As confidentially submitted to the Securities and Exchange Commission on August 12, 2020. This draft registration statement has not been publicly filed with the Securities and Exchange Commission and all information herein remains strictly confidential.

Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM S-1

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

BIODESIX, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**8071**	**20-3986492**
(State or Other Jurisdiction of Incorporation or Organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

Biodesix, Inc.
2970 Wilderness Place, Suite 100
Boulder, Colorado 80301
(303) 417-0500
(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

Scott Hutton
President and Chief Executive Officer
Biodesix, Inc.
2970 Wilderness Place, Suite 100
Boulder, Colorado 80301
(303) 417-0500
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

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Approximate date of commencement of proposed sale to the public:
As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box: ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided to Section 7(a)(2)(B) of the Securities Act. ☐

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	**Proposed Maximum Aggregate Offering Price(1)(2)**	**Amount of Registration Fee(1)(2)**
Common Stock, par value $0.001 per share	$	$

(1) Includes additional common stock that the underwriters have an option to purchase. See "Underwriters."
(2) Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(o) of the Securities Act of 1933, as amended, based on an estimate of the proposed maximum aggregate offering price.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until this Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to such Section 8(a), may determine.

Table of Contents

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities, and we are not soliciting offers to buy these securities, in any jurisdiction where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS (Subject to Completion)
Issued , 2020

Shares

COMMON STOCK

Biodesix, Inc. is offering shares of its common stock. This is our initial public offering and no public market currently exists for our shares of common stock. We anticipate that the initial public offering price will be between $ and $ per share.

We intend to apply for listing of our common stock on The Nasdaq Global Market under the symbol "BDSX."

We are an "emerging growth company" as defined under the federal securities laws. Investing in our common stock involves risks. See "Risk Factors" beginning on page 10.

PRICE $ A SHARE

	Price to Public	***Underwriting Discounts and Commissions(1)***	***Proceeds to Biodesix***
Per share	*$*	*$*	*$*
Total	*$*	*$*	*$*

(1) We have agreed to reimburse the underwriters for certain FINRA-related expenses. See "Underwriters" for a detailed description of the compensation payable to the underwriters.

We have granted the underwriters an option to purchase up to an additional shares of common stock to cover over-allotments at the initial public offering price less underwriting discounts and commissions.

The Securities and Exchange Commission and state securities regulators have not approved or disapproved of these securities, or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares of common stock to purchasers on , 2020.

Morgan Stanley *William Blair*

Canaccord Genuity *BTIG*

, 2020

TABLE OF CONTENTS

Neither we nor the underwriters have authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses we have prepared. Neither we, nor any of the underwriters, take responsibility for, or can provide any assurance as to the reliability of, any information that others may give you. We and the underwriters are not offering to sell, or seeking offers to buy, shares of our common stock in any jurisdiction where such offer or sale is not permitted. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of shares of our common stock. Our business, financial condition, results of operations, and prospects may have changed since that date.

Persons in jurisdictions outside the United States who come into possession of this prospectus and any applicable free writing prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of our common stock and the distribution of this prospectus and any applicable free writing prospectus applicable to such jurisdictions.

Until , 2020 (25 days after the date of this prospectus), all dealers that buy, sell, or trade shares of our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the obligation of dealers to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

ABOUT THIS PROSPECTUS

As used in this prospectus, unless the context otherwise requires, the terms “Biodesix,” “company,” “our,” “us,” and “we” in this prospectus refer to Biodesix, Inc., the issuer of the shares of common stock offered hereby.

Neither we nor any of the underwriters has authorized anyone to provide you any information or to make any representations other than those contained in this prospectus or in any free writing prospectus we have prepared. Neither we, nor any of the underwriters, take responsibility for, or can provide any assurance as to the reliability of, any information that others may give you. This prospectus is an offer to sell only the shares of common stock offered hereby, and only under circumstances and in jurisdictions where it is lawful to do so. You should assume the information contained in this prospectus and any free writing prospectus we authorize to be delivered to you is accurate only as of their respective dates or the date or dates specified in those documents. Our business, financial condition, results of operations and prospects may have changed since those dates.

For investors outside the United States: neither we nor any of the underwriters has done anything that would permit this offering or possession or distribution of this prospectus or the offer and sale of the shares of common stock in any jurisdiction where action for that purpose is required, other than the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside the United States.

Unless otherwise indicated, all references in this prospectus to the number and percentages of shares of our common stock outstanding following the completion of this offering:

- reflects the initial public offering price of $ per share of common stock, which is the midpoint of the estimated offering price range set forth on the cover of this prospectus;
- assumes that our amended and restated certificate of incorporation, which we will file in connection with the closing of this offering, and our amended and restated bylaws adopted in connection with this offering, are effective;
- assumes the conversion of all outstanding shares of our preferred stock and convertible debt into an aggregate of shares of common stock immediately upon the closing of this offering;
- assumes no exercise of the outstanding options or warrants described in this prospectus; and
- assumes no exercise of the underwriters’ over-allotment option.

INDUSTRY AND MARKET DATA

The data included in this prospectus contains estimates, projections and other information concerning our industry and our business, including estimated market size, projected growth rates and the incidence of certain medical conditions. Unless otherwise expressly stated, we obtained this industry, business, market, medical and other information from reports, research surveys, studies and similar data prepared by third parties, industry, medical and general publications, government data and similar sources. In some cases, we do not expressly refer to the sources from which this information is derived. In that regard, when we refer to one or more sources of this type of information in any paragraph, you should assume that other information of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires.

This industry, business, market, medical and other information involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. Third-party industry and general publications, research, surveys and studies generally state that the information contained therein has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe that each of these studies and publications is reliable, we have not independently verified any of the data from third-party sources. Although we are responsible for all of the disclosure contained in this prospectus and we believe the market position, market opportunity, market size and medical information included in this prospectus is reliable, such information is inherently imprecise. Data regarding the industries in which we compete and our market position and market share within these industries are inherently imprecise and are subject to significant business, economic and competitive uncertainties beyond our control, but we believe that they generally indicate size, position and market share within these industries. We believe these estimates to be accurate as of the date of this prospectus. However, this information may prove to be inaccurate because of the method by which we obtained some of the data for the estimates or because this information cannot always be verified with complete certainty due to the limits on the availability and reliability of raw data, the voluntary nature of the data gathering process and other limitations and uncertainties. As a result, you should be aware that market, ranking and other similar industry data included in this prospectus, and estimates and beliefs based on that data, may not be reliable and are subject to change based on various factors, including those discussed under “Risk Factors” and “Special Note Regarding Forward-Looking Statements.”

TRADEMARKS AND TRADE NAMES

“Biodesix,” the Biodesix logo and other trademarks or service marks of Biodesix appearing in this prospectus such as GeneStrat®, VeriStrat®, Nodify XL2™, Nodify CDT™, Diagnostic Cortex®, and DeepMALDI®, among others, are our property. We will assert, to the fullest extent under applicable law, our rights to these trademarks, service marks, trade names and copyrights. This prospectus contains additional trade names, trademarks, and service marks of other companies, which are the property of their respective owners. We do not intend our use or display of other companies’ trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies. Although trademark and registered mark symbols are not used throughout, this does not in any way indicate that we are disclaiming ownership of the words and images with which these trademarks and registered marks are associated.

PROSPECTUS SUMMARY

This summary highlights information contained in greater detail elsewhere in this prospectus. This summary is not complete and does not contain all of the information you should consider before investing in our common stock. You should read the entire prospectus carefully, especially the risks of investing in our common stock discussed under the heading "Risk Factors," and our financial statements and related notes included elsewhere in this prospectus. Unless the context otherwise requires, the terms "Biodesix," "company," "our," "us," and "we" in this prospectus refer to Biodesix, Inc.

BIODESIX, INC.

Business Overview

We are 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 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.

We have four diagnostic blood-based 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.

In response to the COVID-19 global pandemic, we have commercialized the Biodesix WorkSafe™ testing program. 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

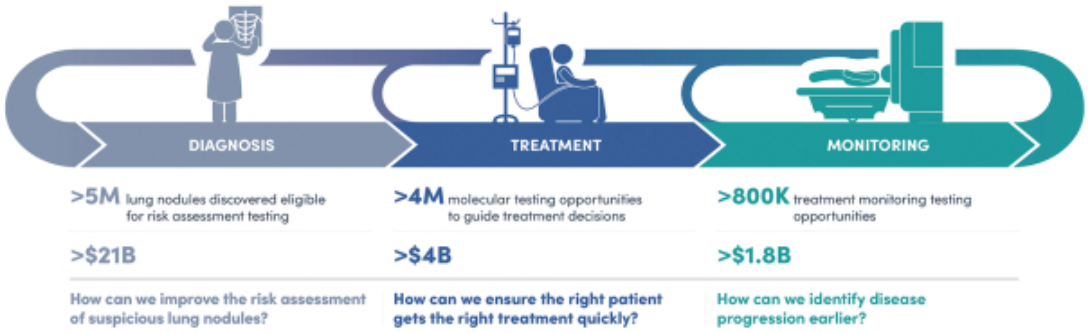
(EUA)-authorized tests, a part of our customizable program. These tests are utilized by healthcare providers, including hospitals and nursing homes, and are also offered to businesses and educational systems to assist in their back-to-work or back-to-school strategies. Recently we announced multiple partnerships for COVID-19 testing, and 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.

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 170,000 tests and continue to generate a large and growing body of clinical evidence. We have participated in 27 clinical studies, four 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.

Our Market Opportunity

Diagnostic Testing

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, 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.

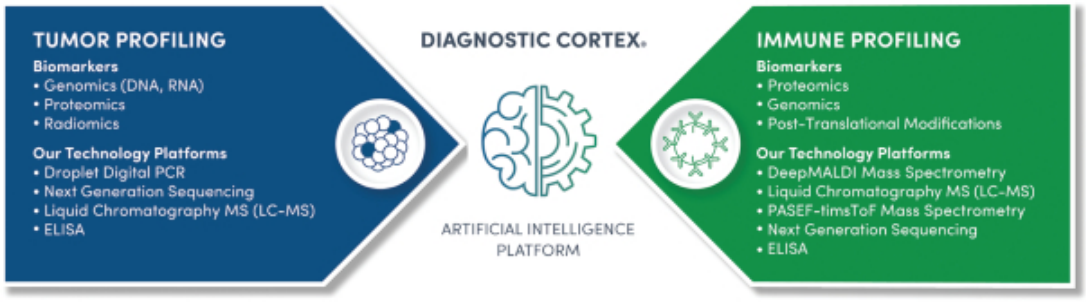


Biomarker Discovery & Companion Diagnostics

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 pipelines and increase chances of drug development success. We estimate that the biopharmaceutical partnering and research opportunities represent over a $2 billion market annually.

Our Platform and Technologies

We use combinations of tumor, immune and host profiling, radiological imaging, patient clinical profiling, and our proprietary AI platform, the Diagnostic Cortex, to provide a holistic view of each patient's dynamic disease state. 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. We employ multiple technologies, as illustrated below, including genomics, proteomics, transcriptomics, and radiomics, generated by different assay techniques, including Droplet Digital PCR™ (ddPCR), next generation sequencing (NGS), liquid chromatography mass spectrometry (LC-MS), enzyme-linked immunosorbent assay (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.



Our Competitive Advantages

We believe the following are our key competitive advantages:

- Our proprietary extensively validated deep learning platform, which is tailored to discover clinical diagnostics that address clinical unmet needs;
- Our data-driven approach to precision medicine combined with our data biobank, which enables us to accelerate development of new tests;
- Our leadership in clinical proteomics, demonstrated research, development, and scientific expertise, combined with our intellectual property portfolio;
- Our demonstrated success commercializing diagnostic tests across a broad continuum of care in lung disease;
- 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; and
- Our commercial infrastructure, which is built on extensive knowledge and experience in sales, marketing, reimbursement, and operations.

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;
- Deepen our relationships with current biopharmaceutical customers and establish new customer opportunities;

- Introduce new diagnostic tests in lung disease;
- Further demonstrate the clinical utility and economic benefits of our diagnostic tests;
- Enhance our proprietary AI platform and expand our technology portfolio; and
- Continue to leverage and expand our biobank.

Summary of Risk Factors

Our business is subject to numerous risks and uncertainties, including those highlighted in the section titled "Risk Factors" immediately following this prospectus summary. These risks include, without limitation, the following:

- 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 tests, 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.

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 Biodesix, Inc.

Our website address is www.biodesix.com. Information contained on, or accessible from, or hyperlinked to, our website is not incorporated by reference into this prospectus, and you should not consider information on our website to be part of this prospectus.

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 this prospectus and in our periodic reports and proxy statements, the requirement that we hold a nonbinding advisory vote on executive compensation and any golden parachute payments, and we have taken advantage of the ability to provide reduced disclosure of financial information in this prospectus, such as being permitted to include only two years of audited financial information and two years of selected financial information in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure. 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 and this Offering—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."

THE OFFERING

Common stock offered by us	shares
Over-allotment option	shares
Common stock to be outstanding after this offering	shares
Use of proceeds	We estimate that the net proceeds from the sale of shares of our common stock that we are selling in this offering will be approximately $ million (or approximately $ million if the underwriters' over-allotment option is exercised in full), based upon an assumed initial public offering price of $ per share, the midpoint of the estimated offering price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We currently expect to use the net proceeds from this offering: (1) to support our commercial expansion of sales, marketing, reimbursement, customer support and business development; (2) to support our product pipeline and research and development; (3) for our Integrated Diagnostics acquisition milestone payment; and (4) for working capital and general corporate purposes. See the section titled "Use of Proceeds" for additional information.
Risk factors	See "Risk Factors" and the other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in our common stock.
Nasdaq Global Market trading symbol	"BDSX"

The number of shares of common stock that will be outstanding after this offering is based on shares of our common stock (reflecting the conversion of all of our shares of preferred stock and convertible debt into shares of our common stock on an as-converted basis) outstanding as of , 2020, and excludes:

- shares of common stock issuable upon the exercise of outstanding stock options as of , 2020, with a weighted-average exercise price of $ per share, plus shares of common stock issuable upon the exercise of stock options granted subsequent to , 2020, with a weighted-average exercise price of $ per share;
- shares of common stock issuable upon the exercise of outstanding warrants to purchase shares of Series G Preferred Stock as of , 2020, with a weighted-average exercise price of $ per share; and

- additional shares of common stock reserved for future issuance under our 2016 Equity Incentive Plan (the 2016 Incentive Plan) as of , 2020, plus an additional shares of common stock reserved for future issuance under this plan subsequent to , 2020.

In addition, unless we specifically state otherwise, all information in this prospectus assumes:

- that our amended and restated certificate of incorporation, which we will file in connection with the closing of this offering, and our amended and restated bylaws adopted in connection with this offering, are effective;
- the conversion of all outstanding shares of our preferred stock and convertible debt into an aggregate of shares of common stock immediately upon the closing of this offering;
- no exercise of the outstanding options or warrants described above; and
- no exercise of the underwriters' over-allotment option.

SUMMARY HISTORICAL FINANCIAL AND OPERATING DATA

The following table sets forth Biodesix, Inc.'s summary historical financial and operating data as of the dates and for the periods indicated. The summary historical financial and operating data as of December 31, 2019 and 2018 and for the years ended December 31, 2019 and 2018 have been derived from our audited financial statements included elsewhere in this prospectus.

The summary historical financial information is not necessarily indicative of the results that may be expected in any future period, and our results of operations for any interim period are not necessarily indicative of the results to be expected for the full year. The following summary historical financial and operating data should be read in conjunction with "Capitalization," "Selected Historical Financial and Operating Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements and related notes appearing elsewhere in this prospectus.

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

	For the Years Ended December 31,	
	2019	2018
Revenues	$ 24,552	$ 20,432
Operating expenses		
Direct costs and expenses	6,074	4,406
Research and development	10,468	8,188
Sales, marketing, general and administrative	30,637	25,899
Accretion of contingent consideration	3,451	1,537
Change in fair value of contingent consideration	663	3,863
Total operating expenses	51,293	43,893
Loss from operations	(26,741)	(23,461)
Other income (expense)		
Interest income	55	24
Interest expense	(3,008)	(2,916)
Change in fair value of warrant liability	(104)	87
Loss on debt extinguishment	—	(202)
Change in fair value of put option liability	(2,000)	—
Other	1,072	302
Total other expense	(3,985)	(2,705)
Net loss	$ (30,726)	$ (26,166)
Net loss per share, basic and diluted	$ (21.31)	$ (22.07)
Weighted-average shares outstanding, basic and diluted	1,442	1,186
Pro forma net loss per share, basic and diluted (unaudited)	$ (0.20)	
Pro forma weighted-average shares outstanding, basic and diluted (unaudited)	155,126	

Balance Sheet Data:
(in thousands)

	December 31, 2019		
	Actual	Pro Forma(1)(3)	Pro Forma As Adjusted(2)
Cash and cash equivalents	$ 5,286	$	$
Total assets	41,633		
Long-term notes payable	23,812		
Convertible debt	12,159		
Contingent consideration	29,114		
Convertible preferred stock	193,959		
Accumulated deficit	(230,864)		
Total stockholders' deficit	(228,539)		

(1) The pro forma statement of operations and comprehensive loss data and pro forma balance sheet data give effect to the automatic conversion of all outstanding shares of our preferred stock and convertible debt into an aggregate of shares of common stock upon the completion of this offering.

(2) The pro forma as adjusted information discussed above gives effect to the adjustment described in footnote (1) and the receipt of $ million in net proceeds from our sale of common stock in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the estimated offering price range set forth on the cover of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

(3) The number of common shares that convertible debt was assumed to convert to was based on our estimated common stock price as of December 31, 2019, as determined by our board of directors with assistance from a valuation firm. The ultimate conversion price will be based on the fair value of our common stock at the completion of this public offering.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should consider and read carefully all of the risks and uncertainties described below, as well as other information included in this prospectus, including our financial statements and related notes appearing at the end of this prospectus, before making an investment decision. The risks described below are not the only ones facing us. The occurrence of any of the following risks or additional risks and uncertainties not presently known to us or that we currently believe to be immaterial could materially and adversely affect our business, financial condition and results of operations. In such case, the trading price of our common stock could decline, and you may lose all or part of your investment. This prospectus also contains forward-looking statements and estimates that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of specific factors, including the risks and uncertainties described below.

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 $30.7 million and $26.2 million for the years ended December 31, 2019 and 2018, respectively. As a result of these losses, as of December 31, 2019, we had $5.3 million in cash and cash equivalents, and an accumulated deficit of approximately $230.8 million. Based on our current planned operations, we expect our cash and cash equivalents, together with amounts raised in 2020, including the proceeds from this offering, 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 to continue to incur significant net losses for the foreseeable future.

Following this offering, 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 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 following this offering due to the additional costs associated with scaling our business operations and testing capacity, particularly with respect to our COVID-19 diagnostic 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; and
- limitations or warnings contained in the labeling cleared or approved by the FDA or other authorities.

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.

We expect increased revenues from our COVID-19 diagnostic and antibody tests over the course of 2020 and the first quarter of 2021, and we expect that such revenue will comprise a significant portion of our revenue over the same period. However, there is no assurance that our COVID-19 diagnostic and antibody tests will continue to be accepted by the market or that other diagnostic tests, such as non-blood based 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 diagnostic 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 June 30, 2020, we had 154 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, 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. In the years ended December 31, 2019 and 2018, revenue from our top biopharmaceutical customer accounted for 20.9% and 6.8% 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 the resulting effects on the number of patients treated or the demand for our non-COVID-19 diagnostic tests;
- the timing and cost of, and level of investment in, research, development, licenses, regulatory approval, 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 or clearances for planned or future improvements or enhancements to our diagnostic tests;
- changes in governmental regulations or in the status of regulatory approvals or applications;
- pricing, discounts and incentives for our diagnostic tests;
- future accounting pronouncements or changes in our accounting policies; and
- general market conditions.

In addition, we expect increased revenue from our COVID-19 diagnostic and antibody tests over the course of 2020 and the first quarter of 2021, and we expect that such revenue will comprise a significant portion of our revenue over the same period. We can provide no assurances that the demand for our COVID-19 diagnostic and antibody tests will be sustained, and even if it is, the period of time for which it would be sustained. As a result, the increase in revenue due to any increase in demand for our COVID-19 diagnostic and antibody tests 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 COVID-19 diagnostic and antibody tests, 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 and COVID-19 diagnostic and antibody tests. 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 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. For more information regarding this license and supply agreement, please see “Business—Non-Exclusive License Agreement.”

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, 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 to most countries and throughout the United States. Numerous 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 global 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 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 developed 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 tests 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 remainder of 2020 and the first quarter of 2021. However, there is no assurance that our COVID-19 diagnostic and antibody tests will continue to be accepted by the market or that other diagnostic tests, such as non-blood based 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 diagnostic 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 international laws (e.g., the 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 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 diagnostic and antibody tests, 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 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 and then offer these negotiated prices to affiliated hospitals and other members. 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.

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).

As part of the Collaboration Agreement, unless we or AVEO exercises our right to opt-out of co-development, we equally share in any income received from licensing rights to ficlatuzumab to any third parties. 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. 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, 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 over a seven-year period. The amount can be payable in stock or cash at our or the Seller's option. The total amount of undiscounted contingent consideration which we may be required to pay under the arrangement is $37.0 million. For the 6 months following the achievement of the milestone, the Seller has the option to require us to pay the contingent consideration in cash over 8 equal installments due each calendar quarter. If the Seller elects not to exercise this option, we have 12 months to either settle the contingent consideration in two equal quarterly cash installments or in 14,959,114 of Series G Preferred Stock.

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.

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. 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. The minimum sales volumes will be adjusted upwards in the event we exercise the screening option.

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 sales people. 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 following this offering 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 (including in connection with this offering), 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 agencies 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. Certain countries, including a number of member states of the EU, set prices and make reimbursement decisions for diagnostics and pharmaceutical products, or medicinal products, as they are commonly referred to in the EU, with limited participation from the marketing authorization or Conformité Européenne (CE) mark holders, or may take decisions that are unfavorable to the authorization or CE mark holder where they have participated in the process. 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 attempt 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 international 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 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. 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 and 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 vast 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, 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 part of the Tax Cuts and Jobs Act of 2017 (TCJA), 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 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 December 31, 2020. 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 Trump administration and Congress may continue to pursue significant changes to the current healthcare laws. 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.

We can provide no assurances that the FDA will not focus 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 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 our COVID-19 tests 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.

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 (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 there is no guarantee that LDTs will continue to be able to operate without broad, sweeping guidance from the FDA. 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. Notwithstanding the discussion paper, the FDA continues to exercise enforcement discretion and may decide to regulate certain LDTs on a case-by-case basis at any time, 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 are covered under CLIA and CMS, although our COVID tests 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. The FDA could, at any time, change its policy with regard to this matter or Congress could take action to amend the law to change the current regulatory framework for in vitro diagnostics and LDTs.

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 notified 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 tests 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 become 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 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 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 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 will 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 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, 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. 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, enforce the QSR and other regulations through periodic inspections. 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 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;
- 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.

Legislative or regulatory reforms may make it more difficult and costly for us to obtain regulatory clearance or approval 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 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. Additionally, a new California ballot initiative, the California Privacy Rights Act, has qualified to be included on the November 2020 ballot, and if voted into law by California voters, would impose additional data protection obligations on companies doing business in California, including additional consumer rights, including regarding 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. 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 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. 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 may in some cases be more stringent than the requirements in the United States. For example, the EU has specific requirements relating to cross-border transfers of personal data to certain jurisdictions, including to the United States. In addition, some countries have stricter consumer notice or consent requirements relating to personal data collection, use or sharing, have more stringent requirements relating to organizations' privacy programs and provide stronger individual rights. Moreover, international privacy and data security regulations may become more complex and result in greater penalties. For instance, since May 25, 2018, the GDPR regulates the

collection and use of personal data of data subjects in the EU and the European Economic Area (EEA). The GDPR applies extra-territorially under certain circumstances and imposes stringent requirements on controllers and processors of personal data, including, for example, requirements to obtain consent or other legal bases from individuals to process their personal data, provide robust disclosures to individuals, accommodate a set of individual data rights, provide data security breach notifications within 72 hours after discovering the breach, limit retention of personal information and apply enhanced protections to health data and other special categories of personal data. The GDPR also applies to pseudonymized data, which is defined as "the processing of personal data in such a way that the data can no longer be attributed to a specific data subject without the use of additional information," and imposes additional obligations when we contract with third-party processors in connection with the processing of any personal data. The GDPR 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 personal data, could cause our costs to increase and could harm our financial condition. Failure to comply with the requirements of the GDPR and the applicable national data protection laws of the EU member states 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. Further, as the GDPR has only recently become enforceable, enforcement priorities and official interpretations of certain provisions are still unclear. To comply with the new data protection rules imposed by the GDPR, we may be required to put in place additional mechanisms ensuring compliance, which may result in 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 imposes strict rules on the transfer of personal data out of the EU to the United States. These obligations may be interpreted and applied in a manner that is inconsistent from one jurisdiction to another and may conflict with other requirements or our practices. In addition, these rules are consistently under scrutiny. For example, following a decision of the Court of Justice of the EU (the ECJ) in October 2015, the transfer of personal data to United States companies that had certified as members of the United States Safe Harbor Scheme (Safe Harbor Scheme) was declared invalid. In July 2016, the European Commission adopted the EU-United States Privacy Shield Framework (Privacy Shield Framework) which replaced the Safe Harbor Scheme. The Privacy Shield Framework is reviewed by European authorities annually, and the ECJ recently ruled that the Privacy Shield Framework is no longer a lawful mechanism for EU-United States data transfers under the GDPR. There is currently litigation challenging other EU mechanisms for adequate data transfers. It is uncertain whether and for how long national regulators will permit companies that have relied on the Privacy Shield Framework to come into compliance with the recent ruling and whether alternative methods for EU-United States data transfers or the standard contractual clauses might similarly be invalidated by European courts. The ECJ's ruling 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.

In connection with this offering, we will adopt 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. 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 Notified 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. 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 may require us to perform additional clinical trials before clearing or approving our marketing applications. A failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory clearance or approval process. In addition, if these parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality, completeness or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or for other reasons, our clinical trials may have to be extended, delayed or terminated.

Many of these factors 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 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 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 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, 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 conditions, 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 COVID-19 test, 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 was developed through the use of United States government funding and is therefore 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; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). The 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 COVID-19, Nodify XL2, Nodify CDT, GeneStrat or VeriStrat tests or utilize similar technology that is not covered by the claims of our patents or that incorporates certain technology in our COVID-19, Nodify XL2, Nodify CDT, GeneStrat or VeriStrat 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.

Risks Related to our Common Stock and this Offering

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

Prior to this offering, there has been no public market for our common stock. An active trading market may not develop following completion of this offering or, if developed, 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.

Upon closing of this offering, we expect that our common stock will be listed on the Nasdaq Global Market. If we fail to satisfy the continued listing standards of the Nasdaq Global Market, however, 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 the shares you purchase in this offering at or above the offering price.

The initial public offering price for the shares of our common stock sold in this offering is determined by negotiation between the representatives of the underwriters and us. This price may not reflect the market price of our common stock following this offering. In addition, 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 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. These fluctuations may be even more pronounced in the trading market for our common stock shortly following this offering. If the market price of shares of our common stock after this offering does not ever exceed the initial public offering price, 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 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. 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.

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.

If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.

Investors purchasing common stock in this offering will pay a price per share that substantially exceeds the pro forma as adjusted net tangible book value per share. As a result, investors purchasing common stock in this offering will incur immediate dilution of $ per share, based on an assumed initial public offering price of $ per share, the midpoint of the estimated offering price range set forth on the cover page of this prospectus, and our pro forma as adjusted net tangible book value per share as of . For more information on the dilution you may suffer as a result of investing in this offering, see the section of this prospectus entitled "Dilution."

This dilution is due to the substantially lower price paid by our investors who purchased shares prior to this offering as compared to the price offered to the public in this offering. It is also due to the conversion of our preferred stock and convertible debt into shares of our common stock upon the completion of this offering and the exercise of stock options granted to our employees as the conversion and exercise prices of such securities and options are substantially below the price offered to the public in this offering.

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. Immediately after this offering, we will have

outstanding shares of common stock based on the number of shares outstanding as of December 31, 2019. This includes the shares that we are selling in this offering, which may be resold in the public market immediately without restriction, unless purchased by our affiliates. Of the remaining shares, shares are currently restricted as a result of securities laws or 180-day lock-up agreements but will be able to be sold after the offering as described in the section of this prospectus entitled "Shares Eligible For Future Sale." Moreover, after this offering, holders of an aggregate of up to shares of our common stock, including shares of our common stock issuable upon the conversion of the shares of our convertible preferred stock that will be outstanding immediately prior to the consummation of this offering, will 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 as described in the section of this prospectus entitled "Shares Eligible For Future Sale—Registration Rights." 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 and the lock-up agreements described in the section of this prospectus entitled "Underwriters."

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.

After this offering, our officers, directors and principal stockholders each holding more than 5% of our common stock will collectively control approximately % 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 may allocate the net proceeds from this offering in ways that you and other stockholders may not approve.

Our management will have broad discretion in the application of the net proceeds from this offering, including for any of the purposes described in the section titled "Use of Proceeds." Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. Our management might not apply our net proceeds in ways that ultimately increase the value of your investment, and the failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from this offering in short- and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the United States government. These investments may not yield a favorable return to our stockholders. If we do not invest or apply the net proceeds from this offering in ways that enhance stockholder value, we may fail to achieve expected results, which could cause our stock price to decline.

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.

Upon completion of this offering, we expect to incur costs associated with corporate governance requirements that will become 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.

Upon the closing of this offering, we will become subject to the periodic reporting requirements of the Exchange Act. We 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 that will become effective upon the closing of this offering 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 that will become effective upon the closing of this offering 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. We believe this 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 that will be in effect at the closing of this offering 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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus 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 prospectus, 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 prospectus, 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 diagnostic and antibody tests and our ability to meet such demand;
- product performance and reliability to maintain and grow our business;
- third party suppliers, including 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 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 set forth in this prospectus, including those set forth under “Risk Factors.”

These risks are not exhaustive. Other sections of this prospectus 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 prospectus 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 prospectus, 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 prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement of which this prospectus is a part 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.

USE OF PROCEEDS

We estimate that the net proceeds to us from the sale of shares of common stock in this offering will be approximately $ million at an assumed initial public offering price of $ per share, the midpoint of the estimated offering price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise their over-allotment option in full, we estimate that the net proceeds to us will be approximately $ million, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

Each $1.00 increase or decrease in the assumed initial public offering price of $ per share would increase or decrease, respectively, our net proceeds by $ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. An increase or decrease of 1,000,000 in the number of shares we are offering would increase or decrease, respectively, the net proceeds from this offering, after deducting underwriting discounts and commissions by $ million, assuming the assumed initial public offering price stays the same.

We currently expect to use the net proceeds from this offering: (1) to support our commercial expansion of sales, marketing, reimbursement, customer support and business development; (2) to support our product pipeline and research and development; (3) for our Integrated Diagnostics acquisition milestone payment; and (4) for working capital and general corporate purposes.

We may also use a portion of our net proceeds to co-develop, acquire or invest in products, technologies or businesses that are complementary to our business. However, we currently have no agreements or commitments to complete any such transaction.

Although we currently anticipate that we will use the net proceeds from this offering as described above, there may be circumstances where a reallocation of funds is necessary. Due to the uncertainties inherent in the product development process, it is difficult to estimate with certainty the exact amounts of the net proceeds from this offering that may be used for the above purposes. The amounts and timing of our actual expenditures will depend upon numerous factors, including our sales and marketing and commercialization efforts, demand for our technology, our operating costs and the other factors described under “Risk Factors” in this prospectus. Accordingly, we will have broad discretion over the uses of the net proceeds from this offering. Pending the use of the proceeds from this offering, we may invest the proceeds in from this offering in short- and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the United States government.

DIVIDEND POLICY

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings, if any, to support operations and to finance the growth and development of our business. We do not intend to declare or pay cash dividends on common stock in the foreseeable future following the consummation of this offering. Any determination to declare dividends will be made at the discretion of our Board of Directors and will depend on, among other factors, our business, financial condition, results of operations and prospects that our Board of Directors may deem relevant. The terms of our outstanding credit facility also restrict our ability to pay dividends, and we may also enter into credit agreements or other borrowing arrangements in the future that will restrict our ability to declare or pay cash dividends on our capital stock. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Contractual Obligations and Commitments.”

CAPITALIZATION

The following table sets forth our cash and cash equivalents and our capitalization as of December 31, 2019, on:

- an actual basis;
- a pro forma basis to reflect (i) the conversion of all the outstanding shares of preferred stock and convertible debt into an aggregate of shares of common stock immediately upon the closing of this offering and (ii) the filing and effectiveness of our amended and restated certificate of incorporation that will be in effect upon the closing of this offering; and
- a pro forma as adjusted basis to further reflect the sale of shares of common stock in this offering at an assumed initial public offering price of $ per share, the midpoint of the estimated offering price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this information together with the sections of this prospectus titled “Prospectus Summary—Summary Historical Financial and Operating Data,” “Selected Historical Financial and Operating Data,” “Description of Capital Stock” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our financial statements and related notes included elsewhere in this prospectus.

	As of December 31, 2019		
	Actual	Pro Forma	Pro Forma As Adjusted(1)
	(in thousands, except share and per share data)		
Cash and cash equivalents	$	$	$
Debt:			
Convertible debt payable	$	$	$
2018 Notes			
Total debt			
Convertible preferred stock; $0.001 par value; 174,237,067 shares authorized, 118,766,273 issued and outstanding, actual; shares authorized and shares issued and outstanding, as adjusted			
Stockholders’ deficit			
Common stock, $0.001 par value; 190,000,000 shares authorized, 1,513,498 issued and outstanding, actual; shares authorized and shares issued and outstanding, as adjusted			
Additional paid-in capital			
Accumulated deficit			
Total stockholders’ deficit			
Total capitalization	$	$	$

(1) Each $1.00 increase or decrease in the assumed initial public offering price of $ per share, the midpoint of the estimated offering price range set forth on the cover page of this prospectus, would increase or decrease, respectively, the amount of cash and cash equivalents, additional paid-in-capital, total stockholders’ equity and total capitalization by approximately $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. An increase or decrease of 1,000,000

in the number of shares we are offering would increase or decrease, respectively, the amount of cash and cash equivalents, additional paid-in-capital, total stockholders' equity and total capitalization by approximately $ million, assuming the assumed initial public offering price per share, as set forth above, remains the same and after deducting underwriting discounts and commissions. The pro forma as adjusted information is illustrative only, and will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing.

The outstanding share information in the table above excludes, as of , 2020, the following shares:

- shares of common stock issuable upon the exercise of stock options outstanding as of , 2020, with a weighted-average exercise price of $ per share, plus shares of common stock issuable upon the exercise of stock options granted subsequent to , 2020, with a weighted-average exercise price of $ per share;
- shares of common stock issuable upon the exercise of outstanding warrants to purchase shares of Series G Preferred Stock as of , 2020, with a weighted-average exercise price of $ per share; and
- additional shares of common stock reserved for future issuance under our 2016 Incentive Plan as of , 2020, plus an additional shares of common stock reserved for future issuance under this plan subsequent to , 2020.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted immediately to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after the closing of this offering.

Our pro forma net tangible book value of our common stock as of June 30, 2020 was $ million, or $ per share, based on the total number of shares of our common stock outstanding as of June 30, 2020. Pro forma net tangible book value per share represents our total tangible assets less our total liabilities, divided by the number of outstanding shares of common stock, after giving effect to the conversion of all outstanding shares of preferred stock and convertible debt into shares of common stock immediately upon the closing of this offering.

After giving effect to the conversion of our outstanding preferred stock into shares of common stock immediately upon the closing of this offering and the receipt of the net proceeds from our sale of shares of common stock in this offering at an assumed initial public offering price of $ per share, the midpoint of the estimated offering price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of June 30, 2020, would have been $ million, or $ per share. This represents an immediate increase in pro forma as adjusted net tangible book value of $ per share to our existing stockholders and immediate dilution of $ per share to investors purchasing common stock in this offering.

The following table illustrates this dilution on a per share basis to new investors:

Assumed initial public offering price per share of our common stock	$
Pro forma net tangible book value per share as of June 30, 2020	$
Increase in pro forma net tangible book value per share attributable to new investors in this offering	$
Pro forma as adjusted net tangible book value per share after this offering	$
Dilution of net tangible book value per share to new investors	$

Each $1.00 increase or decrease in the assumed initial public offering price of $ per share would increase or decrease, respectively, our pro forma as adjusted net tangible book value per share after this offering by $ per share and the dilution to new investors by $ per share, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Each increase of 1,000,000 shares in the number of shares of common stock offered by us would increase the pro forma as adjusted net tangible book value by $ per share and the dilution to new investors would decrease by $ per share, assuming the assumed initial public offering price remains the same and after deducting underwriting discounts and commissions. Each decrease of 1,000,000 shares in the number of shares of common stock offered by us would decrease the pro forma as adjusted net tangible book value by $ per share and the dilution to new investors would increase by $ per share, assuming the assumed initial public offering price remains the same and after deducting underwriting discounts and commissions.

If the underwriters exercise their over-allotment option in full, the pro forma as adjusted net tangible book value per share after giving effect to this offering would be $ per share, and the dilution in pro forma as adjusted net tangible book value per share to new investors in this offering would be $ per share.

The following table summarizes, as of June 30, 2020:

- the total number of shares of common stock purchased from us by our existing stockholders and by new investors purchasing shares in this offering;

- the total consideration paid to us by our existing stockholders and by new investors purchasing shares in this offering, assuming an initial public offering price of $ per share, the midpoint of the estimated offering price range set forth on the cover page of this prospectus, before deducting the underwriting discounts and commissions and estimated offering expenses payable by us in connection with this offering; and
- the average price per share paid by existing stockholders and by new investors purchasing shares in this offering.

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders		%	$	%	$
New investors					
Total		%	$	%	$

Except as otherwise indicated, the above discussion and tables assume no exercise of the underwriters' over-allotment option. If the underwriters exercise their over-allotment option in full, our existing stockholders would own % and our new investors would own % of the total number of shares of common stock outstanding upon the closing of this offering.

