We regularly engage with our customers, key opinion leaders, and scientific experts to stay ahead of the rapidly evolving diagnostic and therapeutic landscape to identify additional clinical unmet needs where a diagnostic test could help improve patient care. Additionally, we incorporate clinical and molecular profiling data from our commercial clinical testing, research studies, clinical trials, and biopharmaceutical customers or academic partnerships, to continue to advance our platform. We have over 140,000 samples and data in our biobank, including tumor profiles and immune profiles, which are used for both internal and external research and development initiatives.

We have commercialized six diagnostic tests which are currently available for use by physicians. Our Nodify XL2 and Nodify CDT tests, marketed as part of our Nodify Lung Nodule Risk Assessment testing strategy, assess the risk of lung cancer to help identify the most appropriate treatment pathway. We believe we are the only company to offer two commercial blood-based tests to help physicians reclassify risk of malignancy in patients with suspicious lung nodules. Our GeneStrat and VeriStrat tests, marketed as part of our Biodesix Lung Reflex testing strategy, are used following diagnosis of lung cancer to measure the presence of mutations in the tumor and the state of the patient's immune system to establish the patient's prognosis and help guide treatment decisions. The GeneStrat tumor profiling test and the VeriStrat immune profiling test have a three-day average turnaround time, providing physicians with timely results to facilitate treatment decisions. In response to the COVID-19 pandemic, through our partnership with Bio-Rad, we commercialized the Biodesix WorkSafe testing program. Our scientific diagnostic expertise, technologies, and existing commercial infrastructure enabled us to rapidly commercialize two FDA EUA authorized tests, a part of our customizable program. Both diagnostic tests are owned and were developed by Bio-Rad and Bio-Rad has granted us permission to utilize both tests for commercial diagnostic services. HHS Secretary Azar declared a public health emergency for COVID-19 in February 2020 which justified the authorization of emergency use of diagnostic tests for the detection and/or diagnosis of COVID-19. The Bio-Rad SARS-CoV-2 ddPCR test and the Platelia SARS-CoV-2 Total Ab test have been granted FDA EUA pursuant to the current emergency declaration. The Bio-Rad SARS-CoV-2 ddPCR test was FDA EUA authorized on May 1, 2020, authorizing performance of the test in laboratories certified under Clinical Laboratory Improvement Amendments (CLIA) to perform high complexity tests. The second test is the Platelia SARS-CoV-2 Total Ab test, which is an antibody test intended for detecting a B-cell immune response to SARS-CoV-2, indicating recent or prior infection. The Platelia SARS-CoV-2 Total Ab test was FDA EUA authorized on April 29, 2020. Medical products that are granted an EUA are only permitted to commercialize their products under the terms and conditions provided in the authorization. The FDA may revoke an EUA where it is determined that the underlying health emergency no longer exists or warrants such authorization, if the conditions for the issuance of the EUA are no longer met, or if other circumstances make revocation appropriate to protect the public health or safety, and we cannot predict how long the EUAs for the SARS-CoV-2 tests will remain in place. Using the Bio-Rad SARS-CoV-2 ddPCR test and the Platelia SARS-CoV-2 Total Ab test, we operate and have commercialized the Biodesix WorkSafe testing program.

Prior to using the Bio-Rad tests as part of our testing program, we performed feasibility, verification, and validation studies, including developing software for process automation, sample accessioning, data management and reporting, all required to demonstrate the test operated as claimed by the manufacturer and as required by our certifying regulatory agencies for high complexity laboratory testing. We secured independent reference specimens run with EUA tests to validate these tests as fit for diagnostic use in our laboratories. Post-launch development support for these tests have included improvements in on-boarding new personnel, logistics of sample collection, sample receipt and data reporting, all required to support our testing program. Additional releases of the laboratory data management software are ongoing and planned for the foreseeable future.

These tests are utilized by healthcare providers, including hospitals and nursing homes, and are also offered to businesses and educational systems to assist in their back-to-work or back-to-school strategies. Recently we announced multiple partnerships for COVID-19 testing, and have entered into an agreement with the State of Colorado to be one of the diagnostic companies to support widespread COVID-19 testing for the State. Additionally, we recently announced that we will oversee and manage onsite testing and validating testing for the Big Ten Conference athletic competitions.

In addition to the six diagnostic tests currently on the market, we perform over 30 assays for research use as part of our laboratory services that have been used by over 50 biopharmaceutical customers and academic partners. All of our diagnostic testing is performed at one of our two certified, high-complexity clinical laboratories in Boulder, Colorado and De Soto, Kansas.

Since our inception, we have performed over 285,000 tests and continue to generate a large and growing body of clinical evidence consisting of over 275 clinical and scientific peer-reviewed publications and presentations. Through ongoing study of each of our tests, we continue to grow our depth of understanding of disease biology and the broad utility of each of our tests. We believe we are poised for rapid growth by leveraging our scientific development and laboratory operations expertise along with our commercial infrastructure which includes sales, marketing, reimbursement, and regulatory affairs.

In the United States, we market our tests to clinical customers through our targeted sales organization, which includes sales representatives that are engaged in sales efforts and promotional activities primarily to pulmonologists, oncologists, cancer centers and nodule clinics. We market our tests and services to biopharmaceutical customers globally through our targeted business development team, which promotes the broad utility of our tests and testing capabilities throughout drug development and commercialization which is of value to pharmaceutical companies and their drug-development process.

We have funded our operations to date principally from net proceeds from an initial public offering of our common stock, the sale of convertible preferred stock, revenue from diagnostic testing and services, and the incurrence of indebtedness. We had cash and cash equivalents of \$62.1 million and \$5.3 million as of December 31, 2020 and 2019, respectively.

## Factors Affecting Our Performance

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

- **Testing volume and customer mix.** Our revenues and costs are affected by the volume of testing and mix of customers from period to period. We evaluate both the volume of our commercial tests, or the number of tests that we perform for patients on behalf of clinicians, as well as tests for biopharmaceutical companies. Our performance depends on our ability to retain and broaden adoption with existing customers, as well as attract new customers. We believe that the test volume we receive from clinicians and biopharmaceutical companies are indicators of growth in each of these customer verticals. Customer mix for our tests has the potential to significantly impact our results of operations, as the average selling price for biopharmaceutical sample testing is currently significantly greater than our average selling price for clinical tests since we are not a contracted provider for, or our tests are not covered by all clinical patients' insurance. We evaluate our average selling price for tests that are covered by Medicare, Medicare Advantage and commercial payers to understand the trends in reimbursement and apply those trends to our revenue recognition policies. Our operating revenues and costs significantly increased during 2020 due to the expected increase in demand for COVID-19 testing.
- **Reimbursement for clinical diagnostic testing.** Our revenue depends on achieving broad coverage and reimbursement for our tests from third-party payers, including both commercial and government payers. Payment from third-party payers differs depending on whether we have entered into a contract with the payers as a "participating provider" or do not have a contract and are considered a "non-participating provider." Payers will often reimburse non-participating providers, if at all, at a lower rate than participating providers.

Historically, we have experienced situations where commercial payers proactively reduced the amounts they were willing to reimburse for our tests, and in other situations, commercial payers have determined that the amounts they previously paid were too high and have sought to recover those perceived excess payments by deducting such amounts from payments otherwise being made. When we contract to serve as a participating provider, reimbursements are made pursuant to a negotiated fee schedule and are limited to only covered indications. Becoming a participating provider generally results in higher reimbursement for covered indications and lack of reimbursement for non-covered indications. As a result, the impact of becoming a participating provider with a specific payer will vary. If we are not able to obtain or maintain coverage and adequate reimbursement from third-party payers, we may not be able to effectively increase our testing volume and revenue as expected. Additionally, retrospective reimbursement adjustments can negatively impact our revenue and cause our financial results to fluctuate.

- **Investment in clinical studies and product innovation to support growth.** A significant aspect of our business is our investment in research and development, including the development of new products and our investments in clinical utility studies. We have invested heavily in clinical studies for our on market and pipeline products. Our studies focus primarily on the clinical utility of our tests including the ongoing INSIGHT study which seeks to enroll up to 5,000 patients to continue our clinical understanding of the predictive and prognostic value of the VeriStrat test. Our recently launched ALTITUDE study seeks to further demonstrate the efficacy of the Nodify XL2 and Nodify CDT test. A secondary focus of our studies is understanding the economic impact of our tests in guiding treatment choices and the potential impact of our tests in reducing overall healthcare costs.

Our clinical research has resulted in over 80 peer-reviewed publications for our tests. In addition to clinical studies, we are collaborating with investigators from multiple academic cancer centers. We believe these studies are critical to gaining physician adoption and driving favorable coverage decisions by payers and expect our investments in research and development to increase. Further we also expect to increase our research and development expenses to fund further innovation and develop new clinically relevant tests.

- **Ability to attract new biopharmaceutical customers and maintain and expand relationships with existing customers.** Our business development team promotes the broad utility of our products for biopharmaceutical companies in the United States and internationally. Our revenue, business opportunities and growth depend in part on our ability to attract new biopharmaceutical customers and to maintain and expand relationships with existing biopharmaceutical customers. We expect to increase our sales and marketing expenses in furtherance of this as we continue to develop these relationships, we expect to support a growing number of investigations and clinical trials. If our relationships expand, we believe we may have opportunities to offer our platform for companion diagnostic development, novel target discovery and validation efforts, and to grow into other commercial opportunities. For example, we believe our multi-omic data including genomic and proteomic data, in combination with clinical outcomes or claims data, has revenue-generating potential, including for novel target identification and companion diagnostic discovery and development.
- **Motivating and expanding our field sales force and customer support team.** Our field sales force is the primary point of contact in the clinical setting. These representatives of the company must cover expansive geographic regions which limits their time for interaction and education of our products in the clinical setting. As a result of the successful capital raise associated with our initial public offering, we plan to invest heavily in the field sales force to increase the total number of sales representatives and thereby reduce the geographic footprint each representative must cover. This investment will allow the larger sales force to maximize their education and selling efforts and achieve greater returns. Additionally, we plan to invest in the Boulder-based marketing and customer support teams to continue to provide the field team with the resources to be successful in the field. Furthermore, as we increase testing volume for our COVID-19 testing program, we plan to hire additional project support members to assist us in managing testing capacity.

While each of these areas present significant opportunities for us, they also pose significant risks and challenges that we must address. See Part II, Item 1A. “Risk Factors” for more information.

## COVID-19 Pandemic

The COVID-19 pandemic has disrupted, and we expect will continue to disrupt, our lung diagnostic testing operations. To protect the health and well-being of our workforce, partners, vendors and customers, we provide voluntary COVID-19 testing for employees working on-site, implemented social distance and building entry policies at work, restricted travel and facility visits, and followed the States of Colorado and Kansas’ public health orders and the guidance from the Centers for Disease Control and Prevention. Employees who can perform their duties remotely are asked to work from home and those on site are asked to follow our social distance guidelines. Our sales, marketing and business development efforts have also been constrained by our operational response to the COVID-19 pandemic due to travel restrictions. We expect to continue to adjust our operational norms to help slow the spread of COVID-19 in the coming months, including complying with government directives and guidelines as they are modified and supplemented.

The COVID-19 pandemic negatively affected, and we expect will continue to negatively affect, our lung diagnostic testing-related revenue and our clinical studies. For example, cancer patients may have more limited access to hospitals, healthcare providers and medical resources as they take steps to control the spread of COVID-19. Our biopharmaceutical customers are facing challenges in recruiting patients and in conducting clinical trials to advance their pipelines, for which our tests could be utilized. As a result of the COVID-19 pandemic, beginning in the latter half of March 2020, we have received fewer samples for non-COVID-19 testing on a daily average basis from our clinical and biopharmaceutical customers than before the outbreak of the COVID-19 pandemic. Further, our clinical studies, such as our ongoing INSIGHT study and our recently launched ALTITUDE study, as well as our arrangements with our biopharmaceutical customers, are expected to take longer to complete than what we expected before the outbreak of the COVID-19 pandemic.

Conversely, we are also experiencing a substantial increase in revenues related to an increase in the demand for our Biodesix WorkSafe testing program, our COVID-19 testing program. We expect that our costs to expand capacity for COVID-19 testing will increase for the first quarter of 2021 and we expect that the revenue that we generate from this expansion will comprise a significant portion of our revenue for these periods. However, there is no assurance that our COVID-19 testing program will continue to be accepted by the market or that other diagnostic tests will become more accepted, produce quicker results or are more accurate. Further, the longevity and extent of the COVID-19 pandemic is uncertain. If the pandemic were to dissipate, whether due to a significant decrease in new infections, due to acquiring herd immunity based on previous natural infection, and the availability and rapid distribution of vaccines, the evolution of variant strains that impact diagnostic test performance, or otherwise, the need for a COVID-19 test could decrease significantly and this could have an adverse effect on our results of operations and profitability. As a result, the increase in revenue due to any increase in demand for these diagnostic tests may not be indicative of our future revenue. See Part II., Item 1A. “Risk Factors” for a description of how the COVID-19 pandemic may adversely affect our business, financial condition and results of operations.

## 2020 Financial and Operational Highlights

Our fiscal year corresponds to a calendar year. The Company generated record revenue in fiscal 2020 of \$45.6 million, representing an increase of 86%, of which \$27.0 million was associated with the three-month period ended December 31, 2020.

The following were significant developments affecting our business, capital structure and liquidity during the year ended December 31, 2020:

- In October 2020 we completed our initial public offering, in which we sold 4.0 million shares of common stock for an offering price of \$18.00 per common share. The successful offering enabled the Company to raise approximately \$63.8 million in net proceeds, after deducting offering costs, underwriting discounts and commissions, providing significant cash resources to fund the Company’s growth strategy and working capital and general corporate purposes;
- As of December 31, 2020, we held cash and cash equivalents of \$62.1 million, an increase of \$56.8 million as compared to December 31, 2019. Our December 31, 2020 cash and cash equivalent balance includes a reduction for a prepayment of approximately \$7 million for three years of premiums for the Company’s directors and officer (D&O) liability insurance coverage;
- Initiated biomarker study to affirm Nodify XL2® test’s importance in clinical decision making (ALTITUDE). The first-in-class biomarker study is aligned with the recommendations from the official 2018 American Thoracic Society (ATS) policy statement of the early detection of lung cancer. Dr. Gerard A. Silvestri of Medical University of South Carolina named Principal Investigator;
- Announced results of study showing the Company’s proprietary blood collection device (BCD) collects, separates, and transports blood at ambient temperature to simplify specimen collection and transport while maintaining accuracy of diagnostic test results;
- Partnered with major public and private institutions, including the BIG 10 athletic conference, Purdue University, Colorado State University and the State of Colorado to support COVID-19 testing.

## **Components of Operating Results**

### ***Revenues***

We derive our revenue from two primary sources: (i) providing diagnostic testing in the clinical setting (Diagnostic Tests); and (ii) providing biopharmaceutical companies with services that include diagnostic research, clinical research, clinical trial testing, development and testing services generally provided outside the clinical setting and governed by individual contracts with third parties as well as development and commercialization of companion diagnostics (Services).

#### ***Diagnostic Tests***

Diagnostic test revenue is generated from delivery of results from our diagnostic tests. In the United States, we performed tests as both an in-network and out-of-network service provider depending on the test performed and the contracted status of the insurer. We provide diagnostic tests in two primary categories (i) lung diagnostics testing and (ii) COVID-19 testing.

We consider diagnostic testing to be completed upon the delivery of test results to our customer, either the prescribing physician or third-party to which we contracted for services to be performed, which is considered the performance obligation. The fees for such services are billed either to a third party such as Medicare, medical facilities, commercial insurance payers, or to the patient. We determine the transaction price related to our contracts by considering the nature of the payer, the historical amount of time until payment by a payer and historical price concessions granted to groups of customers.

#### ***Services***

Services revenue is generated from the delivery of our on-market tests, pipeline tests, custom diagnostic testing, and other scientific services for a purpose as defined by any individual customer. At times we collaborate with large biopharmaceutical companies in an attempt to discover biomarkers that would be helpful in their drug development or marketing. The performance obligations and related revenue for these sales is defined by a written agreement between us and our customer. These services are generally completed upon the delivery of testing results, or other contractually defined milestone(s), to the customer, which is considered the performance obligation. Customers for these services are typically large pharmaceutical companies where collectability is reasonably assured and therefore revenue is accrued upon completion of the performance obligations. Revenue derived from services is often unpredictable and can cause dramatic swings in our overall net revenue line from quarter to quarter.

### ***Operating Expenses***

#### ***Direct costs and expenses***

Cost of diagnostic testing generally consists of cost of materials, direct labor, including bonus, employee benefits, equipment and infrastructure expenses associated with acquiring and processing test samples, including sample accessioning, test performance, quality control analyses, charges to collect and transport samples; curation of test results for physicians; and in some cases, license or royalty fees due to third parties. Costs associated with performing our tests are recorded as the tests are processed regardless of whether revenue was recognized with respect to the tests. Infrastructure expenses include depreciation of laboratory equipment, rent costs, amortization of leasehold improvements and information technology costs. Royalties for licensed technology are calculated as a percentage of revenues generated using the associated technology and recorded as expense at the time the related revenue is recognized. One-time royalty payments related to signing of license agreements or other milestones, such as issuance of new patents, are amortized to expense over the expected useful life of the patents. While we do not believe the technologies underlying these licenses are necessary to permit us to provide our tests, we do believe these technologies are potentially valuable and of possible strategic importance to us or our competitors. Under these license agreements, we are obligated to pay aggregate royalties ranging from 1% to 8% of sales in which the patents or know-how are used in the product or service sold, sometimes subject to minimum annual royalties or fees in certain agreements.

We expect the aggregate cost of diagnostic testing to increase in line with the increase in the number of tests we perform, but the cost per test to decrease modestly over time due to the efficiencies we may gain as test volume increases, and from automation and other cost reductions.

Cost of services includes costs incurred for the performance of development services requested by our customers. Costs of development services will vary depending on the nature, timing and scope of customer projects.

#### *Research and development*

Research and development expenses consist of costs incurred to develop technology and include salaries and benefits, reagents and supplies used in research and development laboratory work, infrastructure expenses, including allocated facility occupancy and information technology costs, contract services, clinical studies, other outside costs and costs to develop our technology capabilities. Research and development expenses account for a significant portion of our operating expenses and consist primarily of external and internal costs incurred in connection with the discovery and development of our product candidates.

External expenses include: (i) payments to third parties in connection with the clinical development of our product candidates, including contract research organizations and consultants; (ii) the cost of manufacturing products for use in our preclinical studies and clinical trials, including payments to contract manufacturing organizations (CMOs) and consultants; (iii) scientific development services, consulting research fees and for sponsored research arrangements with third parties; (iv) laboratory supplies; and (v) allocated facilities, depreciation and other expenses, which include direct or allocated expenses for IT, rent and maintenance of facilities. External expenses are recognized based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers or our estimate of the level of service that has been performed at each reporting date. We track external costs by the stage of program, clinical or preclinical.

Internal expenses include employee-related costs, including salaries and related benefits for employees engaged in research and development functions. We do not track internal costs by product candidate because these costs are deployed across multiple programs and, as such, are not separately classified.

Research and development costs are expensed as incurred. Payments made prior to the receipt of goods or services to be used in research and development are deferred and recognized as expense in the period in which the related goods are received or services are rendered. Costs to develop our technology capabilities are recorded as research and development.

We expect our research and development expenses to increase as we continue to innovate and develop additional products and expand our data management resources. As our services revenue grows, an increasing portion of research and development dollars are expected to be allocated to cost of goods for biopharma service contracts. This expense, though expected to increase in dollars, is expected to decrease as a percentage of revenue in the long term, though it may fluctuate as a percentage of our revenues from period to period due to the timing and extent of these expenses.

#### *Sales, marketing, general and administrative*

Our sales and marketing expenses are expensed as incurred and include costs associated with our sales organization, including our direct sales force and sales management, client services, marketing and reimbursement, as well as business development personnel who are focused on our biopharmaceutical customers. These expenses consist primarily of salaries, commissions, bonuses, employee benefits, and travel, as well as marketing and educational activities and allocated overhead expenses. We expect our sales and marketing expenses to increase in dollars as we expand our sales force, increase our presence within the United States, and increase our marketing activities to drive further awareness and adoption of our tests and our future products. These expenses, though expected to increase in dollars, are expected to decrease as a percentage of revenue in the long term, though they may fluctuate as a percentage of our revenues from period to period due to the timing and extent of these expenses.

Our general and administrative expenses include costs for our executive, accounting, finance, legal and human resources functions. These expenses consist principally of salaries, bonuses, employee benefits, and travel, as well as professional services fees such as consulting, audit, tax and legal fees, and general corporate costs and allocated overhead expenses. We expect that our general and administrative expenses will continue to increase in dollars, primarily due to increased headcount and costs associated with operating as a public company, including expenses related to legal, accounting, regulatory, maintaining compliance with exchange listing and requirements of the SEC, director and officer insurance premiums and investor relations. These expenses, though expected to increase in dollars, are expected to decrease as a percentage of revenue in the long term, though they may fluctuate as a percentage from period to period due to the timing and extent of these expenses.