The number of shares of our common stock that will be outstanding after this offering is based on shares of common stock outstanding as of June 30, 2020, and excludes:

- shares of common stock issuable upon the exercise of stock options outstanding as of June 30, 2020, with a weighted-average exercise price of $ per share, plus shares of common stock issuable upon the exercise of stock options granted subsequent to , 2020, with a weighted-average exercise price of $ per share;
- shares of common stock issuable upon the exercise of outstanding warrants to purchase shares of Series G Preferred Stock as of , 2020, with a weighted-average exercise price of $ per share; and
- additional shares of common stock reserved for future issuance under our 2016 Incentive Plan as of , 2020, plus an additional shares of common stock reserved for future issuance under this plan subsequent to , 2020.

Each $1.00 increase or decrease in the assumed initial public offering price of $ per share, the midpoint of the estimated offering price range set forth on the cover page of this prospectus, would increase or decrease, respectively, the total consideration paid by new investors by $ million and increase or decrease, respectively, the total consideration paid by new investors by %, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and before deducting underwriting discounts and commissions.

In addition, to the extent any outstanding options are exercised, new investors would experience further dilution.

SELECTED HISTORICAL FINANCIAL AND OPERATING DATA

The following table sets forth Biodesix, Inc.'s selected historical financial and operating data as of the dates and for the financial reporting periods indicated. The selected historical financial and operating data as of December 31, 2019 and 2018 and for the years ended December 31, 2019 and 2018 have been derived from our audited financial statements included elsewhere in this prospectus.

The selected historical financial information is not necessarily indicative of the results that may be expected in any future financial reporting period, and our results of operations for any interim financial reporting period are not necessarily indicative of the results to be expected for the full year. The following selected historical financial and operating data should be read in conjunction with "Capitalization," "Prospectus Summary—Summary Historical Financial and Operating Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements and related notes appearing elsewhere in this prospectus.

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

	For the Years Ended December 31,	
	2019	2018
Revenues	$ 24,552	$ 20,432
Operating expenses		
Direct costs and expenses	6,074	4,406
Research and development	10,468	8,188
Sales, marketing, general and administrative	30,637	25,899
Accretion of contingent consideration	3,451	1,537
Change in fair value of contingent consideration	663	3,863
Total operating expenses	51,293	43,893
Loss from operations	(26,741)	(23,461)
Other income (expense)		
Interest income	55	24
Interest expense	(3,008)	(2,916)
Change in fair value of warrant liability	(104)	87
Loss on debt extinguishment	—	(202)
Change in fair value of put option liability	(2,000)	—
Other	1,072	302
Total other expense	(3,985)	(2,705)
Net loss	$ (30,726)	$ (26,166)
Net loss per share, basic and diluted	$ (21.31)	$ (22.07)
Weighted-average shares outstanding, basic and diluted	1,442	1,186
Pro forma net loss per share, basic and diluted (unaudited)	$ (0.20)	
Pro forma weighted-average shares outstanding, basic and diluted (unaudited)	155,126	

Balance Sheet Data:
(in thousands)

	December 31, 2019		
	Actual	Pro Forma(1)(3)	Pro Forma As Adjusted(2)
Cash and cash equivalents	$ 5,286	$	$
Total assets	41,633		
Long-term notes payable	23,812		
Convertible debt	12,159		
Contingent consideration	29,114		
Convertible preferred stock	193,959		
Accumulated deficit	(230,864)		
Total stockholders' deficit	(228,539)		

(1) The pro forma statement of operations and comprehensive loss data and pro forma balance sheet data give effect to the automatic conversion of all outstanding shares of our preferred stock and convertible debt into an aggregate of shares of common stock upon the completion of this offering.

(2) The pro forma as adjusted information discussed above gives effect to the adjustment described in footnote (1) and the receipt of $ million in net proceeds from our sale of common stock in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the estimated offering price range set forth on the cover of this prospectus.

(3) The number of common shares that convertible debt was assumed to convert to was based on our estimated common stock price as of December 31, 2019, as determined by our board of directors with assistance from a valuation firm. The ultimate conversion price will be based on the fair value of our common stock at the completion of this offering.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with the sections of this prospectus titled "Prospectus Summary—Summary Historical Financial and Operating Data," "Selected Historical Financial and Operating Data" and our financial statements and the related notes to those statements included elsewhere in this prospectus. This discussion and analysis and other parts of this prospectus contain forward-looking statements based upon current beliefs, plans and expectations related to future events and our future financial performance that involve risks, uncertainties and assumptions, such as statements regarding our intentions, plans, objectives, expectations, forecasts and projections. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under the section titled "Risk Factors" and elsewhere in this prospectus. You should carefully read the "Risk Factors" to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking 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 included elsewhere in this prospectus. 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. The MD&A is organized as follows:

- ***Overview***. This section provides a general description of our business as well as trends and other factors affecting our business that we believe are necessary to understand our financial condition and results of operations.
- ***Factors Affecting Our Performance***. This section provides a description of the key factors that have historically, and that we expect to continue to, affect our business.
- ***Components of Operating Results***. This section provides a description of our revenues and operating expenses for the years ended December 31, 2019 and 2018.
- ***Results of Operations***. This section provides a discussion of the results of operations on a historical basis for the years ended December 31, 2019 and 2018.
- ***Liquidity and Capital Resources***. This section provides an analysis of our ability to generate cash and to meet existing known or reasonably likely future cash requirements.
- ***Critical Accounting Policies and Significant Judgments and Estimates***. This section discusses the accounting policies and estimates that we consider important to our financial condition and results of operations and that require significant judgment and estimates on the part of management in their application.
- ***Quantitative and Qualitative Disclosures about Market Risk***. This section discusses our exposure to interest rate risk.

Data for the years ended December 31, 2019 and 2018 has been derived from our audited financial statements.

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 R&D 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 global pandemic, we have 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. These tests are utilized by healthcare providers, including hospitals and nursing homes, and also are 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.

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 170,000 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 generated total revenue of $24.6 million and $20.4 million for the years ended December 31, 2019 and 2018, respectively. We also incurred net losses of $30.7 million and $26.2 million for the years ended December 31, 2019 and 2018, respectively. We have funded our operations to date principally from net proceeds from the sale of convertible preferred stock, revenue from diagnostic testing and services, and the incurrence of indebtedness. Most recently in March 2020, we raised $10 million through the sale of convertible debt. We had cash and cash equivalents of $5.3 million as of December 31, 2019.

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. We expect our costs to significantly increase in 2020 and the beginning of 2021 due to a significant increase in demand for COVID-19 diagnostic testing and we expect our related revenues from such tests to also increase.
- **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 goal. 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. 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 diagnostic tests, we plan to hire additional project support members to assist us in expanding testing capacity.

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

COVID-19 Pandemic

The COVID-19 pandemic has disrupted, and we expect will continue to disrupt, our 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 global 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 expected before the outbreak of the COVID-19 pandemic.

We are also experiencing an increase in revenues related to an increase in the demand for our COVID-19 diagnostic testing products. We expect that our costs to expand capacity for COVID-19 testing will increase for the remainder of 2020 and 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 diagnostic and antibody tests will continue to be accepted by the market or that other diagnostic tests, such as non-blood based 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 diagnostic testing 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.

Recent Developments

As of the quarter ended March 31, 2020, we failed to meet the revenue requirements specified in the terms of our 2018 Notes. In accordance with the terms of the 2018 Notes, we cured this failure by receiving $10 million from the sale of additional debt securities by June 30, 2020.

In April 2020, we received loan proceeds in the amount of approximately $3.1 million under the Paycheck Protection Program (PPP). The PPP, established as part of the Coronavirus Aid, Relief and Economic Security Act (CARES Act), provides for loans to qualifying businesses for amounts up to 2.5 times of the average monthly payroll expenses of the qualifying business. The loans and accrued interest are forgivable after 24 weeks as long as the borrower uses the loan proceeds for eligible purposes, including payroll, benefits, rent and utilities, and maintains its payroll levels. The amount of loan forgiveness will be reduced if the borrower terminates employees or reduces salaries during the 24 week period.

In August 2020, we extended the maturity date of all our convertible debt from August 8, 2020 to June 30, 2021.

Components of Operating Results

Revenues

We derive our revenue from two sources: (i) providing diagnostic testing in the clinical setting (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).

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 consider diagnostic testing to be completed upon the delivery of test results to the prescribing physician, 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. Often 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.

Diagnostic test revenue comprised 71% and 93% of our total revenues and services revenue comprised 29% and 7% of total revenues in 2019 and 2018, respectively.

Operating Expenses

Direct costs and expenses

Cost of diagnostic testing generally consists of cost of materials, direct labor, including bonus, benefit and stock-based compensation, 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. For a description of our material license agreements, please see “Business—Intellectual Property” and “—Material 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. Cost 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 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 in absolute dollars 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 absolute 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, travel and stock-based compensation, as well as marketing and educational activities and allocated overhead expenses. We expect our sales and marketing expenses to increase in absolute 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 absolute 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, 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. We expect that our general and administrative expenses will continue to increase in absolute dollars after this offering, 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 absolute 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.

Accretion and Change in Fair Value of Contingent Consideration

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 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 that related milestone event (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.

Other income (expense)

Interest expense (net of interest income)

Interest expense, net of income consists primarily of interest from our term loan, convertible debt and interest earned on our cash and cash equivalents. For 2020, we expect our interest expense to increase as compared to 2019, as our term loan does not begin principal payments until March 2021. Our interest income has not been significant to date but we expect our interest income to increase primarily as we invest the net proceeds from this offering.

Change in fair value of put option liability

During 2019, we issued $13.0 million in convertible debt that is now scheduled to mature on June 30, 2021. The terms of the convertible debt provided discounts upon conversion to the note holders in certain situations, including upon the completion of this offering. The discounts included in the convertible debt created a put option liability that was separated from the convertible debt and reflected as a liability in our balance sheet. Subsequent to the creation of the put options, changes in the fair value of the put options 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 options 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. We will estimate the fair value of the put options until they are exercised or expire.

Results of Operations

The following table sets forth the significant components of our results of operations for the periods presented.

	For the Years Ended December 31,		Change	
	2019	2018	$	%
Revenues	$ 24,552	$ 20,432	$ 4,120	20%
Operating expenses				
Direct costs and expenses	6,074	4,406	1,668	38%
Research and development	10,468	8,188	2,280	28%
Sales, marketing, general and administrative	30,637	25,899	4,738	18%
Accretion of contingent consideration	3,451	1,537	1,914	125%
Change in fair value of contingent consideration	663	3,863	(3,200)	(83)%
Total operating expenses	51,293	43,893	7,400	17%
Loss from operations	(26,741)	(23,461)	(3,280)	14%
Other income (expense)				
Interest income	55	24	31	129%
Interest expense	(3,008)	(2,916)	(92)	3.2%
Change in fair value of warrant liability	(104)	87	(191)	(219)%
Loss on debt extinguishment	—	(202)	202	(100)%
Change in fair value of put option liability	(2,000)	—	(2,000)	—
Other	1,072	302	770	254%
Total other expense	(3,985)	(2,705)	(1,280)	47%
Net loss	$(30,726)	$(26,166)	(4,560)	17%

Revenue

We generate revenue from our diagnostic tests and services that we provide.

	Year Ended December 31,		Change	
	2019	2018	$	%
(in thousands)				
Diagnostic revenue	$17,315	$18,965	($1,650)	(9)%
Services revenue	7,237	1,467	$ 5,770	393%
Total revenue	$24,552	$20,432	$ 4,120	20%

Total revenue was $24.6 million for the year ended December 31, 2019 compared to $20.4 million for the year ended December 31, 2018, an increase of 20%.

Diagnostic test revenue decreased to $17.3 million for the year ended December 31, 2019 compared to $19.0 million for the year ended December 31, 2018, a decrease of $1.7 million or 9%. This decrease was the result of a decrease in tests delivered which was a result of significant restructuring of our field sales force to increase the emphasis on tests in nodule management that came on market following the completion of our recent acquisitions in that space. We recognized $1.0 million in additional diagnostic test revenue in 2019 for claims from a prior period due to a change in coverage for GeneStrat which captured previously unreimbursed revenue.

Services revenue increased to $7.2 million for the year ended December 31, 2019 compared to $1.5 million for the year ended December 31, 2018. The increase in services revenue was due to generally higher demand for biomarker development services and the acceleration of pharmaceutical partners' development efforts at the end of 2019, which resulted in a significant services revenue in December 2019 and is not expected to be recurring.

Costs and Operating Expenses

Direct Cost and Expenses

Cost of revenue was $6.1 million for the year ended December 31, 2019 compared to $4.4 million for the year ended December 31, 2018, an increase of $1.7 million, or 38%. This increase in cost of revenue was primarily due to the introduction of the Nodify XL2 test in November 2018, and which contributed $1.4 million in additional costs without material revenue during the 2019 period.

Research and Development

Research and development expenses were $10.5 million for the year ended December 31, 2019 compared to $8.2 million for the year ended December 31, 2018, an increase of $2.3 million, or 28%. This increase in research and development expense was primarily due to an increase of $1.5 million in costs related to our clinical trials and related costs as we continue to create robust data to support our tests in the clinical setting.

Sales, Marketing, General and Administrative

Sales, Marketing, General and Administrative expenses were $30.6 million for the year ended December 31, 2019 compared to $25.9 million for the year ended December 31, 2018, an increase of $4.7 million, or 18%. This increase was primarily due to an increase of $2.7 million in personnel-related costs for expansion of our sales organization and $1.0 million for increased marketing activity to support sales.

Accretion of and Change in Fair Value of Contingent Consideration

Accretion of and change in fair value of contingent consideration were $4.1 million for the year ended December 31, 2019 compared to $5.4 million for the year ended December 31, 2018, a decrease of $1.3 million, or 24%. The amounts recorded for accretion and change in fair value reflect the passage of time as well as estimates in when the milestones that trigger the payment of contingent consideration will be achieved.

Change in Fair Value of Put Option Liability

During 2019, we recorded a charge of $2.0 million related to the increase in our put option liability related to our convertible debt. This increase was primarily due to the amendment to the conversion discounts included in our convertible debt that were issued in August and September 2019.

Interest Expense, Net

Interest expense, net was $3.0 million for the year ended December 31, 2019 compared to $2.9 million for the year ended December 31, 2018, an increase of $0.1 million, or 2%. This increase was primarily due to payment in kind interest accruing to principal on our existing term loan.

Other Income and Expense

Other income and expense was $1.0 million for the year ended December 31, 2019 compared to $0.1 million for the year ended December 31, 2018, an increase of $1.0 million, which was primarily proceeds related to a one-time legal settlement in our favor.

Liquidity and Capital Resources

We have funded our activities primarily through private equity placement offerings, convertible debt and long-term debt. Based on cash and cash equivalents on hand as of December 31, 2019 and amounts raised subsequent to December 31, 2019, including the proceeds from this offering, we believe that our existing cash, cash equivalents, and cash generated from sales of our products, will be sufficient to meet our anticipated needs for at least the next 12 months from the date of our most recent unaudited interim condensed financial statements.

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 is a summary of our cash flows for the year ended December 31, 2019 and 2018:

(Amounts in thousands)	Year ended December 31, 2019	2018
Net cash flows (used in) provided by:		
Operating activities	$ (21,726)	$ (17,677)
Investing activities	(1,872)	(617)
Financing activities	22,972	19,032
Net (decrease) increase in cash and cash equivalents and restricted cash	$ (626)	$ 738

Our cash flows resulted in a net decrease in cash of $0.6 million during the year ended December 31, 2019 and a net increase in cash of $0.7 million during the year ended December 31, 2018. Net cash used in operating activities during the year ended December 31, 2019 totaled $21.7 million, an increase of $4.0 million, or 23%, compared to the same period in 2018. The net cash used in operating activities increased primarily due to a $4.6 million increase in net operating losses, and an increase in use of working capital items of $1.9 million, offset by an increase in non-cash charges of $2.4 million.

Net cash used in investing activities during the year ended December 31, 2019 totaled $1.9 million, an increase of $1.3 million, or 203%, compared to the same period in 2018. The increase in net cash used in investing activities was primarily due to an increase of $0.8 million in the purchase of research equipment and a $0.5 million payment for Oncimmune assets.

Net cash provided by financing activities during the year ended December 31, 2019 totaled $23.0 million, an increase of $3.9 million, or 21%, compared to the same period in 2018. The net cash provided by financing activities increased primarily due to increased proceeds from issuances of $2.8 million in convertible debt and $1.5 million in preferred stock offset by $0.4 million in financing costs.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations and commitments as of December 31, 2019 (in thousands):

	Payments due by period(5)				
	Total	Less than 1 year	1 to 3 years	4 to 5 years	More than 5 years
Operating lease obligations(4)	$ 3,974	$ 1,590	$ 2,384	$ —	$ —
Term loan(1)(3)	24,088	—	24,088	—	—
Convertible debt(1)(2)	13,158	13,158	—	—	—
	$41,220	$14,748	$26,472	$ —	$ —

(1) Reflected in accompanying balance sheets.

(2) Convertible debt may be prepaid at our option prior to maturity. If not prepaid or otherwise converted, the debt will convert to Series H preferred stock at maturity.
(3) The term loan is subject to a 3% prepayment penalty. In addition, upon maturity, a 2% back-end facility fee of $460,000 is due to the lender.
(4) We are obligated under non-cancellable operating leases for all of our facilities. Lease terms for our facilities in effect as of December 31, 2019, ranged from less than one to three years and generally require us to pay the real estate taxes, certain insurance and operating costs.
(5) Royalty payments that we may owe are not included as the timing of such payments is uncertain.

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 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 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, 2019, 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.

For a description of our other indebtedness, please see "Certain Relationships and Related Person Transactions—Convertible Debt Financings" and "Description of Capital Stock—Convertible Debt."

Off-Balance Sheet Arrangements

As of December 31, 2019, we have not entered into any off-balance sheet arrangements.

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 included elsewhere in this prospectus.

Revenue Recognition

In May 2014, the Financial Accounting Standards Board (FASB) issued ASU 2014-09, “Revenue from Contracts with Customers”, and has subsequently issued several supplemental and/or clarifying ASUs (collectively, ASC 606). ASC 606 prescribes a single common revenue standard that replaces most existing U.S. GAAP revenue recognition guidance. ASC 606 is intended to provide a more consistent interpretation and application of the principles outlined in the standard across filers in multiple industries and within the same industries compared to current practices, which should improve comparability. We adopted the new standard using the modified retrospective method on January 1, 2018 for contracts that are not completed as of the adoption date.

Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. ASC 606 also impacts certain other areas, such as the accounting for costs to obtain or fulfill a contract. The standard also requires disclosure of the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers.

We examined our revenue recognition policies specific to revenue streams for the provisioning of services and providing research and development services to third parties and came to conclusions on the impact of the new standard using the 5-step process prescribed by ASC 606. As noted above, we used the modified retrospective method to adopt the new standard which means we did not restate previously issued financial statements but recorded a one-time adjustment to accumulated deficit and accounts receivable of $0.4 million. This adjustment reflected our ability to establish a transaction price for our non-Medicare pay arrangements as of January 1, 2018 as a result of having sufficient history to determine the transaction price under these contracts. ASC 606 did not have an aggregate impact our net cash provided by operating activities but resulted in offsetting changes in certain assets and liabilities presented within net cash used in operating activities in the accompanying statement of cash flows, as noted above.

Diagnostic service revenues are generally completed upon the delivery of test results to the prescribing physicians, which is considered the performance obligation. Testing services are generally completed upon the delivery of testing results for assay development and testing services, which is considered the performance obligation.

Change in fair value of contingent consideration

In connection with the purchase transaction with 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 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 the related 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.

Accounting for convertible debt

During 2019, we issued $13.0 million in convertible debt that are now scheduled to mature on June 30, 2021. The terms of the convertible debt provided discounts upon conversion to the note holders in certain

situations, including upon the completion of this offering. The discounts included in the convertible debt created a put option liability that was separated from the convertible debt and reflected as a liability in our balance sheet. Subsequent to the creation of the put options, changes in the fair value of the put options 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 options 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. We will estimate the fair value of the put options until they are exercised or expire. The fair value of put options are based on the value of the discounts embedded in the convertible debt and the probability of various settlement scenarios.

Stock-based compensation and common stock valuation

Stock-based compensation related to stock options granted to our employees, directors and nonemployees is measured at the grant date based on the fair value of the award. The fair value is recognized as expense over the requisite service period, which is generally the vesting period of the respective awards. Compensation expense for stock options with performance metrics is calculated based upon expected achievement of the metrics specified in the grant.

Starting January 1, 2019, upon adoption of Accounting Standards Update (ASU) 2018-07, Compensation—Stock Compensation (Topic 718), *Improvements to Nonemployee Share-Based Payment Accounting*, the fair value of stock options issued to nonemployee consultants is determined as of the grant date, and compensation expense is being recognized over the period that the related services are rendered.

We use the Black-Scholes option-pricing model to estimate the fair value of our stock options and stock purchase rights under our 2016 Incentive Plan. The Black-Scholes option-pricing model requires assumptions to be made related to expected term of an award, expected volatility, risk-free rate and expected dividend yield. Starting January 1, 2017, forfeitures were accounted for as they occur.

We account for restricted stock units issued to employees based on the grant date fair value which is determined based on the closing market price of the common stock on the date of grant. The expense is recognized in our statement of operations on a straight-line basis over the requisite vesting period.

In the absence of an active market for our common stock, 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 (the 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, including:

- valuations of our common stock performed by independent third-party valuation specialists;
- our stage of development and business strategy, including the status of research and development efforts, of our products and product candidates, and the material risks related to our business and industry;
- our results of operations and financial position, including our levels of available capital resources;
- the valuation of publicly traded companies in the life sciences and diagnostic testing sectors, as well as recently completed mergers and acquisitions of peer companies;
- the lack of marketability of our common stock as a private company;
- the prices of our convertible preferred stock sold to investors in arm’s length transactions and the rights, preferences, and privileges of our convertible preferred stock relative to those of our common stock;

- the likelihood of achieving a liquidity event for the holders of our common stock, such as an initial public offering or a sale of our company, given prevailing market conditions;
- trends and developments in our industry; and
- external market conditions affecting the life sciences and medical device industry sectors.

Our Board of Directors determined the fair value of our common stock 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. The Practice Aid identifies various available methods for allocating enterprise value across classes and series of capital stock to determine the estimated fair value of common stock at each valuation date.

In allocating enterprise value among the various classes of stock prior to July 2020, we utilized the Option Pricing Method (OPM) given our early stage of development and the absence of a near term liquidity event. Under the OPM, shares are valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class. The values of the preferred and common stock are inferred by analyzing these options. From July 2020 onwards, we have utilized a hybrid OPM and Probability-Weighted Expected Return Method (PWERM). The PWERM is a scenario-based analysis that estimates the value per share based on the probability-weighted present value of expected future investment returns, considering a number of discrete possible outcomes of the business, as well as the economic and control rights of each share class. Under this hybrid method, we considered expected initial public offering liquidity scenarios as well as other market-based non-initial public offering scenarios in the event a near-term initial public offering does not occur. Additionally, in determining the estimated fair value of our common stock, our Board of Directors also considered the fact that our stockholders could not freely trade our common stock in the public markets. Accordingly, we applied discounts to reflect the lack of marketability of our common stock based on the weighted-average expected time to liquidity.

Following the completion of this offering, our Board of Directors will determine the fair value of our common stock based on our closing price as reported on the date of grant on the primary stock exchange on which our common stock is traded.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 1 to our financial statements appearing at the end of this prospectus.

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 money market funds recorded at $4.8 million and $5.2 million at December 31, 2019 and 2018, respectively. These money market funds were measured using Level 1 inputs. As of December 31, 2019, 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. This estimate is based on a sensitivity model that measures market value changes when changes in interest rates occur.

Our December 2019 Notes, August 2019 Notes and our convertible debt all accrue interest at fixed rates.

Implications of Being an Emerging Growth Company and Smaller Reporting Company

We are an "emerging growth company" within the meaning of the 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 this prospectus and in our periodic reports and proxy statements, the requirement that we hold a nonbinding advisory vote on executive compensation and any golden parachute payments, and we have taken advantage of the ability to provide reduced disclosure of financial information in this prospectus, such as being permitted to include only two years of audited financial information and two years of selected financial information in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure. 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. 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) until December 31, 2025 (the year ended December 31st following the fifth anniversary of this 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.

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 partner that the world relies on for data-driven diagnostic solutions in lung disease and beyond.

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 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. Our Nodify XL2 and Nodify CDT, 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 global pandemic, we have 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. These tests are utilized by healthcare providers, including hospitals and nursing homes, and also offered to businesses and educational systems as part of 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.

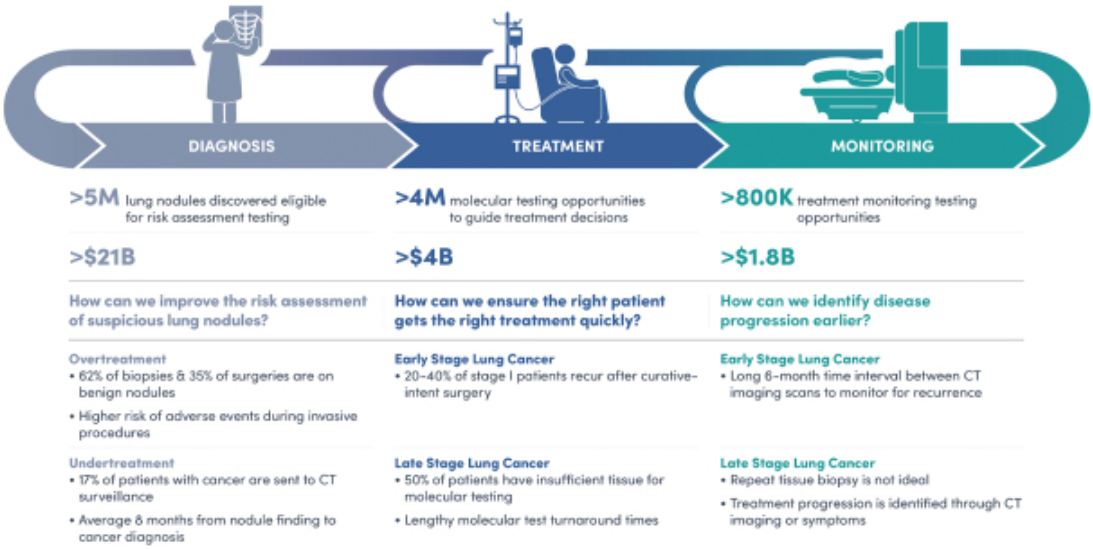
In addition to the six diagnostic tests currently on the market, we perform over 30 assays for research use as part of our laboratory services that have been used by over 50 biopharmaceutical customers and academic partners. All of our diagnostic testing is performed at one of our two certified, high-complexity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

Since our inception, we have performed over 170,000 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.

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 continuum of care, we believe there is a substantial need for novel, advanced testing to improve on the current standard of care. We estimate that the lung cancer continuum of care currently represents over 10 million testing opportunities and over a $27 billion market annually for testing alone in the United States.



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 pipelines and increase their 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. 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.

Our Proprietary AI Platform

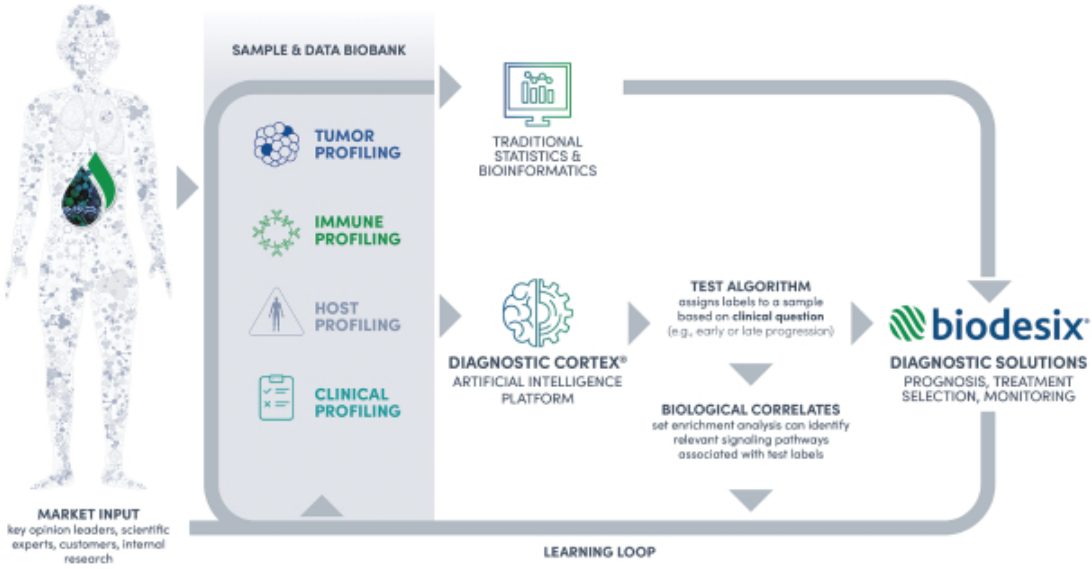
Our core belief is that no single technology will answer all clinical questions that we encounter. Therefore, we employ multiple technologies, including genomics, transcriptomics, proteomics, and radiomics, and leverage our proprietary AI platform, the Diagnostic Cortex, to discover innovative diagnostic tests for clinical use.

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. Researchers commonly encounter issues with machine learning-based biological discoveries that cannot be repeated or validated when assessed in additional specimen cohorts. This challenge occurs when the machine identifies a perfect pattern in an initial training dataset but isn't able to identify the same pattern in a new dataset. For over 15 years, we have focused on developing our platform to overcome this challenge to ensure each test that is discovered can be further developed to perform consistently in the clinical testing environment.

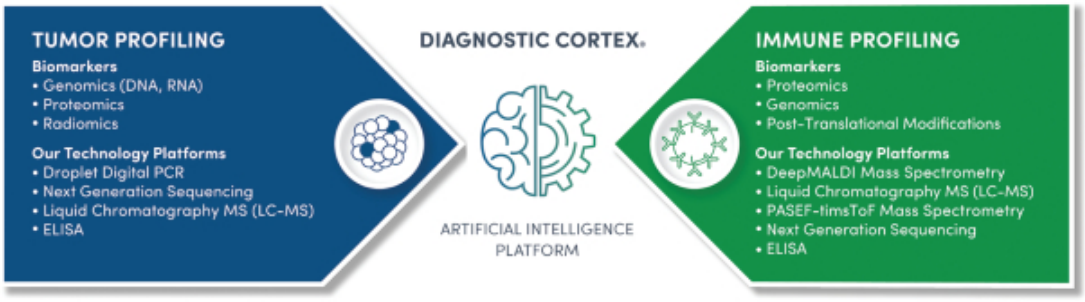
We are able to combine blood-based biological information related to the tumor, immune system, and host-status with clinical and radiomic data through our proprietary AI platform, which enables us to interpret the holistic disease state of each patient or clinical dataset we encounter.

We continuously 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 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 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.

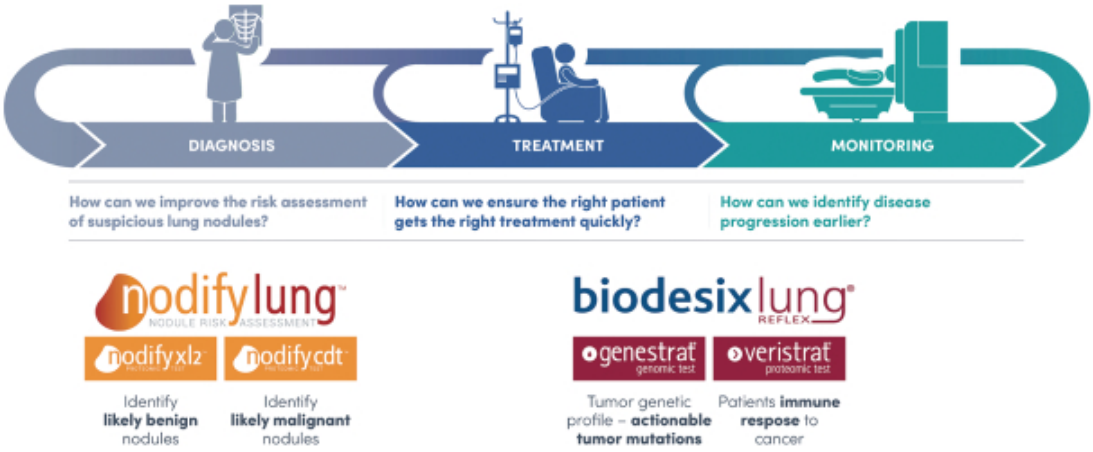
We have four blood-based diagnostic tests across the lung cancer continuum of care to help address clinical unmet needs by physicians.

- **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.

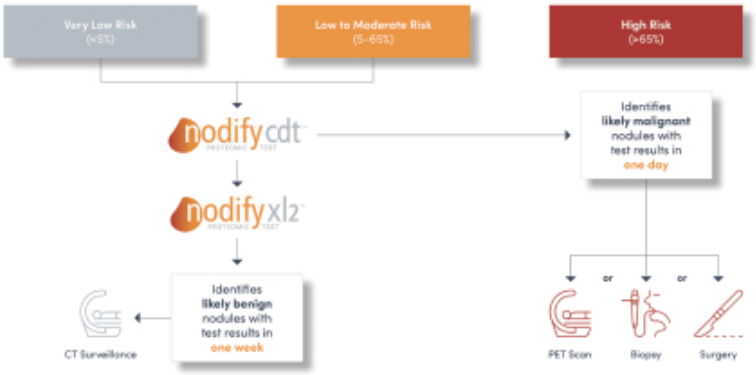
- **Monitoring**: We believe longitudinally monitoring advanced NSCLC patients for the dynamic evolution of their tumor and immune profile while on treatment can provide an earlier indication of treatment resistance and/or disease progression. We offer the Biodesix Lung Reflex testing strategy as a blood-based 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

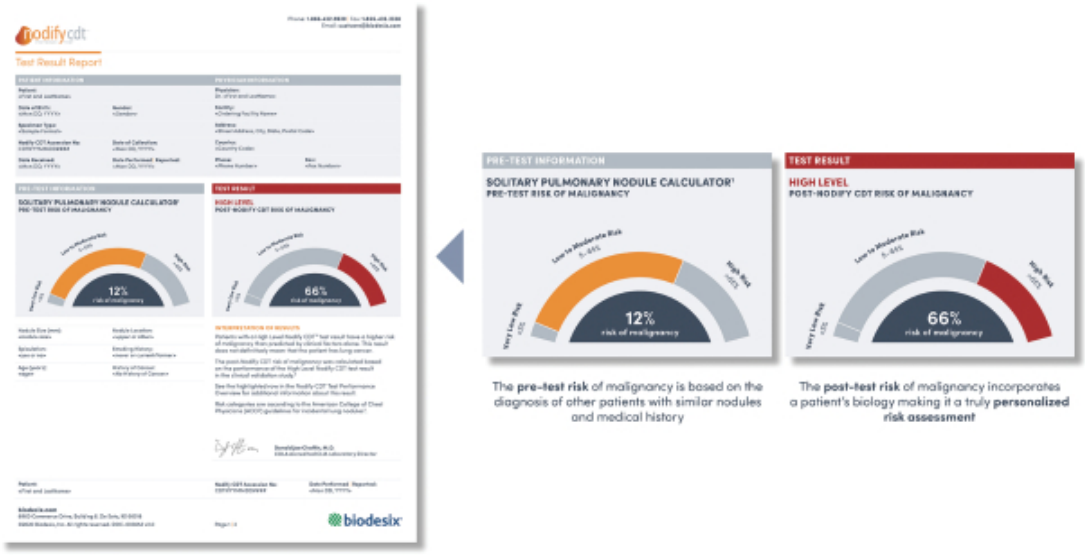
Nodify CDT is a blood-based proteomic test that helps identify patients who have a suspicious lung nodule that is likely malignant or at a higher risk of being cancerous. Results allow physicians to identify patients who may be better candidates for timely invasive diagnostic procedures such as bronchoscopy, 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.

The following is an example of a de-identified Nodify CDT Test Result Report describing a patient's pre-test clinical risk of malignancy and the adjusted post-test risk following a High Level test result. The physician in this scenario may consider recommending the patient for an invasive diagnostic procedure as their post-Nodify CDT risk of malignancy is considered High Risk.



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.

The following is an example of a de-identified Nodify XL2 Test Result Report describing a patient's pre-test clinical risk of malignancy and the adjusted post-test risk following a Likely Benign test result. The physician in this scenario may consider recommending the patient for three or six-month CT surveillance as their post-Nodify XL2 risk of malignancy is considered Very Low Risk.