### Change in Fair Value of Contingent Consideration

In connection with the purchase transaction of Integrated Diagnostics, Inc. (Indi), we recorded contingent consideration pertaining to the amounts potentially payable to Indi shareholder pursuant to the terms of the asset purchase agreement. The fair value of contingent consideration is assessed at each balance sheet date and changes, if any, to the fair value are recognized as operating expenses within the statement of operations. The estimated fair value of the contingent consideration is based upon significant assumptions including probability of successful achievement of a product gross margin target, the estimated timing in which the gross margin target is achieved, and discount rates. The estimated fair value could materially differ from actual values or fair values determined using different assumptions.

### Interest Expense and Interest Income

Interest expense consists of cash and non-cash interest from our term loan, payroll protection program loan, and convertible debt. Our convertible debt, along with the related accrued interest, was automatically converted to 1,848,280 shares of our common stock upon completion of our initial public offering in October 2020. Principal payments for our term loan are scheduled to begin in March 2021. Interest income consists of income earned on our cash and cash equivalents. Our interest income has increased primarily as a result of investment of the net proceeds from our recent offering.

### Results of Operations

The following table sets forth the significant components of our results of operations for the periods presented (in thousands, except percentages):

	Year Ended December,		Change	
	2020	2019	\$	%
Revenues	\$ 45,557	\$ 24,552	\$ 21,005	86%
Operating expenses				
Direct costs and expenses	21,998	6,074	15,924	262
Research and development	10,818	10,468	350	3
Sales, marketing, general and administrative	34,857	30,637	4,220	14
Change in fair value of contingent consideration	818	4,114	(3,296)	(80)
Total operating expenses	68,491	51,293	17,198	34%
Loss from operations	(22,934)	(26,741)	3,807	14%
Other income (expense)				
Interest income	18	55	(37)	(67%)
Interest expense	(7,604)	(3,008)	(4,596)	153
Change in fair value of warrant liability	(1,252)	(104)	(1,148)	1,104
Change in fair value of put option liability	—	(2,000)	2,000	(100)
Other income, net	422	1,072	(650)	(61)
Total other expense	(8,416)	(3,985)	(4,431)	111%
Net loss	\$ (31,350)	\$ (30,726)	\$ (624)	(2%)

### Revenues

We generate revenue from our diagnostic tests and services that we provide. Our revenues for the periods indicated were as follows (in thousands, except percentages):

	Year Ended December,		Change	
	2020	2019	\$	%
Diagnostic revenue	\$ 40,919	\$ 17,315	\$ 23,604	136%
Services revenue	4,638	7,237	(2,599)	(36)%
Total revenue	\$ 45,557	\$ 24,552	\$ 21,005	86%

Total revenue was \$45.6 million for the year ended December 31, 2020 as compared to \$24.6 million for the year ended December 31, 2019, an increase of \$21.0 million, or 86%.

Diagnostic test revenue increased to \$40.9 million for the year ended December 31, 2020, as compared to \$17.3 million for year ended December 31, 2019, an increase of \$23.6 million or 136%. This increase was primarily attributable to the deployment of COVID-19 testing which generated \$28.3 million of revenue and was partially offset by a decline in our lung diagnostic test volumes, which declined by \$4.7 million or 27% as health care practitioners, including pulmonologists, were increasingly diverted to pandemic-related care. In addition, the Company sales efforts continued to be impacted by the reduction in travel and other COVID-19 pandemic related restrictions.

Services revenue decreased to \$4.6 million for the year ended December 31, 2020 compared to \$7.2 million for the prior year ended December 31, 2019, a decrease of \$2.6 million or 36%, due primarily to a reduction in business development activities which was negatively impacted by the COVID-19 pandemic similar to the reduction we experienced in our lung diagnostic testing revenue.

### Direct Costs and Expenses

Direct costs and expenses related to revenue were \$22.0 million for the year ended December 31, 2020 compared to \$6.1 million for the prior year ended December 31, 2019, an increase of \$16.0 million or 262%. The increase in direct costs and expenses were primarily driven by costs associated with the delivery of our COVID-19 tests as well as the release of our Nodify CDT test, offset in part by decreases costs related to our remaining lung diagnostic test costs.

### Research and Development

Research and development expenses were relatively consistent year over year with \$10.8 million for the year ended December 31, 2020 as compared to \$10.5 million for the prior year ended December 31, 2019, an increase of \$0.3 million, or 3%. The overall increase in cost was attributable to an increase in internal costs primarily associated with variable compensation tied to fiscal 2020 performance measures slightly offset by a decrease in external costs.

The following table summarizes our external and internal costs for the years ended December 31, 2020 and 2019 (in thousands, except percentages):

	Year Ended December,		Change	
	2020	2019	\$	%
External expenses:				
Clinical trials and associated costs	\$ 2,487	\$ 2,141	\$ 346	16%
Other external costs	2,823	3,784	(961)	(25)%
Total external costs	5,310	5,925	(615)	(10)%
Internal expenses	5,508	4,543	965	21%
Total research and development expenses	\$ 10,818	\$ 10,468	\$ 350	3%

### Sales, Marketing, General and Administrative

Sales, marketing, general and administrative expenses were \$34.9 million for the year ended December 31, 2020 compared to \$30.6 million for the prior year ended December 31, 2019, an increase of \$4.2 million, or 14%, as a result of variable compensation tied to fiscal 2020 performance measures, including the Company's bonus to equity program for senior executives offset by reductions in employee related costs associated with COVID-19 pandemic restrictions.

### Change in Fair Value of Contingent Consideration

Change in fair value of contingent consideration was \$0.8 million for the year ended December 31, 2020 compared to \$4.1 million for the year ended December 31, 2019, a net decrease of \$3.3 million or 80%. The amounts recorded for change in fair value reflect the passage of time, as well as estimates regarding the period in which targets that trigger the payment of contingent consideration will be achieved and subsequently paid.



## **Interest Expense**

Interest expense was \$7.6 million for the year ended December 31, 2020 compared to \$3.0 million for the year ended December 31, 2019, an increase of \$4.6 million, or 153%. This increase was due to the addition of interest expense related to convertible notes issued to certain shareholders from August 2019 through March 2020, including the non-cash interest expense of \$4.4 million associated with the full amortization of debt discount resulting from the conversion discounts included in the convertible note terms, interest on our existing term loan, and interest on our payroll protection plan loan. Cash and non-cash interest expense for the twelve-month period ended December 31, 2020 was \$1.8 million and \$5.8 million, respectively.

## **Change in Fair Value of Warrant Liability**

During the twelve-month period ended December 31, 2020, we recognized a charge for the change in estimated fair value of our warrant liability related to warrants issued in connection with our Series G preferred stock of \$1.3 million, compared to a charge of \$0.1 million during fiscal year 2019, a change of \$1.2 million. Effective with the closing of our initial public offering in October 2020, the warrants to purchase Series G preferred stock were automatically converted to warrants to acquire common stock and the carrying value of the warrants of \$1.6 million were reclassified to additional paid-in capital.

## **Change in Fair Value of Put Option Liability**

During 2019, we issued \$13.0 million in convertible debt with terms that provided conversion rate discounts to the note holders in certain situations, including upon the completion of an initial public offering. The conversion discounts created a put option liability that was accounted for separately from the convertible debt instrument and reflected as a liability in our balance sheet. Subsequent to the initial measurement of the put option liability, changes in the estimated fair value will be reflected as other income or expense in the statement of operations. During 2019, we recorded a \$2 million increase in the fair value of the put option liability as other expense due to the increase in the conversion discount rate provided to note holders resulting from an amendment to terms of the convertible debt issued in August and September 2019. There were no changes to the fair value of the put option liability that was recorded during 2020.

## **Other Income and Expense, net**

Other income, net, during fiscal 2020 and fiscal 2019 was income of \$0.4 million and \$1.1 million, respectively, a decrease of \$0.7 million or 61%. The decrease was due primarily to proceeds from a non-recurring legal settlement received in fiscal 2019.

## **Liquidity and Capital Resources**

We are an emerging growth company and, as such, have yet to generate positive cash flow from operations. We have funded our operating activities primarily through financing activities, such as debt and equity offerings. In October 2020, we completed an initial public offering, resulting in net proceeds of approximately \$63.8 million after deducting offering costs, underwriting discounts and commissions. As of December 31, 2020 we held cash and cash equivalents of \$62.1 million. We believe that our existing cash, cash equivalents, and cash generated from sales of our products and services will be sufficient to meet our anticipated needs for at least the next 12 months from the date of our most recent audited financial statements, including amounts due under our PPP loan. The Company currently intends to repay the PPP loan in accordance with the underlying terms and conditions.

We expect to continue to incur significant expenses for the foreseeable future and to incur operating losses in the near term while we make investments to support our anticipated growth. We may raise additional capital through the issuance of additional equity financing, debt financings or other sources. If this financing is not available to us at adequate levels, we may need to reevaluate our operating plans. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our existing stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

## Cash Flows

The following summarizes our cash flows for the periods indicated (in thousands):

	Year Ended December 31,	
	2020	2019
Net cash flows (used in) provided by:		
Operating activities	\$ (21,366)	\$ (21,726)
Investing activities	(2,927)	(1,872)
Financing activities	81,131	22,972
Net increase in cash and cash equivalents and restricted cash	<u>\$ 56,838</u>	<u>\$ (626)</u>

### 2020 compared to 2019

Our cash flows resulted in a net increase in cash of \$56.8 million during the year ended December 31, 2020. The net cash used in operating activities decreased by approximately \$0.4 million, primarily due to a year-over-year increase in non-cash charges of: (i) \$4.1 million associated with the increased amortization of convertible notes debt discount resulting from our initial public offering; (ii) \$3.5 million associated with the increased share-based compensation expense from achieving performance thresholds for our 2020 bonus to equity program; (iii) \$1.1 million associated with an increase in the expense recorded as a change in estimated fair value of warrant liability partially offset by; (iv) a \$3.3 million reduction in the year-over-year change in the estimated fair value of contingent consideration; and (v) a \$3.2 million net reduction in operating assets and liabilities

Net cash used in investing activities during the year ended December 31, 2020 totaled \$2.9 million, an increase of \$1.1 million compared to the same period in 2019. The increase in net cash used in investing activities was primarily due to an increase of \$0.8 million in the purchases of research equipment and patent costs, and payments made for Oncimmune assets acquired of \$0.3 million.

Net cash provided by financing activities during the year ended December 31, 2020 totaled \$81.1 million, an increase of \$58.2 million compared to the same period in 2019. The net cash provided by financing activities for the year ended December 31, 2020 primarily resulted from \$72.0 million gross proceeds from our initial public offering, \$13.0 million in proceeds from the issuance of convertible notes payable, \$1.3 million proceeds from stock option exercises, and \$3.1 from proceeds from our paycheck protection program note payable, offset in part by equity issuance costs associated with our initial public offering of \$8.2 million. The net cash provided by financing activities for the year ended December 31, 2019 primarily resulted from \$10.0 million in proceeds from the issuance of our Series H Preferred Stock and \$13.0 million in proceeds from the issuance of convertible notes payable.

## Contractual Obligations and Commitments

The following table summarizes our non-cancelable contractual obligations and commitments as of December 31, 2020 (in thousands):

	Payments due by period (1)				
	Total	Less than 1 year	1 to 3 years	4 to 5 years	More than 5 years
Operating lease obligations (2)	\$ 1,539	\$ 703	\$ 836	\$ —	\$ —
Borrowings and interest (3)	31,517	13,921	17,596	—	—
	<u>\$ 33,056</u>	<u>\$ 14,624</u>	<u>\$ 18,432</u>	<u>\$ —</u>	<u>\$ —</u>

(1) Royalty payments that we may owe are not included as the timing of such payments is uncertain.

(2) We are obligated under non-cancellable operating leases for all of our facilities. Lease terms for our facilities range from less than one to three years and generally require us to pay real estate taxes, certain insurance and operating costs.

(3) Includes a 2% back-end term loan facility fee of \$0.5 million due at maturity. The term loan is also subject to a 3% prepayment penalty which is not included above. In addition, includes principal and accrued interest payable under the Company's payroll protection plan loan.

In connection with the purchase transaction of Integrated Diagnostics, Inc., we recorded contingent consideration pertaining to the amounts potentially payable to Integrated Diagnostics' shareholder pursuant to the terms of the asset purchase agreement. The estimated fair value of contingent consideration is assessed at each balance sheet date and changes, if any, to the fair value are recognized as operating expenses within the statement of operations. The estimated fair value of the contingent consideration is based upon significant assumptions including probability of successful achievement of the Milestone, the estimated timing in which the Milestone is achieved, and discount rates. The estimated fair value could materially differ from actual values or fair values determined using different assumptions. At December 31, 2020, the amount that would be due in cash at the option of the seller at the time the Milestone is met would be approximately \$37 million.

#### **Off-Balance Sheet Arrangements**

None.

#### **Critical Accounting Policies and Significant Judgments and Estimates**

In accordance with accounting principles generally accepted in the United States, we are required to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Certain of these estimates significantly influence the portrayal of our financial condition and results of operations and require us to make difficult, subjective or complex judgments. Our critical accounting policies primarily relate to our fair value estimates, and are described in greater detail in Note 1 to our financial statements in Part 8 of this Annual Report on Form 10-K.

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

We recognize revenue when our customers obtain control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for our goods or services. To determine revenue recognition for our arrangements with our customers, we perform a five-step process, which includes: (i) identifying the contract(s) with a customer; (ii) identifying the performance obligations in the contract; (iii) determining the transaction price; (iv) allocating the transaction price to the performance obligations in the contract; and (v) recognizing revenue when (or as) we satisfy our performance obligations.

Diagnostic service revenues are recognized upon completion of our performance obligation to deliver test results to our customer, either the prescribing physician or third-party to which we contracted for services to be performed. Testing services revenues are recognized upon completion of our performance obligation to deliver testing results for assay development and testing services.

#### ***Change in Fair Value of Contingent Consideration***

In connection with the purchase transaction with Integrated Diagnostics, Inc. (Indi), we recorded contingent consideration pertaining to the amounts potentially payable to Indi's shareholder pursuant to the terms of the asset purchase agreement. The fair value of contingent consideration is assessed at each balance sheet date and changes, if any, to the fair value are recognized as operating expenses within the statements of operations.

The estimated fair value of the contingent consideration is based upon significant assumptions including probabilities of successful achievement of product gross margin targets, the estimated timing in which achievement of the product gross margin target is expected, and discount rates. The estimated fair value could materially differ from actual values or fair values determined using different assumptions.

#### ***Share-based Compensation and Grant Date Fair Value***

Share-based compensation related to stock options granted to our employees, directors and non-employees is measured at the grant date based on the fair value of the award. For our service-based awards, the fair value of each award is recognized as expense on a straight-line basis over the requisite service period, which is generally the vesting period of the respective awards. Compensation expense for share-based awards with performance conditions is recognized based upon the probability the performance conditions will be met as defined in the grant. Restricted stock unit option awards are measured at their grant date fair value using the closing price of our common stock on the date of grant and recognized to expense on a straight-line basis over the vesting period of each award. We estimate forfeitures and adjust these estimates to actual forfeitures as they occur.

We use the Black-Scholes option-pricing model to estimate the fair value of our share-based option awards, which requires assumptions to be made related to expected term of an award, expected volatility, the risk-free rate and expected dividend yield. Following the completion of our initial public offering, our Board of Directors has determined the fair value of our common stock is based on our closing price as reported on the date of grant on the primary stock exchange on which our common stock is traded.

Prior to our initial public offering in October 2020, the fair value of our common stock was determined by our Board of Directors in accordance with the methodologies outlined in the American Institute of Certified Public Accountants Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation Practice Aid (Practice Aid). In doing so, our Board of Directors determined the best estimate of fair value of our common stock, exercising reasonable judgment and considering numerous objective and subjective factors, by first determining the enterprise value of our business, and then allocating the value among the various classes of our equity securities to derive a per share value of our common stock.

### ***Recently Issued Accounting Pronouncements***

In February 2016, the FASB issued Accounting Standards Update (ASU) No. 2016-2, *Leases (Topic 842)*, which requires lessees to recognize a right-of-use asset and corresponding lease liability on the balance sheet for substantially all leases. The ASU is effective for us for beginning January 1, 2022. We expect to recognize right-of-use assets and lease obligations in our balance sheets upon adoption using the modified retrospective method as permitted by ASU No. 2018-11, *Leases (Topic 842): Targeted Improvements*. We do not currently expect adoption of this standard will have a significant effect on our results of operations or cash flows.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments-Credit Losses: Measurement of Credit Losses on Financial Instruments*. This ASU requires measurement and recognition of expected credit losses for financial assets. This guidance will become effective for us beginning January 1, 2022 with early adoption permitted. We have not yet begun evaluating the potential effect of this standard on our financial statements.

### ***Implications of Being an Emerging Growth Company and Smaller Reporting Company***

We are an “emerging growth company” within the meaning of the Jumpstart Our Business Startups Act (JOBS Act). As an emerging growth company, we may take advantage of certain exemptions from various public company reporting requirements, including the requirement that our internal control over financial reporting be audited by our independent registered public accounting firm pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 (the “Sarbanes-Oxley Act”), certain requirements related to the disclosure of executive compensation in our periodic reports and proxy statements, the requirement that we hold a nonbinding advisory vote on executive compensation and any golden parachute payments. We may take advantage of these exemptions until we are no longer an emerging growth company. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act, for complying with new or revised accounting standards. In other words, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies.

We have elected to take advantage of the extended transition period to comply with new or revised accounting standards and to adopt certain of the reduced disclosure requirements available to emerging growth companies. As a result of the accounting standards election, we will 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 will remain an emerging growth company until the earliest to occur of (i) the last day of the fiscal year in which we have more than \$1.07 billion in annual revenue; (ii) the date we qualify as a “large accelerated filer,” with at least \$700 million of equity securities held by non-affiliates; (iii) the date on which we have issued, in any three-year period, more than \$1.0 billion in non-convertible debt securities; and (iv) until December 31, 2025 (the year ended December 31st following the fifth anniversary of our initial public offering).

Additionally, we are a “smaller reporting company” as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the last day of the fiscal year in which: (i) the market value of our common shares held by non-affiliates exceeds \$250 million as of the end of that year’s second fiscal quarter, or (ii) our annual revenues exceeded \$100 million during such completed fiscal year and the market value of our common shares held by non-affiliates exceeds \$700 million as of the end of that year’s second fiscal quarter.

**Item 7A. Quantitative and Qualitative Disclosures About Market Risk.**

We are exposed to market risk in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates.

**Interest Rate Risk**

We are exposed to market risk for changes in interest rates related primarily to our cash and cash equivalents, marketable securities and our indebtedness. We consider all highly liquid instruments purchased with an original maturity of three months or less to be cash equivalents. We continually monitor our positions with, and the credit quality of, the financial institutions with which we invest.

Periodically throughout the year, we have maintained balances in various operating accounts in excess of federally insured limits. Included in cash and cash equivalents are funds held in a bank savings account of \$58.8 million and \$4.7 million at December 31, 2020 and 2019, respectively. As of December 31, 2020, a hypothetical 100 basis point increase in interest rates would not have a material impact on our investment portfolio, financial position or results of operations.

**Item 8. Financial Statements and Supplementary Data.**

The financial statements and supplementary data are as set forth in the index to the financial statements on page F-1.

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

None.

**Item 9A. Controls and Procedures.****Evaluation of Disclosure Controls and Procedures**

We maintain "disclosure controls and procedures," as such term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, or Exchange Act, that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognized that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Our disclosure controls and procedures have been designed to meet reasonable assurance standards. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures 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.

Based on their evaluation as of the end of the period covered by this Annual Report on Form 10-K, our Chief Executive Officer and Chief Financial Officer have concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

This annual report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

**Item 9B. Other Information.**

None.

**Item 10. Directors, Executive Officers and Corporate Governance.**

The information required by this item with respect to directors is incorporated by reference from the information under the caption "Election of Directors" contained in our Proxy Statement to be filed with the Securities and Exchange Commission in connection with the solicitation of proxies for our 2020 Annual Meeting of Stockholders to be held on May 26, 2021. Certain information required by this item concerning executive officers is set forth in Part I of this Report under the caption "Executive Officers of the Registrant" and is incorporated herein by reference.

Item 405 of Regulation S-K calls for disclosure of any known late filing or failure by an insider to file a report required by Section 16(a) of the Exchange Act. This disclosure is contained in the section entitled "Section 16(a) Beneficial Ownership Reporting Compliance" in the Proxy Statement and is incorporated herein by reference.

We have adopted a Code of Business Conduct and Ethics that applies to all of our officers and employees, including our President and Chief Executive Officer, our Chief Financial Officer and other employees who perform financial or accounting functions. The Code of Business Conduct and Ethics sets forth the basic principles that guide the business conduct of our employees. Stockholders may request a free copy of our Code of Business Conduct and Ethics by contacting Biodesix, Inc., Attention: Chief Financial Officer, 2970 Wilderness Place, Suite 100, Boulder, Colorado 80301.

To date, there have been no waivers under our Code of Business Conduct and Ethics. We intend to disclose future amendments to certain provisions of our Code of Business Conduct and Ethics or waivers of such Codes granted to executive officers and directors on our website at <http://www.biodesix.com> within four business days following the date of such amendment or waiver.

Our Board of Directors has appointed an Audit Committee, comprised of Ms. Jean Franchi, as Chairwoman, Mr. Hany Massarany and Dr. Matthew Strobeck. The Board of Directors has determined that Ms. Franchi qualifies as an Audit Committee Financial Expert under the definition outlined by the Securities and Exchange Commission. In addition, each of the members of the Audit Committee qualifies as an "independent director" under the current rules of The NASDAQ Stock Market and Securities and Exchange Commission rules and regulations.

**Item 11. Executive Compensation.**

The information required by this item is incorporated by reference from the information under the captions "Election of Directors—Director Compensation" and "Executive Compensation" contained in the Company's definitive Proxy Statement for the 2021 Annual Meeting of Stockholders and is incorporated herein by reference.

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

The information required by this item is incorporated by reference from the information under the captions "Security Ownership of Certain Beneficial Owners and Management" and "Executive Compensation—Equity Compensation Plan Information" contained in the Company's definitive Proxy Statement for the 2021 Annual Meeting of Stockholders and is incorporated herein by reference.

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

The information required by this item is incorporated by reference from the information under the caption "Election of Directors—Certain Relationships and Related Transactions" and "—Director Independence" contained in the Company's definitive Proxy Statement for the 2021 Annual Meeting of Stockholders and is incorporated herein by reference.

**Item 14. Principal Accounting Fees and Services.**

The information required by this item is incorporated by reference from the information under the caption "Ratification of the Appointment of Independent Registered Public Accounting Firm—Principal Accountant Fees and Services" contained in the Company's definitive Proxy Statement for the 2021 Annual Meeting of Stockholders and is incorporated herein by reference.

## PART IV

### Item 15. Exhibits, Financial Statement Schedules.

(a) Documents filed as a part of the report.

1. Financial Statements

Reference is made to the Index to Financial Statements of Biodesix, Inc. included in Item 8 of Part II hereof

2. Financial Statement Schedules

All schedules have been omitted because they are not required, not applicable, or the required information is included in the financial statements or notes thereto.

3. See Item 15(b) below. Each management contract or compensating plan or arrangement required to be filed has been identified.

(b) Exhibits.

### Item 16. Form 10-K Summary

Not applicable.

## Exhibit Index

Exhibit Number	Description
1.1**	<a href="#"><u>Form of Underwriting Agreement (incorporated by reference to Exhibit 1.1 to the Company's Registration Statement on Form S-1/A filed with the SEC on October 21, 2020).</u></a>
3.1**	<a href="#"><u>Amended and Restated Certificate of Incorporation of Biodesix, Inc., dated October 30, 2020 (incorporated by reference to Exhibit 3.2 to the Company's Quarterly Report on Form 10-Q filed with the SEC on October 12, 2020).</u></a>
3.2**	<a href="#"><u>Amended and Restated Bylaws of Biodesix, Inc. (incorporated by reference to Exhibit 3.2 to the Company's Quarterly Report on Form 10-Q filed with the SEC on October 12, 2020).</u></a>
4.1**	<a href="#"><u>Specimen stock certificate evidencing shares of Common Stock (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1/A filed with the SEC on October 21, 2020).</u></a>
4.2**	<a href="#"><u>Eleventh Amended and Restated Investor Rights Agreement, by and among Biodesix, Inc. and the investors listed on Exhibit A thereto, dated October 10, 2018 (incorporated by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-1 filed with the SEC on October 2, 2020).</u></a>
4.3**	<a href="#"><u>Warrant held by Innovatus Life Sciences Lending Fund I, LP, to Purchase Series G Preferred Stock, dated February 23, 2018 (incorporated by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-1 filed with the SEC on October 2, 2020).</u></a>
4.4**	<a href="#"><u>Secured Promissory Note held by Innovatus Life Sciences Lending Fund I, LP, in Biodesix, Inc., dated February 23, 2018 (incorporated by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-1 filed with the SEC on October 2, 2020).</u></a>
4.5*	<a href="#"><u>Description of Securities Registered Under Section 12 of the Securities Exchange Act of 1934.</u></a>
10.1+**	<a href="#"><u>Biodesix, Inc. Amended and Restated 2006 Employee, Director and Consultant Stock Plan, as amended to date (incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1/A filed with the SEC on October 9, 2020).</u></a>
10.2.1+**	<a href="#"><u>Form of Stock Option Grant Notice under the Amended and Restated 2006 Employee, Director and Consultant Stock Plan (incorporated by reference to Exhibit 10.2.1 to the Company's Registration Statement on Form S-1/A filed with the SEC on October 9, 2020).</u></a>
10.2.2+**	<a href="#"><u>Form of Option Agreement under the Amended and Restated 2006 Employee, Director and Consultant Stock Plan (incorporated by reference to Exhibit 10.2.2 to the Company's Registration Statement on Form S-1/A filed with the SEC on October 9, 2020).</u></a>
10.2.3+**	<a href="#"><u>Form of Notice of Exercise under the Amended and Restated 2006 Employee, Director and Consultant Stock Plan (incorporated by reference to Exhibit 10.2.3 to the Company's Registration Statement on Form S-1/A filed with the SEC on October 9, 2020).</u></a>
10.3+**	<a href="#"><u>Biodesix, Inc. 2016 Equity Incentive Plan, as amended to date (incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-1 filed with the SEC on October 2, 2020).</u></a>
10.4.1+**	<a href="#"><u>Form of Stock Option Grant Notice under the 2016 Equity Incentive Plan (incorporated by reference to Exhibit 10.4.1 to the Company's Registration Statement on Form S-1/A filed with the SEC on October 9, 2020).</u></a>
10.4.2+**	<a href="#"><u>Form of Option Agreement under the 2016 Equity Incentive Plan (incorporated by reference to Exhibit 10.4.2 to the Company's Registration Statement on Form S-1/A filed with the SEC on October 9, 2020).</u></a>



10.4.3+**	<a href="#"><u>Form of Notice of Exercise under the 2016 Equity Incentive Plan (incorporated by reference to Exhibit 10.4.3 to the Company's Registration Statement on Form S-1/A filed with the SEC on October 9, 2020).</u></a>
10.5+**	<a href="#"><u>Biodesix, Inc. 2020 Equity Incentive Plan (incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1/A filed with the SEC on October 26, 2020).</u></a>
10.5.1+*	<a href="#"><u>Forms of Stock Option Grant Notice, Option Agreement and Notice of Exercise under the 2020 Equity Incentive Plan.</u></a>
10.6+**	<a href="#"><u>Biodesix, Inc. 2020 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.6 to the Company's Registration Statement on Form S-1/A filed with the SEC on October 26, 2020).</u></a>
10.7.1+**	<a href="#"><u>Biodesix, Inc., First Amended Bonus-to-Options Program, adopted by the Board of Directors on October 15, 2010 (incorporated by reference to Exhibit 10.5.1 to the Company's Registration Statement on Form S-1 filed with the SEC on October 2, 2020).</u></a>
10.7.2+**	<a href="#"><u>Biodesix, Inc., Second Amended Bonus-to-Options Program, adopted by the Board of Directors on June 21, 2011 (incorporated by reference to Exhibit 10.5.2 to the Company's Registration Statement on Form S-1 filed with the SEC on October 2, 2020).</u></a>
10.7.3+**	<a href="#"><u>Biodesix, Inc., Third Amended Bonus-to-Options Program, adopted by the Board of Directors on December 31, 2015 (incorporated by reference to Exhibit 10.5.3 to the Company's Registration Statement on Form S-1 filed with the SEC on October 2, 2020).</u></a>
10.8.1+**	<a href="#"><u>Form of Stock Option Grant Notice under the Biodesix, Inc. Bonus-To-Options Program (incorporated by reference to Exhibit 10.6.1 to the Company's Registration Statement on Form S-1/A filed with the SEC on October 9, 2020).</u></a>
10.8.2+**	<a href="#"><u>Form of Option Agreement under the Biodesix, Inc. Bonus-To-Options Program (incorporated by reference to Exhibit 10.6.2 to the Company's Registration Statement on Form S-1/A filed with the SEC on October 9, 2020).</u></a>
10.9+**	<a href="#"><u>Form of Indemnification Agreement, by and between Biodesix, Inc. and each of its directors and executive officers (incorporated by reference to Exhibit 10.7 to the Company's Registration Statement on Form S-1/A filed with the SEC on October 14, 2020).</u></a>
10.10.1†+**	<a href="#"><u>Executive Employment Letter, by and between Biodesix, Inc. and Scott Hutton, dated February 16, 2018 (incorporated by reference to Exhibit 10.9.1 to the Company's Registration Statement on Form S-1 filed with the SEC on October 2, 2020).</u></a>
10.10.2†+**	<a href="#"><u>Executive Employment Letter, by and between Biodesix, Inc. and Scott Hutton, dated February 23, 2020 (incorporated by reference to Exhibit 10.9.2 to the Company's Registration Statement on Form S-1 filed with the SEC on October 2, 2020).</u></a>
10.11.1†+**	<a href="#"><u>Employment Letter, by and between Biodesix, Inc. and Robin Harper Cowie, dated March 11, 2011 (incorporated by reference to Exhibit 10.10.1 to the Company's Registration Statement on Form S-1 filed with the SEC on October 2, 2020).</u></a>
10.11.2†+**	<a href="#"><u>Executive Employment Letter, by and between Biodesix, Inc. and Robin Harper Cowie, dated February 23, 2020 (incorporated by reference to Exhibit 10.10.2 to the Company's Registration Statement on Form S-1 filed with the SEC on October 2, 2020).</u></a>
10.12+**	<a href="#"><u>Consulting Agreement, by and between David Brunel and Biodesix, Inc., dated September 19, 2020 (incorporated by reference to Exhibit 10.11 to the Company's Registration Statement on Form S-1 filed with the SEC on October 2, 2020).</u></a>
10.13†+**	<a href="#"><u>Office Lease between Aero-Tech Investments, LLC and Biodesix, Inc., dated October 5, 2011 (incorporated by reference to Exhibit 10.11 to the Company's Registration Statement on Form S-1/A filed with the SEC on October 9, 2020).</u></a>

- 10.14†\*\* [Lease Assignment of De Soto Facility, dated November 1, 2019 \(incorporated by reference to Exhibit 10.13 to the Company's Registration Statement on Form S-1 filed with the SEC on October 2, 2020\).](#)
- 10.15.1†\*\* [Loan and Security Agreement, by and among Innovatus Life Sciences Lending Fund I, LP, the Lenders listed therein, and Biodesix, Inc., dated February 23, 2018 \(incorporated by reference to Exhibit 10.13.1 to the Company's Registration Statement on Form S-1/A filed with the SEC on October 9, 2020\).](#)
- 10.15.2†\*\* [Limited Consent Agreement and Second Amendment to Loan and Security Agreement, by and among Innovatus Life Sciences Lending Fund I, LP, the Lenders listed therein, and Biodesix, Inc., dated June 30, 2018, as amended to date \(incorporated by reference to Exhibit 10.14.2 to the Company's Registration Statement on Form S-1 filed with the SEC on October 2, 2020\).](#)
- 10.16\*\* [Patent Assignment between Biodesix, Inc., and Integrated Diagnostics, Inc., dated June 30, 2018 \(incorporated by reference to Exhibit 10.15 to the Company's Registration Statement on Form S-1 filed with the SEC on October 2, 2020\).](#)
- 10.17†\*\* [IP Assignment Agreement between Oncimmune Limited, and Biodesix, Inc., dated October 31, 2019 \(incorporated by reference to Exhibit 10.15 to the Company's Registration Statement on Form S-1/A filed with the SEC on October 9, 2020\).](#)
- 10.18†\*\* [IP License Agreement between Oncimmune Limited, and Biodesix, Inc., dated October 31, 2019 \(incorporated by reference to Exhibit 10.16 to the Company's Registration Statement on Form S-1/A filed with the SEC on October 9, 2020\).](#)
- 10.19†\*\* [Non-Exclusive License Agreement between Bio-Rad Laboratories, Inc., and Biodesix, Inc., dated August 1, 2019 \(incorporated by reference to Exhibit 10.17 to the Company's Registration Statement on Form S-1/A filed with the SEC on October 9, 2020\).](#)
- 10.20†\*\* [Supply Agreement between Biodesix, Inc., and Oncimmune, dated October 31, 2019 \(incorporated by reference to Exhibit 10.18 to the Company's Registration Statement on Form S-1/A filed with the SEC on October 9, 2020\).](#)
- 10.21†\*\* [Supply Agreement between Bio-Rad Laboratories, Inc., and Biodesix, Inc., dated August 1, 2019 \(incorporated by reference to Exhibit 10.19 to the Company's Registration Statement on Form S-1/A filed with the SEC on October 9, 2020\).](#)
- 10.22†\*\* [Co-Development and Collaboration Agreement between AVEO Pharmaceuticals, Inc., and Biodesix, Inc., dated April 9, 2014, as amended October 14, 2016 \(incorporated by reference to Exhibit 10.20 to the Company's Registration Statement on Form S-1/A filed with the SEC on October 9, 2020\).](#)
- 10.23†\*\* [Contingent Value Rights Agreement between Biodesix, Inc. and Holders on Schedule A mentioned within, dated February 22, 2016 \(incorporated by reference to Exhibit 10.22 to the Company's Registration Statement on Form S-1 filed with the SEC on October 2, 2020\).](#)
- 10.24†\*\* [Asset Purchase Agreement among Biodesix, Inc., Integrated Diagnostics, Inc., and the stockholders of Integrated Diagnostics, Inc., listed therein, dated June 30, 2018 \(incorporated by reference to Exhibit 10.23 to the Company's Registration Statement on Form S-1 filed with the SEC on October 2, 2020\).](#)
- 10.25†\*\* [Asset Purchase Agreement between Oncimmune Limited and Biodesix, Inc., dated June 27, 2019, as amended to date \(incorporated by reference to Exhibit 10.24 to the Company's Registration Statement on Form S-1 filed with the SEC on October 2, 2020\).](#)

10.26†**	<a href="#"><u>COVID-19 Testing Laboratory Services Agreement by and between Biodesix, Inc., and Centura Health Corporation, dated April 3, 2020 (incorporated by reference to Exhibit 10.25 to the Company's Registration Statement on Form S-1 filed with the SEC on October 2, 2020).</u></a>
10.27†**	<a href="#"><u>First Amendment to COVID-19 Testing Laboratory Services Agreement by and between Biodesix, Inc. and Centura Health Corporation, dated April 23, 2020 (incorporated by reference to Exhibit 10.26 to the Company's Registration Statement on Form S-1 filed with the SEC on October 2, 2020).</u></a>
10.28†**	<a href="#"><u>Second Amendment to COVID-19 Testing Laboratory Services Agreement by and between Biodesix, Inc. and Centura Health Corporation, dated May 27, 2020 (incorporated by reference to Exhibit 10.27 to the Company's Registration Statement on Form S-1 filed with the SEC on October 2, 2020).</u></a>
10.29†**	<a href="#"><u>Third Amendment to COVID-19 Testing Laboratory Services Agreement by and between Biodesix, Inc. and Centura Health Corporation, dated August 7, 2020 (incorporated by reference to Exhibit 10.28 to the Company's Registration Statement on Form S-1 filed with the SEC on October 2, 2020).</u></a>
10.30†**	<a href="#"><u>Contract Agreement between Biodesix, Inc. and the Colorado Department of Public Health and Environment, dated September 11, 2020 (incorporated by reference to Exhibit 10.29 to the Company's Registration Statement on Form S-1 filed with the SEC on October 2, 2020).</u></a>
10.31†**	<a href="#"><u>Material Transfer Agreement by and between Biodesix, Inc. and Bio-Rad Laboratories, Inc., dated March 23, 2020 (incorporated by reference to Exhibit 10.30 to the Company's Registration Statement on Form S-1 filed with the SEC on October 2, 2020).</u></a>
10.32†**	<a href="#"><u>First Amendment to Material Transfer Agreement by and between Biodesix, Inc. and Bio-Rad Laboratories, Inc. dated April 3, 2020 (incorporated by reference to Exhibit 10.31 to the Company's Registration Statement on Form S-1 filed with the SEC on October 2, 2020).</u></a>
10.33†**	<a href="#"><u>Material Transfer Agreement by and between Biodesix, Inc. and Bio-Rad Laboratories, Inc., dated April 17, 2020 (incorporated by reference to Exhibit 10.32 to the Company's Registration Statement on Form S-1 filed with the SEC on October 2, 2020).</u></a>
10.34†**	<a href="#"><u>Price Agreement by and between Biodesix, Inc. and Bio-Rad Laboratories, Inc., dated May 12, 2020 (incorporated by reference to Exhibit 10.33 to the Company's Registration Statement on Form S-1 filed with the SEC on October 2, 2020).</u></a>
10.35**	<a href="#"><u>Letter from Bio-Rad Laboratories, Inc. dated August 7, 2020 (incorporated by reference to Exhibit 10.33 to the Company's Registration Statement on Form S-1/A filed with the SEC on October 21, 2020).</u></a>
10.36**	<a href="#"><u>Letter from Bio-Rad Laboratories, Inc. dated August 14, 2020 (incorporated by reference to Exhibit 10.34 to the Company's Registration Statement on Form S-1/A filed with the SEC on October 21, 2020).</u></a>
23.1	<a href="#"><u>Consent of independent registered public accounting firm.</u></a>
24.1	<a href="#"><u>Power of Attorney (included on the signature page of this Form 10-K).</u></a>

31.1*	<a href="#"><u>Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u></a>
31.2*	<a href="#"><u>Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u></a>
32.1*	<a href="#"><u>Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u></a>
32.2*	<a href="#"><u>Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u></a>
101.INS*	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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† Portions of this exhibit have been omitted as the Registrant has determined that the omitted information (i) is not material and (ii) would likely cause competitive harm to the Registrant if publicly disclosed.

+ Indicates management contract or compensatory plan.

\* Filed herewith.

\*\* Previously filed.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Biodesix, Inc.

Date: March 16, 2021

By: /s/ ROBIN HARPER COWIE

*Robin Harper Cowie*  
*Chief Financial Officer, Secretary and Treasurer*

## POWER OF ATTORNEY

Each person whose signature appears below constitutes and appoints Scott Hutton and Robin Harper Cowie, and each of them, his or her true and lawful agent, proxy and attorney-in-fact, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to file with the Securities and Exchange Commission this Form 10-K and any and all amendments and exhibits thereto, and all documents in connection therewith, granting unto each such attorney-in-fact and agent full power and authority to do and perform each and every act and thing necessary or appropriate to be done, as fully for all intents and purposes as he or she might or could do in person, hereby approving, ratifying and confirming all that such agent, proxy and attorney-in-fact or any of his or her substitutes may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
<u>/s/ SCOTT HUTTON</u> Scott Hutton	President, Chief Executive Officer (Principal Executive Officer)	March 16, 2021
<u>/s/ ROBIN HARPER COWIE</u> Robin Harper Cowie	Chief Financial Officer, Secretary and Treasurer	March 16, 2021
<u>/s/ JOHN PATIENCE</u> John Patience	Chairman and Director	March 16, 2021
<u>/s/ JEAN FRANCHI</u> Jean Franchi	Director	March 16, 2021
<u>/s/ HANY MASSARANY</u> Hany Massarany	Director	March 16, 2021
<u>/s/ JACK SCHULER</u> Jack Schuler	Director	March 16, 2021
<u>/s/ MATTHEW STROBECK</u> Matthew Strobeck, Ph.D.	Director	March 16, 2021
<u>/s/ CHARLES WATTS</u> Charles Watts M.D.	Director	March 16, 2021

**Item 8. Financial Statements and Supplementary Data**

**BIODESIX, Inc.**

**INDEX TO FINANCIAL STATEMENTS**

<a href="#"><u>Report of Independent Registered Public Accounting Firm</u></a>	F-2
<a href="#"><u>Balance Sheets as of December 31, 2020 and 2019</u></a>	F-3
<a href="#"><u>Statements of Operations for the Years ended December 31, 2020 and 2019</u></a>	F-4
<a href="#"><u>Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit) for the Years ended December 31, 2020 and 2019</u></a>	F-5
<a href="#"><u>Statements of Cash Flows for the Years ended December 31, 2020 and 2019</u></a>	F-6
<a href="#"><u>Notes to Financial Statements</u></a>	F-8

## Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of  
Biodesix, Inc.:

### *Opinion on the Financial Statements*

We have audited the accompanying balance sheets of Biodesix, Inc. (the Company) as of December 31, 2020 and 2019, the related statements of operations, convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the years in the two-year period ended December 31, 2020, and the related notes (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2020, in conformity with U.S. generally accepted accounting principles.