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

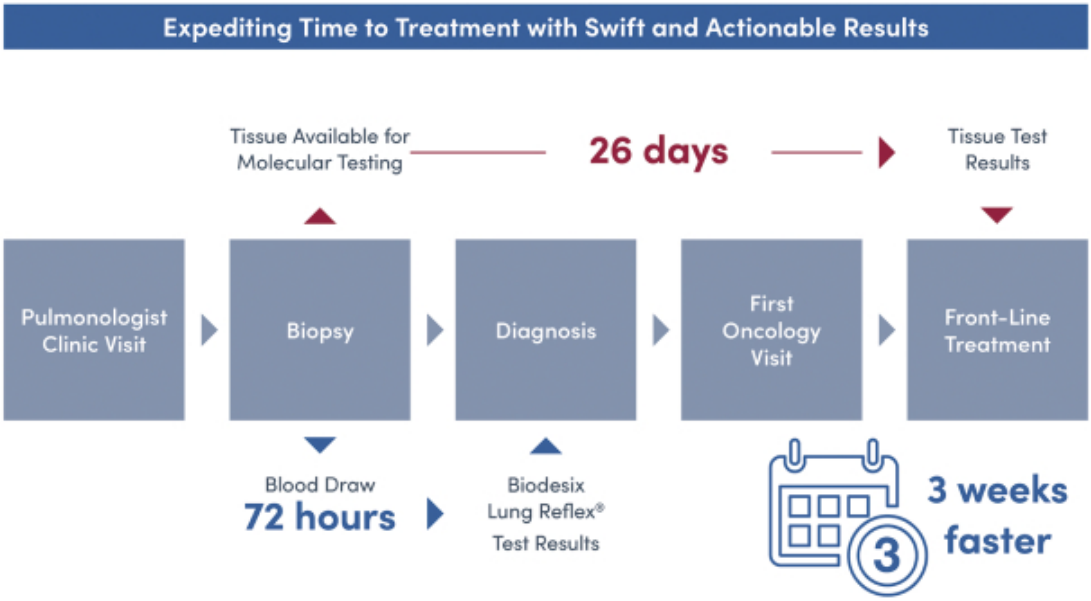
Profiling the tumor through blood-based testing can help identify mutations in genes that may be driving growth of the tumor and may be targets for therapeutics. However, tumors also suppress intrinsic mechanisms

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

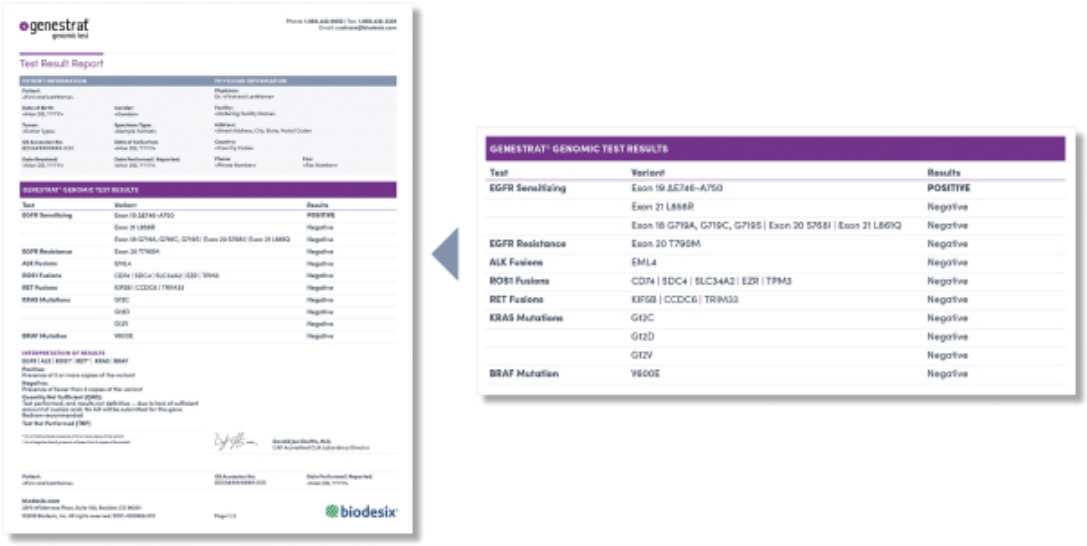
GeneStrat is a blood-based tumor profiling test that detects the guideline recommended, actionable mutations in lung cancer: *EGFR*, *KRAS*, *BRAF*, *EML4-ALK*, *ROS-1*, and *RET*. Physicians can order one or any combination of the genes, whichever they deem medically necessary for the individual patient. 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 patients 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.



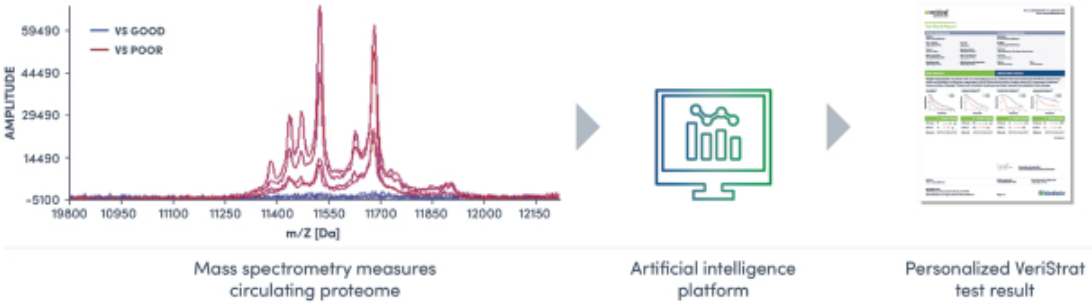
We believe that rapid, blood-based tumor profiling with the GeneStrat test is complementary to both targeted tissue-based testing (including PD-L1) and broad genomic sequencing. Testing with GeneStrat at diagnosis can help quickly identify patients who are eligible for targeted therapies. Additionally,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

The following is an example of a de-identified GeneStrat Test Result Report. The patient in this scenario is positive for the EGFR Sensitizing mutation Exon 19 DE746-A750 variant.



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 VeriStrat testing workflow is represented by the figure below.



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.

The following is an example of a de-identified VeriStrat Test Result Report. The patient's test result is a VeriStrat Good result, indicating the patient has an overall good prognosis and will likely benefit from standard of care therapies.

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 global pandemic, we have 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 assay indicated 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 assay 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.

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 Lacrosse League as they competed in their 2020 tournament.

Bio-Rad SARS-CoV-2 ddPCR test

The Bio-Rad SARS-CoV-2 ddPCR test, also known as a molecular or viral test, is indicated 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

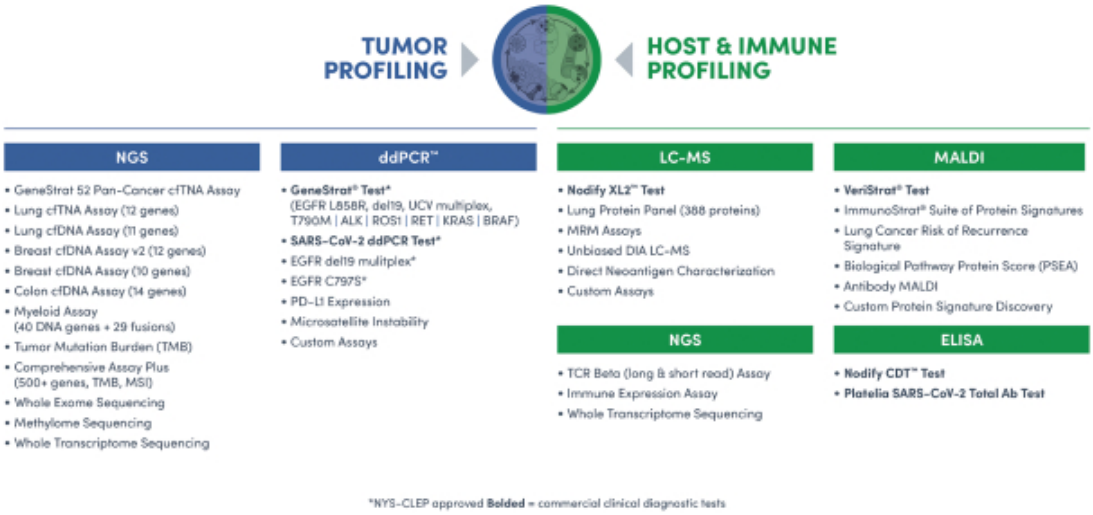
The Platelia SARS-CoV-2 Total Ab assay (also known as a serology or antibody test) is intended for use as an aid in identifying individuals who have developed an adaptive immune response to the SARS-CoV-2 virus, indicating recent or prior infection. The assay uses whole blood to detect circulating antibodies 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 24-48 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.

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 81 issued patents in the United States and internationally, and 26 trademarks issued in the United States. 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.

Overview of the Current Landscape

Lung cancer (both small cell and non-small cell) is the second most common cancer diagnosed in the United States with nearly 230,000 patients diagnosed each year. With an estimated 135,000 patient deaths in 2020, lung cancer is accountable for more deaths annually than the next three deadliest cancers combined (colorectal, pancreas, and breast). Additionally, every year in the United States an estimated 1.6 million people are diagnosed with an incidental nodule in the lung. These nodules can arise from a variety of causes ranging from smoking to fungal infections or other lung diseases. While most lung nodules are found to be benign and ultimately harmless, about 5% are found to be malignant within two years from nodule identification.

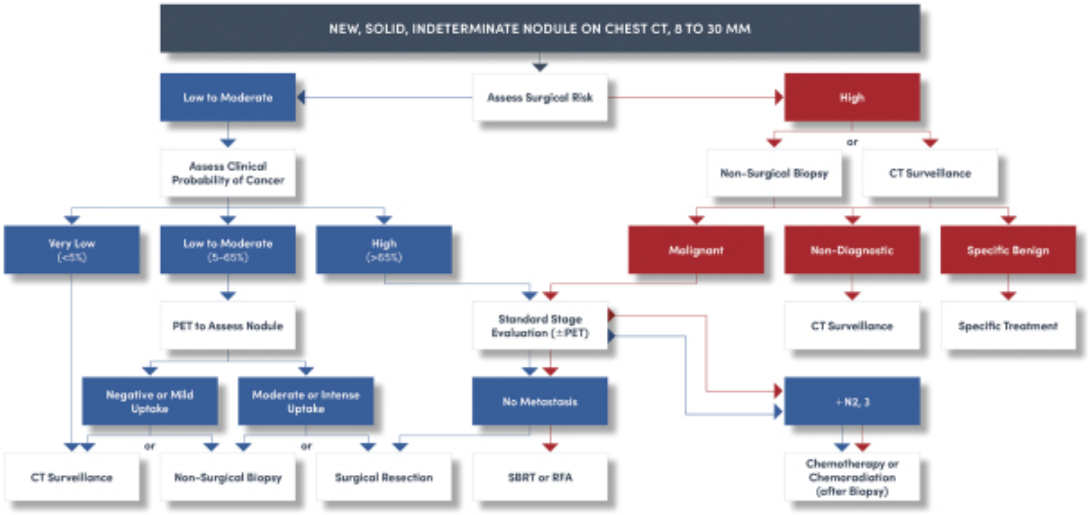
Despite significant advances over the last decade, lung cancer is still the deadliest type of cancer in both men and women in the United States today. While diagnostic testing has become routinely used at certain points in the lung cancer continuum of care, we believe there is a substantial need for 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. We estimate that the biopharmaceutical partnering and research opportunities represent over a $2 billion market annually.

Diagnosis – Nodule Management

Over 1.6 million people are diagnosed with incidental pulmonary nodules annually in the United States. Incidental nodules are identified when a person is being evaluated for another medical concern, typically through X-ray or CT imaging. On July 7, 2020, the United States Preventive Services Task Force (USPSTF) published an updated draft statement to the 2013 low-dose CT (LDCT) screening recommendation that proposes an expansion to the eligible population for lung cancer screening to patients 50 to 80 years old in the United States with a smoking pack-year history of 20 or more years or who currently smoke or quit smoking within the past 15 years. Based upon the new USPSTF recommendation, over 15 million people are eligible for LDCT, which is expected to ultimately lead to the identification of over 4 million lung nodules annually. However, in 2019, only 4.2% of the eligible population underwent screening. Improved patient adherence to screening is expected to result in earlier identification of lung nodules.

Following initial discovery of a lung nodule, patients are typically evaluated by a pulmonologist for risk of lung cancer. A recent study found that on average, patients wait 8 months following initial detection of a lung nodule before diagnosis of cancer. The same study also estimated that approximately two thirds of incidental nodules found did not receive follow-up after initial discovery. If a patient can be diagnosed with cancer at an early stage, their survival chances are greatly increased, including the chance of cure. The volume of patients waiting for evaluation has led to the implementation of “nodule clinics” in centers around the country to try to catch cancer earlier by reducing wait times for diagnostic procedures and increasing the number of patients that are being routinely observed.

The ACCP guidelines for lung nodules management further detail the intervention or monitoring pathways for a patient based on their individual risk of cancer. Several “risk calculators” have been developed to help translate a patient’s clinical risk factors such as age, smoking status, cancer history, nodule size, location, and edge characteristics into a risk percentage. However, standard practice is physician assessed risk of malignancy.



As illustrated above, for patients whose lung cancer risk is determined to be High (greater than 65%), guidelines recommend sending the patient for a stage evaluation and surgical resection if there are no metastases. If the risk of lung cancer is determined to be Very Low (less than 5%), guidelines recommend CT surveillance to monitor the nodule for growth or shrinkage. Approximately 80% of patients fall into the Low to Moderate group (5-65%) where guidelines state CT scans, positron emission tomography (PET) scans, biopsy, bronchoscopy, or surgery are all options and should be chosen based on the physician’s clinical judgement and risk threshold.

With a large and varied set of clinical options, the Low to Moderate risk group represents the area of greatest need for precision diagnostic testing to help reclassify risk and direct patients to the relevant treatment pathway. A 2015 publication of 18 pulmonology clinics across the United States and 377 patients with lung nodules showed 62% of biopsies and 35% of surgeries were performed on patients with benign nodules. Conversely, 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.

In addition to the median workup cost of $2,794 for a non-surgical biopsy and $24,623 for a surgical resection, performing invasive procedures on patients with benign nodules exposes them to potentially serious adverse events and could impede future lung function. In a population-based analysis of patients diagnosed with lung cancer from 2001 to 2010, it was identified that the incidence of at least one hospitalized adverse event occurred in 30% of the population. Specifically, the rate of incidence by invasive procedure type was 26% for a bronchoscopy, 34% for a percutaneous biopsy, and 39% for a surgical resection. A recent cost-benefit analysis showed that among Medicare claims, over 40% of the total cost in management of lung cancer was attributed to benign patients with an invasive procedure. Diagnostic tests can help reduce unnecessary biopsies or surgeries on patents with benign nodules and can help catch those that are malignant earlier. These tests could improve patient outcomes, alleviate patient anxiety, and save costs to both the patient and the healthcare system.

NSCLC Treatment Guidance

Following confirmed diagnosis, the patient’s NSCLC is staged which helps the physician direct the patient to an appropriate treatment pathway. Approximately 70% of patients with lung cancer are diagnosed with

advanced stage disease (typically stage IIIB/IV), resulting in an estimated five-year survival of 6%. Meanwhile, five-year survival for patients diagnosed with early stage (typically stage I-IIIA) disease is 59%.

Early Stage NSCLC

We estimate that there are over 700,000 testing opportunities annually in the United States in early stage lung cancer to assess the risk of recurrence following surgery, and to detect potential target mutations for therapeutics. The current standard of care in early stage disease is surgery with curative intent. Depending on the risk of recurrence for a patient, 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 have a lung cancer recurrence within five years following surgery, representing a sub-group of patients who may have benefited from a more intensive care plan, including increased follow up or additional therapy.

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, which we believe will lead to the need for testing designed specifically for mutation detection. Beyond clinical testing, we believe diagnostic testing for research use as part of our laboratory services could help biopharmaceutical companies identify new patient targets for neoadjuvant or adjuvant therapy in earlier stage disease.

Advanced Stage NSCLC

We estimate that there are over 1.5 million diagnostic testing opportunities annually in the United States to guide advanced stage lung cancer treatment decisions. We believe there is a need for blood-based testing solutions that measure tumor mutations and the patient's immune profile, providing physicians with holistic and timely information to assess the overall prognosis of the patient and personalize treatment plans when tissue is not available.

Traditionally, therapeutics for advanced NSCLC have been FDA-approved based on improvement in response, or survival for a population in a given tumor type. However, data have shown that it is not a one size fits all approach as each patient responds differently based on their individual biology. Today, the NCCN guidelines recommend nearly 50 FDA-approved systemic treatment regimens for patients with advanced NSCLC. Although an increasing number of these therapeutics have companion diagnostic tests to inform treatment, there remains a need for more comprehensive biomarkers to help further identify the right patient for the right treatment. In addition to biomarker analysis, physicians assess the patient's medical history, presence of co-morbidities, and ultimately the patient's prognosis to help guide treatment decisions.

Approximately 50% of patients do not have sufficient tissue collected following diagnosis to facilitate tissue-based molecular testing. Conducting an additional tissue biopsy is costly and has the risk of adverse events. Blood-based testing can provide rapid, actionable, upfront tumor profiling from a minimally invasive blood draw, and eliminate the need for repeat biopsy procedures. Blood-based offerings include testing of individual driver mutations in lung cancer, or broad mutation profiling, typically through next generation sequencing. The broader mutation panels often include genes that are prevalent in and may be tied to therapeutics approved in tumor types outside of lung cancer. Single gene assays or smaller actionable gene panels may be focused more specifically on lung cancer.

In addition to the tumor mutation profiling, the state of the patient's immune system has long been understood to be an important factor in the patient's diagnosis, prognosis, and response to therapy. The causal relationship between inflammation and cancer progression is more widely accepted today as the immunology and oncology communities have continued to collaborate around the advancement of immune-targeting drugs.

However, recent studies indicate that less than 25% of treatment-naïve lung cancer patients were alive after five years when treated with single agent immunotherapy and some patients do not benefit from immunotherapy in comparison to those treated with chemotherapy. These reports underscore the complexity of the underlying biology and the need for immune-related biomarker treatment selection.

Monitoring

We estimate that there are over 1 million 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.

Our Platform and Technologies

Our focus on tumor and immune profiling is central to our core belief that no single technology will answer all clinical questions that we encounter. Therefore, we employ multiple technologies, including genomics, transcriptomics, proteomics, and radiomics, and our proprietary AI platform, Diagnostic Cortex, to discover innovative diagnostic tests for clinical use. Through our learning loop, we continuously revisit our technology strategy and 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.

Diagnostic Cortex Artificial Intelligence Platform

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 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 utilize multiple technologies, including ddPCR, NGS, LC-MS, ELISA, and our proprietary DeepMALDI mass spectrometry platform in our molecular analysis of the tumor, immune system, and host-status of each patient. The data from these technologies feed into our proprietary Diagnostic Cortex platform to discover clinically relevant diagnostic tests.

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. 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 clinical diagnostic tests.

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 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 Clinical Validation Data

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, 4 of which are ongoing, and have published over 275 peer-reviewed publications and presentations. Below we outline our clinical validation data for our six diagnostic tests: Nodify CDT, Nodify XL2, GeneStrat, VeriStrat, SARS-CoV-2 ddPCR, and Platelia SARS-CoV-2 Total Ab.

Nodify CDT

Nodify CDT has been studied in 14 peer reviewed published studies and presentations. Here we highlight an overview of one of our key peer-reviewed clinical validation papers.

- *Healey GF, J Cancer Ther 2017*: In this study, the objective was to assess the clinical test performance of Nodify CDT (previously named EarlyCDT-Lung) and its clinical utility in assessing risk of indeterminate pulmonary nodules. A High Level test result demonstrated a 98% specificity and 28% sensitivity with a positive predictive value (PPV) of 82%. With these test performance metrics, the test is most clinically useful as a tool to ‘rule-in’ cancer, which is can be defined as helping to identify patients who may be at a higher risk of malignancy. Conversely, a result of No Significant Level of Autoantibodies Detected (NSLAD) does not help rule out lung cancer and therefore does not change a patient’s pre-test risk of lung cancer.

Nodify XL2

Nodify XL2 has been studied in 12 peer reviewed published studies and presentations. Here we highlight an overview of two of our key peer-reviewed clinical validation papers.

- *Silvestri G, CHEST, 2018 (PANOPTIC)*: In the prospective, multicenter PANOPTIC clinical study, the test demonstrated a sensitivity of 97%, a specificity of 44% and a negative predictive value of 98% in distinguishing benign from malignant nodules. When compared to traditional cancer risk assessments, Nodify XL2 performed better than a PET scan commonly used and validated lung nodule risk models (including the Swensen nodule calculator), and physicians’ cancer probability estimates. The PANOPTIC study concluded that if the test results were used to direct care, 40% fewer invasive procedures would be performed on benign nodules. As such, Nodify XL2 may have significant clinical utility in guiding incidental lung nodule management decisions, potentially eliminating unnecessary invasive procedures, resulting in improved quality of life for patients as well as reduced financial expense for both the patient and the health system.
- *Pritchett M, Am J Respir Crit Care Med, 2020:* Preliminary results from the ORACLE registry study were accepted as a late breaking abstract at the American Thoracic Society conference. In the study, the Nodify XL2 test resulted in 46% of nodules being re-classified from the “low to moderate risk” (5-65%) into the “very low risk” (less than 5%) category. This redistribution was predicted in the PANOPTIC clinical validation study and is now seen in real-world clinical use in the ORACLE study and through commercial clinical testing. This shift in distribution may lead to a substantial increase in benign nodules correctly routed to CT surveillance, thus a significant reduction of invasive procedures being performed on benign disease.

GeneStrat

GeneStrat has been studied in 30 peer reviewed published studies and presentations. Here we highlight an overview of one of our key peer-reviewed clinical validation papers.

- *Mellert H, J Mol Diagn, 2017*: This study highlights the clinical validation data for the targetable mutations (EGFR, KRAS, ALK) in the blood-based GeneStrat test. The overall clinical test performance of the genes and variants in GeneStrat is 91% sensitivity and 100% specificity. Clinical sensitivity for each gene ranged from 88% to 100%. Clinical specificity for each gene was 100%. Additionally, this study reported on mutation results from our commercial clinical testing. Mutation results were available within 72 hours for 94% of the tests evaluated. The GeneStrat test is a rapid, highly sensitive, and actionable blood-based test that supports faster targeted therapy treatment decisions for patients with NSCLC.

VeriStrat

VeriStrat has been studied in over 85 peer reviewed and published clinical studies across many different types of treatment regimens such as chemotherapy, targeted therapies, immune checkpoint inhibitors, and combination therapies. The presence of a VeriStrat Poor result indicates the presence of chronic inflammation and a chronic acute phase immune response. Typically, patients with a VeriStrat Good result respond better to standard of care treatments than those patients that test as VeriStrat Poor. The results consistently show the test to be predictive of outcomes, independent of other prognostic factors including PD-L1 expression and performance status.

- *Leal T, Curr Med Res Opin, 2020*: Timely assessment of patient-specific prognosis is critical to oncology care, however clinical prognostic factors traditionally used in NSCLC treatment have limitations. This meta-analysis study examined the prognostic performance of VeriStrat through a systematic literature review of 21 published studies. It was found that 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 and line of therapy, 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. The robust prognostic performance of VeriStrat has clinical implications for patient and physician shared decision-making and potential for the introduction of novel treatment strategies.
- *Mitchell BR, J Clin Oncol, 2020*: Recently, we published data at the American Society of Clinical Oncology 2020 virtual meeting on an interim analysis from the INSIGHT clinical study. The data suggest that blood-based VeriStrat testing can provide clinically significant information to predict outcomes and guide treatment choices made by physicians for patients with advanced NSCLC who are eligible for immune checkpoint inhibitor therapy. Specifically, the study identified that patients who have tumors that express PD-L1 greater than 50% and have a VeriStrat Poor result should not be treated with immunotherapy alone.

Biodesix WorkSafe COVID-19 Testing Program

Bio-Rad SARS-CoV-2 ddPCR Test

FDA EUA Authorization—All acceptance criteria for the performance verification of the Bio-Rad SARS-CoV-2 ddPCR test were fulfilled. The sample size used for the clinical evaluation study of the test was 60, and included 30 negative specimens and 30 positive contrived specimens per FDA EUA guidance. Specifically, verification of accuracy revealed 100% agreement with the reference result. An additional study was performed to confirm our first 5 positive and first 5 negative clinical specimens relative to an external laboratory with an orthogonal EUA test. Data from this study demonstrated 100% concordance.

Here we highlight an overview of one of the recent publications on ddPCR testing for SARS-CoV-2:

- *Suo T, Emerging Microbes & Infections, 2020:* Quantitative real time PCR (RT-PCR) is widely used as the gold standard for clinical detection of SARS-CoV-2. However, due to the low viral load specimens and the limitations of RT-PCR, significant numbers of false negative reports are inevitable, which results in failure to timely diagnose, cut off transmission, and assess discharge criteria. To improve this situation, an optimized ddPCR was used for detection of SARS-CoV-2, which showed that the limit of detection of ddPCR is significantly lower than that of RT-PCR. Results showed that the ddPCR test demonstrated 95% accuracy vs. 47% for other "bulk" RT-PCR technologies used in other molecular tests.

Platelia SARS-CoV-2 Total Ab Test

FDA EUA Authorization—All acceptance criteria for the performance verification of the Platelia SARS-CoV-2 Total Ab test were fulfilled. 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. Specifically, verification of accuracy revealed 100% agreement with the reference result. Additionally, precision was evaluated and found to be comparable to that reported by the manufacturer within-run, between-day, between-instrument and between-operator. Finally, all confirmed negative specimens tested were within the reference interval. The sensitivity is 98% and specificity is 99% eight days after the onset of symptoms.

Case Studies

We believe every patient deserves a personalized approach to improve their care. Our objective is to empower physicians with swift, comprehensive, and actionable insights to help address clinical questions across lung disease. The following are case studies provided by our customers from their real-world experience with our diagnostic tests.

Case Study #1: Catching Cancer Earlier with Nodify CDT

Outcome: Appropriate management of patients with incidentally discovered lung nodules must balance between the need to identify malignant nodules earlier and the potential harm of invasive procedures, while keeping patient preferences in consideration. In this case, a 90% post-Nodify CDT risk of malignancy result led to a decision change by the physician and patient to proceed with an invasive diagnostic workup, which led to an earlier diagnosis of stage IA lung cancer.

Case Background: A 64-year-old female presented for medical attention after falling on her right side. A chest X-ray showing a spot on the lung and subsequent CT scan identified a spiculated (nodule edge characteristic), 10 mm lung nodule in the patient's right upper lobe. Based on her clinical risk factors and nodule characteristics, a 39% risk of malignancy was determined by the Solitary Pulmonary Nodule Calculator. At this estimated risk, the patient was not comfortable with any invasive diagnostic procedures but was willing to undergo a follow-up PET/CT scan and a blood draw for Nodify Lung testing. PET/CT results had a standard uptake value (SUV) of 3.3, which is not a strong indicator of benign or malignant disease. The patient's Nodify CDT post-test risk of malignancy was 90%. Through shared decision making based on the test results, the patient proceeded with a biopsy, which was diagnosed as cancerous. Early detection identified the patient as a candidate for a potentially curative procedure.

Case Study #2: Avoiding Unnecessary Procedures with Nodify XL2

Outcome: Traditional diagnostic risk assessment and testing indicated that this patient had a higher risk of malignancy, but because of the patient's health condition, a biopsy was not preferred. A 6% post-Nodify XL2 risk of malignancy result led the physician and patient to make a shared decision to monitor the nodule with a short-term follow-up CT. The follow-up CT demonstrated a reduction in size, indicating a benign diagnosis. Blood-based risk classification provided additional information that enabled a decision to avoid an unnecessary invasive procedure.

Case Background: A 74-year-old male with severe chronic obstructive pulmonary disease (COPD) presented for medical evaluation. The patient's pulmonary function tests showed severe obstruction. A CT scan was completed for evaluation for candidacy of procedure which revealed a spiculated 10 mm nodule in the patient's left upper lobe. The pre-test risk of malignancy with the Solitary Pulmonary Nodule Calculator was calculated as 49%, however biopsy was not a preferred option due to the patient's poor pulmonary function and the difficult location of the lung nodule. The Nodify XL2 test was ordered and returned a result of Likely Benign, with a 6% post-Nodify XL2 risk of malignancy. Subsequent PET/CT imaging showed SUV of 7.0, which is concerning for a lung malignancy. Based upon the Nodify XL2 results and patient preference, a wait and watch approach with repeat chest imaging was pursued. A repeat CT scan demonstrated a reduction in size of the nodule to 7 mm, indicating an inflammatory or benign etiology.

Case Study #3: Biodesix Lung Reflex Results Changed Patient's Cancer Treatment Plan

Outcome: It is important for physicians to have a holistic view of each patient's dynamic disease state to make more informed patient care decisions. In this case, the patient with advanced NSCLC did not have any driver mutations, as identified by GeneStrat. However, the patient's VeriStrat Good result facilitated a conversation between the patient and physician about their positive prognosis and the benefits that more aggressive treatment could provide. Prior to receiving the VeriStrat result, the patient was considering foregoing systemic therapy. The combined Biodesix Lung Reflex results facilitated a shared decision to begin treatment with a combination immunotherapy and chemotherapy regimen.

Case Background: A 79-year-old female presented to the clinic with a cough, fever, and chest pain. The patient was a former smoker who had quit more than 25 years ago. A CT scan identified a lung mass (greater than 30 mm) and the patient was scheduled for bronchoscopy to confirm diagnosis and stage. A blood sample was collected during the pre-operative appointment for Biodesix Lung Reflex testing. The patient's final diagnosis was stage IV adenocarcinoma. The GeneStrat test result was mutation negative and the VeriStrat test result was Good. The patient was reviewed by a multi-disciplinary team of physicians and based on the staging and test results was referred to a medical oncologist for treatment with a combination of immunotherapy and chemotherapy. The patient previously wished to avoid systemic therapy, but our tests supported a shared decision with her physician to move ahead with an aggressive treatment regimen.

Case Study #4: First Do No Harm – Biodesix Lung Reflex Supports Shared Decision Making

Outcome: Lung cancer is a deadly disease, and often patients with advanced disease on average live about 10 months. In this case, an elderly patient was diagnosed with advanced NSCLC, but was hesitant to receive further surgical procedures. This patient received the unfortunate combination of a VeriStrat Poor and a KRAS mutation. The results facilitated a conversation with the physician and the patient's family regarding her overall poor prognosis and short estimated survival. The patient and family decided to pursue end-of-life palliative care, saving the patient from unnecessary procedures and adverse effects.

Case Background: A 92-year-old female presented with back and chest pain and recent difficulty breathing. The patient had also lost 8 to 10 pounds in recent weeks and had a productive cough. The patient had a 40 pack-year smoking history but had quit over 35 years prior. A PET/CT scan revealed metastatic disease with multiple brain metastases, leading to a diagnosis of stage IV lung cancer. The patient and her family were hesitant to proceed with an invasive procedure for further diagnosis and clinical staging to inform a treatment plan. Biodesix Lung Reflex testing was ordered to inform potential treatment pathways. The GeneStrat test result showed the patient was positive for a KRAS G12V mutation, implying a worse prognosis. Additionally, the VeriStrat test result was Poor.

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.

Monitoring – Progression & Resistance

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.

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, 4 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. First patient first visit is expected the second half 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.

INSIGHT Observational Study (NCT03289780)

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 (Pending IRB Submission)

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." IRB submission is planned for the second half of 2020. 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-naive 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.

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.

There are approximately 5,000 actively practicing pulmonologists in the United States, covering a broad range of sub-specialties such as sleep disorders, COPD and asthma as well as lung cancer diagnosis. The commercial team optimizes their activities by targeting pulmonologists and pulmonology clinics specialized in the management of pulmonary nodules and in the diagnosis of lung cancer, reducing the target physician group to approximately 1,000 individuals. 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 enable collection of blood samples outside of the physician office, at home or work for patients across the United States.

For our Biodesix WorkSafe COVID-19 testing program, we have a dedicated outreach team that works with 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 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 tests, 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.

Compliance with applicable laws and regulations, as well as internal compliance policies and procedures adds complexity to the billing process. The CMS are 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 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 assay 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.

Government Payers

Medicare is limited to items and services that are within the scope of a Medicare benefit category and that are reasonable and necessary for the diagnosis and treatment of an illness or an injury. Medicare develops National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs), setting forth additional requirements for coverage for tests such as ours using an evidence-based coverage process with opportunity for public participation. Median age at diagnosis for lung cancer is 71 years old; therefore the Medicare eligible population represents approximately 60-65 % of the addressable market in lung cancer.

Novitas Solutions, the MAC responsible for developing coverage policies for tests performed in the region that includes our Boulder, Colorado clinical laboratory, issued a final LCD *Biomarkers for Oncology* (L35396) that included coverage for the VeriStrat test on October 1, 2015 (most recently revised effective July 1, 2020). This policy provides coverage for patients with non-small cell lung cancer whose *EGFR* gene mutation status is either wild type (negative) or mutation status unknown. The *Biomarkers for Oncology* LCD also includes coverage for the genes in the GeneStrat test for patients with non-small cell lung cancer.

Palmetto GBA, the MAC responsible for administering the molecular diagnostics services program covering many other regions of the United States including the De Soto, Kansas clinical laboratory, issued a positive coverage LCD for the Nodify XL2 test, known under the generic name BDX-XL2 (L37031), effective July 10, 2017 (most recently revised effective October 24, 2019). The test is covered for patients who are 40 years or older, have a suspicious pulmonary nodule between 8 and 30mm, and have a pre-test risk of cancer of equal to or less than 50% as assessed by the Solitary Pulmonary Nodule Malignancy Risk calculator (Mayo Clinic). There is currently no Medicare coverage, and as a result, no Medicare reimbursement, for the Nodify CDT test, but we are actively engaged in efforts to gain such coverage and reimbursement by Medicare.

Our tests and those like ours are typically paid by Medicare Part B under the Clinical Laboratory Fee Schedule (CLFS). In April 2014, Congress passed the Protecting Access to Medicare Act of 2014 (PAMA) which included changes to how prices are assigned to billing codes used to identify these tests. Under PAMA, entities who receive a majority of their Medicare payments under that CLFS or the Physician Fee Schedule are required to report private payer payment rates and volumes every three years, or every year for tests with the Advanced Diagnostic Laboratory Test (ADLT) designation. CMS calculates a weighted median rate for each code, which establishes the Medicare CLFS reimbursement rate for the subsequent three years, or one year for ADLTs.

On December 21, 2018, CMS determined that VeriStrat met the criteria for an “existing ADLT,” meaning an advanced test that was paid on the CLFS prior to January 1, 2018. Assignment of this status meant that beginning on January 1, 2020, the reimbursement rate assigned to the code used to identify VeriStrat would be set annually. Data collected from January to June of 2018 was reported to CMS in the first quarter of 2019 and set the rate of $2,871 for calendar year 2020, representing no change from the rate paid for VeriStrat for calendar year 2019. Data collected from January to June 2019 was reported in the first quarter of 2020 that will be used to set the rate for calendar year 2021.

On May 17, 2019, CMS determined that Nodify XL2 met the criteria for “new ADLT” status. From July 1, 2019 through March 31, 2020, Medicare paid the list price of $3,520. During the period from July 2019 to

November 2019, we collected the required commercial payment data and reported to CMS in December 2019. The data from this period was used to set the payment rate for the test from April 1, 2020 through December 31, 2021, which remains priced at $3,520. The rate for 2022 will be set based on data collected in the first half of 2020 and reported in the first quarter of 2021.

Medicare Advantage plans, which are an alternative to original Medicare and are offered by private companies, such as commercial payers, also cover and reimburse our products. Medicare Advantage plans must provide at least the same level of coverage for Medicare beneficiaries as traditional Medicare; however, reimbursement for our tests by Medicare Advantage plans can depend on our contracts with each plan.

State-based Medicaid and Managed Medicaid plans offered by private companies such as commercial payers, have limited coverage and reimbursement of our products. Payment by Managed Medicaid is also dependent on our contracts with each plan.

Commercial Third-Party Payers

We are actively engaged in efforts to achieve broad coverage and adequate reimbursement for all of our marketed tests. Reimbursement from commercial payers differs depending on if they have established coverage and if we are contracted as a "participating provider" or do not have a contract and are considered a "non-participating provider." Approval of a claim is dependent on coverage, and reimbursement rate and timing of payment is based on the terms of or presence of a contract. When we are not reimbursed in full or at all, we may submit appeals of the denial or underpayment or seek payment from the patient. However, insurance appeal and patient collection efforts take a substantial amount of time and can have varying levels of success.

We bill for the VeriStrat and Nodify XL2 tests using test specific CPT codes—81538 and 0080U, respectively. The GeneStrat test is billed based on the genes that are ordered by the physician using the existing molecular pathology codes. The Nodify CDT test is billed using the unlisted MAAA code.

With the evolution of genomic testing, individual commercial third-party payers' medical coverage policies around the CPT codes we bill and their associated payment rates have changed over time, resulting in changes to our reimbursement revenues. We believe all of our products provide significant clinical value and reduction in downstream healthcare spend, as evidenced in research studies and clinical publications, which we believe will continue to support and drive third-party payer reimbursement.

Our strategy includes educating commercial third-party payers and evidence review organizations regarding our strong clinical data, which we believe validates the value of our tests and will eventually result in more commercial third-party payers covering our tests. The VeriStrat test is covered by many private payers including Aetna, Cigna, Humana, and various Blue Cross Blue Shield plans. We are actively engaged with private payers to expand coverage and contracting for all of our marketed tests.

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 national and state laboratories, 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.

The Nodify XL2, Nodify CDT, and COVID-19 complete 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.

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 and COVID-19 diagnostic and antibody tests. 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 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 also have agreements with Bio-Rad allowing us to market our two diagnostic tests for COVID-19. 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 August 1, 2020, our patent portfolio includes approximately 44 issued United States patents, 37 issued foreign patents which includes 2 European patents that were nationalized in multiple European countries, 35 pending applications (including 3 PCT applications and 19 foreign patent applications). With regard to our product development efforts, PCT applications have been filed around our risk of recurrence and primary immunoresistance 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 XL 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).

Pending 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 patents but can become the basis of PCT and United States non-provisional patent applications, if such PCT or United States non-provisional 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 life 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 August 1, 2020, we have 26 registered United States trademarks, 7 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 (1) strengthen or enhance our competitive position, (2) protect and maintain aspects of our business that are not amenable to, or that we do not presently consider appropriate for, patent protection, and (3) 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 the 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 clinical tests (IVCTs) 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 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 intends 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 regulatory approach for IVCT tests, i.e., IVDs and LDTs, that was risk-based and flexible.
- 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.
- 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.

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 released broad-sweeping guidance, but could choose to do so in the future and if the guidance is released and 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 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 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 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. The CAP accreditation program involves unannounced on-site inspections of our laboratories. 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 NYSDOH, 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 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 recently proposed a rule to harmonize and modernize its QSR, which would supplant the existing requirements with ISO 13485:2016. In March 2020, 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 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 NYS CLEP, based on New York State Public Health Law, Article 5 Title 5. NYS CLEP is exempt from CLIA and establishes their own method of laboratory certification and assay validation approval. To process NYS 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 offing the test in the state of New York. Our GeneStrat and VeriStrat tests have received NYS CLEP approval. NYS CLEP requires semi-annual inspections to ensure the laboratory meets all general and specialty standards. Biodesix passed NYS CLEP inspection in May 2019 and is currently scheduled for a routine re-inspection in May 2021. Although delays related to NYS CLEP's COVID-19 response resulted in the department's inability to complete the review of our Boulder, Colorado and De Soto, Kansas laboratories prior to the permit expiration date, the current permit expiration dates have been extended until NYS CLEP has made a final determination of the application.

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.