### *Basis for Opinion*

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these 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. 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/ KPMG LLP

We have served as the Company's auditor since 2016

Denver, Colorado  
March 16, 2021

**BIODESIX, INC.**  
**Balance Sheets**  
(in thousands, except share data)

	<b>As of December 31,</b>	
	<b>2020</b>	<b>2019</b>
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 62,126	\$ 5,286
Accounts receivable, net	15,304	5,292
Other current assets	8,710	2,122
Total current assets	86,140	12,700
Non-current assets		
Property and equipment, net	3,178	2,120
Intangible assets, net	13,260	15,092
Other long-term assets	3,461	90
Goodwill	15,031	15,031
Total non-current assets	34,930	32,333
Total assets	<u>\$ 121,070</u>	<u>\$ 45,033</u>
<b>Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)</b>		
Current liabilities		
Accounts payable	\$ 8,964	\$ 1,717
Accrued liabilities	7,789	4,180
Deferred revenue	3,532	1,283
Current portion of notes payable	11,840	12,159
Put option liability	—	3,261
Total current liabilities	32,125	22,600
Non-current liabilities		
Warrant liability	—	329
Long-term notes payable	15,926	23,812
Contingent consideration	29,932	29,114
Other long-term liabilities	1,921	358
Total non-current liabilities	47,779	53,613
Total liabilities	79,904	76,213
Commitments and contingencies		
Convertible preferred stock		
Convertible preferred stock, \$0.001 par value, 0 (2020) and 174,237,067 (2019) authorized; 0 (2020) and 118,766,273 (2019) issued and outstanding; liquidation preference of \$202,582 (2019)	—	193,959
Stockholders' equity (deficit)		
Preferred stock, \$0.001 par value, 5,000,000 (2020) and 0 (2019) authorized; 0 (2020 and 2019) issued and outstanding	—	—
Common stock, \$0.001 par value, 200,000,000 (2020) and 190,000,000 (2019) authorized; 26,561,504 (2020) and 254,918 (2019) issued and outstanding	27	1
Additional paid-in capital	299,953	2,324
Accumulated deficit	(258,814)	(227,464)
Total stockholders' equity (deficit)	41,166	(225,139)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	<u>\$ 121,070</u>	<u>\$ 45,033</u>

The accompanying Notes are an integral part of these financial statements.



BIODESIX, INC.

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

	<b>Year Ended December 31,</b>	
	<b>2020</b>	<b>2019</b>
Revenues	\$ 45,557	\$ 24,552
Operating expenses:		
Direct costs and expenses	21,998	6,074
Research and development	10,818	10,468
Sales, marketing, general and administrative	34,857	30,637
Change in fair value of contingent consideration	818	4,114
Total operating expenses	68,491	51,293
Loss from operations	(22,934)	(26,741)
Other income (expense):		
Interest income	18	55
Interest expense	(7,604)	(3,008)
Change in fair value of warrant liability	(1,252)	(104)
Change in fair value of put option liability	—	(2,000)
Other income, net	422	1,072
Total other expense	(8,416)	(3,985)
Net loss	\$ (31,350)	\$ (30,726)
Net loss per share, basic and diluted	\$ (6.48)	\$ (126.97)
Weighted-average shares outstanding, basic and diluted	4,838	242

The accompanying Notes are an integral part of these financial statements.

BIODESIX, INC.

Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)  
(in thousands)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
<b>Balance - January 1, 2019</b>	110,071	\$ 183,962	215	\$ 1	\$ 2,107	\$ (196,738)	\$ (194,630)
Common stock issued upon exercise of stock options	—	—	40	—	47	—	47
Issuance of Series H convertible preferred stock, in February and March 2019 at \$1.15 per share, net of issuance costs of \$3	8,695	9,997	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	170	—	170
Net loss and comprehensive loss	—	—	—	—	—	(30,726)	(30,726)
<b>Balance - December 31, 2019</b>	118,766	193,959	255	1	2,324	(227,464)	(225,139)
Common stock issued upon exercise of stock options	—	—	368	—	1,340	—	1,340
Stock-based compensation expense	—	—	—	—	3,709	—	3,709
Issuance of common stock in initial public offering, net of discounts and commission of \$5,040 and direct offering costs of \$3,203	—	—	4,000	4	63,753	—	63,757
Conversion of preferred stock into common stock upon initial public offering	(118,766)	(193,959)	20,091	20	193,939	—	193,959
Conversion of convertible debt into common stock upon initial public offering	—	—	1,848	2	26,614	—	26,616
Reclassification of preferred stock warrant liability and put option into additional paid-in capital upon initial public offering	—	—	—	—	8,274	—	8,274
Net loss and comprehensive loss	—	—	—	—	—	(31,350)	(31,350)
<b>Balance - December 31, 2020</b>	—	\$ —	26,562	\$ 27	\$ 299,953	\$ (258,814)	\$ 41,166

The accompanying Notes are an integral part of these financial statements.

**BIODESIX, INC.**

**Statements of Cash Flows**  
**(in thousands)**

	<b>Year Ended December 31,</b>	
	<b>2020</b>	<b>2019</b>
Cash flows from operating activities		
Net loss	\$ (31,350)	\$ (30,726)
Adjustments to reconcile net loss to net cash, cash equivalents, and restricted cash used in operating activities		
Depreciation and amortization	2,903	2,793
Amortization of convertible notes debt discount	4,389	262
Stock-based compensation expense	3,709	170
Change in fair value of warrant liability	1,252	104
Change in contingent consideration	818	4,114
Change in fair value of put option	—	2,000
Accrued interest on notes payable and convertible notes payable	1,226	799
Amortization of debt issuance costs	144	144
Provision for doubtful accounts	296	246
Loss on disposals of assets	48	13
Changes in operating assets and liabilities, net of assets acquired and liabilities assumed in acquisitions:		
Accounts receivable	(10,308)	(3,646)
Other current assets	(6,588)	1
Other long-term assets and liabilities	(1,808)	16
Accounts payable and other accrued liabilities	11,654	1,193
Deferred revenue	2,249	791
Net cash and cash equivalents and restricted cash used in operating activities	(21,366)	(21,726)
Cash flows from investing activities		
Purchase of property and equipment	(1,945)	(1,310)
Patent costs and intangible asset acquisition, net	(232)	(106)
Payments to acquire Oncimmune assets	(750)	(456)
Net cash and cash equivalents and restricted cash used in investing activities	(2,927)	(1,872)
Cash flows from financing activities		
Proceeds from initial public offering	72,000	—
Proceeds from exercise of common stock options	1,340	47
Proceeds from issuance of series H preferred stock	—	10,000
Proceeds from issuances of convertible notes payable	12,955	13,044
Proceeds from paycheck protection program note payable	3,085	—
Equity financing costs	(8,243)	(3)
Other	(6)	(116)
Net cash and cash equivalents and restricted cash provided by financing activities	81,131	22,972
Net increase (decrease) in cash and cash equivalents and restricted cash	56,838	(626)
Cash, cash equivalents, and restricted cash - beginning of period	5,468	6,094
Cash, cash equivalents, and restricted cash - end of period	<u>\$ 62,306</u>	<u>\$ 5,468</u>

The accompanying Notes are an integral part of these financial statements.

BIODESIX, INC.

Statements of Cash Flows  
(in thousands)

(Continued from the previous page)

Supplemental cash flow information:

	Year Ended December 31,	
	2020	2019
Conversion of preferred stock into common stock	\$ 193,959	\$ —
Conversion of convertible notes and accrued interest into common stock	26,616	—
Reclassification of put option liability to additional paid-in capital	6,650	—
Value of put option recorded at issuance of convertible debt payable	3,389	1,261
Cash paid for interest	1,844	1,800
Reclassification of warrant liability to additional paid-in capital	1,624	—
Accrued business combination payments	—	750
Cash paid for income taxes	—	—

The accompanying Notes are an integral part of these financial statements.

**Notes to Financial Statements**

**Note 1 – Organization and Description of Business**

Biodesix, Inc. (the “Company”, “Biodesix”, “we” and “our”), formerly Elston Technologies, Inc., was incorporated in Delaware in 2005. The Company’s headquarters are in Colorado, with laboratories in Colorado and Kansas. The Company conducts all of its operations within a single legal entity. Biodesix is a data-driven diagnostic solutions company leveraging state of the art technologies with its proprietary artificial intelligence platform to discover, develop, and commercialize solutions for clinical unmet needs, with a primary focus in lung disease. In addition to diagnostic tests, the Company provides biopharmaceutical companies with services that include diagnostic research, clinical trial testing, and the discovery, development, and commercialization of companion diagnostics.

The Company performs its blood-based diagnostic tests for lung cancer in its laboratory facilities, which are located in Boulder, Colorado and De Soto, Kansas. In May 2020, the Federal Drug Administration (FDA) authorized performance of Bio-Rad SARS-CoV-2 Droplet Digital™ polymerase chain reaction (ddPCR) test to detect Coronavirus Disease 2019 (COVID-19) infection. In April 2020, the FDA authorized our Platelia SARS-CoV-2 Total Ab test to detect COVID-19 antibodies. Medical products that are granted an Emergency Use Authorization (EUA) are only permitted to commercialize their products under the terms and conditions provided in the authorization. The FDA may revoke an EUA where it is determined that the underlying health emergency no longer exists or warrants such authorization, if the conditions for the issuance of the EUA are no longer met, or if other circumstances make revocation appropriate to protect the public health or safety.

**Blood-Based Lung Tests**

The Company offers four blood-based lung cancer tests across the lung cancer continuum of care:

- *Nodify XL2®* and *Nodify CDT™* tests, marketed as part of our Nodify Lung™ Nodule Risk Assessment testing strategy, assess the risk of lung cancer to help identify the most appropriate treatment pathway. We believe we are the only company to offer two commercial blood-based tests to help physicians reclassify risk of malignancy in patients with suspicious lung nodules.
- *GeneStrat®* and *VeriStrat®* tests, marketed as part of our Biodesix Lung Reflex® testing strategy, are used following diagnosis of lung cancer to measure the presence of mutations in the tumor and the state of the patient’s immune system to establish the patient’s prognosis and help guide treatment decisions. The GeneStrat tumor profiling test and the VeriStrat immune profiling test have a three-day average turnaround time, providing physicians with timely results to facilitate treatment decisions.

**COVID-19 Tests**

Using the Bio-Rad SARS-CoV-2 ddPCR test and the Platelia SARS-CoV-2 Total Ab tests, we operate and have commercialized the Biodesix WorkSafe testing program. The Company offers two SARS-CoV-2 tests:

- *Bio-Rad SARS-CoV-2 ddPCR* test, which is authorized by the FDA to be performed by Clinical Laboratory Institute Amendments (CLIA) authorized laboratories that perform high complexity tests. The ddPCR test is designed to detect the presence of infection by the SARS-CoV-2 virus.
- *Platelia SARS-CoV-2 Total Ab* test, which is an antibody test, authorized by the FDA, intended for detecting a B-cell immune response to SARS-CoV-2, indicating recent or prior infection.

These tests are utilized by healthcare providers, including hospitals and nursing homes, and are also offered to businesses and educational systems to assist in their back-to-work or back-to-school strategies, a crucial element of restarting economic activity.

In developing the Company's products, the Company has built or gained access to unique biorepositories, proprietary technology, and bioinformatics that it believes are important to the development of new targeted therapies, determining clinical trial eligibility and guiding treatment selection.

All of the Company's testing services are made available through its clinical laboratories.

### ***Reverse Stock Split***

On October 19, 2020, the Company obtained approval of an amended and restated certificate of incorporation effecting a 0.1684664-for-1 reverse stock split of its issued and outstanding common stock as converted. All common shares, stock options, and per share information presented in these financial statements and notes thereto have been adjusted, where applicable, to reflect the reverse stock split on a retroactive basis for all periods presented.

### ***Approval of Amended and Restated Certificate of Incorporation***

In October 2020, the Company's Board of Directors and stockholders approved an amended and restated certificate of incorporation, which authorized 200,000,000 shares of common stock, par value \$0.001 per share, and 5,000,000 shares of preferred stock, par value \$0.001 per share. The amended and restated certificate of incorporation became effective on October 30, 2020.

### ***Initial Public Offering***

On October 27, 2020, the Company completed its initial public offering, in which it issued and sold 4,000,000 shares of its common stock at a public offering price of \$18.00 per share. The Company received net proceeds of \$63.8 million after deducting underwriting discounts and commissions and offering expenses payable by the Company. In addition, in connection with the initial public offering, all shares of the Company's then-outstanding convertible preferred stock and convertible notes payable were automatically converted into 21,939,025 shares of common stock, and all then outstanding warrants to purchase the Company's Series G convertible preferred stock were automatically converted into warrants to purchase 103,326 shares of the Company's common stock.

## **Note 2 – Summary of Significant Accounting Policies**

### ***Basis of Presentation***

The Company's financial statements have been prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP). The 2019 balance sheet has been updated to reflect an increase in goodwill and a reduction in accumulated deficit of \$3.4 million related to the correction of an immaterial error recorded as part of the acquisition of Integrated Diagnostics, Inc. in 2018. The Company determined that the reduction in the preexisting valuation allowance resulting from the acquisition should have been reflected as an income benefit within the tax provision rather than as a reduction in goodwill. The correction of the immaterial error had no impact on our 2020 or 2019 results of operations.

Certain prior period amounts have been reclassified to conform to the current period presentation.

### ***Segment Reporting***

The chief operating decision maker for the Company is the Chief Executive Officer, who reviews financial information for purposes of allocating resources and assessing financial performance. The Company has a single operating segment focused on providing diagnostic testing services to customers. Substantially all of the Company's revenue and all long-lived assets were derived or located in the United States for the years ended December 31, 2020 and 2019.

### ***Use of Estimates***

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Significant items subject to such estimates include: revenue recognition; the useful lives of property and equipment; the recoverability of long-lived assets; the estimation of the fair value of intangible assets; the valuation of contingent consideration related to a business combination; stock options; income tax uncertainties, including a valuation allowance for deferred tax assets; and contingencies. The Company bases these estimates on historical and anticipated results, trends, and various other assumptions that the Company believes are reasonable under the circumstances, including assumptions as to future events. These estimates form the basis for making judgments about the carrying values of assets and liabilities and recognized revenue and expenses that are not readily apparent from other sources. Actual results could differ from those estimates and assumptions.

## ***Revenue Recognition***

The Company generates revenues from (i) diagnostic tests and (ii) assay development and testing services (services revenue).

Diagnostic test revenues consist of blood-based lung tests and COVID-19 tests, which are recognized in the amount expected to be received in exchange for diagnostic tests when the diagnostic tests are delivered. The Company determines the transaction price related to its blood-based lung diagnostic test contracts using a portfolio approach by considering the nature of the payer and historical price concessions granted to groups of customers. The transaction price associated with COVID-19 testing arrangements are determined on the basis of the individual contract with each customer.

Services revenue consists of various types of tests or other scientific services for a purpose as defined by any individual customer, which are often larger biopharmaceutical companies, as defined by a written agreement between the Company and the customer. These services are generally completed upon the delivery of testing results, or achievement of contractual milestone(s) as defined in the customer agreements. Revenue for these services is recognized upon delivery of the completed test results, or upon completion of the contractual milestone(s).

The Company recognizes revenues related to blood-based lung diagnostic billings based on estimates of the amounts ultimately expected to be collected from customers on a portfolio approach as discussed above. In determining the amount to accrue for a delivered test, the Company considers factors such as payment history, payer coverage, whether there is a reimbursement contract between the payer and the Company, payment as a percentage of agreed upon rate (if applicable), amount paid per test and any current developments or changes that could impact reimbursement. Variable consideration, if any, is estimated based on an analysis of historical experience and adjusted as better estimates become available. These estimates require significant judgment by management.

The Company also provides services to patients with whom the Company does not have contracts as defined in Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC 606). The Company recognizes revenue for these patients when contracts as defined in ASC 606 are established at the amount of consideration to which it expects to be entitled, or when the Company receives substantially all of the consideration subsequent to satisfaction and delivery of the performance obligations.

See Note 13 — *Revenue* for additional information.

## ***Deferred Revenue***

Deferred revenue consists of payments received for research, development, and testing services fees received prior to the completion of performance of these tests and services. As of December 31, 2020, deferred revenue also includes \$2.8 million in a Medicare advance payment on testing services which can either be paid back or earned back starting 1 year from receipt.

## ***Direct Costs and Expenses***

The components of our cost of diagnostic tests and testing services consist of cost of materials, direct labor, including bonus, benefit and stock-based compensation, depreciation of laboratory equipment, rent costs, amortization of leasehold improvements and information technology costs associated with acquiring and processing test samples, including sample accessioning, test performance, quality control analyses, charges to collect and transport samples; curation of test results for physicians; and in some cases, license or royalty fees due to third parties.

Royalties for licensed technology are calculated as a percentage of revenues generated using the associated technology and recorded as expense at the time the related revenue is recognized. One-time royalty payments related to signing of license agreements or other milestones, such as issuance of new patents, are amortized to expense over the expected useful life of the patents. Costs associated with performing tests are expensed as the test is processed regardless of whether and when revenue is recognized with respect to that test.

### ***Research and Development Expenses***

Research and development expenses include external and internal costs incurred to develop our technology, collect clinical samples, and conduct clinical studies to develop and support our products. External costs consist primarily of payments to clinical trial sites, sample acquisition costs and laboratory supplies purchased in connection with the Company's discovery and preclinical activities, process development and clinical development activities. Internal costs consist primarily of salaries and benefits, reagents and supplies used in research and development laboratory work, infrastructure expenses, including allocated facility occupancy and information technology costs.

The Company estimates and accrues its expenses resulting from its obligations under contracts with vendors and consultants in connection with conducting research and development activities. The financial terms of these contracts vary from contract to contract and may result in payments that do not match the periods over which materials or services are provided under such contracts. The Company's estimates depend on the timeliness and accuracy of the data provided by consultants and vendors regarding the status of each activity. The Company periodically evaluates the estimates to determine if adjustments are necessary or appropriate based on information received. Research and development costs are expensed as incurred.

### ***Sales, Marketing, General and Administrative Expenses***

Selling expenses consist primarily of costs associated with our sales organization, including our direct sales force and sales management, client services, marketing, and reimbursement, as well as business development personnel who are focused on our biopharmaceutical customers. These expenses consist primarily of salaries, commissions, bonuses, employee benefits, travel, and stock-based compensation, as well as marketing and educational activities and allocated overhead expenses.

Sales, marketing, general and administrative expenses also include costs for our marketing and sales organizations, and other functions including finance, legal, human resources, and information technology.

These expenses consist principally of salaries, bonuses, employee benefits, travel, and stock-based compensation, as well as professional services fees such as consulting, audit, tax and legal fees, and general corporate costs and allocated overhead expenses.

### ***Concentrations of Credit Risk and Other Uncertainties***

Substantially all of the Company's cash and cash equivalents are deposited with one major financial institution in the United States. The Company continually monitors its positions with, and the credit quality of, the financial institution with which it holds cash. Periodically throughout the year, the Company has maintained balances in various operating accounts in excess of federally insured limits. The Company has not experienced any losses on its deposits of cash and cash equivalents.

Several of the components of the Company's sample collection kit and test reagents, and certain test systems and related test kits are obtained from single-source suppliers. If these single-source suppliers fail to satisfy the Company's requirements on a timely basis, it could suffer delays in being able to deliver its diagnostic solutions, a possible loss of revenue, or incur higher costs, any of which could adversely affect its operating results.

The Company's customers in excess of 10% of total revenue, and their related revenue as a percentage of total revenue were as follows:

	<b>Year Ended December 31, 2020</b>
The Big Ten Conference	30%
Centura Healthcare	17%
Percent of total revenue	47%



One customer, Covance, exceeded 10% of total revenue during 2019, representing 21% of total revenue. In addition to the above table, we collect reimbursement on behalf of customers covered by Medicare, which accounted for 17% and 36% of the Company's total revenue for the years ended December 31, 2020 and 2019, respectively. The Company is subject to credit risk from its accounts receivable related to services provided to its customers. The Company does not perform evaluations of customers' financial condition and does not require collateral. The Company's third-party payors and other customers in excess of 10% of accounts receivable, and their related accounts receivable as a percentage of total accounts receivable were as follows:

	As of December 31,	
	2020	2019
The Big Ten Conference	35%	—%
Centura Healthcare	24%	—%
Medicare	6%	18%
Covance Central Laboratory Services	2%	43%
Janssen Research and Development, LLC	5%	12%
Pfizer, Inc	4%	10%
Percent of total accounts receivable	76%	83%

### ***Cash and Cash Equivalents***

Cash equivalents consist of short-term, highly-liquid instruments with an original maturity of three months or less from the date of purchase.

### ***Restricted Cash***

Restricted cash consists of deposits related to the Company's corporate credit card and a letter of credit related to an operating lease agreement. As of December 31, 2020 and 2019, the Company had \$0.2 million restricted cash, respectively, which was included in 'Other current assets' in the accompanying balance sheets.

### ***Accounts Receivable and Allowance for Doubtful Accounts***

Accounts receivable are stated at the amount management expects to collect from customers based on their outstanding invoices. Management reviews accounts receivable quarterly to determine if any receivable will potentially be uncollectible and to estimate the amount of allowance for doubtful accounts necessary to reduce accounts receivable to its estimated net realizable value based on historical experience, customer creditworthiness, facts, and circumstances specific to outstanding balances, and payment terms. The Company's allowance for doubtful accounts was \$0.2 million as of December 31, 2020 and 2019.

### ***Inventory***

Inventory consists primarily of material supplies, which are consumed in the performance of testing services and charged to cost of sales. Inventory is stated at cost and reported within 'Other current assets' in the balance sheet and were \$3.2 million and \$0.8 million as of December 31, 2020 and 2019, respectively.