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's review of a PMA application generally takes between one and three years, but may take significantly longer. The FDA can delay, limit or deny approval of a PMA application for many reasons, including (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, but can be significant and include civil monetary or criminal penalties. HIPAA is enforced by the Department of Health and Human Services, Office of 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 of 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 new California ballot initiative, the California Privacy Rights Act (CPRA), has garnered enough signatures to be included on the November 2020 ballot in California. If voted into law by California residents, the CPRA would 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 and the United Kingdom, the collection and use of personal data is governed by the GDPR. 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 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. 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**.**

Healthcare Reform

In March 2010, the ACA was enacted in the United States. The ACA made a number of substantial changes to the way healthcare is financed both by governmental and private 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.

The Trump administration and Congress have, and we expect they will continue to, seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the ACA. Since January 2017, the Trump administration has 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 January 22, 2018, the Trump administration signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The 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 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 cut through FY 2030 to offset the cost of such temporary suspension. 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.

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.

Material Agreements

Acquisition of Integrated Diagnostics

On June 30, 2018, we purchased select assets and liabilities from Integrated Diagnostics, Inc. and IND Funding, LLC (collectively, the Seller) which included CLIA lab in Seattle, Washington and all rights to the Nodify XL2 test and the intellectual property 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 Company's 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 over a seven-year period. The amount can be payable in stock or cash at our and the Seller's option. The total amount of undiscounted contingent consideration which we may be required to pay under the arrangement is $37.0 million. For the 6 months following the achievement of the Milestone, the Seller has the option to require us to pay the contingent consideration in cash over 8 equal installments due each calendar quarter. If the Seller elects not to exercise this option, have 12 months to either settle the contingent consideration in two equal quarterly cash installments or in 14,959,114 of Series G Preferred Stock.

Acquisition of Oncimmune USA

On October 31, 2019, we completed an acquisition of United Kingdom-based Oncimmune's United States operations including its CLIA clinical laboratory in De Soto, Kansas and its 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 clinical laboratory 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 PCA defines the general relationship between the parties. Included under the PCA was (a) an asset purchase agreement (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 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.

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 million due within 30 days of exercising the option. 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. The minimum sales volumes will be adjusted upwards in the event we exercise the screening option.

Non-Exclusive License Agreement

In August 2019, we entered into the Bio-Rad License. Bio-Rad is a key supplier of equipment and reagents used to perform ddPCR testing—a service offered by us under a fee for service agreement—and the core technology powering the GeneStrat and COVID ddPCR tests.

Under the terms of the Bio-Rad License, we 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 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, pursuant to a separately executed supply agreement with Bio-Rad. As further consideration for the non-exclusive license, we 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 we do not purchase licensed products under the separate supply agreement for a consecutive twelve month period or for any material breach by us of the supply agreement.

In addition, we have been granted permission by Bio-Rad to use the Bio-Rad SARS-CoV-2 ddPCR assay for commercial diagnostic services.

Debt Refinancing

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 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.

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. 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.

Drug Co-Development

In April 2014, we and AVEO entered into a Co-Development and Collaboration Agreement (AVEO Agreement) whereby the two parties agreed to co-develop AVEO's compound ficlatuzumab and our VeriStrat test. Under the AVEO Agreement, we agreed to use commercially reasonable efforts to continue to develop the VeriStrat test and obtain regulatory approval for VeriStrat as a companion diagnostic for ficlatuzumab in certain major markets. We agreed with AVEO to agree on a development plan for ficlatuzumab and VeriStrat.

We will co-develop their clinical trial asset, ficlatuzumab (HGF-inhibitor), along with our proteomic test, BDX004 (a variant of our VeriStrat test), a test that identifies a subgroup of individuals who derive the most benefit from this drug. In collaboration with AVEO, we reported early clinical data on ficlatuzumab in head and neck cancer, acute myeloid leukemia, and pancreatic cancer. Most recently, we announced data from our phase 1b study in pancreatic cancer, a challenging disease to treat, that demonstrated encouraging responses that support the further assessment of the drug. We believe BDX004 could help differentiate patient benefit to ficlatuzumab across multiple indications and support decision making in therapeutic selection.

As part of the AVEO Agreement, we granted AVEO a perpetual, non-exclusive, royalty-free license to certain background intellectual property related to VeriStrat, our interest in joint inventions developed under the

AVEO Agreement and certain diagnostic data to develop, manufacture, seek regulatory approval for and commercialize ficlatuzumab and certain IVD devices for use in connection with ficlatuzumab. AVEO granted us a perpetual, non-exclusive, royalty-free license to certain background intellectual property related to ficlatuzumab, their interest in joint inventions developed under the AVEO Agreement and certain clinical data and biomarker data to develop, manufacture and commercialize VeriStrat and certain IVD devices other than VeriStrat. We solely own inventions relating to VeriStrat (excluding ficlatuzumab) and AVEO solely owns inventions relating to ficlatuzumab (excluding VeriStrat), and we jointly own all other inventions under the AVEO Agreement.

As consideration for the licenses under the AVEO Agreement, we agreed to reimburse AVEO for $15 million of certain ficlatuzumab clinical development costs. Additionally, we agreed to pay half of AVEO's clinical development costs above that $15 million cap. Unless we or AVEO exercises our right to opt-out of the co-development, we equally share in any income received from licensing rights to ficlatuzumab to any third parties. If either party exercises the right to opt-out prior to the first commercial sale of ficlatuzumab, the party that opts out will receive 25% of any such income.

We and AVEO agreed to negotiate a definitive commercialization agreement for ficlatuzumab in good faith upon results of a clinical trial for ficlatuzumab, pursuant to which AVEO would be the lead commercialization party. Such commercialization agreement would allocate commercialization responsibilities, provide decision-making processes, and include other terms related to the commercialization of ficlatuzumab. The AVEO Agreement provides that under such commercialization agreement, we would share all profits and losses from the commercialization of ficlatuzumab, except that each party would have the option to opt-out of commercialization activities and instead receive a low single-digit royalty of net sales of ficlatuzumab made by the other party. The AVEO Agreement also sets forth certain key provisions to be included in the definitive commercialization agreement. We and AVEO agreed that under such commercialization agreement, we would share all profits and losses from the commercialization of ficlatuzumab, except that each party would have the option to opt-out of commercialization activities and instead receive a low single-digit royalty of net sales of ficlatuzumab made by the other party.

The AVEO Agreement continues in force until terminated by either party for the other's uncured material breach or bankruptcy events, or as terminated under the terms of the commercialization agreement. If we terminate the AVEO Agreement for anything other than a breach by AVEO that prevents or irreparably disrupts certain clinical activities, AVEO will be deemed to have exercised its opt-out rights and will receive 25% of any income received by us for licenses under ficlatuzumab to third parties. If we terminate for a breach by AVEO that prevents or irreparably disrupts certain clinical activities, AVEO will instead receive 12.5% of any such income.

In October 2016 we and AVEO amended the AVEO Agreement to deem our obligation to cover initial pre-clinical costs satisfied in exchange for a one-time payment of all applicable development costs incurred to that date, and to provide that we and AVEO would share development costs. Under the amended terms, we agreed to allow AVEO to recapture these costs that it otherwise would not have been responsible for sharing, from any royalties or revenues eventually derived under the AVEO Agreement.

Ficlatuzumab is currently being evaluated in SCCHN, PDAC, and AML.

Employees

As of June 30, 2020, we had 154 full time employees, 43 of whom were engaged in development activities, and 38 of whom were engaged in general and administrative functions. Our employees are primarily located in Boulder, Colorado, with additional employees located in De Soto, Kansas and remotely across the country. None of our employees are represented by any collective bargaining agreements. We believe that we maintain good relations with our employees.

Facilities

We occupy approximately 29,722 square feet of office and laboratory space in Boulder, Colorado under a lease that ends on January 14, 2023. We also occupy 9,066 square feet of office and laboratory space in De Soto, Kansas under a lease that ends on October 31, 2020. 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.

Legal Proceedings

We may from time to time be involved in various legal proceedings and other matters arising in the normal course of business. For example, we have received, and may in the future continue to, receive letters, claims or complaints from others alleging false advertising, patent infringement, violation of employment practices and trademark infringement. We have also instituted, and may in the future institute additional, legal proceedings to enforce our rights and seek remedies, such as monetary damages, injunctive relief and declaratory relief. We cannot predict the results of any such disputes, and despite the potential outcomes, the existence thereof may have an adverse material impact on us because of diversion of management time and attention as well as the financial costs related to resolving such disputes.

MANAGEMENT

Executive Officers and Directors

The following table sets forth information concerning certain individuals, including their ages as of June 30, 2020, who are expected to serve as our directors and executive officers upon completion of this offering.

Name	Age	Position
Executive Officers		
Scott Hutton	48	President, Chief Executive Officer and Director
Robin Harper Cowie	40	Chief Financial Officer, Secretary, and Treasurer
Kieran O'Kane	43	Chief Commercial Officer
Robert Georgantas III, Ph.D	50	Senior Vice President, Research and Translational Science
Gary Pestano, Ph.D	53	Chief Development Officer
Non-Employee Directors		
David Brunel	65	Chairman and Director
Robert Cawthorn	84	Director
Jean Franchi	53	Director
Hany Massarany	59	Director
Mark Miller	64	Director
John Patience	72	Director
Jack Schuler	79	Director
Matthew Strobeck, Ph.D	47	Director
Charles Watts, M.D	77	Director

(1) Member of the Audit Committee.
(2) Member of the Compensation Committee.
(3) Member of the Nominating and Corporate Governance Committee.

The following are brief biographies describing the backgrounds of our executive officers and non-employee directors:

Executive Officers

Scott Hutton has served as our President, Chief Executive Officer and Director since January 2020, and previously held the role of Chief Operating Officer from March 2018 to December 2019. Additionally, Mr. Hutton has served on the board of Eximis Surgical since February 2018 and was an Observer on the Board of Directors of Aqueduct Critical Care from September 2014 to January 2017. Mr. Hutton joined Biodesix from Spectranetics Corp (NASDAQ: SPNC), a U.S.-based global leader in vascular intervention and lead management solutions (now part of Royal Philips (NYSE: PHG)), where he served as Senior Vice President and General Manager of the Vascular Intervention division from January 2017 to December 2017. Prior to joining Spectranetics, Mr. Hutton held several positions of increasing responsibility, including Vice President and General Manager, at Medtronic plc (NYSE: MDT), a global healthcare products company and manufacturer of medical devices and supplies, over a period of 16 years. From April 2012 to January 2017, Mr. Hutton was Vice President and General Manager of Neurosurgery, where he oversaw the operations of the approximately $1 Billion Neurosurgery Business Unit. From 2008 to 2012, he grew from Senior Director of Global Marketing to Vice President and Business Leader of the Surgical Navigation and Intra-Operative Imaging Business. Mr. Hutton holds a B.A. in Health and Kinesiology from Purdue University. In July 2011, Mr. Hutton received the *Medtronic Wallin Leadership Award* for his focus on talent development, business performance, and his personal and intentional demonstration of leadership.

Robin Harper Cowie has served as our Chief Financial Officer since April 2017. She has been with the Company in multiple financial and reimbursement positions since March 2011, serving as Vice President of Finance from February 2016 to April 2017, Vice President of Reimbursement & Health Economics from February 2015 to February 2016, Senior Director of Reimbursement from January 2014 to February 2015, and Director of Reimbursement from March 2011 to January 2014. Prior to joining Biodesix, Ms. Harper Cowie held a leadership role in payer and government relations at Precision Therapeutics, Inc. Ms. Harper Cowie's background includes corporate finance, managed care and payer relations, reimbursement and regulatory policy, and revenue cycle operations. Additionally, she spent several years as a researcher at the University of Pittsburgh Medical Center. Ms. Harper Cowie holds a B.S. in Molecular Biology from the University of Pittsburgh, and an M.B.A. in Finance from the Joseph M. Katz Graduate School of Business from the University of Pittsburgh.

Kieran O'Kane has served as our Chief Commercial Officer since March 2020 and has been with the Company in multiple marketing management roles since February 2018. From April 2016 to February 2018, prior to joining Biodesix, Mr. O'Kane lead the Global Diagnostics Marketing team at NanoString Technologies, a biotechnology company focused in developing cancer diagnostic tools. He is a highly experienced strategic and tactical global sales and marketing leader for both in-line and pipeline products with a career focus in oncology. Mr. O'Kane has held commercial leadership positions and managed multiple new product launches at Biotheranostics, Cell Therapeutics, Eisai, Cephalon, Bristol-Myers Squibb, and Roche. Mr. O'Kane received a B.S. in Pharmacology at King's College, University of London.

Gary Pestano, Ph.D. has served as our Chief Development Officer since October 2018 and has been with the Company in Product Development and Operations since March 2012. Prior to joining Biodesix, Dr. Pestano held senior positions in Pharma Services, R&D and Project Leadership at Ventana Medical Systems, a member of the Roche Group, from 2003 to 2012. Dr. Pestano's experience in laboratory operations management and assay development for high complexity molecular diagnostics in oncology and virology include molecular and proteomic testing. Dr. Pestano is the co-inventor on multiple national and international patents for diagnostic tests. He has also fostered many collaborations in academia and industry as a part of new product development. Dr. Pestano received a B.S. in Biochemistry from The City College of New York, his Ph.D. in Molecular Cell Biology at The Graduate Center, City University of New York where his thesis focused on vaccine development for novel genetic variants of HIV-1. He conducted his post-doctoral training in Cancer Immunology and AIDS at the Dana Farber Cancer Institute, Harvard Medical School.

Robert W. Georgantas III, Ph.D. has served as our Senior Vice President of Research and Translational Science since August 2019. From 2014 to 2019, prior to joining Biodesix, Dr. Georgantas worked at AbbVie where he served as Director of Immunology Programs and Biomarkers within the Genomics Research Center of Excellence, a group of experts tasked with applying genetics, genomics, epigenetics, and metagenomics to inform the product pipeline primarily regarding new target discovery, biomarkers for clinical trials, and asset positioning. Dr. Georgantas is recognized as a leader of immunology translational science and strategy. Dr. Georgantas completed his Ph.D. in pharmacology and molecular medicine at The Johns Hopkins University School of Medicine.

Board of Directors

David Brunel is a co-founder of Biodesix. He has served as a Director of the Company since 2006 and as Chairman of the Board since January 2020. Mr. Brunel was Chief Executive Officer of Biodesix from 2006 through 2019. Prior to Biodesix, Mr. Brunel was Co-founder in 1999 and President of SomaLogic, Inc., a company focused on creating protein capture arrays for sensitive, high-throughput, quantitative diagnostics. Mr. Brunel was a founder and CEO of Unidata, Inc. when it merged with Vmark Software to create Ardent Software, Inc., where he was President and Chief Operating Officer. He was also a member of the board of Ardent until it was sold to Informix in 1999. He also served as CEO of both Codestream, Ltd, which he sold to Blue Phoenix Solutions, and eMotion, Inc., which sold to Corbus, now part of Getty Images. Additionally, Mr. Brunel serves on the board of Anark Corporation, Xyleme, Inc. and KromaTiD, Inc. Mr. Brunel has a B.S. in Chemistry from Colorado State University and an M.A from the Korbel School of International Studies at the University of Denver.

Robert Cawthorn is a co-founder of Biodesix. He has served as a Director of the Company since 2006 and served as Chairman from 2006 to 2019. Mr. Cawthorn served as Chairman of Actelion from 1997 to 2012. Mr. Cawthorn served as a Managing Director of Global Health Care Partners of DLJ Merchant Banking Partners from 1998 to 2001. He served as Chairman and as Chief Executive Officer of Rhone Poulenc Rorer from 1990 to 1996, having previously been Chairman and Chief Executive Officer of its predecessor, Rorer Group, from 1985. Mr. Cawthorn was an executive with Pfizer International for 17 years and was the first president of Biogen Inc. before joining Rorer Group in 1982. He has served on the boards of CBS, The Vanguard Group of Mutual Funds, Sunoco, First Pennsylvania Bank (now part of Wells Fargo), Leerink Swann and several technology start-ups. He has been active on not-for-profit boards including The University of Pennsylvania, United Way of South Eastern Pennsylvania, Cambridge in America and the Bermuda Institute of Ocean Sciences. Mr. Cawthorn received a B.A. from Cambridge University in the United Kingdom.

Jean M. Franchi has served as a Director of the Company since April 2020. Ms. Franchi is currently Chief Financial Officer at Replimune, a biotechnology company developing oncolytic immuno-gene therapies. Prior to Replimmune, Ms. Franchi was Chief Financial Officer at Merrimack Pharmaceuticals from 2017 to 2019, Dimension Therapeutics from 2015 to 2017, and Good Start Genetics from 2012 to 2015. From 1995 to 2011, Ms. Franchi held various positions at Genzyme Corporation, including Senior Vice President of Corporation Finance, Senior Vice President of Business Unit Finance, and Vice President of Finance and Controller, Product Line and International Group. Ms. Franchi currently serves on the boards of directors of Biophytis BSA and Visioneering Technologies, Inc. Ms. Franchi received her B.A. in Accounting from Hofstra University.

Hany Massarany has served as a Director of the Company since July 2020. Mr. Massarany was President and Chief Executive Officer of GenMark Diagnostics, Inc. (NASDAQ: GNMK) from April 2011 to March 2020. From February 2009 to April 2011, Mr. Massarany served as President of at Ventana Medical Systems and Head of Roche Tissue Diagnostics, a division of F. Hoffman-La Roche Ltd. focused on manufacturing instruments and reagents that automate tissue processing and slide staining diagnostics for cancer. From 1999 to 2009, Mr. Massarany held various global leadership positions with Ventana, including Chief Operating Officer, Executive Vice President, Worldwide Operations, Senior Vice President, Corporate Strategy and Development, and Vice President, North American Commercial Operations. Mr. Massarany also held executive management positions with Bayer Diagnostics and Chiron Diagnostics, working in both the Asia Pacific region and the United States. Mr. Massarany served on the board of directors of GenMark Diagnostics, Inc. from May 2011 to February 2020. Mr. Massarany earned a B.S. in Microbiology and Immunology from Monash University in Australia and an M.B.A. from Melbourne University.

Mark C. Miller has served as a Director of the Company since August 2011. Mr. Miller currently serves as a Director of Accelerate Diagnostics (NASDAQ: AXDX) and served as Chairman of Stericycle until 2018, and an additional year as a director until February 2019 (NASDAQ: SRCL). Before retiring, Mr. Miller served as Chief Executive Officer of Stericycle from 1992 to 2012. Prior to joining Stericycle, Mr. Miller served as Vice President for the Pacific, Asia and Africa in the international division of Abbott Laboratories, a diversified health care company, which he joined in 1976 and where he held a number of management and marketing positions. Mr. Miller formerly served as a director of Ventana Medical Systems, Inc., a developer and supplier of automated diagnostic systems. He received a B.S. in Computer Science from Purdue University, where he graduated Phi Beta Kappa. Mr. Miller was selected by Morningstar, Inc. as its “2009 CEO of the Year”.

John Patience has served as a Director of the Company since June 2008. Mr. Patience currently serves as both a Director and Chairman of the board of Accelerate Diagnostics, Inc. (NASDAQ: AXDX) and has served in that capacity since joining the board in 2012. Mr. Patience served as a director of Ventana Medical Systems, Inc. from 1989 and as Vice Chairman from 1999 until Ventana’s acquisition by Roche in 2008. Mr. Patience also served as a director of Stericycle, Inc. (NASDAQ: SRCL) since its founding in 1989 to June 2018. Mr. Patience is also a founding partner of Crabtree Partners, a private equity investment partnership in Lake Forest, Illinois. Mr. Patience was previously a partner of a venture capital investment firm that provided both Ventana and Stericycle with early stage funding. Mr. Patience was also previously a partner at the consulting firm McKinsey & Co., Inc., specializing

in health care. Mr. Patience holds a B.A. in Liberal Arts and an L.L.B. from the University of Sydney, Australia, and an M.B.A. from the University of Pennsylvania's Wharton School of Business.

Jack Schuler has served as a Director of the Company since June 2008. Mr. Schuler served as a director of Ventana Medical Systems, Inc. from 1991 and as Chairman of the board from 1995 until Ventana's acquisition by Roche in 2008. Prior to joining Ventana, Mr. Schuler was President and Chief Operating Officer of Abbott Laboratories, a diversified health care company, which he joined in 1972 and where he held a number of management and marketing positions, also serving as a director from April 1985 to August 1989. Additionally, Mr. Schuler has served as a director of Abbott Laboratories (NYSE:ABT), Medtronic (Lead Director) (NYSE: MDT), Stericyle (Chairman) (NASDAQ: SRCL), Chiron Corporation, and Quidel Corporation (NASDAQ: QDEL), and currently serves on the board of directors of Accelerate Diagnostics (NASDAQ: AXDX). Mr. Schuler holds a B.S. in Mechanical Engineering from Tufts University and an M.B.A. from Stanford University Graduate School of Business Administration.

Matthew Strobeck, Ph.D. has served as a Director of the Company since January 2012. Dr. Strobeck is currently the Managing Partner of Birchview Capital. In addition, Dr. Strobeck is currently a Director of Quidel Corporation (NASDAQ: QDEL), Accelerate Diagnostics (NASDAQ: AXDX), Tepha Inc., and Monteris Medical. Dr. Strobeck received a B.S. from St. Lawrence University, a Ph.D. from the University of Cincinnati, a S.M. from the Harvard University/MIT Health Sciences Technology Program, and a S.M. from the MIT Sloan School of Management.

Charles Watts, M.D. has served as a Director of the Company since July 2019. Until his retirement, Dr. Watts served as Chief Medical Officer at Northwestern Memorial Hospital (NMH) and Associate Dean for Clinical Affairs at the Feinberg School of Medicine, Northwestern University from 2001 to 2011. Prior to his tenure at Northwestern, Dr. Watts served as Chief of Clinical Affairs and Associate Dean at the University of Michigan Medical Center. He has also served as Executive in Residence for the Health Management Academy, as an active faculty member of a nationally based Physician Leadership Program. Dr. Watts served as a Director of Providence Health and Services (Seattle, Washington) from 2012 to 2016 where he chaired the Quality and Patient Safety Improvement Committee, and served as a Trustee of Swedish Health Services until May 2017, when he accepted an appointment as interim Chief Medical Officer, serving in that capacity until June 2019. He currently serves as a Trustee on the Institute for Systems Biology Board and as a director of Accelerate Diagnostics. Dr. Watts received his medical degree from the University of Michigan.

Board Composition

The primary responsibilities of our Board of Directors are to provide oversight, strategic guidance, counseling and direction to our management. Our Board of Directors meets on a regular basis and additionally as required. Our Board of Directors currently consists of ten directors.

In accordance with our amended and restated certificate of incorporation that will go into effect upon the completion of this offering, our Board of Directors will be divided into three classes with staggered, three-year terms. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Effective upon the completion of this offering, our directors will be divided among the three classes as follows:

- the Class I directors will be and , and their terms will expire at our first annual meeting of stockholders following this offering;
- the Class II directors will be and , and their terms will expire at our second annual meeting of stockholders following this offering; and
- the Class III directors will be and , and their terms will be expire at our third annual meeting of stockholders following this offering.

Our amended and restated certificate of incorporation and amended and restated bylaws that will go into effect upon the completion of this offering will provide that the authorized number of directors may be changed

only by resolution of the Board of Directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our Board of Directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control of our company. Our directors may be removed only for cause by the affirmative vote of the holders of at least two-thirds of our outstanding voting stock entitled to vote in the election of directors.

Director Independence

Under the listing requirements and rules of Nasdaq Global Market, independent directors must comprise a majority of our Board of Directors as a listed company within one year of the closing of this offering.

Our Board of Directors has undertaken a review of its composition, the composition of its committees and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our Board of Directors has determined that , , , and do not have any relationships that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the applicable listing requirements and rules of the Nasdaq Global Market. In making this determination, our Board of Directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our Board of Directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director.

Leadership Structure of the Board

Our corporate governance guidelines, which will become effective immediately prior to the completion of this offering, will provide our Board of Directors with flexibility to combine or separate the positions of Chairman of the board and Chief Executive Officer and/or the implementation of a lead director in accordance with its determination that utilizing one or the other structure would be in the best interests of our company. David Brunel currently serves as the Chairman of our Board of Directors.

Board Committees

Our Board of Directors has established an audit committee, a compensation committee and a nominating and corporate governance committee. Our Board of Directors may establish other committees to facilitate the management of our business. The composition and functions of each committee are described below. Members serve on these committees until their resignation or until otherwise determined by our Board of Directors.

Audit Committee

Effective as of the date the registration statement of which this prospectus forms a part is declared effective by the SEC, our audit committee will consist of , and , each of whom our Board of Directors has determined satisfies the independence requirements under the applicable listing requirements and rules of the Nasdaq Global Market and Rule 10A-3(b)(1) of the Exchange Act. The chair of our audit committee is , whom our Board of Directors has determined is an "audit committee financial expert" within the meaning of the SEC regulations. Each member of our audit committee can read and understand fundamental financial statements in accordance with applicable listing standards. In arriving at these determinations, our Board of Directors has examined each audit committee member's scope of experience and the nature of her or his employment in the corporate finance sector. The functions of this committee include:

- helping our Board of Directors oversee our corporate accounting and financial reporting processes;
- reviewing and discussing with our management the adequacy and effectiveness of our disclosure controls and procedures;

- assisting with design and implementation of our risk assessment functions;
- evaluating the qualifications, performance and independence of our independent registered public accounting firm and deciding whether to retain its services;
- monitoring the rotation of partners of our independent registered public accounting firm on our engagement team as required by law;
- discussing the scope and results of the audit with the independent registered public accounting firm, and reviewing, with management and the independent accountants, our interim and year-end results;
- developing procedures for employees to submit concerns anonymously about questionable accounting or audit matters;
- reviewing related party transactions;
- approving, or as permitted, pre-approving, audit and permissible non-audit services to be performed by an independent registered public accounting firm; and
- reviewing and assessing, at least annually, the performance of the audit committee and adequacy of its charter.

Compensation Committee

Effective as of the date the registration statement of which this prospectus forms a part is declared effective by the SEC, our compensation committee will consist of , and and the chair of our compensation committee will be . Our Board of Directors has determined that each of , and is independent under the applicable listing requirements and rules of the Nasdaq Global Market and is a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act. The functions of this committee include:

- reviewing, modifying and overseeing overall compensation strategy and policies;
- reviewing and approving the compensation and other terms of employment of our chief executive officer, other executive officers and senior management, as appropriate;
- reviewing and approving the compensation arrangements with our executive officers and other senior management, as appropriate;
- reviewing and recommending to the full Board of Directors the compensation of our directors;
- appointing and overseeing the work of compensation consultants, legal counsel or any other advisors and consultants engaged for the purpose of advising the compensation committee;
- adopting and administering equity award plans, compensation plans and similar programs, as well as modification or termination of plans and programs;
- establishing policies with respect to equity compensation arrangements;
- reviewing and evaluating with the chief executive officer the succession plans for our executive officers; and
- reviewing and assessing, at least annually, the performance of the compensation committee and the adequacy of its charter.

Nominating and Corporate Governance Committee

Effective as of the date the registration statement of which this prospectus forms a part is declared effective by the SEC, our nominating and corporate governance committee consists of , and

and the chair of our nominating and corporate governance committee will be . Our Board of Directors has determined that , and are independent under the applicable listing standards. The functions of this committee include:

- reviewing periodically and evaluating director performance of our Board of Directors and its applicable committees, and recommending to our Board of Directors and management areas for improvement;
- identifying, evaluating, nominating and recommending individuals for membership on our Board of Directors;
- reviewing with our chief executive officer the plans for succession to the offices of our executive officers and make recommendations to our Board of Directors with respect to the selection of appropriate individuals to succeed to these positions;
- reviewing and recommending to our Board of Directors any amendments to our corporate governance policies; and
- reviewing and assessing, at least annually, the performance of the nominating and corporate governance committee and the adequacy of its charter.

Code of Conduct

We have adopted a Code of Conduct that applies to all of our employees, officers (including our principal executive officer, principal financial officer and principal accounting officer or controller, or persons performing similar functions), agents and representatives, including directors and consultants. The full text of our Code of Conduct will be posted on our website at www.biodesix.com. We intend to disclose future amendments to certain provisions of our Code of Conduct, or waivers of such provisions, applicable to any principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, and our directors, on our website identified above. The information contained on, or accessible from, or hyperlinked to, our website is not part of, and is not incorporated into, this prospectus.

Compensation Committee Interlocks and Insider Participation

None of the members of the compensation committee is currently, or has been at any time, one of our officers or employees. None of our executive officers currently serve, or has served during the last calendar year, as a member of the Board of Directors or compensation committee of any entity that has one or more executive officers serving as a member of our Board of Directors or compensation committee.

Non-Employee Director Compensation

During the year ended December 31, 2019, none of our non-employee directors received retainers or other cash payments with respect to service on our Board of Directors or any of its committees. In connection with this offering, we expect to adopt a formal non-employee director compensation program.

2019 Director Compensation Table

The following table sets forth information for the fiscal year ended December 31, 2019 regarding the compensation awarded to, earned by or paid to our non-employee directors. The only compensation received by our non-employee directors was in the form of restricted stock units (RSUs) and option awards.

In respect of 2019 service, Messrs. Schuler, Patience, Miller, and Strobeck each received stock options representing the right to purchase 208,696 shares of our common stock. Dr. Watts joined the Board of Directors as of July 16, 2019. The Board of Directors granted him a new member equity award and a pro-rata award for the term from his first board meeting until March 31, 2020, upon availability from the stock option pool. As such,

Dr. Watts received stock options representing the right to purchase 156,522 shares of our common stock. These stock options vest in a series of twelve (12) successive, equal monthly installments measured from the vesting commencement date. Moreover, Dr. Watts received an RSU award with respect to 156,522 shares of our common stock. Two-fifths (2/5) of the shares subject to this RSU award vest on the second anniversary of the vesting commencement date, with the remaining balance vesting in a series of thirty-six (36) successive equal monthly installments measured from the second anniversary of the vesting commencement date, provided that, no shares will be issued until the earlier of Dr. Watts' separation from service other than for cause and the fifth anniversary of the vesting commencement date. In the event Dr. Watts is terminated for cause, this award will be forfeited and no shares will be issued.

Name	Stock Awards ($)(1)	Option Awards ($)(2)	Total ($)
Jack Schuler	—	16,689	16,689
John Patience	—	16,689	16,689
Mark C. Miller	—	16,689	16,689
Matthew Strobeck, Ph.D	—	16,689	16,689
Charles M. Watts, M.D.	20,348	12,517	32,865

(1) The amounts reported represent the aggregate grant date fair market value of the RSUs, calculated in accordance with FASB ASC Topic 718 based on the assumption that the value of each RSU was equal to $0.13.

(2) The amounts reported represent the aggregate grant date fair market value of the stock options calculated in accordance with FASB ASC Topic 718. The assumptions used in calculating the grant date fair value of the award disclosed in this column are set forth in Note 11 of our audited financial statements included elsewhere in this prospectus and under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Significant Judgments and Estimates—Stock-based compensation and common stock valuation" in this prospectus. These amounts do not correspond to the actual value that may be recognized by the named executive officers upon vesting of the applicable awards.

EXECUTIVE COMPENSATION

The following is a discussion of compensation arrangements of our named executive officers. This discussion contains forward-looking statements that are based on our current plans, considerations, expectations, and determinations regarding future compensation programs. Actual compensation programs that we adopt may differ materially from currently planned programs as summarized in this discussion. As an "emerging growth company" (as defined in the JOBS Act), we are not required to include a Compensation Discussion and Analysis and have elected to comply with the scaled disclosure requirements applicable to emerging growth companies.

Overview

Our current executive compensation program is intended to align executive compensation with our performance objectives and business strategy and to enable us to attract, motivate, retain and reward executive officers whose contributions are critical to our long-term success. The compensation paid or awarded to our executive officers is generally based on the assessment of each individual's performance compared against the business objectives established for the fiscal year as well as our historical compensation practices. New-hire executive officers' compensation is primarily determined based on the negotiations of the parties as well as our historical compensation practices. For the year ended December 31, 2019, the material elements of our executive compensation program were base salary, discretionary cash bonus and equity awards in the form of stock options.

Following this offering, we expect that our executive compensation program will evolve to reflect our status as a newly publicly-traded company, while still supporting our overall business and compensation objectives. The compensation committee of our Board of Directors (Compensation Committee) oversees our executive compensation program. In addition, during the year ended December 31, 2019, we retained an independent executive compensation consultant to help advise on elements of our executive compensation program. This section provides a discussion of the compensation paid or awarded to our Chief Executive Officer and our two other most highly compensated executive officers serving as of December 31, 2019, the end of fiscal 2019. We refer to these individuals as our "named executive officers." For the year ended December 31, 2019, our named executive officers were:

- David Brunel, Former Chief Executive Officer;
- Robin Harper Cowie, Chief Financial Officer; and
- Scott Hutton, Former Chief Operating Officer.

Effective December 31, 2019, Mr. Brunel ceased to be our Company's Chief Executive Officer. Effective January 1, 2020, Mr. Brunel became our Company's Chairman of the Board of Directors. Effective January 1, 2020, Mr. Hutton ceased to be our Chief Operating Officer and became our President and Chief Executive Officer.

Compensation of Named Executive Officers

Base Salary

Base salaries are intended to provide a level of compensation sufficient to attract and retain an effective management team, when considered in combination with the other components of our executive compensation program. The relative levels of base salary for our named executive officers are designed to reflect each executive officer's scope of responsibility and accountability to us. Please see the "Salary" column in the 2019 Summary Compensation Table for the base salary amounts received by each named executive officer during the year ended December 31, 2019.

Annual Cash Bonuses

We provide our senior leadership team with short-term incentive compensation through an annual cash bonus program. Annual bonus compensation holds executives accountable, rewards the executives based on actual business results and helps create a "pay for performance" culture. Our annual cash bonus program

provides cash incentive award opportunities based on the achievement of performance goals approved by our Compensation Committee at the beginning of each fiscal year.

Generally, our Compensation Committee establishes a Company-based performance metric as a threshold vesting criteria for any payouts for a particular annual bonus period. In determining bonus payouts, if any, individual performance of our named executive officers with respect to individual goals established at the beginning of the applicable year is only considered if that metric is met or exceeded. For 2019, the Compensation Committee determined that the Company's revenue would be the applicable Company-based metric, and at year end, measured actual revenue against targeted revenue, determined in accordance with U.S. GAAP. No payouts were earned or made under the 2019 annual cash bonus program.

Equity Awards

To further align the interests of our executive officers with the interests of our stockholders and to further focus our executive officers on our long-term performance, we have historically granted equity compensation in the form of stock options. In the year ended December 31, 2019, the Board of Directors awarded Messrs. Brunel, Hutton, and Ms. Harper Cowie stock options representing the right to purchase 270,000, 250,000, and 210,000 shares of our common stock, respectively, on a five-year vesting schedule. Two-fifths (2/5) of these stock options vest on the second anniversary of the vesting commencement date, with the remaining balance vesting in a series of thirty-six (36) successive equal monthly installments measured from the second anniversary of the vesting commencement date, subject to the award recipient's continued employment through the applicable vesting date. In the year ended December 31, 2019, the Board of Directors also awarded Messrs. Brunel, Hutton, and Ms. Harper Cowie stock options representing the right to purchase 160,000, 150,000, and 105,000 shares of our common stock, respectively, on a three-year vesting schedule subject to the achievement of applicable performance criteria. One-third (1/3) of these performance-based stock options vest after each of the first, second and third anniversaries of the vesting commencement date, subject to the Company's achievement of recognized revenue of at least $31 million, $67 million and $134 million for the years ended December 31, 2019, 2020 and 2021, respectively. The Board of Directors has sole discretion to determine if the performance hurdles are met and to determine the vesting date, and shall make such determinations within 90 days after the end of the applicable fiscal year.

Please see "Outstanding Equity Awards at Fiscal 2019 Year-End" for a summary of the outstanding equity awards held by each of the named executive officers as of 2019 year-end.

2019 Summary Compensation Table

The following table shows information regarding the compensation of our named executive officers for services performed during the year ended December 31, 2019.

Name and Principal Position	Fiscal Year	Salary ($)	Non-Equity Incentive Plan Compensation ($)(3)	Option Awards ($)(4)	Total ($)
David Brunel Former Chief Executive Officer (1)	2019	343,750	—	22,531	366,281
Scott Hutton Former Chief Operating Officer (2)	2019	298,475	—	20,959	319,434
Robin Harper Cowie Chief Financial Officer	2019	263,525	—	16,505	280,030

(1) Mr. Brunel's service as our Chief Executive Officer terminated on December 31, 2019, after which he became Chairman of our Board of Directors.
(2) Mr. Hutton's service as our Chief Operating Officer terminated on January 1, 2020, after which he became the President and Chief Executive Officer.

(3) Based on our 2019 performance measured against the Company's objectives, our Compensation Committee determined not to award payouts under the 2019 annual cash bonus program.

(4) The amounts disclosed represent the aggregate grant date fair value of the award as calculated in accordance with FASB ASC Topic 718. The assumptions used in calculating the grant date fair value of the award disclosed in this column are set forth in Note 11 of our audited financial statements included elsewhere in this prospectus. These amounts do not correspond to the actual value that may be recognized by the named executive officers upon vesting of the applicable awards.

Outstanding Equity Awards at Fiscal 2019 Year-End

The following table presents information regarding the outstanding equity awards held by each of the named executive officers as of December 31, 2019. As of the year ended December 31, 2019, none of the named executive officers held any outstanding restricted stock units or other stock awards.