### ***Property and Equipment***

Property and equipment are stated at cost less accumulated depreciation. 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 using the straight-line method over the shorter of the estimated useful life of the asset or the term of the 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 the statements of operations and comprehensive loss in the period realized.

Long-lived assets to be held and used are evaluated for impairment when events or circumstances indicate the carrying value of a long-lived asset or asset group is less than the undiscounted cash flows from the use and eventual disposition over its remaining useful life. The Company assesses recoverability by comparing the sum or projected undiscounted cash flows from the use and eventual disposition of the asset or asset group to its carrying value, and records an impairment loss if the carrying value is greater than the undiscounted future cash flows. There were no impairments for the years ended December 31, 2020 or 2019.

### ***Intangible Assets***

Intangible assets primarily consist of intangible assets acquired as part of business combinations, external costs associated with patent applications that are expected to be successful, and trademark costs. Finite-lived intangibles are stated at cost, net of accumulated amortization. The Company amortizes finite-lived intangible assets using the straight-line method over their estimated useful lives of 9 to 10 years, based on management's estimate of the period over which their economic benefits will be realized, product life and patent life. Trademarks are considered indefinite lived and are not amortized.

Intangible assets are reviewed for impairment whenever events or changes in circumstances indicate a reduction to fair value below their carrying amounts. There were no impairments for the years ended December 31, 2020 or 2019.

### ***Goodwill***

Goodwill represents the excess of purchase price over amounts allocated to acquired assets and liabilities assumed in business combinations. The carrying value of goodwill is evaluated for impairment at least annually or more frequently when events or circumstances occur indicate a potential for impairment. The annual impairment test is performed on the last day of our fourth quarter. Prior to performing a quantitative evaluation, an assessment of qualitative factors may be performed to determine whether it is more likely than not that the fair value of the reporting unit exceeds its carrying value. In the event the Company determines that it is more likely than not the carrying value of our single reporting unit is higher than its estimated fair value, quantitative testing is performed comparing recorded values to estimated fair values. If impairment is present, the impairment loss is measured as the excess of the recorded goodwill over its implied fair value. There were no impairments for the years ended December 31, 2020 or 2019.

### ***Fair Value of Financial Instruments***

U.S. GAAP for fair value establishes a hierarchy that prioritizes fair value measurements based on the types of inputs used for the various valuation techniques (market approach, income approach, and cost approach). We utilize a combination of market and income approaches to value our financial instruments. Our financial assets and liabilities are measured using inputs from the three levels of the fair value hierarchy. Fair value measurements are categorized within the fair value hierarchy based upon the lowest level of the most significant inputs used to determine fair value. The three levels of the hierarchy and the related inputs are as follows:

Level	Inputs
1	Unadjusted quoted prices in active markets for identical assets and liabilities.
2	Unadjusted quoted prices in active markets for similar assets and liabilities; Unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active; or Inputs other than quoted prices that are observable for the asset or liability.
3	Unobservable inputs for the asset or liability.

The carrying amounts of certain financial instruments including cash and cash equivalents, accounts receivable, prepaid expenses and other current assets, accounts payable and accrued liabilities approximate fair value due to their relatively short maturities.

See Note 5 — *Fair Value* for further discussion related to estimated fair value measurements.

### *Contingent Consideration*

In connection with the purchase transaction with Integrated Diagnostics, Inc. (Indi), the Company recorded contingent consideration for amounts potentially payable to Indi's shareholder pursuant to the terms of the asset purchase agreement. The fair value of contingent consideration is assessed at each balance sheet date and changes, if any, to the fair value are recognized as operating expenses within the statements of operations. The estimated fair value of the contingent consideration is based upon significant assumptions including the probability of successful achievement of product gross margin targets included in the acquisition agreement, the estimated timing of achievement of the product gross margin targets, and discount rates. The estimated fair value could materially differ from actual values or fair values determined using different assumptions.

### *Warrant Liability*

Prior to the completion of the Company's initial public offering in October 2020, certain warrants issued to purchase convertible preferred stock were classified as liabilities with changes in the estimated fair value of these liabilities recognized in our results of operations. Upon completion of the Company's initial public offering in October 2020, the warrants were automatically converted to warrants to purchase common stock. Accordingly, the warrants were remeasured to an estimate of fair value and recognized in our results of operations and then reclassified to additional paid-in capital.

### *Put Option Liability*

During 2020 and 2019, the Company issued convertible debt with terms that provided for a conversion rate to the convertible debtholders that was more favorable than the price that other investors would pay for common stock in certain situations, including the completion of an initial public offering. As a result, the convertible debt is a financial instrument that was bifurcated into two instruments, a debt obligation and a put option liability, which represented the estimated fair value of the favorable conversion rate. The estimated fair value of the put option liability was separated from the convertible debt at inception and reported as a liability and debt discount, and amortized to interest expense. As a result of our initial public offering, the convertible debt was automatically converted to common stock and the put option liability was remeasured to an estimate of fair value and recognized in our results of operations and then reclassified to additional paid-in capital.

### ***Share-Based Compensation***

#### *Stock Options*

The Company grants service condition and performance condition stock options. Stock options are granted with exercise prices equal to the fair market value of our common stock on the date of grant. The grant date fair value of each employee stock option is estimated on the date of grant using the Black-Scholes option-pricing model, which requires the use of assumptions, including the expected term of the option, expected volatility of our stock price, expected dividend yield, and the risk-free interest rate, among others. These assumptions involve inherent uncertainties including market conditions and employee behavior that are generally outside of the Company's control. Service condition stock options are expensed based on the grant date fair value of the awards using the straight-line method over the requisite service period, adjusted for forfeitures as they occur. Performance-condition stock options vest based on achievement of multiple weighted performance goals, certification of performance achievement by the Compensation Committee of the Board of Directors, and continued service. For performance-condition stock options, compensation expense is updated for our expected performance level against performance goals at the end of each reporting period, which involves judgment as to achievement of certain performance metrics.

Prior to our initial public offering in October 2020, the fair value of our common stock was determined by the Board of Directors in accordance with the methodologies outlined in the American Institute of Certified Public Accountants Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation Practice Aid (Practice Aid). In doing so, the Board of Directors determined the best estimate of fair value of our common stock, exercising reasonable judgment and considering numerous objective and subjective factors, by first determining the enterprise value of our business, and then allocating the value among the various classes of our equity securities to derive a per share value of our common stock. Subsequent to the Company's initial public offering, the fair value of the Company's common stock is determined based on its traded market price.

### *Restricted Stock Units (RSUs)*

The Company grants service-condition RSUs. As a result of our initial public offering, the grant date fair values of these RSUs are based on the closing market price of our common stock on the grant date. The service-condition RSUs vest based on continued service with compensation expense, net of forfeitures, recognized on a straight-line basis over the requisite service period.

See Note 14 — *Share-Based Compensation* for additional information related to share-based compensation.

### ***Net Loss per Common Share***

Basic net loss per common share is calculated by dividing net loss by the weighted-average number of common shares outstanding during the period, without consideration of common stock equivalents. Diluted net loss per common share is computed by dividing net loss by the weighted-average number of common share equivalents outstanding for the period, if dilutive, using the treasury stock method. Potentially dilutive securities consisting of options to purchase common stock, warrants to purchase common stock, restricted stock units and shares subject to purchase under our employee stock purchase plan were excluded from the calculation of diluted net loss per common share because their effect would be anti-dilutive for all periods presented.

Until the Company's initial public offering in October 2020, basic and diluted net loss attributable to common stockholders per share was calculated using the two-class method. The net loss was attributable entirely to common stockholders because the participating securities did not have a contractual obligation to share in the Company's losses. As the Company has reported a net loss for all periods presented, diluted net loss per common share is the same as basic net loss per common share for all periods presented.

### **Note 3 – Recent Accounting Pronouncements**

#### *Recently Issued Accounting Standards Not Yet Adopted*

In February 2016, the FASB issued Accounting Standards Update (ASU) No. 2016-2, *Leases (Topic 842)*, which requires lessees to recognize a right-of-use asset and corresponding lease liability, including leases currently accounted for as operating leases. The ASU is effective for the Company for interim and annual periods beginning January 1, 2022. The Company expects to recognize right-of-use assets and lease obligations in its balance sheet upon adoption using the modified retrospective method as permitted by ASU No. 2018-11, *Leases (Topic 842): Targeted Improvements*. The Company does not currently expect adoption of this standard will have a significant effect on its statements of operations or cash flows.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments-Credit Losses: Measurement of Credit Losses on Financial Instruments*. This ASU requires measurement and recognition of expected credit losses for financial assets. This guidance will become effective for the Company beginning January 1, 2022 with early adoption permitted. The Company has not yet begun evaluating the potential effect of this standard on its financial statements.

### **Note 4 – Business Combinations**

#### *Oncimmune Limited*

On October 31, 2019, the Company purchased select assets and liabilities from Oncimmune Limited (Oncimmune) for total consideration of \$1.2 million payable in quarterly installments commencing 30 days following the closing of the transaction. Concurrent with the Oncimmune purchase, the Company acquired an exclusive option to license rights within the United States to an additional indication for their product for \$9.0 million. In September 2020, we notified Oncimmune that we would not exercise this option for the expansion of the field of use. As of December 31, 2020, the Company had paid the full \$1.2 million consideration.

The acquisition was accounted for as business combination and resulted in the recognition of goodwill of \$0.8 million representing expected synergies, including expected increases in future revenues as a result of expansion of the acquired technology into additional markets, and lower expected operating expenses. The Company finalized its purchase price allocation of the transaction as of December 31, 2019.

The following table summarizes the aggregate consideration paid by the Company and the allocation of the purchase price to assets acquired and liabilities assumed (in thousands):

Cash	\$	1,206
Total fair value of consideration transferred	\$	1,206
Deposit	\$	6
Inventory		14
Property and equipment		241
Purchase option		121
Goodwill		827
Accrued liabilities		(3)
	\$	1,206

*Integrated Diagnostics, Inc.*

On June 30, 2018, the Company purchased select assets and liabilities from Integrated Diagnostics, Inc. (Indi) for total consideration of \$27.6 million, consisting of \$8.0 million in the Company's Series G Preferred Stock and contingent consideration with an initial estimated fair value of \$19.6 million. The acquisition was accounted for as a business combination and resulted in goodwill of \$14.2 million representing expected synergies, including increases in future revenues as a result of expansion of the acquired technology into additional markets, and lower operating expenses.

The contingent consideration arrangement requires additional consideration to be paid by the Company to Indi upon attainment of a three-consecutive month gross margin target of \$2.0 million within the seven-year period after the acquisition date. If the gross margin target is met, the Company is required to issue 2,520,108 shares of common stock. For the six months following the achievement of the gross margin target, Indi has the option to require the Company to redeem these common shares for \$37.0 million in cash over eight equal quarterly installments. If Indi elects to not exercise its option, the Company has 12 months to repurchase the common stock in two equal and consecutive quarterly cash installments totaling \$37.0 million.

**Note 5 - Fair Value**

*Recurring Fair Value Measurements*

Our borrowing instruments are recorded at their carrying values in the balance sheets, which may differ from their respective fair values. The fair values of outstanding borrowings, which are classified as Level 2, approximate their carrying values at December 31, 2020 and 2019, based on interest rates currently available for similar borrowings and were:

	As of December 31,			
	2020		2019	
	Carrying Value	Fair Value	Carrying Value	Fair Value
Borrowings	\$ 27,766	\$ 27,766	\$ 35,971	\$ 35,971

The financial liabilities that are measured and recorded at estimated fair value on a recurring basis consist of our contingent consideration associated with our acquisition of Indi, and prior to the completion of our initial public offering in October 2020, the warrant liability and put option liability granted to certain holders of our convertible preferred stock and debt instruments, which were accounted for as liabilities and remeasured through our statements of operations. The table below presents the reported fair values of these liabilities, all of which are classified as Level 3 in the fair value hierarchy, as of the dates indicated (in thousands):

Description	As of December 31,	
	2020	2019
Contingent consideration	\$ 29,932	\$ 29,114
Put option liability	—	3,261
Warrant liability	—	372
Contingent value rights	—	60

The following table presents the changes in these financial liabilities for the year ended December 31, 2020 (in thousands):

Level 3 Rollforward	Contingent Consideration	Put Option Liability	Warrant Liability	Contingent Value Rights
Beginning balances	\$ 29,114	\$ 3,261	\$ 372	\$ 60
Additions	—	3,389	—	—
Changes in fair value	818	—	1,252	(60)
Reclassified to additional paid-in capital	—	(6,650)	(1,624)	—
Ending balances	<u>\$ 29,932</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

#### Contingent Consideration

In connection with the acquisition of Indi, the Company recorded contingent consideration for amounts contingently payable to Indi's selling shareholders pursuant to the Asset Purchase Agreement (See Note 4 – *Business Combinations*). The significant unobservable inputs used in the measurement of fair value include the probability of successful achievement of the specified product gross margin targets, the period in which the targets are expected to be achieved, and discount rates which ranged from 12.2% to 13.5%. Significant increases or decreases in any of these inputs would result in a significantly higher or lower fair value measurement.

Contingent consideration is recorded in the balance sheets as long-term liabilities. The net change to contingent consideration during the years ended December 31, 2020 and 2019 was an increase of \$0.8 million and \$4.1 million, respectively, and are recorded as operating expenses in the statements of operations.

#### Put Option Liability

The put option liability was valued based on the calculated returns as a result of the various discounts included in the Company's convertible notes payable and the related probability assessments of the various settlement scenarios. During 2020, the Company recognized an addition to the put option liability of \$3.4 million in connection with a favorable conversion rate granted to holders of issued convertible debt. The put option liability was settled upon the closing of the Company's initial public offering in October 2020 and reclassified to additional paid-in capital.

#### Warrant Liability

In connection with entering into the 2018 Notes, the Company issued to the lender a warrant to purchase 613,333 shares of Series G convertible preferred stock, at an exercise price of \$0.75 per share, subject to adjustment upon specified dilutive issuances. The warrant was immediately exercisable upon issuance and expires on February 23, 2028. The estimated fair value of the warrant on the issuance date of \$0.3 million was recorded as a debt discount and as a preferred stock warrant liability. Through the effective date of the Company's initial public offering, the Series G warrants were remeasured to an estimate of fair value using a Black Scholes pricing model. As a result of the Company's initial public offering, the preferred stock warrants were automatically converted to warrants to purchase 103,326 shares of common stock with a weighted average exercise price of \$4.46 and were also transferred to additional paid-in capital. During 2020, the Company recorded an increase in the value of the warrant liability of \$1.3 million.

### *Contingent Value Rights*

In addition to the shares of Series F Preferred Stock that were issued in January 2016, investors who purchased more than their pro-rata amount in the financing described above received a calculated number of contingent value rights (CVRs). In connection with the Series F financing, the Company issued 3,999 CVRs originally valued at \$0.5 million. One CVR represents 0.00375% of the Company's interest in the drug ficlatuzumab. The initial estimated value of the CVRs were recorded as a liability and as a reduction to the Series F proceeds. Upon receipt by the Company or a milestone, royalty, or any other type of payment from the Company's ownership rights in the drug, the Company was required to make a cash payment to the CVR holders equal to 15% of net proceeds, as defined. In September 2020, the Company exercised its opt-out right with AVEO Oncology (AVEO) for the payment of 50% of development and regulatory costs for ficlatuzumab. As a result, the CVRs were settled effective December 2, 2020. See Note 17 – *Commitments and Contingencies* for a discussion of the Co-Development Agreement with AVEO.

### *Non-Financial Assets and Liabilities*

Our non-financial assets, which primarily consist of property and equipment, goodwill, and other intangible assets, are not required to be carried at fair value on a recurring basis and are reported at carrying value. There were no changes to the valuation methods during the periods presented.

### **Note 6 – Property and Equipment**

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

	<b>As of December 31,</b>	
	<b>2020</b>	<b>2019</b>
Lab equipment	\$ 5,730	\$ 4,221
Leasehold improvements	1,845	1,894
Computer equipment	871	869
Furniture and fixtures	424	427
Software	651	503
Construction in process	381	592
	9,902	8,506
Less accumulated depreciation	(6,724)	(6,386)
Total property and equipment, net	<u>\$ 3,178</u>	<u>\$ 2,120</u>

Depreciation expense related to property and equipment, reported in 'Direct costs and expenses' and 'Sales, marketing, general and administrative' was:

	<b>Year ended December 31,</b>	
	<b>2020</b>	<b>2019</b>
Direct costs and expenses	\$ 361	\$ 183
Sales, marketing, general and administrative	478	636
Total	<u>\$ 839</u>	<u>\$ 819</u>

### *Disposals of Property and Equipment*

Gains on disposal of property and equipment were not significant for the years ended December 31, 2020 and 2019, and are included in 'Sales, marketing, general and administrative' in the statements of operations.

**Note 7 – Goodwill and Intangible Assets***Goodwill*

Changes in goodwill for the years ended December 31, 2020 and 2019 were (in thousands):

Balance at January 1, 2019	\$	14,204
Attributable to acquisition of Oncimmune, Ltd.		827
Balance at December 31 2019	\$	<u>15,031</u>
Balance at December 31, 2020	\$	<u>15,031</u>

*Intangible Assets, Net*

Intangible assets consist of the following (in thousands):

	December 31, 2020			December 31, 2019		
	Cost	Accumulated Amortization	Net Carrying Value	Cost	Accumulated Amortization	Net Carrying Value
Intangible assets subject to amortization						
Patents	\$ 1,474	\$ (494)	\$ 980	\$ 1,245	\$ (411)	\$ 834
Purchased technology	16,900	(4,694)	12,206	16,900	(2,817)	14,083
Purchase option	—	—	—	121	(17)	104
Intangible assets not subject to amortization						
Trademarks	74	—	74	71	—	71
Total	<u>\$ 18,448</u>	<u>\$ (5,188)</u>	<u>\$ 13,260</u>	<u>\$ 18,337</u>	<u>\$ (3,245)</u>	<u>\$ 15,092</u>

Amortization expense related to definite-lived intangible assets was (in thousands):

	Year ended December 31,	
	2020	2019
Direct costs and expenses	\$ 13	\$ 15
Sales, marketing, general and administrative	2,051	1,959
Total	<u>\$ 2,064</u>	<u>\$ 1,974</u>

Future estimated amortization expense of intangible assets is (in thousands):

	As of December 31, 2020
2021	\$ 1,946
2022	1,940
2023	1,936
2024	1,928
2025	1,924
Thereafter	3,512
Total	<u>\$ 13,186</u>

There have been no impairments of intangible assets for the twelve-month periods ended December 31, 2020 and December 31, 2019.



**Note 8 – Accrued Liabilities**

Amounts reported in ‘Accrued liabilities’ in the balance sheets were (in thousands):

	December 31,	
	2020	2019
Compensation related accruals	\$ 3,975	\$ 1,165
Accrued clinical trial expense	715	620
Other expenses	3,099	2,352
Warrant liability, current	-	43
Total accrued liabilities	<u>\$ 7,789</u>	<u>\$ 4,180</u>

**Note 9 – Debt****Notes Payable**

Long-term notes payable were as follows (in thousands):

	As of December 31,	
	2020	2019
2018 Notes	\$ 24,972	\$ 24,270
Payroll protection plan	3,107	—
Convertible notes payable	—	13,159
Unamortized debt discount and debt issuance costs	(313)	(1,458)
	<u>27,766</u>	<u>35,971</u>
Less: current maturities	11,840	12,159
Long-term notes payable	<u>\$ 15,926</u>	<u>\$ 23,812</u>

In February 2018, the Company issued long-term debt of \$23.0 million to Innovatus Life Sciences Lending Fund (Innovatus or Lender) (the 2018 Notes). Innovatus is also a holder of the Company’s common stock.

At the time of issuance, the Company paid a facility fee of \$0.2 million and issued a warrant to Innovatus, with an initial estimated fair value of \$0.3 million, for the purchase of 613,333 shares of Series G preferred stock. The facility fee and the estimated warrant fair value were recorded as debt discount and is amortized to interest expense over the term of the 2018 Notes. The 2018 Notes bear annual interest at 10%, of which 7.5% is payable in cash, with the remaining 2.5% added to principal through December 31, 2020. Total interest added to principal was \$1.7 million and \$1.1 million as of December 31, 2020 and 2019, respectively. Commencing March 2021 and continuing through the maturity date February 2023, the outstanding principal is repayable in 24 equal monthly installments.

The loan may be prepaid by the Company at any time, subject to a prepayment penalty of up to 3% of the principal amount, depending on the date of prepayment. Upon payment of the 2018 Notes at maturity or prepayment on any earlier date, unless waived, a 2% back-end facility fee will apply to the amounts paid or prepaid. The 2% fee is recognized as additional interest expense over the loan term. The 2018 Notes are senior to all of the Company’s other indebtedness including any contingent consideration payable to Indi.