Name	Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date
David Brunel	4/26/2010	41,824	—	—	2.75	4/25/2020
	4/22/2011	66,964	—	—	2.80	4/21/2021
	8/8/2011	125,000	—	—	0.56	8/7/2021
	1/30/2012	115,000	—	—	0.56	1/29/2022
	1/30/2012	50,426	—	—	3.52	1/29/2022
	2/5/2013	5,250	—	—	4.00	2/4/2023
	3/11/2013	111,500	—	—	0.58	3/10/2023
	2/4/2014	110,000	—	—	0.74	2/3/2024
	2/20/2014	85,365	—	—	4.10	2/19/2024
	4/8/2015	49,167	833(1)	—	0.74	4/7/2025
	4/7/2016	306,083	54,167(1)	—	0.14	4/6/2026
	10/14/2016	27,563	—	—	0.14	10/13/2026
	5/16/2017	116,667	83,333(1)	—	0.07	5/15/2027
	4/4/2018	76,667	123,333(1)	—	0.07	4/3/2028
	4/4/2018	400,000	—	—	0.75	12/31/2027
	3/22/2019	—	270,000(2)	160,000(3)	0.13	12/31/2028
Scott Hutton	4/4/2018	—	500,000(2)	—	0.07	4/3/2028
	3/22/2019	—	250,000(2)	150,000(3)	0.13	12/31/2028
Robin Harper Cowie	4/22/2011	15,000	—	—	0.44	4/21/2021
	2/4/2014	60,000	—	—	0.74	2/3/2024
	4/8/2015	40,000	—	—	0.74	4/7/2025
	4/7/2016	213,010	45,500(1)	—	0.14	4/6/2026
	5/16/2017	58,333	41,667(1)	—	0.07	5/15/2027
	4/4/2018	47,917	77,083(1)	—	0.07	4/3/2028
	3/22/2019	—	210,000(2)	105,000(3)	0.13	12/31/2028

(1) These stock options vest in a series of sixty (60) successive, equal monthly installments measured from the vesting commencement date.

(2) Two-fifths (2/5) of these stock options vest on the second anniversary of the vesting commencement date, with the remaining balance vesting in a series of thirty-six (36) successive equal monthly installments measured from the second anniversary of the vesting commencement date, subject to the award recipient's continued employment through the applicable vesting date.

(3) In the year ended December 31, 2019, the Board of Directors awarded Messrs. Brunel, Hutton, and Ms. Harper Cowie stock options representing the right to purchase 160,000, 150,000 and 105,000 shares of our common stock, respectively. One-third (1/3) of these performance-based stock options vest (or could have vested) after each of the first, second and third anniversaries of the vesting commencement date, subject to the Company's achievement of recognized revenue of at least $31 million, $67 million and $134 million for the years ended December 31, 2019, 2020 and 2021, respectively. The Board of Directors has sole discretion to determine if the performance hurdles are met and to determine the vesting date, and shall make such determinations within 90 days after the end of the applicable fiscal year. For the year ended December 31, 2019, the Board of Directors determined that the performance hurdle was not met. As a result one-third (1/3) of each executive's award was cancelled, and the remaining two-thirds (2/3) of each executive's award is currently outstanding.

Additional Matters

Harper Cowie Offer Letters

For the year ended December 31, 2019, Ms. Harper Cowie was party to an offer letter agreement with the Company, dated as of March 11, 2011, as amended (the 2011 Harper Cowie Offer Letter). Effective February 16, 2019, Ms. Harper Cowie's base salary was raised to $265,000 annually, and she is eligible to receive a bonus of up to 50% of her base salary if certain milestones and objectives determined by the Company were achieved.

Ms. Harper Cowie and the Company entered into a new offer letter agreement, dated as of February 23, 2020, which supersedes the 2011 Harper Cowie Offer Letter (the 2020 Harper Cowie Offer Letter). Under the terms of the 2020 Harper Cowie Offer Letter, Ms. Harper Cowie is entitled to a base salary of $290,000 annually effective the beginning of the first month after this offering, and she is eligible to receive a bonus of up to 50% of her base salary after approval from the Compensation Committee and Board of Directors that relevant objectives have been achieved. In addition, Ms. Harper Cowie is entitled to certain severance benefits in the event that her employment with the Company is terminated without Cause, as defined in the 2011 Harper Cowie Offer Letter, including but not limited to a termination following a change in control. The severance benefits consist of (i) base salary continuation for a period of 6 months following the effective date of a general release of claims, less standard deductions and withholdings, and (ii) if Ms. Harper Cowie timely elects healthcare continuation coverage under the Consolidated Omnibus Reconciliation Act of 1985, as amended (COBRA), Company-paid COBRA premiums (including in respect of coverage for eligible dependents) for a period starting on Ms. Harper Cowie's termination date and ending 12 months thereafter, subject to earlier termination if Ms. Harper Cowie becomes eligible for health coverage from a subsequent employer, or if Ms. Harper Cowie ceases to be eligible for COBRA continuation for any reason including plan termination. Any change in control which results in a change of position for Ms. Harper Cowie also results in accelerated vesting of 100% of all unvested and then outstanding options held by Ms. Harper Cowie. In order to receive the severance benefits, Ms. Harper Cowie is required to execute a release of all claims in favor of the Company which becomes irrevocable, and to be in continued compliance with cooperation, non-disparagement or confidentiality provisions contained therein and with obligations under the Company's Confidentiality and Inventions Assignment Agreement, including non-solicit provisions thereof.

Pursuant to the 2020 Harper Cowie Offer Letter, in the event Ms. Harper Cowie resigned, or if her employment was terminated by the Company for Cause or due to death or disability, Ms. Harper Cowie would be entitled to any salary earned but unpaid prior to such termination, any reimbursable business expenses that were incurred but not reimbursed as of Ms. Harper Cowie's last day of employment, and, if applicable, all accrued but unused vacation. Any unvested stock options or other equity awards shall cease to vest and be forfeited on Ms. Harper Cowie's last day of employment.

Hutton Offer Letters

For the year ended December 31, 2019, Mr. Hutton was party to an offer letter agreement with the Company, dated as of February 8, 2018, as amended (the 2018 Hutton Offer Letter). Effective February 16, 2019, Mr. Hutton's base salary was raised to $300,000 annually. Under the terms of the 2018 Hutton Offer Letter, Mr. Hutton is eligible to receive a bonus of up to 50% of his base salary if certain milestones and objectives determined by the Company are achieved. Mr. Hutton and the Company entered into a new offer letter agreement, dated as of February 23, 2020,

which supersedes the 2018 Hutton Offer Letter (the 2020 Hutton Offer Letter). Under the terms of the 2020 Hutton Offer Letter, effective January 1, 2020, Mr. Hutton's base salary was raised to $350,000 annually. Effective the beginning of the first month after this offering, Mr. Hutton's base salary will be further adjusted to $425,000 annually, and he will be eligible to receive a bonus of up to 100% of his base salary.

In addition, Mr. Hutton is entitled to certain severance benefits in the event that his employment with the Company is terminated without Cause, as defined in the 2018 Hutton Offer Letter, including but not limited to a termination following a change in control or, following a change in control, a successor's failure to assume the terms and conditions of the 2018 Hutton Offer Letter as it relates to Mr. Hutton's salary, duties and responsibilities or severance provisions. The severance benefits consist of (i) base salary continuation for a period of 12 months following the effective date of a general release of claims, less standard deductions and withholdings, and (ii) if Mr. Hutton timely elects healthcare continuation coverage under COBRA, Company-paid COBRA premiums (including in respect of coverage for eligible dependents) for a period starting on Mr. Hutton's termination date and ending 12 months thereafter, subject to earlier termination if Mr. Hutton becomes eligible for health coverage from a subsequent employer, or if Mr. Hutton ceases to be eligible for COBRA continuation for any reason including plan termination. In order to receive the severance benefits, Mr. Hutton is required to execute and allow to become effective a release of all claims in favor of the Company, which becomes irrevocable and to be in continued compliance with any cooperation, non-disparagement or confidentiality provisions contained therein and with obligations under the Company's Confidentiality and Inventions Assignment Agreement, including non-solicit provisions thereof.

Pursuant to the 2018 Hutton Offer Letter, in the event Mr. Hutton resigned, or if his employment was terminated by the Company for Cause or due to death or disability, Mr. Hutton would be entitled to any salary earned but unpaid prior to such termination, any reimbursable business expenses that were incurred but not reimbursed as of Mr. Hutton's last day of employment, and, if applicable, all accrued but unused vacation. Any unvested stock options or other equity awards shall cease to vest and be forfeited on Mr. Hutton's last day of employment. In the event that Mr. Hutton's employment is terminated by the Company without Cause, as defined in the 2020 Hutton Offer Letter, he is entitled to the same severance benefits as provided for under the 2018 Hutton Offer Letter, plus an additional payout of target bonus previously established by the Compensation Committee. Furthermore, any change in control which results in a change of position will trigger the accelerated vesting of 100% of all unvested and then outstanding options held by Mr. Hutton.

401(k) Plan

The Company participates in a multiple employer tax-qualified 401(k) savings plan which allows participants to defer eligible compensation up to the maximum amount allowed under Internal Revenue Service guidelines. The Company does not currently make any discretionary or employer matching contributions under the plan.

Equity Compensation Plans

2016 Equity Incentive Plan

In 2016, our Board of Directors adopted the 2016 Incentive Plan. The following summary describes the material terms of the 2016 Incentive Plan. This summary is not a complete description of all provisions of the 2016 Incentive Plan and is qualified in its entirety by reference to the 2016 Incentive Plan, which will be filed as an exhibit to the registration statement of which this prospectus is a part.

The purpose of the 2016 Incentive Plan is to help secure and retain persons performing services to the Company, provide incentives for such persons to exert maximum efforts for the success of the Company and any affiliate, and provide a means by which such persons may benefit from increases in value of the Company's common stock. The 2016 Incentive Plan provides for the grant of incentive stock options (within the meaning of Section 422 of the Code), nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock units (RSUs), and other stock awards. Only directors, employees and consultants who provide services to us or any affiliate of ours are eligible to receive such awards.

Stock Subject to the Plan. The number of shares reserved for issuance under the 2016 Incentive Plan as of December 31, 2019 was 10,999,384, all of which may be issued in satisfaction of incentive stock option awards.

To the extent an equity award granted under the 2016 Incentive Plan or the Company's predecessor plan expires or otherwise terminates without having been exercised or settled in full, or is settled in cash, or the shares underlying an award are forfeited, cancelled or repurchased by the Company, the shares subject to such award will become available for future issuance under the 2016 Incentive Plan. In addition, to the extent shares subject to an award are withheld to satisfy a participant's tax withholding obligations on a stock award, or are reacquired by the Company as consideration for the exercise or purchase price of a stock award, such shares will become available for future issuance under the 2016 Incentive Plan.

As of December 31, 2019, our employees, directors and consultants hold outstanding stock options granted under the 2016 Incentive Plan for the purchase of up to 9,887,733 shares of our common stock, with 3,626,699 of those options vested as of such date, and outstanding RSUs with respect to 156,522 shares of our common stock.

Plan Administration. Our Board of Directors, or a committee or committees delegated by our Board of Directors, administers the 2016 Incentive Plan. Subject to the terms of the 2016 Incentive Plan, our Board of Directors will have the authority to determine the eligibility for awards and the terms, conditions, and restrictions, including vesting terms, the number of shares subject to an award, and any performance goals applicable to awards made under the 2016 Incentive Plan. The Board of Directors also will have the authority, subject to the terms of the 2016 Incentive Plan, to construe and interpret the 2016 Incentive Plan and awards.

Participants. Employees, directors and consultants of the Company and any affiliate are eligible to participate in the 2016 Incentive Plan, if selected for participation by the plan administrator.

Stock Options and Stock Appreciation Rights. Our Board of Directors may grant incentive stock options, nonstatutory stock options, and stock appreciation rights under the 2016 Incentive Plan, provided that incentive stock options are granted only to employees of the Company, a parent corporation or a subsidiary corporation. The exercise price of stock options and stock appreciation rights under the 2016 Incentive Plan must equal to at least 100% of the fair market value of our common stock on the date of grant. The term of an option or stock appreciation right may not exceed ten years; provided, however, that an incentive stock option held by an employee who owns more than 10% of all of our classes of stock, or of certain of our affiliates, may not have a term in excess of five years, and must have an exercise price of at least 110% of the fair market value of our common stock on the grant date. Subject to the provisions of the 2016 Incentive Plan, the Board of Directors will determine the remaining terms of the options and stock appreciation rights, including the number of shares subject to the award, vesting, and the nature of any performance measures. Upon a participant's termination of service, the participant may exercise his or her option or stock appreciation right, to the extent vested (unless the Board of Directors permits otherwise), as specified in the award agreement.

Stock Awards. Our Board of Directors will decide at the time of grant whether an award will be in the form of restricted stock, RSUs, or other stock awards. The Board of Directors will determine the terms of the awards, including the number of shares subject to the award, vesting, and the nature of any performance measures. Our Board of Directors may grant other stock awards that are valued in whole or in part by reference to, or otherwise based on, shares of our common stock, including the appreciation in value thereof.

Transferability of Awards. The 2016 Incentive Plan does not allow options or stock appreciation rights to be transferred other than by will or the laws of descent and distribution following the participant's death. Restricted stock awards may be transferable by the participant only upon such terms and conditions as set forth in the award agreement, as the Board of Directors determines in its sole discretion.

Certain Adjustments. If any change is made in our common stock, without the receipt of consideration by us, such as through a merger, consolidation, reorganization, reincorporation, recapitalization, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, stock split, reverse stock split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure, or any similar equity restructuring transaction, appropriate and proportionate adjustments will be made in the number, class, and price of shares subject to each outstanding award and the number and kind of shares subject to the plan.

Corporate Transactions. In the event we experience a corporate transaction under the terms of the 2016 Incentive Plan, subject to the terms of the applicable award agreement or any other written agreement between the participant and the Company or any affiliate, or unless otherwise expressly provided by the Board of Directors at the time of grant of an award, our Board of Directors may (i) arrange for the surviving or acquiring corporation to assume or continue the stock awards, or to substitute stock awards; (ii) arrange for the assignment of any reacquisition or repurchase rights held by the Company in respect of common stock issued pursuant to stock awards to the surviving or acquiring corporation; (iii) accelerate the vesting, in whole or in part, of stock awards, and terminate such awards if not exercised; (iv) arrange for the lapse, in whole or in part, of any reacquisition or repurchase rights held by the Company with respect to stock awards; (v) cancel or arrange for the cancellation of stock awards in exchange for such cash consideration or no consideration as our Board of Directors, in its sole discretion, may consider appropriate; or (vi) make a payment (in the form determined by the Board of Directors) equal to the excess, if any, of the value of the property a participant would have received upon the exercise of a stock award immediately prior to the effective time of the corporate transaction over any exercise price payable by such participant in connection with such exercise, which payments may be made subject to conditions or contingencies applicable to shareholders of common stock in the transaction. The Board of Directors is not required to take the same action or actions with respect to all stock awards or portions thereof with respect to all participants, and may take different actions with respected to vested and unvested portions of stock awards.

Change in Control. In the event we experience a change in control under the terms of the 2016 Incentive Plan, an award may be subject to additional acceleration of vesting and exercisability as may be provided in the award agreement or in any other written agreement between the Company or any affiliate and the participant.

New Plan Benefits. The Board of Directors has the discretion to grant awards under the 2016 Incentive Plan, and therefore it is not possible at the time of filing of this prospectus to determine future awards that will be received by our named executive officers or others under the 2016 Incentive Plan. Only directors, employees, and consultants are eligible for consideration to participate in the 2016 Incentive Plan.

Amendment and Termination. The Board of Directors has the authority to amend or terminate the 2016 Incentive Plan, subject to any stockholder approval required by law. No amendment may impair the rights of a holder of an outstanding award without the consent of such holder.

Amended and Restated 2006 Employee, Director and Consultant Stock Plan

The following is a description of the material terms of the Biodesix, Inc. 2006 Employee, Director and Consultant Stock Plan, as amended and restated in 2008, 2011 and 2013 (the 2006 Incentive Plan). The summary below does not contain a complete description of all provisions of the 2006 Incentive Plan and is qualified in its entirety by reference to the plan, a copy of which will be included as an exhibit to the registration statement of which this prospectus forms a part.

The 2006 Incentive Plan was replaced by the 2016 Incentive Plan. The 2006 Incentive Plan governs outstanding awards granted prior to the adoption of the 2016 Incentive Plan, but no further awards will be granted pursuant to the 2006 Incentive Plan.

Authorized Shares. At the time the 2006 Incentive Plan was replaced by the 2016 Incentive Plan, 801,585 shares of our common stock remained reserved for issuance under the 2006 Incentive Plan and became available for issuance under the 2016 Incentive Plan. In addition, from and after the date on which the 2016 Incentive Plan was adopted, to the extent that any equity award granted under the 2006 Incentive Plan expires or otherwise terminates without having been exercised or settled in full, or is settled in cash, or the shares underlying an award are forfeited, cancelled or repurchased by the Company, the shares subject to such award will become available for future issuance under the 2016 Incentive Plan. As of December 31, 2019, our employees, directors and consultants hold outstanding stock options granted under the 2006 Incentive Plan for the purchase of up to 1,488,414 shares of our common stock, with 1,468,054 of those options vested as of such date.

Plan Administration. Our Board of Directors, or a committee delegated by our board of directors, administers the 2006 Incentive Plan. Subject to the provisions of our 2006 Incentive Plan, the plan administrator has the authority to, among other things, determine the eligibility for awards and the terms, conditions, and restrictions, including vesting terms, the number of shares subject to an award, and any performance goals applicable to awards made under the 2006 Incentive Plan, construe and interpret the 2006 Incentive Plan and all awards granted thereunder, and to exercise powers and to perform acts necessary or expedient to promote the best interests of the Company.

Participants. Employees, directors and consultants of the Company and any affiliate were eligible to participate in the 2006 Incentive Plan, if selected for participation by the plan administrator.

Types and Terms of Awards. Under the 2006 Incentive Plan, we were authorized to grant stock options, stock appreciation rights, restricted stock awards, RSUs, and other stock awards. Stock options and stock appreciation rights may not be exercised beyond a ten-year term (or such shorter period as required with respect to incentive stock options held by certain holders). The terms of the awards are specified in an underlying award agreement approved by the plan administrator.

Termination of Employment. Under the terms of the 2006 Incentive Plan relating to stock options and stock appreciation rights, upon a participant's termination of service, the participant may exercise his or her options or stock appreciation rights, to the extent vested (unless the Board of Directors permits otherwise), as specified in the award agreement.

Certain Adjustments. If any change is made in our common stock, without the receipt of consideration by us, such as through a merger, consolidation, reorganization, reincorporation, recapitalization, stock dividend, dividend in property other than cash, stock split, reverse stock split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure, or other similar transaction, appropriate and proportionate adjustments will be made in the number, class, and price of shares subject to each outstanding award and the number and kind of shares subject to the plan.

Corporate Transactions. In the event we experience a corporate transaction under the terms of the 2006 Incentive Plan, subject to the terms of the applicable instrument evidencing the stock award or any other written agreement between the participant and the Company or any affiliate, or unless otherwise expressly provided by the Board of Directors at the time of grant of an award, the surviving or acquiring corporation may assume or continue any or all outstanding stock awards, or substitute similar stock awards, and any reacquisition or repurchase rights held by the Company in respect of common stock issued pursuant to stock awards may be assigned by the Company to its successor in connection with such corporate transaction. However, if a surviving or acquiring corporation or its respective parent chooses to assume or substitute none or only a portion of the stock awards, the stock awards that have not been assumed, continued, or substituted for similar awards, unless otherwise determined by the Board of Directors, terminate if not exercised at or prior to the effective time of the corporate transaction, and any reacquisition or repurchase rights held by the Company with respect to the stock awards shall lapse. Notwithstanding the forgoing, in the event a stock award will terminate if not exercised prior to the effective time of a corporate transaction, our Board of Directors may provide, in its sole discretion, that the participant will receive a payment (in the form determined by the Board of Directors) equal to the excess, if any, of the value of the property the participant would have received upon the exercise of a stock award immediately prior to the effective time of the corporate transaction over any exercise price payable by such participant in connection with such exercise.

Change in Control. In the event we experience a change in control under the terms of the 2006 Incentive Plan, an award may be subject to additional acceleration of vesting and exercisability as may be provided in the award agreement or in any other written agreement between the Company or any affiliate and the participant.

Amendment and Termination. The Board of Directors may, at any time, amend or terminate the 2006 Incentive Plan as it shall deem advisable, subject to any stockholder approval required by law. No amendment may impair the rights of a holder of an outstanding award without the consent of such holder.

Amended and Restated Bonus-to-Options Program

The following is a description of the material terms of the Biodesix, Inc. Bonus-to-Options Program, as amended and restated in 2015 (the Bonus-to-Options Program). The Bonus-to-Options Program was initially adopted by the Board of Directors in 2008, and subsequently amended and restated in 2010, 2011 and 2015. The summary below does not contain a complete description of all provisions of the Bonus-to-Options Program and is qualified in its entirety by reference to the plan, a copy of which will be included as an exhibit to the registration statement of which this prospectus forms a part.

The Bonus-to-Options Program is only available to the Chief Executive Officer, direct reports to the Chief Executive Officer and vice presidents of the Company. The Bonus-to-Options Program allows executives to convert some or all of their annual cash bonus into fully vested, non-qualified stock options to purchase shares of our common stock. Executives must declare their intent to participate in this program not later than the last day of the calendar year prior to the taxable year for which bonuses will be awarded. For the first year in which an executive becomes eligible to participate, the executive has 30 days to declare his or her intent to participate in this program. Executives may declare their intent to convert a percentage of their bonus, up to 100%, or designate a maximum dollar amount of bonus to be converted into options under this program. None of our named executive officers received option awards under this program during the year ended December 31, 2019.

The exercise price for the options under the Bonus-to-Options Program equals the greater of the “Deemed Preferred Price” or the then current price for the shares of our common stock. The Deemed Preferred Price is determined by dividing (i) the sum of the products of (A) the share price in each of the most recent sales of preferred stock of the Company and (B) with respect to each such sale, the number of months elapsed between such sale and earlier to occur of the next subsequent sale of preferred stock of the Company or the final day of the calendar year by (ii) 12, rounded down to the nearest whole cent. Options issued under this program 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 executives. If the executive team has elected to receive options that, in the aggregate, would total more than the maximum allotment for the year, then a maximum percentage of each person’s bonus to be converted to options will be set such that the 1% threshold is not exceeded. As of December 31, 2019, our executives hold outstanding stock options granted under the Bonus-to-Options Program for the purchase of up to 1,116,295 shares of our common stock.

CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

The following is a description of certain relationships and transactions that exist or have existed or that we have entered into with our directors, executive officers, or stockholders who are known to us to beneficially own more than five percent of our voting securities and their affiliates and immediate family members, other than compensation arrangements which are described in the sections titled “Executive Compensation” and “Management—Non-Employee Director Compensation.”

We believe the terms obtained or consideration that we paid or received, as applicable, in connection with the transactions described below were comparable to terms available or the amounts that would be paid or received, as applicable, in arm’s-length transactions.

Related Party Transaction Policy

We have established a written related party transaction policy that provides procedures for the review of transactions in excess of $120,000 in any year between us and any covered person having a direct or indirect material interest with certain exceptions. Covered persons include any director, executive officer, director nominee or stockholders known to us to beneficially own 5% or more of our voting securities or any affiliates and immediate family members of the foregoing. Any such related party transactions shall require advance approval by a majority of our independent directors or by our audit committee.

Preferred Stock Financings

We have issued preferred stock from time to time to finance our operations or to make acquisitions. The purchasers of some of our preferred stock are covered persons or their affiliates.

In April 2017, May 2017, July 2017, December 2017, and February 2018, we sold an aggregate of 35,496,613 shares of Series G Preferred Stock to accredited investors at a purchase price of $0.75 per share for an aggregate purchase price of approximately $26.6 million, including conversion of indebtedness.

In June 2018, we issued an aggregate of 10,649,904 shares of Series G Preferred Stock to Integrated Diagnostics as consideration for certain assets and liabilities. See “Business—Material Agreements.” The shares issued at closing also include 2,219,981 shares that were deposited in an escrow account to be used to satisfy any indemnification obligations of the seller that may arise.

In October 2018, February 2019, and May 2019, we sold an aggregate of 23,923,188 shares of Series H Preferred Stock to accredited investors at a purchase price of $1.15 per share for an aggregate purchase price of approximately $27.5 million, including conversion of indebtedness.

The following table sets forth the number of shares of Series G Preferred Stock and Series H Preferred Stock purchased in the foregoing transactions by holders of more than 5% of our capital stock and their affiliated entities and our directors. None of our executive officers purchased shares of Series G Preferred Stock or Series H Preferred Stock in the foregoing transactions.

Name of Stockholder	Series G Preferred Stock	Series H Preferred Stock
Jack Schuler and entities affiliated with Jack Schuler(1)	12,556,930	8,959,765
Entities affiliated with John Patience(2)	7,668,930	4,182,413
Manlia Limited(3)	4,913,376	2,024,338
Matthew Strobeck and entities affiliated with Matthew Strobeck(4)	1,660,268	996,664
Life Sciences Alternative Financing and entities affiliated with Life Sciences Alternative Financing(5)	10,649,904	1,651,389
Lawrence T. Kennedy, Jr. Revocable Trust UAD 6/19/01(6)	4,000,000	2,597,236

(1) Includes shares of preferred stock purchased by Jack Schuler, a member of our Board of Directors who together with his affiliates holds more than 5% of our capital stock, and by Jack W. Schuler Living Trust, Schuler GC 2010 Continuation Trust, Schuler Grandchildren LLC, Tanya Eva Schuler, Trust, Therese Heidi Shuler, Trust, and Tino Hans Schuler, Trust.
(2) Includes shares of preferred stock purchased by John Patience Trust, dated July 23, 1993 and Patience Enterprises LP, entities affiliated with John Patience, a member of our Board of Directors who together with his affiliates holds more than 5% of our capital stock.
(3) Mr. Cawthorn, a member of our Board of Directors is an affiliate of Manlia Limited, which holds more than 5% of our capital stock.
(4) Includes shares of preferred stock purchased by Clajer Capital LLC. Dr. Strobeck, a member of our Board of Directors is an affiliate of Clajer Capital LLC.
(5) Includes shares of preferred stock acquired by Life Sciences Alternative Financing LLC and IND Funding LLC in connection with the acquisition of certain assets and liabilities of Integrated Diagnostics, Inc., which together hold more than 5% of our capital stock.
(6) Lawrence T. Kennedy, Jr. Revocable Trust UAD 6/19/01 holds more than 5% of our capital stock.

Upon the closing of this 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 will convert into one share of common stock. Upon the closing of this offering, each share of Series B-1 Preferred Stock will convert into approximately 1.16363 shares of common stock. For a description of the material rights and privileges of the preferred stock, see “Description of Capital Stock—Preferred Stock.”

Convertible Debt Financings

In December 2019, we issued $6.0 million in convertible debt (the December 2019 Notes), that were scheduled to mature in August 2020. In August 2020, the maturity date of this debt was extended to June 30, 2021. The December 2019 Notes were issued in two tranches of $3.0 million, with the first tranche funded in December 2019. Interest on the December 2019 Notes is 3% per annum and is 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. On or before the maturity date 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 at the completion of this offering. The conversion price will be equal to 80% of the price per share paid for the common stock sold in this offering. We may prepay the December 2019 Notes in whole or in part at any time with prior consent of at least two-thirds of noteholders. In the event of a corporate transaction, the unpaid principal and accrued interest shall become immediately due and payable in the same form of consideration and on the same terms and conditions as the consideration to be received by the holders of our equity securities in such transaction. The holders of the December 2019 Notes included a number of our directors and their affiliates.

In August and September 2019 we issued $10.0 million in convertible debt (the August 2019 Notes) that was scheduled to mature in August 2020. In August 2020, the maturity date of this debt was extended to June 30, 2021. Interest on the August 2019 Notes is 3% per annum and is payable in full upon maturity through the conversion to Series H Preferred Stock at the original issuance price of $1.15 per share. On or before the maturity date 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 at the completion of this offering. The conversion price would be equal to 95% of the price per share paid for the common stock sold in this offering. We may prepay the August 2019 Notes in whole or in part at any time with prior consent of at least two-thirds of the August 2019 noteholders. In the event of a corporate transaction, the unpaid principal and accrued interest shall become immediately due and payable in the same form of consideration and on the same terms and conditions as the consideration to be received by the holders of our equity securities in such transaction. The holders of the August 2019 Notes include a number of our directors and their affiliates.

In connection with the issuance of the December 2019 Notes, the conversion price on the August 2019 Notes was amended to 80% of the price per share paid for the preferred stock in any subsequent qualified financing or the common stock in an initial public offering. In addition, the conversion price to Series H preferred stock at the maturity date was amended to be 80% of the Series H original issuance price of $1.15 per share.

Investor Rights Agreement

In October 2018, we entered into an amended and restated investor rights agreement (IRA) with certain holders of our preferred stock and common stock, including certain holders of 5% of our capital stock, and including certain members of, and affiliates of, our directors and certain of our executive officers. The IRA provides the holders of our preferred stock with certain registration rights, including the right to demand that we file a registration statement or request that their shares be covered by a registration statement that we are otherwise filing. The IRA also provides certain major stockholders with information rights, which will terminate upon the closing of this offering, and a right of first refusal with regard to certain issuances of our capital stock, which will not apply to, and will terminate upon, the closing of, this offering. After the closing of this offering, the holders of shares of common stock issuable on conversion of outstanding preferred stock, will be entitled to rights with respect to the registration of their shares of common stock under the Securities Act under this agreement. For a description of these registration rights, see “Description of Capital Stock—Registration Rights.”

Voting Agreement

In October 2018, we entered into an amended and restated voting agreement with certain holders of our preferred stock and common stock, including certain holders of 5% of our capital stock, and including certain members of, and affiliates of, our directors and certain of our executive officers. Pursuant to the Voting Agreement, certain holders of our preferred stock and common stock have agreed to vote their shares in favor of specified transactions approved by the requisite supermajority of the shares of our voting capital stock held by investors party thereto. The Voting Agreement will terminate upon the closing of this offering.

Right of First Refusal and Co-Sale Agreement

In October 2018, we entered into an amended and restated right of first refusal and co-sale agreement (Co-Sale Agreement) with certain holders of our preferred stock and common stock, including certain holders of 5% of our capital stock, and including certain members of, and affiliates of, our directors and certain of our executive officers. Pursuant to the Co-Sale Agreement, we have a right of first refusal in respect of certain sales of securities by certain holders of our capital stock. To the extent we do not exercise such right in full, certain holders of our preferred stock are granted certain rights of first refusal and co-sale in respect of such sales. The Co-Sale Agreement will terminate upon the closing of this offering.

PRINCIPAL STOCKHOLDERS

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of June 30, 2020:

- each of our named executive officers;
- each of our directors;
- all of our directors and executive officers as a group; and
- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock.

We have determined beneficial ownership in accordance with the rules of the SEC, and therefore it represents sole or shared voting or investment power with respect to our securities. Unless otherwise indicated below, to our knowledge, the persons and entities named in the table have sole voting and sole investment power with respect to all shares that they beneficially owned, subject to community property laws where applicable. We have deemed shares of common stock subject to options that are currently exercisable or exercisable within 60 days of June 30, 2020, to be outstanding and to be beneficially owned by the person holding the option for the purpose of computing the percentage ownership of that person but have not treated them as outstanding for the purpose of computing the percentage ownership of any other person.

We have based percentage ownership of common stock before this offering on shares of common stock outstanding as of , 2020, which includes shares of common stock resulting from the conversion of all outstanding shares of preferred stock immediately upon the closing of this offering, as if this conversion had occurred as of , 2020. Percentage ownership of common stock after this offering assumes the sale of shares of common stock in this offering and no exercise of the underwriters' over-allotment option.

Unless otherwise indicated, the address for each beneficial owner listed in the table below is c/o Biodesix, Inc., 2970 Wilderness Place, Suite 100, Boulder, Colorado 80301.

Name and Address of Beneficial Owner	Shares Beneficially Owned Prior to this Offering		Shares Beneficially Owned Following this Offering	
	Shares	%	Shares	%
Principal Stockholders:				
Jack Schuler and entities affiliated with Jack Schuler(1)	39,726,309	32.8%		
John Patience and entities affiliated with John Patience(2)	27,443,229	22.6%		
Life Sciences Alternative Financing LLC and entities affiliated with Life Sciences Alternative Financing LLC(3)	12,301,293	10.2%		
Robert Cawthorn and entities affiliated with Robert Cawthorn(4)	10,833,313	8.9%		
Entities affiliated with Lawrence T. Kennedy, Jr.(5)	6,597,236	5.5%		
Directors and Named Executive Officers:				
Scott Hutton(6)	346,667	*		
Robin Harper Cowie(7)	513,260	*		
David Brunel(8)	1,973,227	1.6%		
Jack Schuler(9)	39,726,309	32.8%		
John Patience(10)	27,443,229	22.6%		
Robert Cawthorn(11)	10,833,313	8.9%		
Matthew Strobeck, Ph.D.(12)	5,365,866	4.4%		
Mark Miller(13)	1,454,075	1.2%		
Charles Watts, M.D.(14)	226,087	*		
Jean Franchi(15)	58,101	*		
Hany Massarany(16)	17,391	*		
All directors and named executive officers as a group (14 persons)	88,425,409	70.6%		

* Represents beneficial ownership of less than 1%.

(1) Consists of (a) 278,261 shares of common stock issuable upon the exercise of options held by Jack Schuler that are vested and exercisable within 60 days of June 30, 2020, (b) 979,601 shares of common stock issuable upon conversion of (i) 49,975 shares of Series D Preferred Stock, (ii) 51,317 shares of Series E Preferred Stock, (iii) 218,713 shares of Series F Preferred Stock, (iv) 313,690 shares of Series G Preferred Stock and (v) 345,906 shares of Series H Preferred Stock held by JS Grandchildren Trust, (c) 979,601 shares of common stock issuable upon conversion of (i) 49,975 shares of Series D Preferred Stock, (ii) 51,317 shares of Series E Preferred Stock, (iii) 218,713 shares of Series F Preferred Stock, (iv) 313,690 shares of Series G Preferred Stock and (v) 345,906 shares of Series H Preferred Stock held by Schuler Descendants Trust, (d) 2,047,488 shares of common stock issuable upon conversion of (i) 83,085 shares of Series C Preferred Stock, (ii) 99,950 shares of Series D Preferred Stock, (iii) 107,834 shares of Series E Preferred Stock, (iv) 437,427 shares of Series F Preferred Stock, (v) 627,380 shares of Series G Preferred Stock and (vi) 691,812 shares of Series H Preferred Stock held by Schuler Grandchildren LLC, (e) 2,092,584 shares of common stock issuable upon conversion of (i) 83,416 shares of Series C Preferred Stock, (ii) 99,950 shares of Series D Preferred Stock, (iii) 107,834 shares of Series E Preferred Stock, (iv) 437,427 shares of Series F Preferred Stock, (v) 627,380 shares of Series G Preferred Stock and (vi) 736,577 shares of Series H Preferred Stock held by Therese Heidi Schuler, Trust, (f) 2,092,584 shares of common stock issuable upon conversion of (i) 83,416 shares of Series C Preferred Stock, (ii) 99,950 shares of Series D Preferred Stock, (iii) 107,834 shares of Series E Preferred Stock, (iv) 437,427 shares of Series F Preferred Stock, (v) 627,380 shares of Series G Preferred Stock and (vi) 736,577 shares of Series H Preferred Stock held by Tanya Eva Schuler, Trust, (g) 29,163,606 shares of common stock issuable upon conversion of (i) 1,454,545 shares of Series B Preferred Stock, (ii) 1,250,000 shares of Series B-1 Preferred Stock, (iii) 333,333 shares of Series C Preferred Stock, (iv) 3,101,784 shares of Series D Preferred Stock, (v) 1,759,853 shares of Series E Preferred Stock, (vi) 6,273,780 shares of Series F Preferred Stock, (vii) 9,419,362 shares

of Series G Preferred Stock, and (viii) 5,366,411 shares of Series H Preferred Stock held by Jack W. Schuler Living Trust and (h) 2,092,584 shares of common stock issuable upon conversion of (i) 83,416 shares of Series C Preferred Stock, (ii) 99,950 shares of Series D Preferred Stock, (iii) 107,834 shares of Series E Preferred Stock, (iv) 437,427 shares of Series F Preferred Stock, (v) 627,380 shares of Series G Preferred Stock and (vi) 736,577 shares of Series H Preferred Stock held by Tino Hans Schuler, Trust.

(2) Consists of (a) 278,261 shares of common stock issuable upon the exercise of options held by John Patience that are vested and exercisable within 60 days of June 30, 2020, (b) 10,858,953 shares of common stock issuable upon conversion of (i) 1,454,545 shares of Series B Preferred Stock, (ii) 250,000 shares of Series D Preferred Stock, (iii) 809,200 shares of Series E Preferred Stock, (iv) 3,205,681 shares of Series F Preferred Stock, (v) 957,114 shares of Series G Preferred Stock and (vi) 4,182,413 shares of Series H Preferred Stock held by Patience Enterprises LP and (c) 16,306,015 shares of common stock issuable upon conversion of (i) 1,250,000 shares of Series B-1 Preferred Stock, (ii) 666,666 shares of Series C Preferred Stock, (iii) 2,932,534 shares of Series D Preferred Stock, (iv) 1,484,624 shares of Series E Preferred Stock, (v) 3,055,837 shares of Series F Preferred Stock and (vi) 6,711,816 shares of Series G Preferred Stock held by John Patience Trust, dated July 23, 1993.

(3) Consists of (a) 10,649,904 shares of common stock issuable upon conversion of 10,649,904 shares of Series G Preferred Stock held by IND Funding LLC and (b) 1,651,389 shares of common stock issuable upon conversion of 1,651,389 shares of Series H Preferred Stock held by Life Sciences Alternative Financing LLC.

(4) Consists of (a) 10 shares of common stock, (b) 278,261 shares of common stock issuable upon the exercise of options held by Robert Cawthorn that are vested and exercisable within 60 days of June 30, 2020 and (c) 10,555,052 shares of common stock issuable upon conversion of (i) 392,292 shares of Series A-1 Preferred Stock, (ii) 60,000 shares of Series A-2 Preferred Stock, (iii) 120,665 shares of Series A-3 Preferred Stock, (iv) 187,273 shares of Series B Preferred Stock, (v) 312,500 shares of Series B-1 Preferred Stock, (vi) 233,333 shares of Series C Preferred Stock, (vii) 299,000 shares of Series D Preferred Stock, (viii) 452,602 shares of Series E Preferred Stock, (ix) 1,508,529 shares of Series F Preferred Stock, (x) 4,913,376 shares of Series G Preferred Stock and (xi) 2,024,338 shares of Series H Preferred Stock held by Manlia Limited.

(5) Consists of (a) 4,594,651 shares of common stock issuable upon conversion of (i) 2,666,668 shares of Series G Preferred Stock and (ii) 1,927,983 shares of Series H Preferred Stock held by Lawrence T. Kennedy, Jr. Revocable Trust UAD 6/19/01 and as amended from time to time and (b) 2,002,585 shares of common stock issuable upon conversion of (i) 1,333,332 shares of Series G Preferred Stock and (ii) 669,253 shares of Series H Preferred Stock held by Lawrence T. Kennedy, Jr. Perpetuity Trust UAD 6/30/16.

(6) Consists of 346,667 shares of common stock issuable upon the exercise of options held by Scott Hutton that are vested and exercisable within 60 days of June 30, 2020.

(7) Consists of 513,260 shares of common stock issuable upon the exercise of options held by Robin Harper Cowie that are vested and exercisable within 60 days of June 30, 2020.

(8) Consists of (a) 455,477 shares of common stock, (b) 1,333,151 shares of common stock issuable upon the exercise of options held by David Brunel that are vested and exercisable within 60 days of June 30, 2020 and (c) 184,599 shares of common stock issuable upon conversion of (i) 660 shares of Series A-1 Preferred Stock, (ii) 110,399 shares of Series A-3 Preferred Stock and (iii) 73,540 shares of Series B Preferred Stock.

(9) Consists of 39,726,309 shares beneficially owned by Jack Schuler and entities affiliated with Jack Schuler, as set forth in footnote (1).

(10) Consists of 27,443,229 shares beneficially owned by John Patience and entities affiliated with John Patience, as set forth in footnote (2).

(11) Consists of 10,833,313 shares beneficially owned by Robert Cawthorn and entities affiliated with Robert Cawthorn, as set forth in footnote (4).

(12) Consists of (a) 298,261 shares of common stock issuable upon the exercise of options held by Dr. Matthew Strobeck that are vested and exercisable within 60 days of June 30, 2020 and (b) 4,937,172 shares of common stock issuable upon conversion of (i) 100,000 shares of Series C Preferred Stock, (ii) 686,250 shares of Series D Preferred Stock, (iii) 750,907 shares of Series E Preferred Stock, (iv) 903,516 shares of Series F Preferred Stock, (v) 1,660,268 shares of Series G Preferred Stock and (vi) 836,231 shares of Series H Preferred Stock held by Dr. Matthew Strobeck and (c) 130,433 shares of common stock issuable upon conversion of 130,433 shares of Series H Preferred Stock held by Clajer Capital LLC.

(13) Consists of (a) 298,261 shares of common stock issuable upon the exercise of options held by Mark Miller that are vested and exercisable within 60 days of June 30, 2020, (b) 1,089,148 shares of common stock issuable upon conversion of (i) 726,750 shares of Series D Preferred Stock and (ii) 362,398 shares of Series E Preferred Stock held by Tiger's Family LLC and (c) 66,666 shares of common stock issuable upon conversion of 66,666 shares of Series C Preferred Stock held by Mark C. Miller Trust. Mark Miller disclaims beneficial ownership of the shares the 362,398 shares of Series E Preferred Stock held by Tiger's Family LLC.

(14) Consists of 226,087 shares of common stock issuable upon the exercise of options held by Dr. Charles Watts that are vested and exercisable within 60 days of June 30, 2020.

(15) Consists of 58,101 shares of common stock issuable upon the exercise of options held by Jean Franchi that are vested and exercisable within 60 days of June 30, 2020.

(16) Consists of 17,391 shares of common stock issuable upon the exercise of options held by Hany Massarany that are vested and exercisable within 60 days of June 30, 2020.

DESCRIPTION OF CAPITAL STOCK

The description below of our capital stock and provisions of our amended and restated certificate of incorporation and amended and restated bylaws are summaries and are qualified by reference to the amended and restated certificate of incorporation and the amended and restated bylaws to be in effect upon the closing of this offering, which are filed as exhibits to the registration statement of which this prospectus is part, and by the applicable provisions of Delaware law.

General

Upon the closing of this offering, our amended and restated certificate of incorporation will authorize us to issue up to shares of common stock, $0.001 par value per share, and shares of preferred stock, $0.001 par value per share.

As of , 2020, there were shares of common stock issued and outstanding, held by stockholders of record.

As of , 2020, after giving effect to the conversion of all outstanding shares of preferred stock into shares of common stock, there would have been shares of common stock issued and outstanding, held by stockholders of record.

Common Stock

Voting Rights

Each holder of common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Under our amended and restated certificate of incorporation and amended and restated bylaws, our stockholders will not have cumulative voting rights. Because of this, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election.

Dividend Rights

Subject to preferences that may apply to any then-outstanding preferred stock, the holders of common stock are entitled to receive ratably those dividends, if any, as may be declared from time to time by the Board of Directors out of legally available funds. We do not anticipate paying any cash dividends in the foreseeable future.

Liquidation Rights

In the event of our liquidation, dissolution or winding up, holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then-outstanding shares of preferred stock.

Preemptive or Similar Rights

Holders of common stock have no preemptive, conversion or subscription rights and there are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate in the future.

Preferred Stock

As of , 2020, there were shares of preferred stock outstanding, which will be converted into shares of common stock upon the closing of the offering. On the closing of this offering and under

our amended and restated certificate of incorporation, our Board of Directors may, without further action by our stockholders, fix the rights, preferences, privileges and restrictions of up to an aggregate of shares of preferred stock in one or more series and authorize their issuance. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of common stock. Any issuance of preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders would receive dividend payments and payments on liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deterring or preventing a change of control or other corporate action. No shares of preferred stock will be outstanding immediately following the closing of this offering. We have no present plan to issue any shares of preferred stock.

Preferred Stock Financings

We have issued preferred stock from time to time to finance our operations or to make acquisitions. The purchasers of some of our preferred stock are covered persons or their affiliates.

In April 2017, May 2017, July 2017, December 2017, and February 2018, we sold an aggregate of 35,496,613 shares of Series G Preferred Stock to accredited investors at a purchase price of $0.75 per share for an aggregate purchase price of approximately $26.6 million, including conversion of indebtedness.

In June 2018, we issued an aggregate of 10,649,904 shares of Series G Preferred Stock to Integrated Diagnostics as consideration for certain assets and liabilities. See “Business—Material Agreements.” The shares issued at closing also include 2,219,981 shares that were deposited in an escrow account to be used to satisfy any indemnification obligations of the seller that may arise.

In October 2018, February 2019, and May 2019, we sold an aggregate of 23,923,188 shares of Series H Preferred Stock to accredited investors at a purchase price of $1.15 per share for an aggregate purchase price of approximately $27.5 million, including conversion of indebtedness.

Upon the closing of this 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 will convert into one share of common stock. Upon the closing of this offering, each share of Series B-1 Preferred Stock will convert into approximately 1.16363 shares of common stock.

Convertible Debt

The December 2019 Notes were scheduled to mature in August 2020, but in August 2020 we extended the maturity date of this debt to June 30, 2021. The December 2019 Notes were issued in two tranches of $3.0 million, with the first tranche funded in December 2019. Interest on the December 2019 Notes is 3% per annum and is 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. On or before the maturity date 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 at the completion of this offering. The conversion price will be equal to 80% of the price per share paid for the common stock sold in this offering. We may prepay the December 2019 Notes in whole or in part at any time with prior consent of at least two-thirds of the noteholders. In the event of a corporate transaction, the unpaid principal and accrued interest shall become immediately due and payable in the same form of consideration and on the same terms and conditions as the consideration to be received by the holders of our equity securities in such transaction. The holders of the December 2019 Notes include a number of our directors and their affiliates.

The August 2019 Notes were scheduled to mature in August 2020, but in August 2020 we extended the maturity date of this debt to June 30, 2021. Interest on the August 2019 Notes is 3% per annum and is payable

in full upon maturity through the conversion to Series H Preferred Stock at the original issuance price of $1.15 per share. On or before the maturity date 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 at the completion of this offering. The conversion price would be equal to 95% of the price per share paid for the common stock sold in this offering. We may prepay the August 2019 Notes in whole or in part at any time with prior consent of at least two-thirds of the August 2019 noteholders. In the event of a corporate transaction, the unpaid principal and accrued interest shall become immediately due and payable in the same form of consideration and on the same terms and conditions as the consideration to be received by the holders of our equity securities in such transaction. The holders of the August 2019 Notes include a number of our directors and their affiliates.

In connection with the issuance of the December 2019 Notes, the conversion price on the August 2019 Notes was amended to 80% of the price per share paid for the preferred stock in any subsequent qualified financing or the common stock in an initial public offering. In addition, the conversion price to Series H preferred stock at the maturity date was amended to be 80% of the Series H original issuance price of $1.15 per share.

The discounts on the automatic conversions created a put option liability that was separated from the December 2019 Notes. The estimated value of the put option liability as of the issuance of the December 2019 Notes and December 31, 2019 was $0.8 million. The put option liability was reflected as a debt discount on the December 2019 Notes, which is being amortized over the term of the December 2019 Notes. The unamortized debt discount was $0.7 million as of December 31, 2019.

The discounts on the automatic conversions created a put option liability that was separated from the August 2019 Notes. The estimated value of the put option liability as of the issuance of the August 2019 Notes was $0.5 million. The put option liability was reflected as a debt discount on the August 2019 Notes which is being amortized over the term of the August 2019 Notes. The unamortized debt discount was $0.3 million as of December 31, 2019.

In connection with the issuance of the December 2019 Notes, the conversion price on the August 2019 Notes was amended to 80% of the price per share paid for the preferred stock in any subsequent qualified financing or the common stock in an initial public offering. In addition, the conversion price to Series H preferred stock at the maturity date was amended to be 80% of the Series H original issuance price of $1.15 per share. The changes to the discounts on the conversions of the August 2019 Notes created an increase to the put option liability on the August 2019 Notes 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 accompany 2019 statement of operations.

As of December 31, 2019, accrued interest of $0.1 million is included in the convertible debt balance included on the accompanying balance sheet.

Warrants

We have issued warrants from time to time to purchase shares of preferred stock in conjunction with the sale of preferred stock and debt. The grant date fair value and fair value at each reporting date of the warrants was determined using the Black-Scholes option pricing model with weighted average assumptions relatively consistent with those for our granted stock options, other than term, which is the contractual term of the warrant and the use of the exercise price and current estimated fair value of the respective series of preferred stock.

The following table presents the activity for convertible preferred stock warrants outstanding (in thousands, except weighted average exercise price):

	Series D		Series E		Series G	
	Warrants	Weighted Average Exercise Price	Warrants	Weighted Average Exercise Price	Warrants	Weighted Average Exercise Price
Outstanding - December 31, 2017	907	$ 4.00	1,827	$ 5.00	—	$ —
Granted	—	—	—	—	613	0.75
Forfeited/canceled	(907)	4.00	—	—	—	—
Exercised	—	—	—	—	—	—
Outstanding - December 31, 2018	—	$ —	1,827	$ 5.00	613	$ 0.75
Granted	—	—	—	—	—	—
Forfeited/canceled	—	—	(902)	$ 5.00	—	—
Exercised	—	—	—	—	—	—
Outstanding - December 31, 2019	—	$ —	925	$ 5.00	613	$ 0.75
Weighted average remaining contractual life at December 31, 2019			0.46 years		8.0 years	

Stock Options

As of , 2020, options to purchase an aggregate of shares of common stock were outstanding under our 2006 Incentive Plan and no additional shares of common stock were reserved for future issuance under our 2006 Incentive Plan. As of , 2020, options to purchase an aggregate of shares of common stock were outstanding under our 2016 Incentive Plan, and subsequent to , 2020, we granted options to purchase an additional shares of common stock. As of , 2020, shares of common stock were reserved for future issuance under our 2016 Incentive Plan. Subsequent to , 2020, we reserved an additional shares of common stock for future issuance under our 2016 Incentive Plan. For additional information regarding the terms of these plans, see the section titled “Executive Compensation—Employee Benefit Plans.”

Registration Rights

We are party to an IRA which provides that certain holders of shares of common stock, including those shares of common stock that will be issued upon conversion of preferred stock in connection with this offering. These shares are referred to as registrable securities. The holders of these registrable securities possess registration rights pursuant to the terms of the IRA and are described in additional detail below. We, along with , as well as other stockholders, are parties to the IRA. We entered into the IRA in connection with the issuance of Series H Preferred Stock in October 2018. The following summary discusses certain material provisions of the IRA and is qualified by the full text of the agreement, which is filed as an exhibit to the registration statement of which this prospectus is a part.

The registration of shares of common stock pursuant to the exercise of registration rights described below would enable the holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective. We will pay the registration expenses (other than underwriting discounts, selling commissions and stock transfer taxes) of the shares registered pursuant to the demand, piggyback and Form S-3 registrations described below.

Generally, in an underwritten offering, if we determine in good faith in consultation with the underwriters, we have the right, subject to specified conditions, to limit the number of shares the holders may include. The

demand, piggyback and Form S-3 registration rights described below will terminate on the date five years following the closing part of this offering.

Demand Registration Rights

The holders of an aggregate of shares of common stock issuable upon conversion of outstanding shares of preferred stock will be entitled to certain demand registration rights. Ending on the date six months following the effective date of the registration statement of which this prospectus is a part, upon the written request of the holders of a majority of our registrable securities then outstanding that we file a registration statement under the Securities Act covering at least a majority of our registrable securities then outstanding, or lesser percent if the anticipated aggregate offering price, net of underwriting discounts and commissions, would exceed $5.0 million we are obligated to register the sale of all registrable securities that the holders may request in writing to be registered. We are required to effect no more than two registration statements that are declared or ordered effective. We may postpone the filing of a registration statement for up to 120 days once in a 12-month period if in the good faith judgment of our Board of Directors such registration would be seriously detrimental to us.

Piggyback Registration Rights

The holders of registrable securities will be entitled to certain piggyback registration rights.

If we register any of our securities for public sale, either for our own account or for the account of other security holders, we will also have to register all registrable securities that the holders of such securities request in writing be registered. This piggyback registration right does not apply to a registration relating to any of our stock plans, stock purchase or similar plan, a transaction under Rule 145 of the Securities Act or a registration related to stock issued upon conversion of debt securities. We, based on consultation with the underwriters of any underwritten offering will have the right to limit the number of shares registered by these holders if the underwriters determine that including all registrable securities will jeopardize the success of the offering.

Form S-3 Registration Rights

The holders of at least 10% of the registrable securities then outstanding will be entitled to certain registration rights on Form S-3. The holders of these shares can request that we register all or a portion of their shares on Form S-3 if we are eligible to file a registration statement on Form S-3 and the aggregate price to the public of the shares offered is in excess of $5.0 million. We are required to effect no more than two Form S-3 registration statements that are declared or ordered effective in any 12-month period. We may postpone the filing of a registration statement for up to 120 days not more than once in a 12-month period if in the good faith judgment of our Board of Directors such registration would be seriously detrimental to us.

Anti-Takeover Provisions

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the Board of Directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon closing of the transaction that 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 began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (i) by persons who

are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- on or after such date, the business combination is approved by the Board of Directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines a "business combination" to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines an "interested stockholder" as an entity or person who, together with the person's affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

A Delaware corporation may "opt out" of these provisions with an express provision in its original certificate of incorporation or an express provision in its amended and restated certificate of incorporation or amended and restated bylaws resulting from a stockholders' amendment approved by at least a majority of the outstanding voting shares. We have not opted out of these provisions. As a result, mergers or other takeover or change in control attempts of us may be discouraged or prevented.

Certificate of Incorporation and Bylaws to be in Effect Upon the Closing of this Offering

Among other things, our amended and restated certificate of incorporation and amended and restated bylaws will:

- permit our Board of Directors to issue up to shares of preferred stock, with any rights, preferences and privileges as they may designate, including the right to approve an acquisition or other change of control;
- provide that the authorized number of directors may be changed only by resolution of our Board of Directors;
- provide that our Board of Directors will be classified into three classes of directors;
- provide that, subject to the rights of any series of preferred stock to elect directors, directors may only be removed for cause, which removal may be effected, subject to any limitation imposed by law, by the holders of at least 66 2/3% of the voting power of all of our then-outstanding shares of the capital stock entitled to vote generally at an election of directors;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent or electronic transmission;

- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder's notice;
- provide that special meetings of our stockholders may be called only by the chairman of our Board of Directors, our chief executive officer or by our Board of Directors pursuant to a resolution adopted by a majority of the total number of authorized directors; and
- not provide for cumulative voting rights, therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose.

The amendment of any of these provisions would require approval by the holders of at least 66 2/3% of the voting power of all of our then-outstanding capital stock entitled to vote generally in the election of directors, voting together as a single class.

The combination of these provisions will make it more difficult for our existing stockholders to replace our Board of Directors as well as for another party to obtain control of us by replacing our Board of Directors. Since our Board of Directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our Board of Directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are intended to enhance the likelihood of continued stability in the composition of our Board of Directors and its policies and to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce our vulnerability to hostile takeovers and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock.

Choice of Forum

Our amended and restated certificate of incorporation will provide that the Court of Chancery of the State of Delaware will be the exclusive forum for: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a breach of fiduciary duty owed by any director, officer or other employee to us or our stockholders; (iii) any action asserting a claim against us or any director or officer or other employee arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or amended and restated bylaws; or (iv) any action asserting a claim against us or any director or officer or other employee that is governed by the internal affairs doctrine. Our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act.

Limitations of Liability and Indemnification

See the section titled "Executive Compensation—Limitations on Liability and Indemnification Matters."

Exchange Listing

Our common stock is currently not listed on any securities exchange. We have applied to list our common stock on The Nasdaq Global Market under the symbol "BDSX".

Transfer Agent and Registrar

The transfer agent and registrar for our common stock will be . The transfer agent's address , and its telephone number is .

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, no public market existed for our common stock. Future sales of shares of our common stock in the public market after this offering, and the availability of shares for future sale, could adversely affect the market price of our common stock prevailing from time to time. As described below, only a limited number of shares will be available for sale shortly after this offering due to contractual and legal restrictions on resale. Nonetheless, sales of substantial amounts of our common stock, or the perception that these sales could occur, could adversely affect prevailing market prices for our common stock and could impair our future ability to raise equity capital.

Sales of Restricted Shares

Based on the number of shares outstanding on , 2020, upon the closing of this offering, shares of common stock will be outstanding, assuming no exercise of the underwriters' over-allotment option, and no exercise of outstanding options. All of the shares of common stock sold in this offering will be freely tradable without restrictions or further registration under the Securities Act, except for any shares sold to our "affiliates," as that term is defined under Rule 144 under the Securities Act.

The remaining shares of common stock and common stock subject to stock options will be on issuance "restricted securities," as that term is defined in Rule 144 under the Securities Act. Restricted securities may be sold in the public market only if registered under the Securities Act or if they qualify for exemption from registration under Rules 144 or 701 under the Securities Act, which are summarized below. Restricted securities may also be sold outside of the United States to non-United States persons in accordance with Rule 904 of Regulation S.

Rule 144

In general, persons who have beneficially owned restricted shares of our common stock for at least six months, and any of our affiliates who own either restricted or unrestricted shares of our common stock, are entitled to sell their securities without registration with the SEC under an exemption from registration provided by Rule 144 under the Securities Act.

In general, a person who has beneficially owned restricted shares of our common stock for at least six months would be entitled to sell their securities provided that (i) such person is not deemed to have been one of our affiliates at the time of, or at any time during the 90 days preceding, a sale, (ii) we have been subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale, and (iii) we are current in our Exchange Act reporting at the time of sale. Persons who have beneficially owned restricted shares of our common stock for at least six months, but who are our affiliates at the time of, or any time during the 90 days preceding, a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three-month period only a number of securities that does not exceed the greater of either of the following:

- 1% of the number of shares of common stock then outstanding, which will equal approximately shares immediately after the closing of this offering based on the number of shares of common stock outstanding as of , 2020; or
- the average weekly trading volume of our common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale;

provided, in each case that we have been subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Such sales both by affiliates and by non-affiliates must also comply with the manner of sale, current public information and notice provisions of Rule 144.

Substantially all of the restricted shares are subject to lock-up agreements as described below and in the section titled "Underwriters."

Rule 701

Rule 701 under the Securities Act, as in effect on the date of this prospectus, permits resales of shares in reliance upon Rule 144 but without compliance with certain restrictions of Rule 144, including the holding period requirement. Most of our employees, executive officers or directors who purchased shares under a written compensatory plan or contract may be entitled to rely on the resale provisions of Rule 701, but all holders of Rule 701 shares are required to wait until 90 days after the date of this prospectus before selling their shares. However, substantially all Rule 701 shares are subject to lock-up agreements as described below and in the section titled "Underwriters" and will become eligible for sale upon the expiration of the restrictions set forth in those agreements.

Form S-8 Registration Statements

As soon as practicable after the closing of this offering, we intend to file with the SEC one or more registration statements on Form S-8 under the Securities Act to register the shares of common stock that are issuable pursuant to our 2006 Incentive Plan and 2016 Incentive Plan. These registration statements will become effective immediately upon filing. Shares covered by these registration statements will then be eligible for sale in the public markets, subject to vesting restrictions, the applicable lock-up agreements described below and Rule 144 limitations applicable to affiliates.

Lock-Up Agreements

We and all of our directors and officers, as well as the other holders of substantially all of our common stock and securities convertible into or exercisable or exchangeable for our common stock outstanding immediately upon the closing of this offering, have agreed with Morgan Stanley & Co. LLC and William Blair & Company, L.L.C. on behalf of the underwriters that, for a period ending on and including the 180th day following the date of this prospectus, subject to certain exceptions, we and they will not, and will not publicly disclose an intention to, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock, file any registration statement with the SEC relating to the offering of any shares of common stock or any securities convertible into or exercisable or exchangeable for common stock, or enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the common stock, except with the prior written consent of Morgan Stanley & Co. LLC and William Blair & Company, L.L.C., in their sole discretion, with or without notice, on behalf of the underwriters. See the section titled "Underwriters" for a more complete description of the lock-up agreements with the underwriters.

In addition to the restrictions contained in the lock-up agreements described above, we have entered into agreements with certain security holders, including our IRA and our standard forms of notice of exercise under our 2006 Incentive Plan and our 2016 Incentive Plan, that contain market stand-off provisions imposing restrictions on the ability of such security holders to offer, sell or transfer our equity securities for a period ending on and including the 180th day following the date of this prospectus.

Registration Rights

Upon the closing of this offering, the holders of shares of our common stock issuable upon conversion of outstanding shares of preferred stock, or their transferees, will be entitled to certain rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act immediately upon the effectiveness of the registration. See the section titled "Description of Capital Stock—Registration Rights" for additional information.

MATERIAL UNITED STATES FEDERAL INCOME TAX CONSEQUENCES TO NON-UNITED STATES HOLDERS OF OUR COMMON STOCK

The following is a summary of the material United States federal income tax consequences to non-United States holders (as defined below) of the acquisition, ownership and disposition of our common stock issued pursuant to this offering. This discussion is not a complete analysis of all potential United States federal income tax consequences relating thereto, does not address the potential application of the Medicare contribution tax on net investment income, and does not address any estate or gift tax consequences or any tax consequences arising under any state, local or foreign tax laws, or any other United States federal tax laws. This discussion is based on the Code and applicable Treasury Regulations promulgated thereunder, judicial decisions and published rulings and administrative pronouncements of the Internal Revenue Service (IRS) all as in effect as of the date hereof. These authorities are subject to differing interpretations and may change, possibly retroactively, resulting in United States federal income tax consequences different from those discussed below. We have not requested a ruling from the IRS with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS or a court will agree with such statements and conclusions.

This discussion is limited to non-United States holders who purchase our common stock pursuant to this offering and who hold our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all of the United States federal income tax consequences that may be relevant to a particular holder in light of such holder's particular circumstances. This discussion also does not consider any specific facts or circumstances that may be relevant to holders subject to special rules under the United States federal income tax laws, including:

- certain former citizens or long-term residents of the United States;
- partnerships or other pass-through entities (and investors therein);
- "controlled foreign corporations";
- corporations that accumulate earnings to avoid United States federal income tax;
- banks, financial institutions, investment funds, insurance companies, brokers or dealers in securities;
- tax-exempt organizations and governmental organizations;
- foreign pension funds;
- tax-qualified retirement plans;
- persons subject to the alternative minimum tax;
- persons that own, or have owned, actually or constructively, more than 5% of our common stock;
- accrual-method taxpayers subject to special tax accounting rules under Section 451(b) of the Code;
- persons who have elected to mark securities to market; and
- persons holding our common stock as part of a hedging or conversion transaction or straddle, or a constructive sale, or other risk reduction strategy or integrated investment.

If an entity or arrangement that is classified as a partnership for United States federal income tax purposes holds our common stock, the United States federal income tax treatment of a partner in the partnership will generally depend on the status of the partner and the activities of the partnership. Partnerships (including entities or arrangements treated as partnerships for United States federal income tax purposes) holding our common stock and the partners in such partnerships are urged to consult their tax advisors about the particular United States federal income tax consequences to them of holding and disposing of our common stock.

PROSPECTIVE INVESTORS SHOULD CONSULT THEIR TAX ADVISORS REGARDING THE PARTICULAR UNITED STATES FEDERAL INCOME TAX CONSEQUENCES TO THEM OF ACQUIRING, OWNING AND DISPOSING OF OUR COMMON STOCK, AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL OR FOREIGN TAX LAWS, AN APPLICABLE TAX TREATY OR ANY OTHER UNITED STATES FEDERAL TAX LAWS. IN ADDITION, YOU SHOULD ALSO CONSULT WITH YOUR TAX ADVISOR WITH RESPECT TO POTENTIAL CHANGES IN UNITED STATES FEDERAL TAX LAW AS WELL AS POTENTIAL CHANGES IN STATE, LOCAL OR FOREIGN TAX LAWS.

Definition of Non-United States Holder

For purposes of this discussion, a non-United States holder is any beneficial owner of our common stock that is not a "United States person" or a partnership (including any entity or arrangement treated as a partnership) for United States federal income tax purposes. A United States person is any person that, for United States federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation (or entity treated as a corporation for United States federal income tax purposes) created or organized under the laws of the United States, any state thereof or the District of Columbia;
- an estate, the income of which is subject to United States federal income tax regardless of its source; or
- a trust (1) whose administration is subject to the primary supervision of a United States court and which has one or more United States persons who have the authority to control all substantial decisions of the trust or (2) that has a valid election in effect under applicable Treasury Regulations to be treated as a United States person.

Distributions on Our Common Stock

As described under the section titled "Dividend Policy," we have not paid and do not anticipate paying dividends in the foreseeable future. However, if we make cash or other property distributions on our common stock, such distributions will constitute dividends for United States federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under United States federal income tax principles. Amounts not treated as dividends for United States federal income tax purposes will constitute a return of capital and will first be applied against and reduce a holder's tax basis in our common stock, but not below zero. Any excess will be treated as gain realized on the sale or other disposition of our common stock and will be treated as described under the section titled "—Gain on Disposition of Our Common Stock" below.

Subject to the discussions below regarding effectively connected income, backup withholding and Sections 1471 through 1474 of the Code (commonly referred to as FATCA), dividends paid to a non-United States holder of our common stock generally will be subject to United States federal withholding tax at a rate of 30% of the gross amount of the dividends or such lower rate specified by an applicable income tax treaty. To receive the benefit of a reduced treaty rate, a non-United States holder must furnish us or our paying agent with a valid IRS Form W-8BEN or IRS Form W-8BEN-E (or applicable successor form) certifying such holder's qualification for the reduced rate. This certification must be provided to us or our paying agent before the payment of dividends and must be updated periodically. If the non-United States holder holds the stock through a financial institution or other agent acting on the non-United States holder's behalf, the non-United States holder will be required to provide appropriate documentation to the agent, which then will be required to provide certification to us or our paying agent, either directly or through other intermediaries.

Non-United States holders that do not provide the required certification on a timely basis, but that qualify for a reduced treaty rate, may be eligible to obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS.

If a non-United States holder holds our common stock in connection with the conduct of a trade or business in the United States, and dividends paid on our common stock are effectively connected with such holder's United States trade or business (and are attributable to such holder's permanent establishment in the United States if required by an applicable tax treaty), the non-United States holder will be exempt from United States federal withholding tax. To claim the exemption, the non-United States holder must generally furnish a valid IRS Form W-8ECI (or applicable successor form) to the applicable withholding agent certifying eligibility for exemption.

However, any such effectively connected dividends paid on our common stock generally will be subject to United States federal income tax on a net income basis at the regular graduated United States federal income tax rates in the same manner as if such holder were a resident of the United States. A non-United States holder that is a foreign corporation also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year (as adjusted for certain items), which will include effectively connected dividends. Non-United States holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

Gain on Disposition of Our Common Stock

Subject to the discussions below regarding backup withholding and FATCA, a non-United States holder generally will not be subject to United States federal income tax on any gain realized on the sale or other disposition of our common stock, unless:

- the gain is effectively connected with the non-United States holder's conduct of a trade or business in the United States, and if required by an applicable income tax treaty, is attributable to a permanent establishment maintained by the non-United States holder in the United States;
- the non-United States holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition, and certain other requirements are met; or
- our common stock constitutes a "United States real property interest" by reason of our status as a United States real property holding corporation (USRPHC) for United States federal income tax purposes at any time within the shorter of the five-year period preceding the disposition or the non-United States holder's holding period for our common stock, and our common stock is not regularly traded on an established securities market during the calendar year in which the sale or other disposition occurs.

Determining whether we are a USRPHC depends on the fair market value of our United States real property interests relative to the fair market value of our other trade or business assets and our foreign real property interests. We believe that we are not currently and do not anticipate becoming a USRPHC for United States federal income tax purposes, although there can be no assurance we will not in the future become a USRPHC.

Gain described in the first bullet point above generally will be subject to United States federal income tax on a net income basis at the regular graduated United States federal income tax rates in the same manner as if such holder were a resident of the United States. A non-United States holder that is a foreign corporation also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year (as adjusted for certain items), which will include effectively connected gain. Gain described in the second bullet point above will be subject to United States federal income tax at a flat 30% rate (or such lower rate specified by an applicable income tax treaty), but may be offset by certain United States-source capital losses (even though the individual is not considered a resident of the United States), provided that the non-United States holder has timely filed United States federal income tax returns with respect to such losses. Non-United States holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

Information Reporting and Backup Withholding

Annual reports are required to be filed with the IRS and provided to each non-United States holder indicating the amount of dividends on our common stock paid to such holder and the amount of any tax withheld with respect to those dividends. These information reporting requirements apply even if no withholding was required because the dividends were effectively connected with the holder's conduct of a United States trade or business, or withholding was reduced or eliminated by an applicable income tax treaty. This information also may be made available under a specific treaty or agreement with the tax authorities in the country in which the non-United States holder resides or is established. Backup withholding, currently at a 24% rate, generally will not apply to payments to a non-United States holder of dividends on or the gross proceeds of a disposition of our common stock provided the non-United States holder furnishes the required certification for its non-United States status, such as by providing a valid IRS Form W-8BEN, IRS Form W-8BEN-E or IRS Form W-8ECI, or certain other requirements are met. Backup withholding may apply if the payer has actual knowledge, or reason to know, that the holder is a United States person who is not an exempt recipient.

Information reporting and backup withholding generally are not required with respect to the amount of any proceeds from the sale or other disposition of our common stock by a non-United States holder outside the United States through a foreign office of a foreign broker that does not have certain specified connections to the United States. However, if a non-United States holder sells or otherwise disposes of its shares of common stock through a United States broker or the United States offices of a foreign broker, the broker will generally be required to report the amount of proceeds paid to the non-United States holder to the IRS and also backup withhold on that amount unless such non-United States holder provides appropriate certification to the broker of its status as a non-United States person (and the payer does not have actual knowledge or reason to know that such holder is a United States person) or otherwise establishes an exemption. Information reporting will also apply if a non-United States holder sells its shares of common stock through a foreign broker deriving more than a specified percentage of its income from United States sources or having certain other connections to the United States, unless such broker has documentary evidence in its records that such non-United States holder is a non-United States person (and the payer does not have actual knowledge or reason to know that such holder is a United States person) and certain other conditions are met, or such non-United States holder otherwise establishes an exemption.

Backup withholding is not an additional tax. If any amount is withheld under the backup withholding rules, the non-United States holder should consult with a United States tax advisor regarding the possibility of and procedure for obtaining a refund or a credit against the non-United States holder's United States federal income tax liability, if any.

Withholding on Foreign Entities

FATCA imposes a United States federal withholding tax of 30% on dividends paid on our common stock to a "foreign financial institution" (as specially defined under these rules) unless such institution enters into an agreement with the United States government to withhold on certain payments and to collect and provide to the United States tax authorities substantial information regarding certain United States account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with United States owners) or an exemption applies. FATCA also generally will impose a United States federal withholding tax of 30% on dividends paid on our common stock to a non-financial foreign entity unless such entity provides the withholding agent a certification identifying certain direct and indirect United States owners of the entity or an exemption applies. An intergovernmental agreement between the United States and an applicable foreign country may modify these requirements. Under certain circumstances, a non-United States holder might be eligible for refunds or credits of such taxes. FATCA currently applies to dividends paid on our common stock. The Treasury Secretary has issued proposed regulations providing that the withholding provisions under FATCA do not apply with respect to gross proceeds from a sale or other disposition of our common stock, which may be relied upon by taxpayers until final regulations are issued.

Prospective investors are encouraged to consult with their own tax advisors regarding the possible implications of this legislation on their investment in our common stock.

UNDERWRITERS

Under the terms and subject to the conditions in an underwriting agreement dated the date of this prospectus, the underwriters named below, for whom Morgan Stanley & Co. LLC and William Blair & Company, L.L.C. are acting as representatives, have severally agreed to purchase, and we have agreed to sell to them, severally, the number of shares indicated below:

Name	Number of Shares
Morgan Stanley & Co. LLC	
William Blair & Company, L.L.C.	
Canaccord Genuity LLC	
BTIG, LLC	
Total:	

The underwriters and the representatives are collectively referred to as the "underwriters" and the "representatives," respectively. The underwriters are offering the shares of common stock subject to their acceptance of the shares from us and subject to prior sale. The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the shares of common stock offered by this prospectus are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriters are obligated to take and pay for all of the shares of common stock offered by this prospectus if any such shares are taken. However, the underwriters are not required to take or pay for the shares covered by the underwriters' over-allotment option described below.

The underwriters initially propose to offer part of the shares of common stock directly to the public at the offering price listed on the cover page of this prospectus and part to certain dealers at a price that represents a concession not in excess of $ per share under the public offering price. After the initial offering of the shares of common stock, the offering price and other selling terms may from time to time be varied by the representatives.

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to additional shares of common stock at the public offering price listed on the cover page of this prospectus, less underwriting discounts and commissions. The underwriters may exercise this option solely for the purpose of covering over-allotments, if any, made in connection with the offering of the shares of common stock offered by this prospectus. To the extent the option is exercised, each underwriter will become obligated, subject to certain conditions, to purchase about the same percentage of the additional shares of common stock as the number listed next to the underwriter's name in the preceding table bears to the total number of shares of common stock listed next to the names of all underwriters in the preceding table.

The following table shows the per share and total public offering price, underwriting discounts and commissions, and proceeds before expenses to us. These amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase up to an additional shares of common stock.

	Per Share	Total	
		No Exercise	Full Exercise
Public offering price	$	$	$
Underwriting discounts and commissions to be paid by us:	$	$	$
Proceeds, before expenses, to us	$	$	$

The estimated offering expenses payable by us, exclusive of the underwriting discounts and commissions, are approximately $. We have agreed to reimburse the underwriters for expenses relating to clearance of this offering with the Financial Industry Regulatory Authority up to $.

The underwriters have informed us that they do not intend sales to discretionary accounts to exceed 5% of the total number of shares of common stock offered by them.

We intend to apply to list our common stock on the Nasdaq Global Market under the trading symbol “BDSX”.

We and all directors and officers and the holders of substantially all of our outstanding stock and stock options have agreed that, without the prior written consent of the representatives on behalf of the underwriters, we and they will not, and will not publicly disclose an intention to, during the period ending 180 days after the date of this prospectus (the restricted period):

- offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock;
- file any registration statement with the Securities and Exchange Commission relating to the offering of any shares of common stock or any securities convertible into or exercisable or exchangeable for common stock; or
- enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the common stock.

whether any such transaction described above is to be settled by delivery of common stock or such other securities, in cash or otherwise. In addition, we and each such person agrees that, without the prior written consent of the representatives on behalf of the underwriters, we or such other person will not, during the restricted period, make any demand for, or exercise any right with respect to, the registration of any shares of common stock or any security convertible into or exercisable or exchangeable for common stock.

The restrictions described in the immediately preceding paragraph to do not apply to:

- the sale of shares to the underwriters;
- the issuance by the Company of shares of common stock upon the exercise of an option or a warrant or the conversion of a security outstanding on the date of this prospectus of which the underwriters have been advised in writing;
- transactions by any person other than us relating to shares of common stock or other securities acquired in open market transactions after the completion of the offering of the shares; provided that no filing under Section 16(a) of the Exchange Act, is required or voluntarily made in connection with subsequent sales of the common stock or other securities acquired in such open market transactions; or
- facilitating the establishment of a trading plan on behalf of a shareholder, officer or director of the Company pursuant to Rule 10b5-1 under the Exchange Act for the transfer of shares of common stock, provided that (i) such plan does not provide for the transfer of common stock during the restricted period and (ii) to the extent a public announcement or filing under the Exchange Act, if any, is required of or voluntarily made by the Company regarding the establishment of such plan, such announcement or filing shall include a statement to the effect that no transfer of common stock may be made under such plan during the restricted period.

The representatives, in their sole discretion, may release the common stock and other securities subject to the lock-up agreements described above in whole or in part at any time.

In order to facilitate the offering of the common stock, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of the common stock. Specifically, the underwriters may sell

more shares than they are obligated to purchase under the underwriting agreement, creating a short position. A short sale is covered if the short position is no greater than the number of shares available for purchase by the underwriters under the over-allotment option described above. The underwriters can close out a covered short sale by exercising the over-allotment option or purchasing shares in the open market. In determining the source of shares to close out a covered short sale, the underwriters will consider, among other things, the open market price of shares compared to the price available under the over-allotment option. The underwriters may also sell shares in excess of the over-allotment option, creating a naked short position. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in this offering. As an additional means of facilitating this offering, the underwriters may bid for, and purchase, shares of common stock in the open market to stabilize the price of the common stock. These activities may raise or maintain the market price of the common stock above independent market levels or prevent or retard a decline in the market price of the common stock. The underwriters are not required to engage in these activities and may end any of these activities at any time.