The 2018 Notes contain customary affirmative covenants, and contain negative covenants limiting the ability of the Company to, among other things, incur future debt, transfer assets except for the ordinary course of business, make acquisitions, make certain restricted payments, or to sell assets, subject to certain exceptions. In addition, the 2018 Notes require the Company to comply with a minimum daily liquidity covenant and a rolling monthly revenue requirement. Failure to comply with the covenants and loan requirements may result in early amortization of the loan in a 24- or 36-month payment schedule. As of December 31, 2020, the Company was in compliance with all terms and covenants.

The Company granted the Lender a security interest in all of the Company’s assets through a pledge and security agreement, patent security agreement and trademark security agreement, each between the Company and the Lender.

### ***Paycheck Protection Program Note Payable***

In April 2020, the Company entered into a loan pursuant to the Paycheck Protection Program under the CARES Act, as administered by the U.S. Small Business Administration (the SBA). The loan, in the principal amount of \$3.1 million (the PPP Loan), was disbursed by JPMorgan Chase Bank (JPM) pursuant to a Paycheck Protection Program Promissory Note and Agreement (the Note and Agreement).

The PPP Loan matures on the two-year anniversary of the funding date, April 2022, and bears interest at a fixed rate of 1.00% per annum. Monthly principal and interest payments, less the amount of any potential forgiveness (as discussed below), will commence in September 2021. The Company did not provide any collateral or guarantees in connection with the PPP Loan, nor did the Company pay any facility charge to obtain the PPP Loan. The Note and Agreement provides for customary events of default, including those relating to failure to make payment, bankruptcy, breaches of representations and material adverse effects. The Company may prepay the principal of the PPP Loan at any time without incurring any prepayment charges.

All or a portion of the PPP Loan may be forgiven by the SBA and JPM upon application by the Company. Under the CARES Act, loan forgiveness is available for the sum of documented payroll costs, covered rent payments, and covered utilities during the eight-week period beginning on the approval date of the PPP Loan. For purposes of the CARES Act, payroll costs exclude compensation of an individual employee earning more than \$100,000, prorated annually. Not more than 40% of the forgiven amount may be for non-payroll costs. Forgiveness is reduced if full-time headcount declines, or if salaries and wages for employees with salaries of \$100,000 or less annually are reduced by more than 25%. The Company currently intends to repay the PPP loan in accordance with the underlying terms and conditions. To the extent we elect to seek forgiveness, the Company cannot assure that the PPP Loan will be forgiven, in whole or in part. If the loan is forgiven in part or in whole, and legal release is received, the Company will reduce the liability by the amount forgiven and record a gain on extinguishment in the statements of operations.

### ***Convertible Notes Payable***

#### ***March 2020 Notes***

In March 2020, the Company issued \$10.0 million of convertible notes primarily to existing stockholders that were originally scheduled to mature in August 2020 (the March 2020 Notes). In August 2020, the Company and its lenders agreed to extend the maturity date to June 30, 2021. The March 2020 Notes were issued in two tranches of \$5.0 million, with the first in March 2020 and the second in June 2020. Interest on the March 2020 Notes was 3% per annum, payable in full upon maturity through conversion to Series H Preferred Stock at 80% of the original issuance price of \$1.15 per share. Under the terms of the March 2020 Notes, on or before the maturity date and if the March 2020 Notes are unpaid, the outstanding principal and unpaid accrued interest under the March 2020 Notes shall be automatically converted into common stock in an initial public offering at a conversion price of 80% of the per share price of common stock sold in the initial public offering. The discount on the automatic conversion was separated from the March 2020 Notes and reported as a debt discount and put option liability of \$2.5 million and was amortized over the term of the March 2020 Notes. Following the closing of the initial public offering in October 2020, the March 2020 Notes were automatically converted into 703,503 shares of common stock at a conversion price of \$14.40, or 80% of the initial public offering price per common share.

#### ***December 2019 Notes***

In December 2019, the Company issued \$6.0 million of convertible notes primarily to existing preferred shareholders that were originally scheduled to mature in August 2020 (the December 2019 Notes). In August 2020, the Company and its lenders agreed to extend the maturity date to June 30, 2021. The December 2019 Notes were issued in two tranches of \$3.0 million, the first in December 2019 and the second in February 2020. Interest on the December 2019 Notes was 3% per annum and payable in full upon maturity through the conversion to Series H Preferred Stock at 80% of the original issuance price of \$1.15 per share. Under the terms of the December 2019 Notes, on or before the maturity date and if the December 2019 Notes are unpaid, the outstanding principal and unpaid accrued interest under the December 2019 Notes shall be automatically converted into common stock in an initial public offering at a conversion price of 80% of the per share price of common stock sold in the initial public offering. The discount on the automatic conversion was separated from the December 2019 Notes and reported as a debt discount and put option liability of \$1.5 million and was amortized over the term of the December 2019 Notes. Following the closing of the initial public offering in October 2020, the December 2019 Notes were automatically converted into 426,386 shares of common stock at a conversion price of \$14.40, or 80% of the initial public offering price per common share.

In August and September 2019 (the August 2019 Notes), the Company issued \$10.0 million of convertible notes primarily to existing preferred shareholders that were originally scheduled to mature in August 2020. In August 2020, the Company and its lenders agreed to extend the maturity date to June 30, 2021. Interest on the August 2019 Notes was 3% per annum and payable in full upon maturity through the conversion to Series H Preferred Stock at 95% of the original issuance price of \$1.15 per share. Under the terms of the August 2019 Notes, on or before the maturity date and if the August 2019 Notes are unpaid, the outstanding principal and unpaid accrued interest under the August 2019 Notes shall be automatically converted into common stock in an initial public offering at a conversion price of 95% of the per share price of common stock sold in the initial public offering. In connection with the issuance of the December 2019 Notes, the conversion price on the August 2019 Notes was amended to 80%. The initial discount on the automatic conversion created an initial put option liability of \$0.5 million that was separated from the August 2019 Notes. The amendment to the conversion price of the August 2019 Notes in December 2019 resulted in an increase to the put option liability of \$2.0 million to a total estimated value of \$2.5 million as of December 31, 2019. The increase in the value of the put option liability was reflected as a change in put option in the 2019 statement of operations. Following the closing of the initial public offering in October 2020, the August 2019 Notes were automatically converted into 718,391 shares of common stock at a conversion price of \$14.40, or 80% of the initial public offering price per common share.

Scheduled principal repayments (maturities) of long-term obligations as of December 31, 2020 were as follows (in thousands):

<b>Year Ending December 31,</b>	<b>As of December 31, 2020</b>
2021	\$ 11,840
2022	13,919
2023	2,320
2024	—
2025	—
Thereafter	—
	<u>\$ 28,079</u>

#### **Note 10 – Convertible Preferred Stock**

The Company had issued convertible preferred stock from time to time to fund its operations and to make acquisitions. In February and March 2019, the Company issued 8,695,621 shares of Series H Preferred Stock at \$1.15 per share for total cash proceeds of \$10.0 million.

The Company's convertible preferred stock was reported as temporary equity in the Company's balance sheet because the preferred shareholders held a majority of the Company's Board of Directors seats and as a result could have caused certain events to occur outside of the Company's control, with the result the Company could have been obligated to redeem the convertible preferred stock.

Immediately prior to the Company's initial public offering and as of December 31, 2019, the Company had issued 118,766,273 convertible preferred shares. On October 27, 2020, upon closing of the Company's initial public offering, each outstanding share of Series A-1 Preferred Stock, Series A-2 Preferred Stock, Series A-3 Preferred Stock, Series B Preferred Stock, Series C Preferred Stock, Series D Preferred Stock, Series E Preferred Stock, Series F Preferred Stock, Series G Preferred Stock and Series H Preferred Stock automatically converted into 0.1684664 share of common stock; and each share of Series B-1 Preferred Stock automatically converted into 0.196 shares of common stock. In the aggregate, all Series of preferred stock were converted into 20,090,745 shares of common stock. As a result, as of December 31, 2020 there are no longer any series of convertible preferred stock outstanding.

## Note 11 – Warrants to Purchase Convertible Preferred Stock

The Company issued warrants to purchase shares of convertible preferred stock in conjunction with the sale of certain of the convertible preferred shares and issuance of debt. The estimated grant date fair value as well as the estimated fair value at each reporting date of the warrants was determined using the Black-Scholes option pricing model with weighted average assumptions substantially consistent with those disclosed for stock options (see Note 14 – *Shared Based Compensation*), other than term, which is the contractual term of the warrant and the use of the exercise price and estimated fair value of the underlying series of convertible preferred stock. At December 31, 2019 and through the closing of the Company's initial public offering, the preferred warrants were classified as liabilities with estimated fair value remeasured at each reporting date reported within in the accompanying statements of operations.

The following table presents the activity for convertible preferred stock warrants (in thousands, except weighted average exercise price):

	Series E		Series G	
	Warrants	Weighted Average Exercise price	Warrants	Weighted Average Exercise price
Outstanding - December 31, 2019	925	\$ 5.00	613	\$ 0.75
Granted	—	—	—	—
Forfeited/canceled	(925)	(5.00)	—	—
Exercised	—	—	—	—
Reclassification of warrant liability to additional paid-in capital	—	—	(613)	(0.75)
Outstanding - December 31, 2020	—	\$ —	—	\$ —

Upon closing of the Company's initial public offering, the then outstanding Series G convertible preferred stock was automatically converted to common stock and the outstanding warrants to purchase Series G convertible preferred stock were automatically converted to warrants to purchase 103,326 shares of common stock at \$4.46 per share and expire in February 2028. The warrants were remeasured to an estimate of fair value as of the initial public offering with the change in fair value of \$1.3 million recognized in our statements of operations. The carrying value of the warrants was reclassified to additional paid-in capital as a result of the initial public offering.

## Note 12 – Equity

### Common Stock

The Company's Restated Certificate of Incorporation authorizes the Company to issue up to 200,000,000 shares of common stock with a par value of \$0.001 per share. The holder of each share of common stock is entitled to one vote per share. The common shareholders are entitled to dividends whenever funds and assets are legally available and when and if declared by the Board of Directors. The Company is currently subject to restrictions on the payment of dividends (see Note 9 - *Debt*) and no dividends have been declared as of December 31, 2020.

On October 27, 2020, the Company issued and sold 4,000,000 shares of common stock in a registered initial public offering at a price to the public of \$18.00 per share. The net proceeds to the Company were approximately \$63.8 million, after deducting underwriting discounts and commissions of \$5.0 million and direct offering expenses of approximately \$3.2 million.

### Preferred Stock

The Company's Restated Certificate of Incorporation authorizes the Company to issue up to 5,000,000 shares of preferred stock with a par value of \$0.001 per share. As of December 31, 2020, no shares of preferred stock were issued or outstanding.

## Note 13 - Revenue

The Company's revenue is generated from (i) diagnostic tests and (ii) assay development and testing services. Diagnostic test revenues consist of blood-based lung tests and COVID-19 tests, which are recognized in the amount expected to be received in exchange for diagnostic tests when the diagnostic tests are delivered. The Company conducts diagnostic tests and delivers the completed test results to the prescribing physician or patient, as applicable. The fees for diagnostic tests are billed either to a third party such as Medicare, medical facilities, commercial insurance payers, or to the patient. The Company determines the transaction price related to its diagnostic test contracts by considering the nature of the payer and historical price concessions granted to groups of customers. For diagnostic test revenue, the Company estimates the transaction price, which is the amount of consideration it expects to be entitled to receive in exchange for providing services based on its historical collection experience, using a portfolio approach. The Company recognizes revenues for diagnostic tests upon delivery of the tests to the physicians requesting the tests or patient, as applicable.

Services revenue consists of on-market tests, pipeline tests, custom diagnostic testing, and other scientific services for a purpose as defined by any individual customer, which is often with large biopharmaceutical companies. The performance obligations and related revenue for these sales is defined by a written agreement between the Company and the customer. These services are generally completed upon the delivery of testing results, or other contractually defined milestone(s), to the customer. Revenue for these services is recognized upon delivery of the completed test results, or upon completion of the contractual milestone(s).

Revenues consisted of the following (in thousands):

	Year Ended December 31,	
	2020	2019
Diagnostic tests	\$ 40,919	\$ 17,315
Services	4,638	7,237
Total revenue	<u>\$ 45,557</u>	<u>\$ 24,552</u>

The Company's fiscal 2020 diagnostic test revenue consists of \$28.3 million in COVID-19 test revenue, which began in late fiscal 2020, and \$12.6 million in lung diagnostic revenue.

## Contract Liabilities

Contract liabilities consist of cash payments from customers received in advance of delivery (advance deposits). As products are shipped and control transfers, the Company recognizes the deferred revenue in 'Revenues' in the statements of operations. At January 1 and December 31, 2020, \$1.3 million and \$3.5 million, respectively, of advance deposits were reported in 'Deferred revenue' in the accompanying balance sheets. Of the \$1.3 million in deferred revenue recorded at January 1, 2020, \$0.7 million was recognized in revenues during the year ended December 31, 2020. The deferred revenue of \$3.5 million at December 31, 2020 is expected to be recognized in revenues during 2021 as test results are delivered.

## Note 14 – Share Based Compensation

### 2016 Equity Incentive Plan and Predecessor 2006 Equity Incentive Plan

In February 2016, the Company adopted the 2016 Equity Incentive Plan (2016 Plan) as a successor to and continuation of the prior 2006 Equity Incentive Plan (2006 Plan). The 2016 Plan provides for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock units, and other stock awards to directors, employees, and consultants. Awards granted under the 2016 Plan or the 2006 Plan that expired or otherwise terminated, or were forfeited, cancelled, or repurchased by the Company, became available for future issuance under the 2016 Plan. In addition, shares subject to an award were withheld to satisfy a participant's tax withholding obligations, or were reacquired by the Company as consideration for the exercise or purchase price of a stock award also became available for future issuance under the 2016 Incentive Plan.

## *2020 Equity Incentive Plan*

Effective upon the closing of our initial public offering, the Company's Board of Directors approved the 2020 Equity Incentive Plan (2020 Plan), which replaced the 2016 Plan. The 2020 Plan provides for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock units, performance awards and other stock awards. Officers, directors, employees, consultants, agents, and independent contractors who provide services to the Company may receive awards. The terms of all awards are governed by an agreement between the Company and the recipients, as administered and approved by the Compensation Committee of the Board of Directors.

### *Employee Stock Purchase Plan*

Effective with our initial public offering in October 2020, the Company's Board of Directors and its stockholders approved the Company's Employee Stock Purchase Plan (ESPP). A total of 338,106 shares of our common stock have been reserved for issuance under the ESPP. The maximum number of shares of our common stock available under the ESPP will automatically increase on the first trading day of each calendar year, commencing January 2021, by an amount equal to the lesser of (i) 1% of the shares of our common stock issued and outstanding on December 31 of the immediately preceding calendar year, and (ii) an amount determined by our Board of Directors.

Subject to any plan limitations, the ESPP allows eligible employees to contribute, normally through payroll deductions, up to 15% of their earnings for the purchase of the Company's common stock at a discounted price per share. The price at which common stock is purchased under the ESPP is equal to 85% of the fair market value of the Company's common stock on the first or last day of the offering period, whichever is lower. No employee may participate in an offering period if the employee owns 5% or more of the total combined voting power or value of the Company's stock. The initial offering period will commence from January 1, 2021 through August 31, 2021. On a going forward basis, the ESPP provides for successive six-month offering periods beginning on September 1st and March 1st of each year.

### *Shares Reserved Subject to All Plans*

The number of shares reserved for issuance under the 2020 Plan is 1,893,395, plus an annual increase added on the first day of each calendar year, beginning with the calendar year ending December 31, 2022, and continuing until, and including, the calendar year ending December 31, 2030. The annual increase will be equal to the lesser of (i) 4% of the number of shares of our common stock issued and outstanding as of December 31st of the immediately preceding calendar year and (ii) such lesser amount determined by the Board of Directors. Up to 1,893,395 shares of our common stock that may be issued under the 2020 Plan may be issued in satisfaction of incentive stock option awards.

Under the 2006 Plan, the Company is authorized to grant incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards and restricted stock units up to 831,389 total award shares. No additional awards may be granted under the 2006 Plan. Unallocated shares under the 2006 Plan were added to the shares available for issuance under the 2016 Plan.

Under the 2016 Plan, which is a successor to and continuation of the 2006 Plan, the Company is authorized to grant incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock units and stock appreciation rights up to 1,431,964 total shares, plus any shares subject to stock awards made under the 2006 Plan.

Our Compensation Committee may grant other stock awards that are based on or related to shares of our common stock, such as awards of shares of common stock granted as bonus and not subject to any vesting conditions, deferred stock units, stock purchase rights, and shares of our common stock issued in lieu of our obligations to pay cash under any compensatory plan or arrangement. To date, the Company has granted service-condition RSUs.

To the extent an equity award granted under the 2020 Plan (other than any substitute award) or granted under any other equity plan maintained by us under which awards are outstanding as of the effective date of the 2020 Plan (the Prior Plans) expires or otherwise terminates without having been exercised or paid in full, or is settled in cash, the shares subject to such award will become available for future grant under the 2020 Plan. In addition, to the extent shares subject to an award are withheld to satisfy a participant's tax withholding obligation upon the exercise or settlement of such award (other than any substitute award) or to pay the exercise price of a stock option granted under the 2020 Plan or a Prior Plan, such shares will become available for future grant under the 2020 Plan. The total number of shares available for grant under all Plans was 4,647,380 at December 31, 2020.

### *Description of Awards Granted*

The Company has granted incentive stock options, non-statutory stock options, performance-based stock options, and restricted stock units.

Incentive stock options, which may only be issued to employees, are granted at an exercise price per share equal to the fair market value per share of the underlying common stock on the grant date, and vest over time as determined by the Compensation Committee, provided that the term of the options may not exceed ten years from the date of grant. Accelerated vesting may occur in the event of an optionee's death, disability, or other events.

Non-statutory stock options may be issued to non-employees and directors, with exercise prices, vesting conditions, option term and other conditions as determined by the Compensation Committee.

Performance-based stock options are typically granted on an annual basis and consist of a performance-based and service-based component. The performance targets and vesting conditions for performance-condition options are based on achievement of recognized revenue targets. Performance-based options vest in three equal annual installments beginning one year after the grant date, pending certification of performance achievement by the Compensation Committee and continued service. The fair value of performance-condition awards is based on the closing market price of the Company's common stock on the grant date. Compensation expense, net of forfeitures, is updated for the Company's expected performance level against performance goals at the end of each reporting period. On January 1, 2019, the Company granted 168,466 performance-condition options, with an exercise price of \$0.77 per share and a term of ten years. During the year ended December 31, 2020, the performance conditions were met and 56,155 options vested. During the year ended December 31, 2019, the performance conditions were not met and 56,155 options were forfeited. As of December 31, 2020, there were 56,156 performance condition options outstanding with a remaining life of approximately eight years.

Restricted stock units and the related terms and conditions are awarded at the discretion of the Compensation Committee. RSU holders have a contractual right to receive a share of common stock when vested. RSUs generally vest over three years. RSU agreements may provide for accelerated vesting in the event of a stock unit holder's death, disability, or retirement or other events.

### *Bonus-To-Options Program*

The Company also has a Bonus-to-Options Program (the "Bonus Option Program"), which is separate from predecessor Plans and was initially adopted by the Board of Directors in 2008, and subsequently amended and restated in 2010, 2011 and 2015. For fiscal year 2021, the Bonus Option Program is subject to the shares reserved under the 2020 Plan. The Bonus Option Program, which is limited to participation of the Chief Executive Officer, direct reports to the Chief Executive Officer and Vice Presidents of the Company, allows participants who so elect to convert all or a portion of their annual cash bonus into fully vested, non-qualified stock options to purchase shares of common stock (Bonus Options). The exercise price for the options under the Bonus Option Program equals the then current price for the shares of the common stock as of the grant date, as disclosed below under "*Fair Value of Common Stock*". Bonus Options issued must be exercised within a ten-year term. A maximum of 1% of the fully diluted equity, as of December 31 of the year for which the bonus was awarded, may be issued in any one year to the participants. As of December 31, 2020, there were 173,229 options outstanding under the Bonus Option Program. These options are fully vested and have a weighted average exercise price of \$11.11 per share and have an intrinsic value of approximately \$1.6 million as of December 31, 2020.

During the twelve-month period ended December 31, 2020, the Company accrued \$3.4 million as stock compensation expense associated with the estimate of options to be delivered to eligible participants under the Bonus Option Program and which were granted in February 2021 by the Compensation Committee of the Board of Directors. In determining the amount of stock compensation to recognize under the Bonus Option Program, the Company estimates the bonus attainment for the year and determines the expected number of options to be delivered to eligible participants. A Black-Scholes option pricing model is used to determine the estimated fair value of the expected number of options to be delivered to eligible participants. The key elements in determining the estimated fair value include assumptions for volatility, the risk free interest rate, expected dividends and strike price, utilizing the measurement date closing stock price until the grants are authorized.

## Share-Based Compensation Expense

Pre-tax share-based compensation expense reported in the Company's statements of operations was (in thousands):

	Year Ended December 31,	
	2020	2019
Research and development	\$ 589	\$ 33
Sales, marketing, general and administrative	3,120	137
Total	<u>\$ 3,709</u>	<u>\$ 170</u>

The unrecognized remaining share-based compensation expense for options and RSUs was approximately \$0.6 million as of December 31, 2020, and is expected to be amortized to expense over the next 3.7 years.