We and the underwriters have agreed to indemnify each other against certain liabilities, including liabilities under the Securities Act.

A prospectus in electronic format may be made available on websites maintained by one or more underwriters, or selling group members, if any, participating in this offering. The representatives may agree to allocate a number of shares of common stock to underwriters for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters that may make Internet distributions on the same basis as other allocations.

Other Relationships

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. Certain of the underwriters and their respective affiliates have, from time to time, performed, and may in the future perform, various financial advisory and investment banking services for us, for which they received or will receive customary fees and expenses.

In addition, in the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers and may at any time hold long and short positions in such securities and instruments. Such investment and securities activities may involve our securities and instruments. The underwriters and their respective affiliates may also make investment recommendations or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long or short positions in such securities and instruments.

Pricing of the Offering

Prior to this offering, there has been no public market for our common stock. The initial public offering price was determined by negotiations between us and the representatives. Among the factors considered in determining the initial public offering price were our future prospects and those of our industry in general, our sales, earnings and certain other financial and operating information in recent periods, and the price-earnings ratios, price-sales ratios, market prices of securities, and certain financial and operating information of companies engaged in activities similar to ours.

Selling Restrictions

Canada

The shares of our common stock may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the shares of our common stock must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

European Economic Area

In relation to each Member State of the EEA (each, a Member State), no securities have been offered or will be offered pursuant to the offering to the public in that Member State prior to the publication of a prospectus in relation to the securities which has been approved by the competent authority in that Member State or, where appropriate, approved in another Member State and notified to the competent authority in that Member State, all in accordance with the Prospectus Regulation, except that offers of securities may be made to the public in that Member State at any time under the following exemptions under the Prospectus Regulation:

(a) to any legal entity which is a qualified investor as defined in the Prospectus Regulation;

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined in the Prospectus Regulation), subject to obtaining the prior consent of the representatives; or

(c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of shares shall require us or any of the representatives to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation and each person who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with each of the representatives and us that it is a "qualified investor" as defined in the Prospectus Regulation.

In the case of any shares being offered to a financial intermediary as that term is used in Article 5 of the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a nondiscretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any shares to the public other than their offer or resale in a Member State to qualified investors as so defined or in circumstances in which the prior consent of the representatives has been obtained to each such proposed offer or resale.

For the purposes of this provision, the expression an "offer of shares to the public" in relation to any shares in any Member State means the communication in any form and by means of sufficient information on the terms of the offer and the shares to be offered so as to enable an investor to decide to purchase shares, the expression "Prospectus Regulation" means Regulation (EU) 2017/1129 (as amended).

United Kingdom

Each underwriter has represented and agreed that:

(a) it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000 (FSMA) received by it in connection with the issue or sale of the shares of our common stock in circumstances in which Section 21(1) of the FSMA does not apply to us; and

(b) it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares of our common stock in, from or otherwise involving the United Kingdom.

Japan

No registration pursuant to Article 4, paragraph 1 of the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) (the FIEL) has been made or will be made with respect to the solicitation of the application for the acquisition of the shares of common stock.

Accordingly, the shares of common stock have not been, directly or indirectly, offered or sold and will not be, directly or indirectly, offered or sold in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan) or to others for re-offering or re-sale, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan except pursuant to an exemption from the registration requirements, and otherwise in compliance with, the FIEL and the other applicable laws and regulations of Japan.

For Qualified Institutional Investors (QII)

Please note that the solicitation for newly-issued or secondary securities (each as described in Paragraph 2, Article 4 of the FIEL) in relation to the shares of common stock constitutes either a “QII only private placement” or a “QII only secondary distribution” (each as described in Paragraph 1, Article 23-13 of the FIEL). Disclosure regarding any such solicitation, as is otherwise prescribed in Paragraph 1, Article 4 of the FIEL, has not been made in relation to the shares of common stock. The shares of common stock may only be transferred to QIIs.

For Non-QII Investors

Please note that the solicitation for newly-issued or secondary securities (each as described in Paragraph 2, Article 4 of the FIEL) in relation to the shares of common stock constitutes either a “small number private placement” or a “small number private secondary distribution” (each as is described in Paragraph 4, Article 23-13 of the FIEL). Disclosure regarding any such solicitation, as is otherwise prescribed in Paragraph 1, Article 4 of the FIEL, has not been made in relation to the shares of common stock. The shares of common stock may only be transferred en bloc without subdivision to a single investor.

Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (SIX) or on any other stock exchange or regulated trading facility in Switzerland. This document does not constitute a prospectus within the meaning of, and has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, the Company, the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA (FINMA), and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes (CISA). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed upon for us by Sidley Austin LLP, San Francisco, California. Certain legal matters in connection with this offering will be passed upon for the underwriters by Davis Polk & Wardwell LLP, New York, New York. Partners of Sidley Austin LLP own less than 1% of our outstanding common stock.

EXPERTS

The financial statements of Biodesix, Inc. as of December 31, 2019 and 2018, and for each of the years in the two-year period ended December 31, 2019, have been included herein and in the registration statement in reliance upon the report of KPMG LLP, independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act, with respect to the shares of common stock being offered by this prospectus. This prospectus, which constitutes part of the registration statement, does not contain all of the information in the registration statement and its exhibits. For further information with respect to our company and the common stock offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

We are not currently subject to the informational requirements of the Exchange Act. Upon the closing of this offering, we will be subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements and other information with the SEC. The SEC also maintains a website (*http://www.sec.gov*) that contains reports, proxy and information statements and other information that we file electronically with the SEC. We also maintain a website at *www.biodesix.com*, at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained on, or accessible from, or hyperlinked to, our website is not part of this prospectus by reference or otherwise.

BIODESIX, INC.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of
Directors Biodesix, Inc.:

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Biodesix, Inc. (the Company) as of December 31, 2019 and 2018, the related statements of operations, changes in convertible preferred stock and stockholders' deficit, and cash flows for each of the years in the two-year period ended December 31, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2019, 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 and in accordance with auditing standards generally accepted in the United States of America. 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

We have served as the Company's auditor since 2016.

/s/ KPMG LLP

Denver, Colorado
May 27, 2020, except for earnings per share and Note 1(aa), as to which the date is August 12, 2020

BIODESIX, INC.

STATEMENTS OF OPERATIONS
(in thousands, except share data)

	For the Years Ended December 31,	
	2019	2018
Revenues	$ 24,552	$ 20,432
Operating expenses		
Direct costs and expenses	6,074	4,406
Research and development	10,468	8,188
Sales, marketing, general and administrative	30,637	25,899
Accretion of contingent consideration	3,451	1,537
Change in fair value of contingent consideration	663	3,863
Total operating expenses	51,293	43,893
Loss from operations	(26,741)	(23,461)
Other income (expense)		
Interest income	55	24
Interest expense	(3,008)	(2,916)
Change in fair value of warrant liability	(104)	87
Loss on debt extinguishment	—	(202)
Change in fair value of put option liability	(2,000)	—
Other	1,072	302
Total other expense	(3,985)	(2,705)
Net loss	$ (30,726)	$ (26,166)
Net loss per share, basic and diluted	$ (21.31)	$ (22.07)
Weighted-average shares outstanding, basic and diluted	1,441,925	1,185,858
Pro forma net loss per share, basic and diluted (unaudited)	$ (0.20)	
Pro forma weighted-average shares outstanding, basic and diluted (unaudited)	155,126	

See notes to financial statements.

BIODESIX, INC.

BALANCE SHEETS
(in thousands, except share data)

	December 31, 2019	December 31, 2018
Assets		
Current assets		
Cash and cash equivalents	$ 5,286	$ 5,914
Accounts receivable	5,292	1,892
Other current assets	2,122	2,107
Total current assets	12,700	9,913
Non-current assets		
Property and equipment, net	2,120	1,388
Intangible assets, net	15,092	16,852
Deposits	90	100
Goodwill	11,631	10,804
Total non-current assets	28,933	29,144
Total assets	$ 41,633	$ 39,057
Liabilities and Stockholders' Deficit		
Current liabilities		
Accounts payable	$ 1,717	$ 886
Accrued liabilities	4,180	3,090
Deferred revenue	1,283	492
Convertible debt payable	12,159	—
Put option liability	3,261	—
Total current liabilities	22,600	4,468
Non-current liabilities		
Warrant liability	329	268
Other liabilities	358	290
Long-term notes payable	23,812	23,099
Contingent consideration	29,114	25,000
Total non-current liabilities	53,613	48,657
Total liabilities	76,213	53,125
Commitments and contingencies		
Convertible Preferred stock		
Convertible preferred stock, $0.001 par value, 174,237,067 (2019) and 156,350,836 (2018) authorized; 118,766,273 (2019) and 110,070,652 (2018) issued and outstanding; liquidation preference of $202,582 (2019)	193,959	183,962
Stockholders' deficit		
Common stock, $0.001 par value, 190,000,000 (2019) and 180,000,000 (2018) authorized; 1,513,498 (2019) and 1,275,791 (2018) issued and outstanding	1	1
Additional paid-in capital	2,324	2,107
Accumulated deficit	(230,864)	(200,138)
Total stockholders' deficit	(228,539)	(198,030)
Total liabilities and stockholders' deficit	$ 41,633	$ 39,057

See notes to financial statements.

BIODESIX, INC.

STATEMENTS OF CHANGES IN CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
FOR THE YEARS ENDED DECEMBER 31, 2019 AND 2018
(in thousands)

	Series A-1		Series A-2		Series A-3		Series B		Series B-1	
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount
Balance—December 31, 2017	700	$ 800	267	$ 400	750	$1,672	3,642	$9,907	2,999	$9,551
Cumulative effect of ASC 606 Adoption	—	—	—	—	—	—	—	—	—	—
Exercise of stock options	—	—	—	—	—	—	—	—	—	—
Issuance of Series G Preferred Stock—net of issuance costs of $11	—	—	—	—	—	—	—	—	—	—
Issuance of Series G Preferred Stock related to business combination	—	—	—	—	—	—	—	—	—	—
Issuance of Series H Preferred Stock, net of issuance costs of $44	—	—	—	—	—	—	—	—	—	—
Issuance of Series H for debt conversion	—	—	—	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	—	—
Balance—December 31, 2018	700	$ 800	267	$ 400	750	$1,672	3,642	$9,907	2,999	$9,551
Exercise of stock options	—	—	—	—	—	—	—	—	—	—
Issuance of Series H Preferred Stock, net of issuance costs of $3	—	—	—	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	—	—
Balance—December 31, 2019	700	$ 800	267	$ 400	750	$1,672	3,642	$9,907	2,999	$9,551

See notes to financial statements.

BIODESIX, INC.

STATEMENTS OF CHANGES IN CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
FOR THE YEARS ENDED DECEMBER 31, 2019 AND 2018
(in thousands)

(Continued from the previous page)

	Series C		Series D		Series E		Series F	
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount
Balance—December 31, 2017	2,357	$ 7,040	10,875	$ 41,266	7,640	$ 32,736	19,468	$ 28,585
Cumulative effect of ASC 606 Adoption	—	—	—	—	—	—	—	—
Exercise of stock options	—	—	—	—	—	—	—	—
Issuance of Series G Preferred Stock—net of issuance costs of $11	—	—	—	—	—	—	—	—
Issuance of Series G Preferred Stock related to business combination	—	—	—	—	—	—	—	—
Issuance of Series H Preferred Stock, net of issuance costs of $44	—	—	—	—	—	—	—	—
Issuance of Series H for debt conversion	—	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—
Balance—December 31, 2018	2,357	$ 7,040	10,875	$ 41,266	7,640	$ 32,736	19,468	$ 28,585
Exercise of stock options	—	—	—	—	—	—	—	—
Issuance of Series H Preferred Stock, net of issuance costs of $3	—	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—
Balance—December 31, 2019	2,357	$ 7,040	10,875	$ 41,266	7,640	$ 32,736	19,468	$ 28,585

See notes to financial statements.

BIODESIX, INC.

STATEMENTS OF CHANGES IN CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
FOR THE YEARS ENDED DECEMBER 31, 2019 AND 2018
(in thousands)

(Continued from the previous page)

	Series G		Series H		Total Convertible Preferred Stock	Common Stock		Additional Paid-In Capital	Accumulate Deficit	Total Stockholder Deficit
	Shares	Amount	Shares	Amount		Shares	Amount			
Balance—December 31, 2017	33,497	$ 25,061	—	$ —	$ 157,018	1,070	$ 1	$ 1,915	$ (174,411)	$ (172,495)
Cumulative effect of ASC 606 Adoption	—	—	—	—	—		—		439	439
Exercise of stock options	—	—	—	—	—	206	—	50	—	50
Issuance of Series G Preferred Stock—net of issuance costs of $11	2,000	1,489	—	—	1,489	—	—	—	—	—
Issuance of Series G Preferred Stock related to business combination	10,650	7,987	—	—	7,987	—	—	—	—	—
Issuance of Series H Preferred Stock, net of issuance costs of $44	—	—	6,087	6,956	6,956		—		—	—
Issuance of Series H for debt conversion	—	—	9,141	10,512	10,512		—		—	—
Stock-based compensation	—	—	—	—	—	—	—	142	—	142
Net loss	—	—	—	—	—	—	—	—	(26,166)	(26,166)
Balance—December 31, 2018	46,147	$ 34,537	15,228	$ 17,468	$ 183,962	1,276	$ 1	$ 2,107	$ (200,138)	$ (198,030)
Exercise of stock options	—	—	—	—	—	237	—	47	—	47
Issuance of Series H Preferred Stock, net of issuance costs of $3	—	—	8,695	9,997	9,997	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	170	—	170
Net loss	—	—	—	—	—	—	—	—	(30,726)	(30,726)
Balance—December 31, 2019	46,147	$ 34,537	23,923	$ 27,465	$ 193,959	1,513	$ 1	$ 2,324	$ (230,864)	$ (228,539)

See notes to financial statements.

BIODESIX, INC.

STATEMENTS OF CASH FLOWS
(in thousands)

	For the Years Ended December 31,	
	2019	2018
Cash flows from operating activities		
Net loss	$ (30,726)	$ (26,166)
Adjustments to reconcile net loss to net cash, cash equivalents, and restricted cash used in operating activities		
Depreciation and amortization	2,793	1,740
Amortization of convertible debt discount	262	—
Gain on disposal of assets	—	(20)
Non-cash portion of loss on extinguishment of debt	—	85
Stock-based compensation expense	170	142
Change in fair value of warrant liability	104	(87)
Change in fair value of contingent consideration	4,114	5,400
Change in fair value of put option	2,000	—
Write off of assets	13	69
Accrued interest on debt payable and convertible debt payable	799	802
Amortization of debt issuance costs	144	105
Provision for doubtful accounts	246	—
Changes in operating assets and liabilities, net of assets acquired and liabilities assumed in acquisitions:		
Accounts receivable	(3,646)	(146)
Other current assets	1	(395)
Other long-term assets	16	6
Accounts payable and other accrued liabilities	1,193	342
Deferred revenue	791	446
Net cash and cash equivalents and restricted cash used in operating activities	(21,726)	(17,677)
Cash flows from investing activities		
Purchase of property and equipment	(1,310)	(498)
Patent costs and intangible asset acquisition, net	(106)	(119)
Payments to acquire Oncimmune assets	(456)	—
Net cash and cash equivalents and restricted cash used in investing activities	(1,872)	(617)
Cash flows from financing activities		
Proceeds from issuance of series G preferred stock	—	1,500
Proceeds from issuance of series H preferred stock	10,000	7,000
Proceeds from issuance of convertible debt payable	13,044	10,283
Proceeds from exercise of common stock options	47	50
Proceeds from long-term notes payable	—	23,000
Payments of equipment financing and notes payable	—	(22,518)
Other	(116)	128
Debt and equity financing costs	(3)	(411)
Net cash and cash equivalents and restricted cash provided by financing activities	22,972	19,032
Net (decrease) increase in cash and cash equivalents and restricted cash	(626)	738
Cash, cash equivalents, and restricted cash—beginning of year	6,094	5,356
Cash, cash equivalents, and restricted cash—end of year	$ 5,468	$ 6,094

See notes to financial statements.

BIODESIX, INC.

STATEMENTS OF CASH FLOWS
(in thousands)

(Continued from the previous page)

Supplemental disclosure of cash flow information:

There was no cash paid for income taxes during the years ended December 31, 2019 and 2018.

Cash paid for interest for the years ended December 31, 2019 and 2018 was $1.8 million.

Supplemental disclosure of non-cash activity (in thousands):

	December 31,	
	2019	2018
Accrued business combination payments	$ 750	$ —
Value of put option recorded at issuance of convertible debt payable	1,261	—
Issuance of Series G Preferred Stock in business combination	—	7,987
Fair value of warrants issued as part of 2018 loan agreement	—	346
Conversion of convertible debt payable plus accrued interest into Series H Preferred Stock	—	10,512

See notes to financial statements.

BIODESIX, INC.

NOTES TO FINANCIAL STATEMENTS

Note 1—Description of Business and Summary of Significant Accounting Policies

(a) Organization and Nature of Operations

Biodesix, Inc. (the "Company"), formerly Elston Technologies, Inc., was incorporated in Delaware in 2005. The Company's headquarters are in Colorado, with laboratories in Colorado, Kansas, and Washington. 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 is subject to various risks and uncertainties frequently encountered by early stage life science companies. Such risks and uncertainties include, but are not limited to, undeveloped technology, strict regulatory requirements and approval of products, a limited operating history, competition from other service providers, dependence on key personnel, the need for ongoing capital to fund operations, and management of rapid growth. To address these risks, the Company must, among other things, successfully develop its customer base, successfully execute its business and marketing strategy, successfully develop its technology, raise capital on acceptable terms to the Company, and attract, retain, and motivate qualified personnel. There can be no guarantee that the Company will be successful in addressing these or other such risks.

(b) Basis of Presentation

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (U.S. GAAP).

(c) Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America 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 revenues and expenses during the reporting period. Areas of the financial statements where estimates have the most significant effect include the valuation of contingent consideration and purchased technology related to the Company's business acquisition, stock-based compensation, valuation of put option liabilities, and the valuation allowance related to net deferred tax assets. Actual results could differ from those estimates.

(d) Segment Information

The Company operates in one operating segment and, accordingly, no segment disclosures have been presented herein. All equipment, leasehold improvements, and other fixed assets are physically located within the United States.

(e) Comprehensive Loss

Comprehensive loss is defined as the change in equity during a period from transactions and other events and/or circumstances from non-owner sources. If the Company had comprehensive gains (losses), they would be

reflected in the statement of operations and comprehensive loss and as a separate component in the statement of stockholders' deficit. There were no elements of comprehensive loss during the years ended December 31, 2019 and 2018.

(g) Concentration of Risk

The Company is subject to credit risk from its accounts receivable related to services provided to its customers. Reimbursement on behalf of customers covered by Medicare accounted for 59% and 60% of the Company's diagnostic test revenue for the years ended December 31, 2019 and 2018, respectively, and represented 18% and 44% of the Company's total accounts receivable balance as of December 31, 2019 and 2018, respectively. One services customer represented 44% and 25% of the Company's total accounts receivable balance as of December 31, 2019 and 2018, respectively. As of December 31, 2019, two services customers represented 12% and 10% of the Company's total accounts receivable balance as of December 31, 2019.

(h) Cash, Cash Equivalents, and Restricted Cash

The Company considers all highly liquid instruments purchased with an original maturity of three months or less to be cash equivalents. The Company continually monitors its positions with, and the credit quality of, the financial institutions with which it invests. Periodically throughout the year, the Company has maintained balances in various operating accounts in excess of federally insured limits. Included in cash and cash equivalents are money market funds recorded at $4.8 million and $5.2 million at December 31, 2019 and 2018, respectively. These money market funds were measured using Level 1 inputs.

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, 2019 and 2018, the Company had $0.2 million in restricted cash, which was included in other current assets in the accompanying balance sheets.

(i) Accounts Receivable

The Company provides an allowance for doubtful accounts based on experience and specifically identified risks. Accounts receivable are recorded at carrying value and charged off against the allowance for doubtful accounts when it is determined that recovery is unlikely and cease collection efforts cease.

The Company analyzes trade accounts receivable quarterly and considers historic experience, customer creditworthiness, facts and circumstances specific to outstanding balances, and payment terms when evaluating the adequacy of the allowance for doubtful accounts. The Company recorded an allowance for doubtful accounts of $0.2 million as of December 31, 2019.

(j) Inventory

Inventories are stated at the lower of cost or net realizable value on a first-in, first-out basis. Inventory consists primarily of supplies, which are consumed when processing tests. The Company does not maintain any finished goods inventory. Inventory balances were $0.8 million and $0.7 million as of December 31, 2019 and 2018, respectively, and are included in other current assets in the accompanying balance sheets.

(k) Property and Equipment

Property and equipment are stated at cost. Depreciation is provided utilizing the straight-line method over the estimated useful lives, ranging from three to five years.

BIODESIX, INC.

NOTES TO FINANCIAL STATEMENTS

(l) Intangible Assets

Intangible assets are stated at cost, net of accumulated amortization and include patents, trademarks, and acquired developed technology. Trademarks have an indefinite life and are not being amortized but are reviewed for impairment on an annual basis. External costs associated with patents are capitalized as long as such efforts are expected to be successful. Upon approval of the patent, the related capitalized costs are amortized over the lesser of the contractual term of the patent or the estimated useful life of 10 years. Acquired developed technology is amortized over a useful life of 9 years. See Note 3, Business Combination, for further information.

(m) Long-Lived Assets

The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recovered. The Company looks primarily to the undiscounted future cash flows in its assessment of whether or not long-lived assets have been impaired. The Company has determined that no impairments are necessary for the periods presented.

(n) Deferred Rent

The Company leases office space under non-cancelable, long-term operating leases that include scheduled increases in minimum rents and renewal provisions at the option of the Company. The expense associated with leases that have escalating payment terms is recognized on a straight-line basis over the lease term. Tenant improvement allowances received from a lessor are recorded as a deferred rent liability and recognized evenly as a reduction to rent expense over the remaining lease term. The portion of the deferred rent liability that will reverse in the next 12 months is not significant to the balance sheets; therefore, the entire amount was recorded as non-current in the accompanying financial statements.

(o) Goodwill

Goodwill is recorded when the purchase price paid for an acquisition exceeds the estimated fair value of the net identified tangible and intangible assets acquired. Goodwill is not amortized and is tested for impairment at the reporting unit level on an annual basis as of December 31 and between annual tests if an event occurs or circumstances change that would more likely than not reduce the fair value of the reporting unit below its carrying value. The Company may first perform a qualitative assessment to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying value. If it is concluded that this is the case, it is necessary to perform a quantitative two-step goodwill impairment test. Otherwise, the two-step goodwill impairment test is not required. The quantitative two-step goodwill impairment review process compares the fair value of the reporting unit in which goodwill resides to its carrying value. Multiple valuation techniques can be used to assess the fair value of the reporting unit. All these techniques include the use of estimates and assumptions that are inherently uncertain. Changes in these estimates and assumptions could materially affect the determination of fair value or goodwill impairment, or both. The Company assessed qualitative factors to determine whether it is more likely than not that the fair value of Goodwill exceeded the carrying value. Based on that assessment, there were no events or circumstances in 2019 and 2018 to indicate that the fair value of goodwill exceeded its carrying value, and thus a quantitative analysis was not performed.

BIODESIX, INC.

NOTES TO FINANCIAL STATEMENTS

The following summarizes the Company's goodwill activity (in thousands):

Balance—December 31, 2017	$ —
Attributable to 2018 acquisition	10,804
Balance—December 31, 2018	10,804
Attributable to 2019 acquisition	827
Outstanding—December 31, 2019	$ 11,631

The Company did not have any goodwill impairments for the years ended December 31, 2019 and 2018.

(p) Revenue Recognition

Revenues are recognized when control of the promised services is transferred to customers, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those services.

The Company's revenue is generated from the following:

- Diagnostic tests. These services are completed upon the delivery of test results to the prescribing physician, 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.
- Services. These services are generally completed upon the delivery of test results for assay development and testing services, which is considered the performance obligation. Customers for these services are typically large pharmaceutical companies.

For the years ended December 31, 2019 and 2018 revenue from these services consisted of the following (in thousands):

	December 31,	
	2019	2018
Diagnostic tests	$ 17,315	$ 18,965
Services	7,237	1,467
Total revenue	$ 24,552	$ 20,432

Diagnostic test revenue that were reimbursed by Medicare comprised 60% and 61% of diagnostic test revenue in 2019 and 2018, respectively. One services customer comprised 71% and 95% of services revenue in 2019 and 2018, respectively.

Revenue from diagnostic tests are recognized when the performance obligation is satisfied, which is when a customer receives results of the Company's tests, which is generally upon delivery to the requesting physician. Revenue from services are recognized when the performance obligation is satisfied, which is when a customer receives results of the Company's tests, which is generally upon the delivery of test results for assay development and testing services. The Company also provides services to patients with whom the Company does not have contracts as defined in ASC 606, *Revenue from Contracts with Customers* (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 the performance obligations being satisfied.

BIODESIX, INC.

NOTES TO FINANCIAL STATEMENTS

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 as a practical expedient to account for patient contracts as collective groups rather than individually.

(q) Deferred Revenue

Deferred revenue primarily consists of services fee payments received in advance.

(r) Research and Development Expenses and Accrued Research and Development Expenses

Expenditures made for research and development are charged to expense as incurred. External costs consist primarily 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 primary of employee-related costs, facilities, depreciation and costs related to compliance with regulatory requirements.

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 payment flows 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 we receive.

(s) Stock-Based Compensation

The Company accounts for stock-based compensation arrangements with employees and recognizes compensation expense for stock-based awards based on the estimated fair value of the awards. Compensation expense for all employee stock-based awards is based on the estimated grant-date fair value and recognized as an expense on a straight-line basis over the requisite service period (generally the vesting period).

(t) Income Taxes

The Company recognizes deferred tax assets and liabilities based on the differences between the tax basis of assets and liabilities and their reported amounts in the financial statements and net operating loss carryforwards that will result in taxable or deductible amounts in future years. The Company establishes a valuation allowance for all deferred tax assets to the extent it is more likely than not that a deferred tax asset will not be realized.

(u) Warrant Liability

Freestanding financial instruments that permit the holder to acquire shares that are either puttable by the holder, redeemable or contingently redeemable are required to be reported as liabilities in the financial statements. The issuer must present such liabilities on the balance sheets at their estimated fair values. Changes in fair value of the liability are calculated each reporting period, and any change in value is recognized in operations. The Company has determined that certain warrants issued to investors and lenders, which are exercisable for shares of the Company's convertible preferred stock, shall be classified as liabilities due to a contingent redemption provision.

BIODESIX, INC.

NOTES TO FINANCIAL STATEMENTS

(v) Changes in Fair Value of Contingent Consideration

In connection with the purchase transaction with Integrated Diagnostics, Inc., the Company recorded contingent consideration pertaining to the amounts potentially payable to Integrated Diagnostics' 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 the related milestone event ("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.

(w) Fair Value of Financial Instruments

The carrying amounts of financial instruments, including cash and cash equivalents, receivables, other current assets, accounts payable, and accrued liabilities, approximated fair value as of December 31, 2019 and 2018 because of the relatively short maturity of these instruments.

The carrying amounts of long-term notes payable and convertible debt payable issued approximated fair value as of December 31, 2019 and 2018 because interest rates on these instruments approximate market interest rates.

(x) Business Combinations

The Company evaluates acquisitions of assets and other similar transactions to assess whether or not the transaction should be accounted for as a business combination by assessing whether or not the Company has acquired inputs and processes that have the ability to create outputs. If determined to be a business combination, the Company accounts for business acquisitions under the acquisition method of accounting as indicated in the FASB issued Accounting Standards Codification ("ASC") Topic 805, *Business Combinations* ("ASC 805"), which requires the acquiring entity in a business combination to recognize the fair value of all assets acquired and liabilities assumed and establishes the acquisition date as the fair value measurement point. Accordingly, the Company recognizes assets acquired and liabilities assumed in business combinations, including contingent assets and liabilities, and non-controlling interest in the acquiree based on the fair value estimates as of the date of acquisition. In accordance with ASC 805, the Company recognizes and measures goodwill as of the acquisition date, as the excess of the fair value of the consideration paid over the fair value of the identified net assets acquired.

(y) Recently Issued Accounting Standards Adopted

In May 2014, the Financial Accounting Standards Board ("FASB") issued ASU 2014-09, "Revenue from Contracts with Customers", and has subsequently issued several supplemental and/or clarifying ASUs (collectively, "ASC 606"). ASC 606 prescribes a single common revenue standard that replaces most existing U.S. GAAP revenue recognition guidance. ASC 606 is intended to provide a more consistent interpretation and application of the principles outlined in the standard across filers in multiple industries and within the same industries compared to current practices, which should improve comparability. The Company adopted the new standard using the modified retrospective method on January 1, 2018 for contracts that are not completed as of the adoption date.

BIODESIX, INC.

NOTES TO FINANCIAL STATEMENTS

Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. ASC 606 also impacts certain other areas, such as the accounting for costs to obtain or fulfill a contract. The standard also requires disclosure of the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers.

The Company examined its revenue recognition policies specific to revenue streams for diagnostic testing and services provided to third parties and came to conclusions on the impact of the new standard using the 5-step process prescribed by ASC 606. As noted above, the Company used the modified retrospective method to adopt the new standard which means the Company did not restate previously issued financial statements but recorded a one-time adjustment to accumulated deficit and accounts receivable of $0.4 million. This adjustment reflected the Company's ability to establish a transaction price for the Company's non-Medicare pay arrangements as of January 1, 2018 as a result of having sufficient history to determine the transaction price under these contracts.

ASC 606 did not have an aggregate impact the Company's net cash provided by operating activities but resulted in offsetting changes in certain assets and liabilities presented within net cash used in operating activities in the accompanying statement of cash flows, as noted above.

(z) Recently Issued Accounting Standards Not Yet Adopted

In February 2016, the Financial Accounting Standards Board ("FASB") issued ASU No. 2016-02, *Leases* (ASC Topic 842). The new guidance maintains two classifications of leases: finance leases, which replace capital leases, and operating leases. Lessees will need to recognize a right-of-use asset and a lease liability on the statement of financial position for those leases previously classified as operating leases under the old guidance. The liability will be equal to the present value of lease payments. The asset will be based on the liability, subject to adjustment, such as for direct costs. The accounting standard will be effective for the Company beginning January 1, 2021. The Company is currently evaluating the impact of the lease guidance on the Company's financial statements.

(aa) Net loss per share and unaudited pro format net loss per share

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, the convertible preferred stock, common stock options, restricted stock units, preferred stock warrants and convertible debt are considered to be potentially dilutive securities. Basic and diluted net loss attributable to common stockholders per share is presented in conformity with the two-class method required for participating securities as the convertible preferred stock is considered a participating security. The Company's participating securities do not have a contractual obligation to share in the Company's losses. As such, the net loss was attributed entirely to common stockholders. 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 those periods.

BIODESIX, INC.

NOTES TO FINANCIAL STATEMENTS

The following table sets forth the computation of the basic and diluted net loss per share attributable to common stockholders (in thousands, except per share amounts):

	Year ended December 31,	
	2019	2018
Numerator		
Net loss attributable to common stockholders	$ (30,726)	$ (26,166)
Denominator		
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	1,442	1,186
Net loss per share, basic and diluted	$ (21.31)	$ (22.07)

The following outstanding shares of potentially dilutive securities were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods presented because including them would have been anti-dilutive (in thousands, except for per share amounts):

	Year ended December 31,	
	2019	2018
Options to purchase common stock	12,492	9,085
Convertible preferred stock	119,257	110,562
Warrants	1,538	2,440
Restricted stock units	157	—
Convertible debt	125,429(1)	—
Total	258,873	122,087

(1) 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. The ultimate conversion price will be based on the fair value of the Company's common stock at the completion of an initial public offering.

Unaudited pro forma net loss per share

Unaudited pro forma basic and diluted net loss per share is calculated to give effect to the one-for-one conversion of all outstanding shares of the Company's convertible preferred stock and convertible debt into shares of common stock in using the as-converted method as though the conversion had occurred as of the beginning of the period presented or the date of issuance, if later.

BIODESIX, INC.

NOTES TO FINANCIAL STATEMENTS

The following table sets forth the computation of the basic and diluted unaudited pro forma net loss per share (in thousands):

	Year ended December 31, 2019
Numerator	
Net loss	$ (30,726)
Add back: Interest expense on convertible debt	375
Net loss used in computing proforma net loss per share, basic and diluted	$ (30,351)
Denominator	
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	1,442
Adjust: Assumed weighted-average effect of conversion of convertible preferred stock	117,541
Adjust: Assumed weighted-average effect of conversion of convertible debt	36,143(1)
Weighted-average shares outstanding used in computing pro forma net loss per share, basic and diluted	155,126
Pro forma net loss per share, basic and diluted	$ (0.20)

(1) 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. The ultimate conversion price will be based on the fair value of the Company's common stock at the completion of an initial public offering.

Note 2—Liquidity

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and liquidation of liabilities in the ordinary course of business. To date, the Company has funded its activities primarily through private equity placement offerings, convertible debt payable, and long-term debt. The Company is still in its early stage and has yet to generate revenues sufficient to create positive cash flows and most likely will be dependent upon future private equity placements or additional borrowings to execute its business plan. The Company has cash and cash equivalents of $5.3 million, cumulative net losses of $230.9 million, and stockholders' deficit of $228.5 million as of December 31, 2019. Based on cash and cash equivalents on hand and amounts raised subsequent to December 31, 2019, management has determined that additional private equity placement offerings will be necessary to fund operations through May 2021. As a result, the Company has obtained commitment letters from two significant investors which requires that they will provide funding to the Company to meet its obligations and debt service requirements through at least May 2021.

Note 3—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 option to license rights within the United States to an additional indication for their product for $9 million. This option, which is exclusive to the Company, expires on the earlier of 30 days following Food and Drug Administration approval or December 31, 2020. As of December 31, 2019, $0.5 million has been paid with the remaining amount due of $0.7 million being included in accounts payable and accrued liabilities.

BIODESIX, INC.

NOTES TO FINANCIAL STATEMENTS

The Company accounted for the transaction as a business combination in accordance with ASC 805. As such, the assets acquired and liabilities assumed were recorded at fair value, with the remaining purchase price recorded as goodwill. The goodwill associated with the acquisition is the result of expected synergies and expansion of the technology into additional markets.

The following summarizes the aggregate consideration paid by the Company and the allocation of the purchase price (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

As of December 31, 2019, the Company has finalized its accounting for this business combination.

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 (10,649,604 shares) of the Company’s Series G Preferred Stock and contingent consideration with an initial fair value of $19.6 million. The 10,649,904 shares issued at closing include 2,129,981 shares that were deposited in an escrow account to be used to satisfy any indemnification obligations of Indi that may arise.

The Company accounted for the transaction as a business combination in accordance with ASC 805. As such, the assets acquired and liabilities assumed were recorded at fair value, with the remaining purchase price recorded as goodwill. The estimated fair values of acquired assets and assumed liabilities were determined by management with the assistance of an independent third party. The goodwill associated with the acquisition is the result of expected synergies and expansion of the technology into additional markets.

The following summarizes the aggregate consideration paid by the Company and the allocation of the purchase price (in thousands):

Preferred stock issued—10,694,904 shares	$ 7,987
Contingent consideration	19,600
Total fair value of consideration transferred	$27,587
Prepaid expenses and other assets	$ 50
Inventory	394
Property and equipment	316
Technology	16,900
Goodwill	10,804
Liabilities	(877)
	$27,587

BIODESIX, INC.

NOTES TO FINANCIAL STATEMENTS

The acquisition of Indi included a contingent consideration arrangement that requires additional consideration to be paid by the Company to Indi based on the Milestone of the attainment of a three consecutive month gross margin target within a seven-year period. For the six months following the achievement of the Milestone, Indi has the option to require the Company to pay the contingent consideration in cash over eight equal installments due each calendar quarter or through the issuance of shares of Series G Preferred Stock. The total amount of undiscounted contingent consideration which the Company may be required to pay under the arrangement is $37.0 million. If Indi elects not to exercise these options, the Company has 12 months to either settle the contingent consideration in two equal quarterly cash installments or in 14,959,114 shares of Series G Preferred Stock.

The fair value of $19.6 million contingent consideration recognized on the acquisition date was estimated by management with the assistance of an independent third party. These fair value measurements were based on significant inputs not observable in the market and thus represent Level 3 fair value measurements. See Note 4, Fair Value Accounting, for a discussion of the fair value of the contingent consideration and changes in fair value subsequent to the acquisition date.

Intangible assets acquired, amortization method and estimated useful lives as of June 30, 2018 was as follows (dollars in thousands):

	Useful Life	Amortization Method	Fair Value
Technology	9 years	Straight-line	$ 16,900

As of December 31, 2018, the Company had finalized its accounting for this business combination.

Note 4—Fair Value Accounting

The Company accounts for certain assets and liabilities that are required to be recorded at fair value under a framework for measuring fair value that requires enhanced disclosures about fair value measurements. This framework requires disclosure about how fair value is determined for assets and liabilities and establishes a hierarchy for which these assets and liabilities must be grouped based on significant levels of inputs as follows:

Level 1: Quoted prices in active markets for identical assets or liabilities;

Level 2: Quoted prices in active markets for similar assets and liabilities and inputs that are observable for the asset or liability; or

Level 3: Unobservable inputs in which there is little or no market data, which requires the reporting entity to develop its own assumptions.

The determination of where assets and liabilities fall within this hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

BIODESIX, INC.

NOTES TO FINANCIAL STATEMENTS

The following tables set forth by level, within the fair value hierarchy, the Company's liabilities measured at fair value on a recurring basis (in thousands):

December 31, 2019: Description	Level 1	Level 2	Level 3	Total
Warrant liability	$ —	$ —	$ 372	$ 372
Contingent value rights	$ —	$ —	$ 60	$ 60
Contingent consideration	$ —	$ —	$29,114	$29,114

December 31, 2018: Description	Level 1	Level 2	Level 3	Total
Warrant liability	$ —	$ —	$ 268	$ 268
Contingent value rights	$ —	$ —	$ 60	$ 60
Contingent consideration	$ —	$ —	$25,000	$25,000

Due to the unobservable inputs needed to calculate the fair value of these balances, these liabilities are classified as Level 3 liabilities. The following is a reconciliation of the beginning and ending balances for assets measured at fair value on a recurring basis using significant unobservable inputs (in thousands):

	December 31, 2019	December 31, 2018
Warrant liability		
Beginning balance	$268	$ 9
Issuances	—	346
Exercises	—	—
Change in fair value	104	(87)
Ending balance	$372	$268

	December 31, 2019	December 31, 2018
Contingent value rights		
Beginning balance	$ 60	$ 60
Issuances	—	—
Exercises	—	—
Change in fair value	—	—
Ending balance	$ 60	$ 60

BIODESIX, INC.