## Stock Options

Stock option activity during the year ended December 31, 2020, excluding the Bonus Option Program described above, was (in thousands, except weighted average exercise price and weighted average contractual life):

	Number of Options	Weighted Average Exercise Price	Weighted Average Contractual Life (Years)	Aggregate Intrinsic Value
Outstanding - December 31, 2019	1,916	\$ 1.72	7.6	\$ —
Granted	828	2.81	—	—
Forfeited/canceled	(55)	0.60	—	—
Exercised	(368)	3.65	—	—
Outstanding - December 31, 2020	<u>2,321</u>	<u>\$ 1.82</u>	<u>7.4</u>	<u>\$ 42,580</u>
Exercisable - December 31, 2020	<u>1,190</u>	<u>\$ 2.35</u>	<u>6.3</u>	<u>\$ 21,194</u>

## Fair Value of Common Stock

Prior to the Company's initial public offering, the fair value of the Company's common stock underlying the stock options was determined by the Board of Directors with assistance from management and, in part, on input from an independent third-party valuation firm. The Board of Directors determined the fair value of common stock by considering a number of objective and subjective factors, including valuations of comparable companies, sales of convertible preferred stock, operating and financial performance, the lack of liquidity of the Company's common stock and the general and industry-specific economic outlook. Subsequent to the Company's initial public offering, the fair value of the Company's common stock is determined based on its closing market price.

The fair value of each option grant prior was estimated on the grant date using the Black-Scholes option pricing model with the following weighted average assumptions for the year ended December 31, 2020:

Risk-free rate	0.34%
Expected term (in years)	5.73
Expected dividend yield	—%
Expected volatility	77%

The Company estimated volatility based on the historical volatility of its peer group and average expected life based on the review of historical exercise behavior of option grants with similar vesting periods.



### Restricted Stock Units and Restricted Stock Unit Activity

Service-condition RSUs were granted to Board members and vest over three years, 40% over the first two years and the remaining 60% over the third year from the grant date. During the year ended December 31, 2020, the Company granted 52,736 service-condition RSUs. As of December 31, 2020, there were 79,104 RSUs outstanding, with a weighted average grant date fair value of \$6.83 per share.

### Note 15 – Earnings per Share

Excluded from determination of diluted net loss attributable to common stockholders for the periods presented because inclusion would be anti-dilutive are the instruments below, the terms of which are described in further detail in Note 14 – *Share Based Compensation*. The potentially dilutive securities as of December 31, 2020 and 2019 primarily represent the shares subject to future issuance under stock options awards, warrants and RSUs and would be subject to the treasury stock method when dilutive. The number of common shares that convertible debt was assumed to convert to was based on the Company's estimated common stock price as of December 31, 2019, as determined by the Company's Board of Directors with assistance from a valuation firm.

	Year Ended December 31	
	2020	2019
Numerator		
Net loss attributable to common stockholders	\$ (31,350)	\$ (30,726)
Denominator		
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	4,838	242
Net loss per share, basic and diluted	<u>\$ (6.48)</u>	<u>\$ (126.97)</u>

The following outstanding common stock equivalents were excluded from diluted net loss attributable to common stockholders for the periods presented because inclusion would be anti-dilutive (in thousands):

	Year Ended December 31	
	2020	2019
Options to purchase common stock	2,495	2,104
Convertible preferred stock	—	119,257
Warrants	103	1,538
Restricted stock units	79	26
Convertible debt	—	21,131
Total	<u>2,677</u>	<u>144,056</u>

**Note 16 - Income Taxes**

Since inception, the Company has incurred net taxable losses, and accordingly, no current provision for income taxes has been recorded. The effective income tax rate of the provision for income taxes differs from the federal statutory rate as follows:

	<b>Years Ended December 31,</b>	
	<b>2020</b>	<b>2019</b>
Federal statutory income tax rate	21%	21%
State income taxes, net of federal benefit	2	4
Research and developments credits	(1)	2
Permanent items	(6)	(4)
Change in valuation allowance	(16)	(23)
Effective income tax rate	—%	—%

The tax effects of temporary differences that give rise to significant portions of the deferred income tax assets and liabilities are as follows (in thousands):

	<b>Years Ended December 31,</b>	
	<b>2020</b>	<b>2019</b>
Deferred Tax Assets:		
Net operating loss carryforwards	\$ 53,128	\$ 50,360
Research and development tax credits	2,860	3,040
Property and equipment	279	370
Stock-based compensation	865	—
Accruals and reserves	1,406	286
Total	58,538	54,056
Valuation allowance	(56,083)	(51,135)
Total deferred tax assets after valuation allowance	2,455	2,921
Deferred Tax Liabilities:		
Intangible assets	(2,455)	(2,921)
Total deferred tax liabilities	(2,455)	(2,921)
Net deferred tax assets and liabilities	\$ —	\$ —

At December 31, 2020, the Company had \$233.6 million and \$3.6 million of net operating loss and research and experimentation tax carryforwards, respectively, which are set to expire beginning in 2026. The Internal Revenue Code contains provisions that may limit the net operating loss carryovers available to be used in any year if certain events occur, including significant changes in ownership interest.

In assessing the realizability of its deferred tax assets, the Company considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. The Company considers the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. As the Company does not have any historical taxable income, projections of future taxable income over the periods in which the deferred tax assets are deductible, and after consideration of the history of operating losses, the Company does not believe it is more likely than not that it will realize the benefits of net deferred tax assets and, accordingly, has established a valuation allowance equal to 100% of net deferred tax assets. The valuation allowance increased by \$4.9 million during 2020 and \$7.0 million during 2019.

During 2020, the Company determined that it now has uncertain tax positions related to its U.S. research and development credits. As of December 31, 2020 and 2019, there was no accrued interest related to uncertain tax positions. The Company does not believe it is reasonably possible that its unrecognized tax benefits will significantly change in the next twelve months. A reconciliation of beginning and ending balances for unrecognized tax benefits is as follows (in thousands):

	<b>Year Ended December 31, 2020</b>
Balance at January 1	\$ —
Additions for tax positions related to the current year	106
Additions for tax positions related to prior years	609
Reductions for tax positions related to prior years	—
Reductions related to settlements	—
Reductions related to a lapse of statute	—
Balance at December 31	<u>\$ 715</u>

The Company monitors proposed and issued tax law, regulations, and cases to determine the potential impact of uncertain income tax positions. At December 31, 2020, the Company had not identified any potential subsequent events that would have a material impact on unrecognized income tax benefits within the next twelve months.

All years will remain open for examining by federal and state authorities for three and four years, respectively, from the date of utilization of any net operating loss carryforwards.

#### **Note 17 – Commitments and Contingencies**

##### *Leases*

The Company leases facilities under non-cancelable operating leases. Rent expense was \$1.7 million and \$2.1 million for the years ended December 31, 2020 and 2019, respectively.

Future minimum lease payments for operating lease obligations are as follows as of December 31, 2020 (in thousands):

<b>Year Ending December 31,</b>	
2021	\$ 703
2022	724
2023	112
2024	—
2025	—
Thereafter	—
	<u>\$ 1,539</u>

### *Co-Development Agreement*

In April 2014 and amended in October 2016, the Company entered into a worldwide agreement with AVEO to develop and commercialize AVEO's hepatocyte growth factor inhibitory antibody ficlatuzumab with the Company's proprietary companion diagnostic test, BDX004, a version of the Company's serum protein test that is commercially available to help physicians guide treatment decisions for patients with advanced non-small cell lung cancer (NSCLC). Under the terms of the agreement, AVEO will conduct a proof-of-concept (POC) clinical study of ficlatuzumab for NSCLC in which BDX004 will be used to select clinical trial subjects (the NSCLC POC Trial). The Company and AVEO will share equally in the costs of the NSCLC POC Trial, and each will be responsible for 50% of development and regulatory costs associated with all future clinical trials agreed upon by the Company and AVEO. The Company and AVEO continue to conduct POC clinical trials of ficlatuzumab in combination with BDX004 with each responsible for 50% of development and regulatory costs.

In September 2020, the Company exercised its opt-out right with AVEO for the payment of 50% of development and regulatory costs for ficlatuzumab effective December 2, 2020. The Company had \$0.3 million in remaining obligations related to the AVEO agreement as of the opt-out date. Following the effective date, the Company is entitled to a 10% royalty of net sales of ficlatuzumab and 25% of license income generated from the licensing of ficlatuzumab from AVEO.

Expenses related to this agreement for the years ended December 31, 2020 and 2019 were approximately \$0.9 million and \$0.9 million, respectively.

### *License Agreement*

In August 2019, we entered into a non-exclusive license agreement with Bio-Rad Laboratories, Inc. (Bio-Rad) (the Bio-Rad License). Under the terms of the Bio-Rad License, the Company received a non-exclusive license, without the right to grant sublicenses, to utilize certain of Bio-Rad's intellectual property, machinery, materials, reagents, supplies and know-how necessary for the performance of Droplet Digital PCR™ (ddPCR) in cancer detection testing for third parties in the United States. The Company also agreed to purchase all of the necessary supplies and reagents for such testing exclusively from Bio-Rad, pursuant to a separately executed supply agreement (the Supply Agreement) with Bio-Rad. As further consideration for the non-exclusive license, the Company agreed to pay a royalty of 2.5% on the net revenue received for the performance of such ddPCR testing collected from third parties. The Bio-Rad License expires in August 2024. Either party may terminate for the other's uncured material breach or bankruptcy events. Bio-Rad may terminate the Bio-Rad License if the Company does not purchase licensed products under the Supply Agreement for a consecutive twelve-month period or for any material breach by us of the Supply Agreement. The Company incurred royalty expense of \$0.1 million and \$0.1 million for the years ended December 31, 2020 and 2019, respectively, under the Bio-Rad License.

### *Revenue Share Agreement*

As part of the acquisition of Oncimmune, the Company entered into several agreements to govern the relationship between the parties. The Company agreed to a revenue share payment related to an acquired diagnostic test of 8% of recognized revenue for non-screen tests up to an annual minimum volume and 5% thereafter, with an escalating minimum through the first four years of sales. Revenue share expenses of \$0.3 million were recognized for the year ended December 31, 2020.

### **Note 18 – Defined Contribution 401(k) Plan**

The Company sponsors a 401(k) defined contribution plan covering all eligible employees. The Company did not make any discretionary or employer matching contributions under the plan during the years ended December 31, 2020 or 2019.

**DESCRIPTION OF THE REGISTRANT’S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES  
EXCHANGE ACT OF 1934, AS AMENDED**

*The following summary describes the capital stock of Biodesix, Inc., (the “Company,” “we,” “us,” and “our”) and the material provisions of our amended and restated certificate of incorporation and our amended and restated bylaws, the amended and restated registration rights agreement to which we and certain stockholders are parties and of the General Corporation Law of the State of Delaware. Because the following is only a summary, it does not contain all of the information that may be important to you. For a complete description, you should refer to our amended and restated certificate of incorporation, amended and restated bylaws, and amended and restated registration rights agreement, copies of which are incorporated by reference as exhibits to our Annual Report on Form 10-K.*

As of December 31, 2020, Biodesix Inc. (the “Company”) had common stock, \$0.001 par value per share, registered under Section 12 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and listed on the Nasdaq Global Select Market under the trading symbol “BDSX.”

**General**

Our amended and restated certificate of incorporation authorizes the issuance of 205,000,000 shares of capital stock, consisting of (i) 200,000,000 shares of common stock, \$0.001 par value per share (the “Common Stock”) and (ii) 5,000,000 shares of preferred stock, par value \$0.001 per share, the rights, preferences and privileges of which may be designated from time to time by our board of directors.

**Common Stock**

***Dividend Rights***

Subject to preferences that may apply to shares of preferred stock outstanding at the time, the holders of outstanding shares of our common stock are entitled to receive dividends out of funds legally available if our board of directors, in its discretion, determines to issue dividends and only then at the times and in the amounts that our board of directors may determine.

***Voting Rights***

The holders of our common stock are entitled to one vote per share. Stockholders do not have the ability to cumulate votes for the election of directors. Our amended and restated certificate of incorporation and bylaws provide for a classified board of directors consisting of three classes of approximately equal size, each serving staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms.

***Preemptive or Other Rights***

Our common stock is not entitled to preemptive rights and is not subject to redemption or sinking fund provisions.

***Right to Receive Liquidation Distributions***

Upon our liquidation, dissolution or winding-up, the assets legally available for distribution to our stockholders would be distributable ratably among the holders of our common stock and any participating preferred stock outstanding at that time, subject to prior satisfaction of all outstanding debt and liabilities and the preferential rights of and the payment of liquidation preferences, if any, on any outstanding shares of preferred stock.

**Preferred Stock**

Our amended and restated certificate of incorporation provides that shares of preferred stock may be issued from time to time in one or more series. Our Board is authorized to fix the voting rights, if any, designations, powers, preferences and relative, participating, optional, special and other rights, if any, and any qualifications, limitations and restrictions thereof, applicable to the shares of each series. Our Board is able, without stockholder approval, to issue preferred stock with voting and other rights that could adversely affect the voting power and other rights of the holders of the Common Stock and could have anti-takeover effects. The ability of the our Board to issue preferred stock without stockholder approval could have the effect of delaying, deferring or preventing a change of control of us or the removal of existing management. We have no preferred stock outstanding at the date hereof. Although we do not currently intend to issue any shares of preferred stock, we cannot assure you that we will not do so in the future.

## **Certain Anti-Takeover Provisions of Delaware Law, the Company's Certificate of Incorporation and Bylaws**

The provisions of the DGCL, our amended and restated certificate of incorporation and our bylaws could have the effect of delaying, deferring or discouraging another person from acquiring control of our company. These provisions, which are summarized below, are expected to discourage certain types of coercive takeover practices and inadequate takeover bids and encourage persons seeking to acquire control of our company to first negotiate with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire us because negotiation of these proposals could result in an improvement of their terms.

### ***Section 203 of the DGCL***

We are subject to the provisions of Section 203 of the DGCL regulating corporate takeovers. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the date that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, our board of directors approved either the business combination or the transaction, which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction, which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans in some instances, but not the outstanding voting stock owned by the interested stockholder; or
- at or after the time the stockholder became interested, the business combination was approved by our board and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock, which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, lease, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance of transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

### ***Amended and Restated Certificate of Incorporation and Bylaw Provisions***

Our amended and restated certificate of incorporation and our bylaws include a number of provisions that may have the effect of deterring hostile takeovers, or delaying or preventing changes in control of our management team or changes in our board of directors or our governance or policy, including the following:

#### ***Board Vacancies***

Our amended and restated certificate of incorporation and bylaws authorize generally only our board of directors to fill vacant directorships resulting from any cause or created by the expansion of our board of directors. In addition, the number of directors

constituting our board of directors may be set only by resolution adopted by a majority vote of our entire board of directors. These provisions prevent a stockholder from increasing the size of our board of directors and gaining control of our board of directors by filling the resulting vacancies with its own nominees.

#### *Classified Board*

Our amended and restated certificate of incorporation and bylaws provide that our board of directors is classified into three classes of directors. The existence of a classified board of directors could delay a successful tender offeror from obtaining majority control of our board of directors, and the prospect of that delay might deter a potential offeror.

#### *Directors Removed Only for Cause*

Our amended and restated certificate of incorporation provides that stockholders may remove directors only for cause.

#### *Supermajority Requirements for Amendments of Our Amended and Restated Certificate of Incorporation and Bylaws*

Our amended and restated certificate of incorporation further provide that the affirmative vote of holders of at least two-thirds of the voting power of our outstanding common stock is required to amend certain provisions of our amended and restated certificate of incorporation, including provisions relating to the classified board, the size of the board of directors, removal of directors, special meetings, actions by written consent and designation of our preferred stock. The affirmative vote of holders of at least two-thirds of the voting power of our outstanding common stock is required to amend or repeal our bylaws, although our bylaws may be amended by a simple majority vote of our board of directors.

#### *Stockholder Action; Special Meetings of Stockholders*

Our amended and restated certificate of incorporation provides that our stockholders may not take action by written consent, but may only take action at annual or special meetings of our stockholders. As a result, holders of our capital stock are not able to amend our bylaws or remove directors without holding a meeting of our stockholders called in accordance with our bylaws. Our amended and restated certificate of incorporation and our bylaws provide that special meetings of our stockholders may be called only by a majority of our board of directors, the chairperson of our board of directors, our chief executive officer, our president or the lead independent director, thus prohibiting a stockholder from calling a special meeting. These provisions might delay the ability of our stockholders to force consideration of a proposal or for stockholders to take any action, including the removal of directors.

#### *Advance Notice Requirements for Stockholder Proposals and Director Nominations*

Our bylaws provide advance notice procedures for stockholders seeking to bring business before our annual meeting of stockholders or to nominate candidates for election as directors at our annual meeting of stockholders. To be timely, a stockholder's notice generally must be delivered to us not later than the close of business on the 90th day nor earlier than the close of business on the 120th day prior to the first anniversary of the preceding year's annual meeting of stockholders. Our bylaws also specify certain requirements regarding the form and content of a stockholder's notice. With respect to nominations of persons for election to our board of directors, the notice shall provide information about the nominee, including, among other things, name, age, address, principal occupation, ownership of our capital stock and whether they meet applicable independence requirements. With respect to the proposal of other business to be considered by our stockholders at an annual meeting, the notice shall provide a brief description of the business desired to be brought before the meeting, the text of the proposal or business, the reasons for conducting such business at the meeting and any material interest in such business by such stockholder and any beneficial owners and associated persons on whose behalf the notice is made, or the proposing persons. In addition, a stockholder's notice must set forth certain information related to the proposing persons, including, among other things:

- the name and address of the proposing persons;
- information as to the ownership by the proposing persons of our capital stock and any derivative interest or short interest in any of our securities held by the proposing persons;
- information as to any material relationships and interest between the proposing persons and us, any of our affiliates and any of our principal competitors;
- a representation that the stockholder is a holder of record of our stock entitled to vote at that meeting and that the stockholder intends to appear in person or by proxy at the meeting to propose such nomination or business; and

- a representation whether the proposing persons intend or are part of a group which intends to deliver a proxy statement or form of proxy to holders of at least the percentage of our outstanding capital stock required to elect the nominee or carry the proposal.

These provisions may preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders. We expect that these provisions might also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our company.

#### *No Cumulative Voting*

The DGCL provides that stockholders are not entitled to the right to cumulate votes in the election of directors unless a corporation's certificate of incorporation provides otherwise. Our amended and restated certificate of incorporation and bylaws will not provide for cumulative voting.

#### *Issuance of Undesignated Preferred Stock*

Our board has the authority, without further action by the stockholders, to issue up to 5,000,000 shares of undesignated preferred stock with rights and preferences, including voting rights, designated from time to time by our board of directors. The existence of authorized but unissued shares of preferred stock enables our board of directors to render more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise.

#### *Exclusive Forum*

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf under Delaware law, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (3) any action arising pursuant to any provision of the DGCL or our amended and restated certificate of incorporation or bylaws, (4) any other action asserting a claim that is governed by the internal affairs doctrine or (5) any other action asserting an "internal corporate claim," as defined in Section 115 of the DGCL, shall be the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware) in all cases subject to the court having jurisdiction over indispensable parties named as defendants. These exclusive-forum provisions do not apply to claims under the Securities Act or the Exchange Act. Any person or entity purchasing or otherwise acquiring any interest in our securities shall be deemed to have notice of and consented to this provision. Although we believe these provisions benefit us by providing increased consistency in the application of Delaware law for the specified types of actions and proceedings, the provisions may have the effect of discouraging lawsuits against us or our directors and officers.

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.

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. However, our amended and restated certificate of incorporation, which will become effective immediately prior to the completion of this offering, contains a federal forum provision which provides that unless the Company consents in writing to the selection of an alternative forum, the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act.

#### **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A.



BIODESIX, INC.

STOCK OPTION GRANT NOTICE  
(2020 EQUITY INCENTIVE PLAN)

**Biodesix, Inc.** (the “**Company**”), pursuant to its 2020 Equity Incentive Plan (as amended and/or restated as of the Date of Grant set forth below, the “**Plan**”), has granted to Optionholder an option to purchase the number of shares of the Common Stock set forth below (the “**Option**”). The Option is subject to all of the terms and conditions as set forth in this Stock Option Grant Notice (the “**Grant Notice**”) and in the Plan, the Option Agreement, and the Notice of Exercise, all of which are attached to this Grant Notice and incorporated into this Grant Notice in their entirety. Capitalized terms not explicitly defined in this Grant Notice but defined in the Plan or the Option Agreement shall have the meanings set forth in the Plan or the Option Agreement, as applicable. If the Company uses an electronic capitalization table system (such as Carta or Shareworks) and the fields below are blank or the information is otherwise provided in a different format electronically, the blank fields and other information (such as exercise schedule and type of grant) shall be deemed to come from the electronic capitalization system and is considered part of this Grant Notice.

Optionholder:	
Date of Grant:	
Vesting Commencement Date:	
Number of Shares Subject to Option:	
Exercise Price (Per Share) <sup>1</sup> :	
Total Exercise Price:	
Expiration Date:	
Exercise Schedule:	Same as Vesting Schedule
Type of Grant <sup>2</sup> :	[Incentive Stock Option] [Nonstatutory Stock Option]

<sup>1</sup> The exercise price may be paid by one or a combination of the methods permitted in the Option Agreement.

<sup>2</sup> If this is an Incentive Stock Option, it (plus other outstanding Incentive Stock Options) cannot be first *exercisable* for more than \$100,000 in value (measured by exercise price) in any calendar year. Any excess over \$100,000 is a Nonstatutory Stock Option.

**Vesting Schedule:**

**Optionholder Acknowledgements:** By Optionholder’s signature below or by electronic acceptance or authentication in a form authorized by the Company, Optionholder understands and agrees that the Option is governed by this Grant Notice, and the provisions of the Plan and the Option Agreement and the Notice of Exercise, all of which are made a part of this document.

By accepting this Option, Optionholder consents to receive this Grant Notice, the Option Agreement, the Plan, and any other Plan-related documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company. Optionholder represents that he or she has read and is familiar with the provisions of the Plan and the Option Agreement. Optionholder acknowledges and agrees that this Grant Notice and the Option Agreement may not be modified, amended or revised in a manner that materially impairs the rights of the Optionholder except in a writing signed by Optionholder and a duly authorized officer of the Company.

Optionholder further acknowledges that in the event of any conflict between the provisions in this Grant Notice, the Option Agreement, the Notice of Exercise and the terms of the Plan, the terms of the Plan shall control. Optionholder further acknowledges that the Option Agreement sets forth the entire understanding between Optionholder and the Company regarding the acquisition of Common Stock and supersedes all prior oral and written agreements, promises and/or representations on that subject with the exception of other equity awards previously granted to Optionholder and any written employment agreement, offer letter, severance agreement, written severance plan or policy, or other written agreement between the Company and Optionholder, in each case that specifies the terms that should govern this Option.

This Grant Notice may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, Uniform Electronic Transactions Act or other applicable law) or other transmission method and any counterpart so delivered will be deemed to have been duly and validly delivered and be valid and effective for all purposes.

**Biodesix, Inc.**

**Optionholder:**

By: \_\_\_\_\_  
(Signature)

Title: \_\_\_\_\_

Date: \_\_\_\_\_

By: \_\_\_\_\_  
(Signature)

Email: \_\_\_\_\_

Date: \_\_\_\_\_

**Attachments:** Option Agreement, 2020 Equity Incentive Plan and Notice of Exercise

BIODESIX, INC.

2020 EQUITY INCENTIVE PLAN

OPTION AGREEMENT  
(INCENTIVE STOCK OPTION OR NONSTATUTORY STOCK OPTION)

Pursuant to your Stock Option Grant Notice (“**Grant Notice**”) and this Option Agreement, **Biodesix, Inc.** (the “**Company**”) has granted you an option under its 2020 Equity Incentive Plan (the “**Plan**”) to purchase the number of shares of the Company’s Common Stock indicated in your Grant Notice at the exercise price indicated in your Grant Notice. The option is granted to you effective as of the date of grant set forth in the Grant Notice (the “**Date of Grant**”). If there is any conflict between the terms in this Option Agreement and the Plan, the terms of the Plan will control. Capitalized terms not explicitly defined in this Option Agreement or in the Grant Notice but defined in the Plan will have the same definitions as in the Plan.

The details of your option, in addition to those set forth in the Grant Notice and the Plan, are as follows:

1. **Vesting.** Your option will vest as provided in your Grant Notice. Vesting will cease upon the termination of your Continuous Service (as defined herein).
2. **Number of Shares and Exercise Price.** The number of shares of Common Stock subject to your option and your exercise price per share in your Grant Notice will be adjusted in accordance with Section 5.7 of the Plan for changes in the capitalization of the Company.
3. **Definitions.** For purposes of this Option Agreement, the following terms shall have the meanings set forth below.

(a) “**Cause**” shall have the meaning ascribed to such term in any written agreement between you and the Company defining such term and which is in effect as of the Date of Grant and, in the absence of such agreement, such term means the occurrence of any of the following events: (i) your commission of any felony or any crime involving fraud, dishonesty or moral turpitude under the laws of the United States or any state thereof; (ii) your attempted commission of, or participation in, a fraud or act of dishonesty against the Company, or any of its employees or directors; (iii) your intentional, material violation of any contract or agreement between you and the Company, the Company’s employment policies, or of any statutory or other duty owed to the Company, (iv) your unauthorized use or disclosure of the Company’s confidential information or trade secrets; or (v) your gross misconduct. The determination that a termination of your Continuous Service is either for Cause or without Cause will be made by the Company (or, if you are subject to Section 16 of the Exchange Act, the Committee), in its sole discretion. Any determination by the Company that your Continuous Service was terminated with or without Cause for the purposes of this Option Agreement will have no effect upon any determination of the rights or obligations of the Company or you for any other purpose. Notwithstanding anything in the Plan or any award agreement to the contrary, the Company (or Committee, as applicable) may deem a termination or separation from service to be for Cause if, after such termination or separation (regardless of how originally designated), it discovers facts, circumstances or omissions that would constitute Cause if you were still employed.

(b) “**Continuous Service**” means that your service with the Company or a Subsidiary, whether as an employee, director or consultant, is not interrupted or terminated. A change in the capacity in which you render service to the Company or a Subsidiary as an employee, director or consultant or a change in the entity for which you render such service, provided that there is no interruption or termination of your service with the Company or a Subsidiary, will not terminate your Continuous Service; *provided, however*, that if the entity for which you are rendering services ceases to qualify as a Subsidiary, as determined by the Board in its sole discretion, your Continuous Service will be considered to have terminated on the date such entity ceases to qualify as a Subsidiary.

(c) “**Disability**” means your inability to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment that can be expected to result in death or that has lasted or

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can be expected to last for a continuous period of not less than twelve (12) months as provided in Sections 22(e)(3) and 409A(a)(2)(c)(i) of the Code, and will be determined by the Board on the basis of such medical evidence as the Board deems warranted under the circumstances.

**4. Exercise and Method of Payment.** Subject to the limitations set forth in this Option Agreement, you may exercise your option, to the extent vested, (a) by delivering to the Company an Exercise Notice in the form prescribed by the Company specifying the number of whole shares of Common Stock to be purchased and by accompanying such notice with payment therefor in full (or by arranging for such payment to the Company's satisfaction) either (i) in cash, (ii) to the extent permitted by the Company (or, if you are subject to Section 16 of the Exchange Act, the Committee), by delivery to the Company (either actual delivery or by attestation procedures established by the Company) of shares of Common Stock having an aggregate Fair Market Value, determined as of the date of exercise, equal to the aggregate purchase price payable pursuant to the option by reason of such exercise, (iii) to the extent permitted by the Company (or, if you are subject to Section 16 of the Exchange Act, the Committee), by authorizing the Company to withhold whole shares of Common Stock which would otherwise be delivered having an aggregate Fair Market Value, determined as of the date of exercise, equal to the amount necessary to satisfy such obligation, (iv) except as may be prohibited by applicable law, in cash by a broker-dealer acceptable to the Company to whom you have submitted an irrevocable notice of exercise or (v) by a combination of (i), (ii) and (iii), and (b) by executing such documents as the Company may reasonably request. No share of Common Stock or certificate representing a share of Common Stock shall be issued or delivered until the full purchase price therefor and any withholding taxes thereon, as described in Section 11, have been paid. If your option is an Incentive Stock Option, by exercising your option you agree that you will notify the Company in writing within 15 days after the date of any disposition of any of the shares of the Common Stock issued upon exercise of your option that occurs within two years after the Date of Grant or within one year after such shares of Common Stock are transferred upon exercise of your option.

**5. Securities Law Compliance.** In no event may you exercise your option unless the shares of Common Stock issuable upon exercise are then registered under the Securities Act of 1933, as amended (the "**Securities Act**") or, if not registered, the Company has determined that your exercise and the issuance of the shares would be exempt from the registration requirements of the Securities Act. The exercise of your option also must comply with all other applicable laws and regulations governing your option, and you may not exercise your option if the Company determines that such exercise would not be in material compliance with such laws and regulations (including any restrictions on exercise required for compliance with Treas. Reg. 1.401(k)-1(d)(3), if applicable).

**6. Term.** You may not exercise your option before the Date of Grant or after the expiration of the option's term. Except as set forth in your Grant Notice, the term of your option expires upon the earliest of the following:

(a) immediately upon the termination of your Continuous Service for Cause;

(b) three months after the termination of your Continuous Service for any reason other than Cause, your Disability or your death (except as otherwise provided in Section 6(d) below); *provided, however*, that if during any part of such three month period your option is not exercisable solely because of the condition set forth in the section above relating to "Securities Law Compliance," your option will not expire until the earlier of the Expiration Date or until it has been exercisable for an aggregate period of three months after the termination of your Continuous Service; *provided further*, that if (i) your Continuous Service terminates within six months after the Date of Grant, and (ii) you have vested in a portion of your option at the time of your termination of Continuous Service, your option will not expire until the earlier of (x) the later of (A) the date that is seven months after the Date of Grant, and (B) the date that is three months after the termination of your Continuous Service, and (y) the Expiration Date;

(c) 12 months after the termination of your Continuous Service due to your Disability (except as otherwise provided in Section 6(d) below);

(d) 18 months after your death if you die either during your Continuous Service or within three (3) months after your Continuous Service terminates for any reason other than Cause; or

(e) the Expiration Date indicated in your Grant Notice.

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If your option is an Incentive Stock Option, note that to obtain the federal income tax advantages associated with an Incentive Stock Option, the Code requires that at all times beginning on the Date of Grant and ending on the day three months before the date of your option's exercise, you must be an employee of the Company or a Subsidiary, except in the event of your death or Disability. The Company has provided for extended exercisability of your option under certain circumstances for your benefit but cannot guarantee that your option will necessarily be treated as an Incentive Stock Option if you continue to provide services to the Company or a Subsidiary as a consultant or director after your employment terminates or if you otherwise exercise your option more than three months after the date your employment with the Company or a Subsidiary terminates.

**7. Non-Transferability.** Except as otherwise provided in this Section 7, your option is not transferable, except by will or by the laws of descent and distribution, and is exercisable during your life only by you.

**(a) Certain Trusts.** Upon receiving written permission from the Board or its duly authorized designee, you may transfer your option to a trust if you are considered to be the sole beneficial owner (determined under Section 671 of the Code and applicable state law) while the option is held in the trust. You and the trustee must enter into transfer and other agreements required by the Company.

**(b) Domestic Relations Orders.** Upon receiving written permission from the Board or its duly authorized designee, and provided that you and the designated transferee enter into transfer and other agreements required by the Company, you may transfer your option pursuant to the terms of a domestic relations order, official marital settlement agreement or other divorce or separation instrument as permitted by Treasury Regulation 1.421-1(b)(2) that contains the information required by the Company to effectuate the transfer. You are encouraged to discuss the proposed terms of any division of this option with the Company prior to finalizing the domestic relations order or marital settlement agreement to help ensure the required information is contained within the domestic relations order or marital settlement agreement. If this option is an Incentive Stock Option, this option may be deemed to be a Nonstatutory Stock Option as a result of such transfer.

**(c) Beneficiary Designation.** Upon receiving written permission from the Board or its duly authorized designee, you may, by delivering written notice to the Company, in a form approved by the Company and any broker designated by the Company to handle option exercises, designate a third party who, on your death, will thereafter be entitled to exercise this option and receive the Common Stock or other consideration resulting from such exercise. In the absence of such a designation, your executor or administrator of your estate will be entitled to exercise this option and receive, on behalf of your estate, the Common Stock or other consideration resulting from such exercise.

**8. Issuance or Delivery of Shares.** Upon the exercise of the option, in whole or in part, the Company shall issue or deliver, subject to the conditions of this Option Agreement, the number of shares of Common Stock purchased against full payment therefor. Such issuance shall be evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company. The Company shall pay all original issue or transfer taxes and all fees and expenses incident to such issuance, except as otherwise provided in Section 11.

**9. Option Confers No Rights as Stockholder.** You shall not be entitled to any privileges of ownership with respect to shares of Common Stock subject to the option unless and until such shares are purchased and issued upon the exercise of the option, in whole or in part, and you become a stockholder of record with respect to such issued shares. You shall not be considered a stockholder of the Company with respect to any such shares not so purchased and issued.

**10. Option not a Service Contract.** Your option is not an employment or service contract, and nothing in your option will be deemed to create in any way whatsoever any obligation on your part to continue in the employ or service of the Company or an affiliate, or of the Company or an affiliate to continue your employment or service. In addition, nothing in your option will obligate the Company or an affiliate, their respective stockholders, boards of directors, officers or employees to continue any relationship that you might have as a director or consultant for the Company or an affiliate.

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**11. Withholding Obligations.**

(a) As a condition precedent to the issuance of Common Stock following the exercise of the option, you shall, upon request by the Company, pay to the Company in addition to the purchase price of the shares, such amount as the Company determines is required, under all applicable federal, state, local or other laws or regulations, to be withheld and paid over as income or other withholding taxes (the “**Required Tax Payments**”) with respect to such exercise of the option. If you shall fail to advance the Required Tax Payments after request by the Company, the Company may, in its discretion, deduct any Required Tax Payments from any amount then or thereafter payable by the Company to you.

(b) You may elect to satisfy your obligation to advance the Required Tax Payments by any of the following means: (i) a cash payment to the Company; (ii) to the extent permitted by the Company (or, if you are subject to Section 16 of the Exchange Act, the Committee), delivery to the Company (either actual delivery or by attestation procedures established by the Company) of previously owned whole shares of Common Stock having an aggregate Fair Market Value, determined as of the date on which such withholding obligation arises (the “**Tax Date**”), equal to the Required Tax Payments; (iii) to the extent permitted by the Company (or, if you are subject to Section 16 of the Exchange Act, the Committee), authorizing the Company to withhold whole shares of Common Stock which would otherwise be delivered to you upon exercise of the option having an aggregate Fair Market Value, determined as of the Tax Date, equal to the Required Tax Payments; (iv) except as may be prohibited by applicable law, a cash payment by a broker-dealer acceptable to the Company to whom you have submitted an irrevocable notice of exercise or (v) any combination of (i), (ii) and (iii). Shares of Common Stock to be delivered or withheld may not have a Fair Market Value in excess of the amount determined by applying the maximum individual statutory tax rate in your jurisdiction; provided that the Company shall be permitted to limit the number of shares so withheld to a lesser number if necessary, as determined by the Company, to avoid adverse accounting consequences or for administrative convenience. No share of Common Stock or certificate representing a share of Common Stock shall be issued or delivered until the Required Tax Payments have been satisfied in full.

**12. Tax Consequences.** You hereby agree that the Company does not have a duty to design or administer the Plan or its other compensation programs in a manner that minimizes your tax liabilities. You will not make any claim against the Company, or any of its officers, directors, employees, affiliates or representatives related to tax liabilities arising from your option or your other compensation.

**13. Notices.** Any notices provided for in your option or the Plan will be given in writing (including electronically) and will be deemed effectively given upon receipt or, in the case of notices delivered by mail by the Company to you, five days after deposit in the United States mail, postage prepaid, addressed to you at the last address you provided to the Company. The Company may, in its sole discretion, decide to deliver any documents related to participation in the Plan and this option by electronic means or to request your consent to participate in the Plan by electronic means. By accepting this option, you consent to receive such documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

**14. Decisions of Board or Committee.** The Board or the Committee shall have the right to resolve all questions which may arise in connection with the option or its exercise. Any interpretation, determination or other action made or taken by the Board or the Committee regarding the Plan or this Option Agreement shall be final, binding and conclusive.

**15. Successors.** This Option Agreement shall be binding upon and inure to the benefit of any successor or successors of the Company and any person or persons who shall, upon your death, acquire any rights hereunder in accordance with this Option Agreement or the Plan.

**16. Protected Rights.** Pursuant to 18 U.S.C. § 1833(b), “an individual shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that-(A) is made-(i) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal.” Accordingly, you have the right to disclose in confidence trade secrets to federal, state, and local government officials, or to an attorney, for the sole

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purpose of reporting or investigating a suspected violation of law. You also have the right to disclose trade secrets in a document filed in a lawsuit or other proceeding, but only if the filing is made under seal and protected from public disclosure. Nothing in this Option Agreement is intended to conflict with 18 U.S.C. § 1833(b) or create liability for disclosures of trade secrets that are expressly allowed by 18 U.S.C. § 1833(b). You understand that nothing contained in this Option Agreement limits your ability to file a charge or complaint with the Equal Employment Opportunity Commission, the National Labor Relations Board, the Occupational Safety and Health Administration, the Securities and Exchange Commission or any other federal, state or local governmental agency or commission (“**Government Agencies**”). You further understand that this Option Agreement does not limit your ability to communicate with any Government Agencies or otherwise participate in any investigation or proceeding that may be conducted by any Government Agency, including providing documents or other information, without notice to the Company. This Option Agreement does not limit your right to receive an award for information provided to any Government Agencies.

**17. Governing Plan Document.** Your option is subject to all the provisions of the Plan, the provisions of which are hereby made a part of your option, and is further subject to all interpretations, amendments, rules and regulations, which may from time to time be promulgated and adopted pursuant to the Plan. If there is any conflict between the provisions of your option and those of the Plan, the provisions of the Plan will control.

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**BIODESIX, INC.**  
**NOTICE OF EXERCISE**

This constitutes notice to **Biodesix, Inc.** (the “**Company**”) under my stock option that I elect to purchase the below number of shares of Common Stock of the Company (the “**Shares**”) for the price set forth below. Use of certain payment methods is subject to Company and/or Committee consent and certain additional requirements set forth in the Option Agreement and the Plan. If the Company uses an electronic capitalization table system (such as Carta or Shareworks) and the fields below are blank, the blank fields shall be deemed to come from the electronic capitalization system and is considered part of this Notice of Exercise.

**Option Information**

Type of option (check one):	Incentive <input type="checkbox"/> Nonstatutory <input type="checkbox"/>
Stock option dated:	_____
Number of Shares as to which option is exercised:	_____
Shares to be issued in name of: <sup>3</sup>	_____

**Exercise Information**

Date of Exercise:	_____
Total exercise price:	_____
Cash: <sup>4</sup>	_____
Value of _____ Shares delivered with this notice: <sup>5</sup>	_____
Value of _____ Shares withheld pursuant to net exercise:	_____

By this exercise, I agree (i) to provide such additional documents as you may require pursuant to the terms of the Plan, (ii) to provide for the payment by me to you (in the manner designated by you) of your withholding obligation, if any, relating to the exercise of this option, and (iii) if this exercise relates to an incentive stock option, to notify you in writing within 15 days after the date of any disposition of any of the Shares issued upon exercise of this option that occurs within two years after the date of grant of this option or within one year after such Shares are issued upon exercise of this option. I further agree that this Notice of Exercise may be delivered via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, Uniform Electronic Transactions Act or other applicable law) or other transmission method and will be deemed to have been duly and validly delivered and be valid and effective for all purposes.

Very truly yours,

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
Name (Please Print)

Address of Record: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Email: \_\_\_\_\_

<sup>3</sup> If left blank, will be issued in the name of the option holder.

<sup>4</sup> Cash may be in the form of cash, check, bank draft, electronic funds transfer or money order payment.

<sup>5</sup> Shares must be valued in accordance with the terms of the option being exercised, and must be owned free and clear of any liens, claims, encumbrances or security interests.



**Consent of Independent Registered Public Accounting Firm**

The Board of Directors  
Biodesix, Inc.:

We consent to the incorporation by reference in the registration statement (No. 333-249805) on Form S-8 of Biodesix, Inc. of our report dated March 16, 2021, with respect to the balance sheets of Biodesix, Inc. as of December 31, 2020 and 2019, the related statements of operations, convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the years in the two-year period ended December 31, 2020, and the related notes, which report appears in the December 31, 2020 annual report on Form 10-K of Biodesix, Inc.

/s/ KPMG LLP

Denver, Colorado  
March 16, 2021

**PRINCIPAL EXECUTIVE OFFICER CERTIFICATION**

I, Scott Hutton, certify that:

1. I have reviewed this Annual Report on Form 10-K of Biodesix, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) [Paragraph omitted in accordance with Exchange Act Rule 13a-14(a)];
  - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 16, 2021

By: /s/ SCOTT HUTTON  
 Scott Hutton  
 Chief Executive Officer

**CERTIFICATION PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Robin Harper Cowie, certify that:

1. I have reviewed this Annual Report on Form 10-K of Biodesix, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) [Paragraph omitted in accordance with Exchange Act Rule 13a-14(a)];
  - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 16, 2021

By: /s/ ROBIN HARPER COWIE  
Robin Harper Cowie  
Chief Financial Officer

**CERTIFICATION PURSUANT TO**

**18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO**

## SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Bidesix, Inc. (the “Company”) on Form 10-K for the year ending December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 16, 2021

By: /s/ SCOTT HUTTON  
Scott Hutton  
Chief Executive Officer

By: /s/ ROBIN HARPER COWIE  
Robin Harper Cowie  
Chief Financial Officer