NOTES TO FINANCIAL STATEMENTS

	December 31, 2019	December 31, 2018
Contingent consideration		
Beginning balance	$ 25,000	$ —
Additions	—	19,600
Changes in fair value	663	3,863
Accretion	3,451	1,537
Payments	—	—
Ending balance	$ 29,114	$ 25,000

There were no changes to the valuation methods during the years presented.

See Note 12 for further discussion of preferred stock warrants.

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"), but only to the extent that the total amount raised in the financing exceeded $20,202,323. One CVR represents 0.00375% of the Company's interest in the drug ficlatuzumab (see Note 10). In connection with the Series F financing, the Company issued 3,999 CVRs originally valued at $0.5 million. 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 will make a cash payment to the CVR holders equal to 15% of net proceeds, as defined. In addition, the CVRs will be adjusted to their estimated fair values each reporting period. During 2019 and 2018, there was no change to the estimated value of the CRVs. The value of these CVRs was $0.1 million as of December 31, 2019 and 2018.

Contingent Consideration

In connection with the transaction with Indi, the Company recorded contingent consideration pertaining to the amounts potentially payable to Indi's Selling Shareholders pursuant to the Asset Purchase Agreement (See Note 3). Contingent consideration is measured at fair value and is based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The valuation of contingent consideration uses assumptions the Company believes would be made by a market participant. The Company assesses these estimates on an on-going basis as additional data impacting the assumptions is obtained. Future changes in the fair value of contingent consideration related to updated assumptions and estimates are recognized within the statements of operations.

Contingent consideration may change significantly as development progresses and additional data are obtained, impacting the Company's assumptions regarding probabilities of successful achievement of related Milestone used to estimate the fair value of the liability and the timing in which they are expected to be achieved. In evaluating the fair value information, considerable judgment is required to interpret the market data used to develop the estimates. The estimates of fair value may not be indicative of the amounts that could be realized in a current market exchange. Accordingly, the use of different market assumptions and/or different valuation techniques could result in materially different fair value estimates. The fair value of the Company's contingent consideration liability was estimated using significant unobservable inputs. The fair value of $19.6 million contingent consideration recognized on the acquisition date was estimated by management with the assistance of an independent third party.

BIODESIX, INC.

NOTES TO FINANCIAL STATEMENTS

Changes in the fair value measurement each period reflect the passage of time as well as the impact of adjustments, if any, to the likelihood of achieving the specified targets. Contingent consideration is recorded in the balance sheets in long-term liabilities. The $4.1 million adjustment to the contingent consideration during 2019 was primarily due to $3.4 million resulting from the reduction of estimated time to first payment and $0.7 million due to the impact of the acceleration of expected revenue and decreases in expected costs. The $5.4 million adjustment to the contingent consideration during 2018 was primarily due to $3.9 million resulting from the impact of the acceleration of expected revenue and decreases in expected costs as a result of events occurring after the acquisition date, as well as $1.5 million resulting from the reduction of estimated time to first payment.

The significant unobservable inputs used in the measurement of fair value of the Company's contingent consideration are probabilities of successful achievement of the Milestone, the period in which the Milestone is expected to be achieved and discount rates ranging 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.

Note 5—Balance Sheet Disclosures

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

	December 31,	
	2019	2018
Lab equipment	$ 4,221	$ 3,513
Leasehold improvements	1,894	1,881
Computer equipment	869	765
Furniture and fixtures	427	424
Software	503	373
Construction in process	592	—
	8,506	6,956
Less accumulated depreciation	(6,386)	(5,568)
Total property and equipment	$ 2,120	$ 1,388

Depreciation expense for each of the years ended December 31, 2019 and 2018 was $0.8 million and $0.7 million, respectively.

BIODESIX, INC.

NOTES TO FINANCIAL STATEMENTS

Intangible assets consist of the following (in thousands):

	December 31, 2019	December 31, 2018
Patents	$ 1,245	$ 1,176
Less accumulated amortization	(411)	(345)
	$ 834	$ 830
Purchased technology	$16,900	$16,900
Less accumulated amortization	(2,817)	(939)
	$14,083	$15,961
Purchase option	$ 121	$ —
Less accumulated amortization	(17)	—
	$ 104	$ —
Trademarks (indefinite life)	$ 71	$ 61
Total intangible assets	$15,092	$16,852

The Company recorded amortization expense of $2.0 million and $1.0 million for the years ended December 31, 2019 and 2018, respectively. Amortization related to the remaining net intangible assets is scheduled to amortize as follows (in thousands):

Year Ending December 31,	
2020	$ 2,229
2021	1,944
2022	1,937
2023	1,936
2024	1,927
Thereafter	5,048
Total future amortization expense	$ 15,021

Accrued liabilities consist of the following (in thousands):

	December 31, 2019	December 31, 2018
Compensation related accruals	$1,165	$ 996
Accrued clinical trial expense	620	572
Other expenses	2,352	1,522
Warrant liability, current	43	—
Total accrued liabilities	$4,180	$3,090

Note 6—Convertible Debt Payable

In December 2019, the Company issued $6 million in convertible debt (the “December 2019 Notes”) that is scheduled to mature in August 2020. The December 2019 Notes were issued in two tranches of $3 million,

BIODESIX, INC.

NOTES TO FINANCIAL STATEMENTS

with the first tranche being funded in December 2019. Interest on the December 2019 Notes is at 3% per annum and is 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. 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, the earlier of, the preferred stock sold at the close of the Company's next equity financing (Qualified Financing) or common stock in an initial public offering (IPO). The conversion price would be equal to 80% of the price per share paid for the preferred stock in the Qualified Financing or common stock sold in an IPO. The December 2019 Notes may be prepaid in whole or in part at any time by the Company with prior consent of at least two-thirds of the note holders. In the event of a corporate transaction, the unpaid principal and accrued interest shall become immediately due and payable in the same form of consideration and on the same terms and conditions as the consideration to be received by the holders of the equity securities of the Company in such transaction. The discounts on the automatic conversions created a put option liability that was separated from the December 2019 Notes. The estimated value of the put option liability as of the issuance of the December 2019 Notes and December 31, 2019 was $0.8 million. The put option liability was reflected as a debt discount on the December 2019 Notes which is being amortized over the term of the December 2019 Notes. The unamortized debt discount was $0.7 million as of December 31, 2019.

In August and September 2019 (the "August 2019 Notes"), the Company issued $10 million in convertible debt that is scheduled to mature in August 2020. Interest on the August 2019 Notes is at 3% per annum and is payable in full upon maturity through the conversion to Series H Preferred Stock at the original issuance price of $1.15 per share. 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, the earlier of, the preferred stock sold at the close of the Company's next equity financing (Qualified Financing) or common stock sold in the event of an IPO. The conversion price would be equal to 95% of the price per share paid for the preferred stock in the Qualified Financing or common stock sold in an IPO. The August 2019 Notes may be prepaid in whole or in part at any time by the Company with prior consent of at least two-thirds of the August 2019 Note holders. In the event of a corporate transaction, the unpaid principal and accrued interest shall become immediately due and payable in the same form of consideration and on the same terms and conditions as the consideration to be received by the holders of the equity securities of the Company in such transaction. The discounts on the automatic conversions created a put option liability that was separated from the August 2019 Notes. The estimated value of the put option liability as of the issuance of the August 2019 Notes was $0.5 million. The put option liability was reflected as a debt discount on the August 2019 Notes which is being amortized over the term of the August 2019 Notes. The unamortized debt discount was $0.3 million as of December 31, 2019.

In connection with the issuance of the December 2019 Notes, the conversion price on the August 2019 Notes was amended to 80% of the price per share paid for the preferred stock in the Qualified Financing or common stock in an IPO. In addition, the conversion price to Series H preferred stock at the maturity date was amended to be 80% of the Series H original issuance price of $1.15 per share. The changes to the discounts on the conversions of the August 2019 Notes created an increase to the put option liability on the August 2019 Notes of $2 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 accompany 2019 statement of operations.

As of December 31, 2019, accrued interest of $0.1 million is included in the convertible debt balance included on the accompanying balance sheet.

In April and July 2018, the Company issued $10.3 million in convertible debt that was scheduled to mature in April 2019 (the "April 2018 Notes"). Interest on the April 2018 Notes was at 6% per annum and was

payable in full upon maturity. On or before the maturity date and if the April 2018 Notes are unpaid, the outstanding principal and unpaid accrued interest under the April 2018 Note shall be automatically converted into the preferred stock sold at the close of the Company's next equity financing (Qualified Financing). The conversion price would be equal to 100% of the price per share paid for the preferred stock in the Qualified Financing. The April 2018 Notes may be prepaid in whole or in part at any time by the Company with prior consent of at least two-thirds of the April 2018 Notes holders. In the event of a corporate transaction, the unpaid principal and accrued interest shall become immediately due and payable in the same form of consideration and on the same terms and conditions as the consideration to be received by the holders of the equity securities of the Company in such transaction.

In October 2018, the Company issued 6,086,941 shares of Series H Preferred Stock at $1.15 per share for total cash proceeds of $7.0 million. In connection with this issuance, the $10.3 million in convertible debt issued in April and July 2018 and accrued interest of $0.2 million automatically converted into 9,140,616 shares of Series H Preferred Stock as a Qualified Financing occurred prior to the maturity date.

Note 7—Long-Term Debt

In February 2018, the Company extinguished a Note that originated in 2013 (the "2013 Notes") through the issuance of new long-term debt with a different private investment company (the "2018 Notes"). The lender for the 2018 Notes is also a holder of the Company's Series G preferred stock. The Company recorded a $0.2 million loss on the extinguishment of the 2013 Notes.

The initial amount borrowed under the 2018 Notes was $23 million and the maturity date is February 2023. At the time of the issuance of the 2018 Notes, the Company paid a 1% facility fee of $0.2 million and issued a warrant to the private investment company for the purchase of 613,333 shares of Series G preferred stock, which had an initial fair value of $0.3 million. The facility fee and the value of the warrants were recorded as reductions to the carrying value of the 2018 Notes and are being amortized to interest expense over the term of the 2018 Notes. The 2018 Notes bears interest at 10% with 7.5% being paid in cash and 2.5% being added to the principal value of the 2018 Notes through December 31, 2020. The Company is required to make quarterly interest payments beginning in June 2018 and outstanding principal is due in 24 equal installments commencing in March 2021. As of December 31, 2019 and 2018, the interest added to the principal value of the 2018 Notes was $1.1 million and $0.5 million, respectively.

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 being recorded as additional interest expense over the term of the 2018 Notes.

The 2018 Notes contains customary affirmative covenants, including covenants regarding compliance with applicable laws and regulations, payment of taxes, insurance coverage, notice of certain events, and reporting requirements. Further, the 2018 Notes contains customary negative covenants limiting the ability of the Company to, among other things, to incur future debt, transfer assets except for the ordinary course of business, make acquisitions, make certain restricted payments, and sell assets, subject to certain exceptions. In addition, the 2018 Notes requires 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, 2019, the Company was not in default under the terms of the 2018 Notes.

BIODESIX, INC.

NOTES TO FINANCIAL STATEMENTS

In accordance with the 2018 Notes, 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.

Long-term notes payable as of December 31, 2019 and 2018 was as follows (in thousands):

	2019	2018
2018 Notes	$24,088	$23,495
Other	12	128
Final payment fee	170	78
Unamortized debt discount and debt issuance costs	(458)	(602)
	$23,812	$23,099

Maturities of long-term obligations as of December 31, 2019 are as follows (in thousands):

Year Ending December 31,	
2020	$ —
2021	10,044
2022	12,049
2023	2,177
2024	—
Thereafter	—
	$ 24,270

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 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.

Note 8—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:

	Years Ended December 31,	
	2019	2018
Federal statutory income tax rate	21%	21%
State income taxes, net of federal benefit	4	4
Research and development credits	2	2
Permanent items	(4)	(6)
Change in valuation allowance	(23)	(21)
Effective income tax rate	—%	—%

BIODESIX, INC.

NOTES TO FINANCIAL STATEMENTS

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):

	December 31	
	2019	2018
Net operating loss carryforwards	$ 55,411	$ 49,406
Research and development tax credits	3,040	2,555
Accruals and reserves	286	275
Intangible assets	(3,514)	(3,982)
Total	55,223	48,254
Valuation allowance	(55,223)	(48,254)
Net deferred tax assets	$ —	$ —

At December 31, 2019, the Company had $222.1 million and $3.0 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 $7.0 million during 2019 and $5.5 million during 2018.

The Company has concluded that there were no significant uncertain tax positions relevant to the jurisdictions where the Company is required to file income tax returns requiring recognition in the financial statements for the years ended 2019 and 2018.

The Company has recognized no interest for the years ended December 31, 2019 and 2018 related to uncertain tax positions. As of December 31, 2019, and 2018, there was no accrued interest related to uncertain tax positions.

The Company monitors proposed and issued tax law, regulations, and cases to determine the potential impact of uncertain income tax positions. At December 31, 2019, 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.

The Company’s federal and state tax returns remain open for 2013 through 2019 to examination by tax authorities.

BIODESIX, INC.

NOTES TO FINANCIAL STATEMENTS

Note 9—Commitments

Leases

The Company leases facilities under non-cancelable operating leases. Rent expense for the years ended December 31, 2019 and 2018 was $2.1 and $1.6 million, respectively, and was inclusive of common area maintenance charges.

Future minimum lease payments for operating lease obligations, net of sublease income are as follows (in thousands):

Year Ending December 31,	
2020	$1,590
2021	1,254
2022	1,107
2023	23
2024	—
Thereafter	—
	$3,974

Co-Development Agreement

In April 2014 and amended in October 2016, the Company entered into a worldwide agreement with AVEO Oncology ("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, referred to as 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. AVEO may recapture certain of its costs under the agreement from royalties and other revenue received under the agreement. Expenses related to this agreement for the years ended December 31, 2019 and 2018 were approximately $0.9 million and $0.3 million, respectively.

License Agreement

In August 2019, the Company entered into 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 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 separate supply agreement for a

consecutive twelve-month period or for any material breach by the Company of the supply agreement. The Company incurred royalty expense of $0.1 million during 2019 under this agreement.

Note 10—Convertible Preferred Stock

The following table details, by series, the Company's convertible preferred stock at December 31, 2019 (in thousands, except shares and original issue price):

Series	Shares Authorized	Shares Issued and Outstanding	Defined Original Issue Price	Liquidation Preference
Series H	41,836,231	23,923,188	$ 1.15	$ 27,512
Series G	76,464,035	46,146,517	0.75	34,610
Series F	19,468,203	19,468,203	1.50	29,202
Series E	13,972,954	7,639,556	5.00	38,198
Series D	11,781,710	10,874,876	4.00	43,499
Series C	2,356,597	2,356,596	3.00	7,070
Series B-1	2,998,852	2,998,852	3.20	9,596
Series B	3,641,817	3,641,817	2.75	10,015
Series A-3	750,000	750,000	2.24	1,680
Series A-2	266,668	266,668	1.50	400
Series A-1	700,000	700,000	1.14	800
	174,237,067	118,766,273		$ 202,582

Series H

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.

In October 2018, the Company issued 6,086,941 shares of Series H Preferred Stock at $1.15 per share for total cash proceeds of $7.0 million. In connection with this issuance, the $10.3 million in convertible debt issued in April and July 2018 and accrued interest of $0.2 million converted into 9,140,616 shares of Series H Preferred Stock.

Series G

In June 2018, concurrent with the closing of the transaction with Indi, the Company issued 10,649,904 shares of Series G Preferred Stock to Indi, including 2,129,981 shares that were deposited in an escrow account to be used to satisfy any indemnification obligations of the seller that may arise. See Note 3, Business Combination, for further information.

In February 2018, the Company issued 2.0 million shares of Series G Preferred Stock to the lender of the 2018 Notes at $0.75 per share for total cash proceeds of $1.5 million. See Note 7, Long-term Debt, for further information.

The Company's convertible preferred stock has been classified as temporary equity in the accompanying balance sheets given that a majority of the Company's Board of Directors seats are held by convertible preferred stock holders and could cause certain events to occur that are outside of the Company's control whereby the

BIODESIX, INC.

NOTES TO FINANCIAL STATEMENTS

Company could be obligated to redeem the convertible preferred stock. The Company has not adjusted the carrying values of the convertible preferred stock to the respective liquidation preferences of such shares as the instruments are currently not redeemable and the Company believes it is not probable that the instruments will become redeemable at this point in time. Adjustments to increase the carrying values to the respective liquidation preferences will be made if and when it becomes probable that an event would occur obligating the Company to pay such amounts.

Conversion Rights

The holders of Series A-1, Series A-2, and Series A-3 (collectively, "Series A"); Series B and Series B-1 (collectively, "Combined Series B"); Series C; Series D; Series E; Series F, Series G, and Series H are entitled to convert their shares into common stock at the option of the holder, at any time, into fully paid and non-assessable shares of common stock. The number of shares of common stock to which a holder of the Series A, Combined Series B, Series C, Series D, Series E, Series F, Series G, and Series H (collectively, "Series Preferred") can convert is obtained by multiplying the conversion rate that is in effect by the number of shares of Series Preferred being converted. The conversion rate is determined by dividing the Original Issue Price by the applicable conversion price (initially the Original Issue Price for all classes of Series Preferred except Series B-1, for which the conversion price is initially $2.75). Each share of Series Preferred will be automatically converted into shares of common stock (based on the then-effective Series Preferred conversion price) if there is an affirmative election of 65% of the holders of the outstanding shares of Series Preferred or immediately upon the closing of a firmly underwritten public offering in which the offer and sale of common stock, voting together as a single class on an as-if-converted-to-common-stock basis, is at a per-share price of at least $2.00 (adjusted for stock splits, dividends, and recapitalizations) and gross cash proceeds to the Company (before underwriting discounts, commissions, and fees) are at least $40 million.

Dividend Rights

The Series Preferred holders are entitled to receive non-cumulative cash dividends. The dividends are required to be declared by the Board of Directors and are calculated at an annual rate of 8% of the Original Issue Price of the respective Series Preferred shares. Series Preferred holders have the following order of preference on dividends: Series H holders, Series G holders, Series F holders, Series E holders, Series D holders, Series C holders, Combined Series B holders, Series A holders. The Series A holders have preference over the common stockholders. In the event that dividends are paid on any class of Series Preferred, the Company shall pay an additional dividend on all outstanding shares of a higher preference in a per-share amount on an as-if-converted-to-common-stock basis. In the event dividends are paid on any common stock, the Company shall pay an additional dividend on all outstanding shares of Series Preferred stock in a per-share amount on an as-if-converted-to-common-stock basis.

Voting Rights

The holders of each share of Series Preferred stock have the right to one vote for each share of common stock on an as-if-converted basis. When converted, the common stock and Series Preferred stockholders have equal voting and power rights.

As long as any Series Preferred stock remains outstanding, a majority vote of the respective class of holders would be required to amend any provisions of the Company's articles of incorporation or bylaws that would adversely affect them.

BIODESIX, INC.

NOTES TO FINANCIAL STATEMENTS

Redemption

Series Preferred stockholders are subject to automatic redemption in the consolidation or merger of the Company or sale of all or substantially all of the Company's assets in which the stockholders of the Company immediately prior to the transaction hold less than 50% of the outstanding securities of the surviving entity. Proceeds available for distribution from such transaction will be distributed consistent with a liquidation event.

Liquidation

In accordance with the articles of incorporation, upon a defined event of acquisition or asset transfer, liquidation, dissolution, or winding up of the Company, any amounts that are available for distribution are to be paid out to its stockholders in the following order of preference, in an amount equal to the per-share Original Issue Price, plus any accrued, declared, and unpaid dividends: Series H holders, Series G holders, Series F holders, Series E holders, Series D holders, Series C holders, Combined Series B holders, Series A holders. If the assets of the Company are insufficient to make payments in full to a class of holders of preferred stock, in the order of preference previously described, then remaining assets shall be distributed among the holders of that class of preferred stock ratably in proportion to the full amounts to which they would otherwise be respectively entitled and the holders of lower preference shares will receive nothing. Upon payment of all preferential amounts required to be paid to the Series Preferred, the holders of common stock and Series Preferred shall be entitled to receive a ratable portion, calculated on an as-if-converted basis, of the remaining assets of the Company available for distribution to its stockholders.

Note 11—Stock Options

In May 2006, the Company adopted the 2006 Employee, Director, and Consultant Stock Plan (the "2006 Incentive Plan") under which the Company is authorized to grant stock awards to employees, directors, and consultants of the Company. The Company is authorized to grant incentive stock options, non-statutory stock options, restricted stock awards, restricted stock unit awards, and stock appreciation rights up to 4,935,043 total shares of stock awards. The award price and vesting terms are determined by the Board of Directors of the Company and evidenced in the award agreement extended to the employee, director, or consultant. The options granted generally terminate ten years from the date of grant and vest over various periods as determined by the Board of Directors of the Company.

In February 2016, the Company adopted the 2016 Equity Incentive Plan ("2016 Incentive Plan") as a successor to and continuation of the 2006 Incentive Plan. As of February 2016, no additional stock awards may be granted under the 2006 Incentive Plan and any unallocated shares remaining available for issuance pursuant to the exercise of options or issuance or settlement of stock awards not previously granted under the 2006 Incentive Plan will cease to be available under the 2006 Incentive Plan and will be added to the share reserve of the 2016 Incentive Plan and be immediately available for issuance pursuant to the stock awards granted in the 2016 Incentive Plan. In addition, all outstanding stock awards granted under the 2006 Incentive Plan will remain subject to the terms of the 2006 Incentive Plan unless they expire, terminate or are forfeited, cancelled or otherwise returned to the Company and will immediately be added to the share reserve and become available for issuance under the 2016 Plan.

Under the 2016 Incentive Plan, the Company is authorized to grant stock awards to employees, directors, and consultants of the Company. The Company is authorized to grant incentive stock options, non-statutory stock options, restricted stock awards, restricted stock unit awards, and stock appreciation rights up to 8,500,000 total shares, plus any shares subject to outstanding stock awards granted under the 2006 Incentive Plan. The award price and vesting terms are determined by the Board of Directors of the Company and evidenced in the award agreement extended to the employee, director, or consultant. The options granted generally terminate 10 years from the date of grant and vest over various periods as determined by the Board of Directors of the Company.

BIODESIX, INC.

NOTES TO FINANCIAL STATEMENTS

The following table presents the activity for options and restricted stock units (RSUs) outstanding (in thousands, except for weighted average exercise price and weighted average grant date value per share):

	Stock Options	Weighted Average Exercise Price	RSUs	Weighted Average Grant Date Value Per Share
Outstanding—December 31, 2017	6,824	$ 0.27	—	$ —
Granted	2,872	0.07	—	—
Forfeited/canceled	(1,624)	0.36	—	—
Exercised	(205)	0.24	—	—
Outstanding—December 31, 2018	7,867	$ 0.21	—	$ —
Granted	5,070	0.37	157	0.13
Forfeited/canceled	(1,323)	0.14	—	—
Exercised	(238)	0.20	—	—
Outstanding—December 31, 2019	11,376	$ 0.29	157	$ 0.13

The following table presents the composition of options outstanding and exercisable as of December 31, 2019 (in thousands, except price):

	Options Outstanding			Options Exercisable	
Exercise Prices	Number	Price*	Life (years)*	Number	Price*
$0.07 – $0.14	8,688	$0.11	8	2,931	$ 0.11
$0.44 – $0.63	807	0.57	2.4	807	0.57
$0.74 – $0.75	681	0.74	4.8	661	0.74
$1.15	1,200	1.15	9.5	696	1.15
Total—December 31, 2019	11,376	$0.29	7.6	5,095	$ 0.41

* Price and Life reflect the weighted average exercise price and weighted average remaining contractual life, respectively.

There were 157,000 restricted stock units outstanding at December 31, 2019, none of which had vested as of December 31, 2019.

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model with the following weighted average assumptions (dollars in thousands):

	For the Years Ended December 31,	
	2019	2018
Approximate risk—free rate	2.26%	2.64%
Average expected life	5.58 years	5.94 years
Dividend yield	—%	—%
Volatility	91%	81%
Estimated fair value of total options granted	$ 447	$ 201

BIODESIX, INC.

NOTES TO FINANCIAL STATEMENTS

The Company estimates 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. The expense recorded for options granted under the Plan is net of estimated forfeitures of 10%.

The following table presents the impact of employee stock-based compensation expense on statements of income line items for the periods indicated (in thousands):

	For the Years Ended December 31,	
	2019	2018
Research and development	$ 33	$ 27
Sales, marketing, general and administrative	137	115
Total stock-based compensation expense	$ 170	$ 142

The unrecognized remaining stock-based compensation balance for shares issued inside of the Plan was approximately $0.3 million as of December 31, 2019 which will be amortized over the next three years.

As of December 31, 2019, the Company has issued a total of 1,218,140 stock options outside the 2006 Incentive Plan to employees of the Company. These options are issued at the discretion of the Board of Directors of the Company to the Chief Executive Officer and their direct reports who wish to convert all or a portion of their incentive compensation to options. The value of the options at the date of grant was calculated using the Black-Scholes option pricing model using approximately the same assumptions as in the previous table other than the term, which is approximately five years. As of December 31, 2019, 1,116,295 options outside of the 2006 Incentive Plan are outstanding and exercisable and have a weighted average exercise price of $1.94, a weighted average remaining life of six years, and were fully vested on the grant date. There was no unrecognized remaining stock-based compensation balance for shares issued outside of the 2006 Incentive Plan as of December 31, 2019.

Note 12—Warrants for Convertible Preferred Stock

The Company has issued warrants to purchase shares of preferred stock in conjunction with the sale of certain preferred shares and certain debt issuances. The grant date fair value and fair value at each reporting date of the warrants was determined using the Black-Scholes option pricing model with weighted average assumptions relatively consistent with those disclosed for stock options above, other than term, which is the contractual term of the warrant and the use of the exercise price and current estimated fair value of the respective series of preferred stock. The preferred warrants are classified as liabilities on the accompanying balance sheets as the underlying preferred stock has a contingent redemption feature. As these warrants are classified as a liability, they are revalued on each reporting date or exercise date, and any change in value is recorded to change in fair value of the warrant liability in the accompanying statements of operations.

BIODESIX, INC.

NOTES TO FINANCIAL STATEMENTS

The following table presents the activity for convertible preferred stock warrants outstanding (in thousands, except weighted average exercise price):

	Series D		Series E		Series G	
	Warrants	Weighted Average Exercise Price	Warrants	Weighted Average Exercise Price	Warrants	Weighted Average Exercise Price
Outstanding—December 31, 2017	907	$ 4.00	1,827	$ 5.00	—	$ —
Granted	—	—	—	—	613	0.75
Forfeited/canceled	(907)	4.00	—	—	—	—
Exercised	—	—	—	—	—	—
Outstanding—December 31, 2018	—	$ —	1,827	$ 5.00	613	$ 0.75
Granted	—	—	—	—	—	—
Forfeited/canceled	—	—	(902)	$ 5.00	—	—
Exercised	—	—	—	—	—	—
Outstanding—December 31, 2019	—	$ —	925	$ 5.00	613	$ 0.75
Weighted average remaining contractual life at December 31, 2019			0.46 years		8.0 years	

Note 13—Subsequent Events

The Company has evaluated all subsequent events through the auditors' report date, which is the date the financial statements were available for issuance.

As of the quarter ended March 31, 2020, the Company failed to meet the revenue requirements specified in the fifth amendment to the 2018 Notes. In accordance with the 2018 Notes, a cure of this failure can be achieved by receiving $10 million from the sale of the Company's debt or equity securities, or a lesser amount if approved by the lender by June 30, 2020. If the Company does not receive this amount from the sale of the Company's securities, amortization of payments for the 2018 Notes will become payable in 24 equal monthly installments beginning June 30, 2020. The Company intends to pursue the equity cure.

In February 2020, the Company called the second mandatory closing of the December 2019 Notes for total cash proceeds of $3.0 million. In March 2020, the Company issued $10 million in convertible debt in two tranches of $5 million, with the first tranche being funded in March 2020. The terms of this debt were the same as the December 2019 Notes (see Note 6).

In March 2020, the World Health Organization declared the outbreak of COVID-19, a novel strain of Coronavirus, a global pandemic. This outbreak is causing major disruptions to businesses and markets worldwide as the virus spreads. The extent of the effect on the Company's operational and financial performance will depend on future developments, including the duration, spread and intensity of the pandemic, and governmental, regulatory and private sector responses, all of which are uncertain and difficult to predict. Although the Company is unable to estimate the financial effect of the pandemic, at this time, if the pandemic continues to evolve into a severe worldwide crisis, it could have a material adverse effect on the Company's business, results of operations, financial condition, and cash flows. The financial statements do not reflect any adjustments as a result of the pandemic.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BIODESIX, INC.

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth all costs and expenses, other than underwriting discounts and commissions, payable by us in connection with the sale of the common stock being registered. All amounts shown are estimates except for the SEC registration fee, the Financial Industry Regulatory Authority (FINRA), filing fee and Nasdaq Global Market initial listing fee.

Item	Amount
SEC registration fee	$ *
FINRA filing fee	*
Initial listing fee	*
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Transfer agent and registrar fees and expenses	*
Miscellaneous	*
Total	$ *

* To be filed by amendment.

Item 14. Indemnification of Directors and Officers.

Section 145 of the Delaware General Corporation Law authorizes a court to award, or a corporation's board of directors to grant, indemnity to directors and officers in terms sufficiently broad to permit such indemnification under certain circumstances for liabilities, including reimbursement for expenses incurred, arising under the Securities Act of 1933, as amended, (Securities Act). Our amended and restated certificate of incorporation to be in effect upon the closing of this offering allows for our indemnification of our directors, officers, employees and other agents to the maximum extent permitted by the Delaware General Corporation Law, and our amended and restated bylaws to be in effect upon the closing of this offering provide for indemnification of our directors and executive officers to the maximum extent permitted by the Delaware General Corporation Law.

We have entered into indemnification agreements with our directors and officers, whereby we have agreed to indemnify our directors and officers to the fullest extent permitted by law, including indemnification against expenses and liabilities incurred in legal proceedings to which the director or officer was, or is threatened to be made, a party by reason of the fact that such director or officer is or was a director, officer, employee, or agent of Biodesix, Inc., provided that such director or officer acted in good faith and in a manner that the director or officer reasonably believed to be in, or not opposed to, the best interest of Biodesix, Inc.

At present, there is no pending litigation or proceeding involving a director or officer of Biodesix, Inc. regarding which indemnification is sought, nor is the registrant aware of any threatened litigation that may result in claims for indemnification.

We maintain insurance policies that indemnify our directors and officers against various liabilities arising under the Securities Act and the Securities Exchange Act of 1934, as amended, that might be incurred by any director or officer in his or her capacity as such.

The underwriters are obligated, under certain circumstances, pursuant to the underwriting agreement to be filed as Exhibit 1.1 hereto, to indemnify us, our officers and our directors against liabilities under the Securities Act.

Item 15. Recent Sales of Unregistered Securities.

The following sets forth information regarding all unregistered securities sold since January 1, 2017.

Issuances of Capital Stock

In April 2017, May 2017, July 2017, December 2017 and February 2018, the Registrant sold an aggregate of 35,496,613 shares of Series G Preferred Stock to accredited investors, including to its directors and their respective affiliates, at a purchase price of $0.75 per share for an aggregate purchase price of approximately $26.6 million, including conversion of indebtedness.

In June 2018, the Registrant issued an aggregate of 10,649,904 shares of Series G Preferred Stock to Integrated Diagnostics as consideration for certain assets and liabilities. See “Business—Material Agreements.” The shares issued at closing also include 2,219,981 shares that were deposited in an escrow account to be used to satisfy any indemnification obligations of the seller that may arise.

In October 2018, February 2019 and May 2019, the Registrant sold an aggregate of 23,923,188 shares of Series H Preferred Stock to accredited investors at a purchase price of $1.15 per share for an aggregate purchase price of approximately $27.5 million, including conversion of indebtedness.

Warrant Issuances

In February 2018, the Registrant issued a warrant to purchase 613,333 shares of Series G Preferred Stock at an exercise price of $0.75 per share to a lender in connection with a loan agreement.

Convertible Promissory Note Issuances

In December 2019, the Registrant issued $6.0 million in convertible debt (the December 2019 Notes) that was scheduled to mature in August 2020. In August 2020, the maturity date of this debt was extended to June 30, 2021. The December 2019 Notes were issued in two tranches of $3.0 million, with the first tranche funded in December 2019. Interest on the December 2019 Notes is 3% per annum and is 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. On or before the maturity date 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 at the completion of this offering. The conversion price will be equal to 80% of the price per share paid for the common stock sold in this offering. In the event of a corporate transaction, the unpaid principal and accrued interest shall become immediately due and payable in the same form of consideration and on the same terms and conditions as the consideration to be received by the holders of the Registrant’s equity securities in such transaction. The holders of the December 2019 Notes include a number of the Registrant’s directors and their affiliates.

In August and September 2019 the Registrant issued $10.0 million in convertible debt (the August 2019 Notes) that was scheduled to mature in August 2020. In August 2020, the maturity date of this debt was extended to June 30, 2021. Interest on the August 2019 Notes is 3% per annum and is payable in full upon maturity through the conversion to Series H Preferred Stock at the original issuance price of $1.15 per share. On or before the maturity date 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 at the completion of this offering. The conversion price would be equal to 95% of the price per share paid for the common stock sold

in this offering. The Registrant may prepay the August 2019 Notes in whole or in part at any time with prior consent of at least two-thirds of the August 2019 noteholders. In the event of a corporate transaction, the unpaid principal and accrued interest shall become immediately due and payable in the same form of consideration and on the same terms and conditions as the consideration to be received by the holders of the equity securities of the Registrant in such transaction. The holders of the August 2019 Notes include a number of the Registrant's directors and their affiliates. In connection with the issuance of the December 2019 Notes, the conversion price of the August 2019 Notes was amended to 80% of the price per share paid for the preferred stock in the Qualified Financing or common stock in an IPO.

Option and Common Stock Issuances

From January 1, 2017 through April 2020, the Registrant granted to certain of its directors, employees, consultants and other service providers options to purchase 5,448,478 shares of common stock with per share exercise prices ranging from $0.07 to $1.15 and have issued shares of its common stock upon exercise of such options.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering. Unless otherwise specified above, the Registrant believes these transactions were exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act (and Regulation D promulgated thereunder), or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer not involving any public offering or under benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed on the share certificates issued in these transactions. All recipients had adequate access, through their relationships with the Registrant, to information about the Registrant. The sales of these securities were made without any general solicitation or advertising.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits.

Exhibit No.	Description
1.1*	Form of Underwriting Agreement.
3.1*	Fifteenth Amended and Restated Certificate of Incorporation of Biodesix, Inc., as currently in effect.
3.2*	Form of Amended and Restated Certificate of Incorporation of Biodesix, Inc., to be in effect upon the closing of the offering.
3.3*	Amended and Restated Bylaws of Biodesix, Inc., as currently in effect.
3.4*	Form of Amended and Restated Bylaws of Biodesix, Inc., to be in effect upon the closing of the offering.
4.1*	Specimen stock certificate evidencing shares of Common Stock.
4.2*	Eleventh Amended and Restated Investor Rights Agreement, by and among Biodesix, Inc. and the investors listed on Exhibit A thereto, dated October 10, 2018.
4.3*	Warrant held by Innovatus Life Sciences Lending Fund I, LP, to Purchase Series G Preferred Stock, dated February 23, 3018.
4.4*	Secured Promissory Note held by Innovatus Life Sciences Lending Fund I, LP, in Biodesix, Inc., dated February 23, 2018.
5.1*	Form of Opinion of Sidley Austin LLP.
10.1*+	Biodesix, Inc. Amended and Restated 2006 Employee, Director and Consultant Stock Plan, as amended to date.
10.2*+	Forms of Stock Option Grant Notice, Option Agreement and Notice of Exercise under Amended and Restated 2006 Employee, Director and Consultant Stock Plan.

Exhibit No.	Description
10.3*+	Biodesix, Inc. 2016 Equity Incentive Plan, as amended to date.
10.4*+	Forms of Stock Option Grant Notice, Option Agreement and Notice of Exercise under 2016 Equity Incentive Plan.
10.5*+	Biodesix, Inc., Third Amended Bonus-to-Options Program, adopted by the Board of Directors on December 31, 2015.
10.6*+	Forms of Stock Option Grant Notice and Option Agreement under the Biodesix, Inc. Bonus-To-Options Program
10.7*+	Form of Indemnification Agreement, by and between Biodesix, Inc. and each of its directors and executive officers.
10.8*+	Non-Employee Director Compensation Policy to be in effect upon the closing of this offering.
10.9*+	Executive Employment Agreement, by and between Biodesix, Inc. and , effective as of .
10.10†*	Office Lease between Aero-Tech Investments, LLC and Biodesix, Inc., dated October 5, 2011.
10.11†*	Lease Assignment of De Soto Facility, dated November 1, 2019.
10.12†*	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, as amended to date.
10.13†*	Patent Assignment between Biodesix, Inc., and Integrated Diagnostics, Inc., dated June 30, 2018.
10.14†*	IP Assignment Agreement between Oncimmune Limited, and Biodesix, Inc., dated October 31, 2019.
10.15†*	IP License Agreement between Oncimmune Limited, and Biodesix, Inc., dated October 31, 2019.
10.16†*	Non-Exclusive License Agreement between Bio-Rad Laboratories, Inc., and Biodesix, Inc., dated August 1, 2019.
10.17†*	Supply Agreement between Biodesix, Inc., and Oncimmune, dated October 31, 2019.
10.18†*	Supply Agreement between Bio-Rad Laboratories, Inc., and Biodesix, Inc., dated August 1, 2019.
10.19†*	Co-Development and Collaboration Agreement between AVEO Pharmaceuticals, Inc., and Biodesix, Inc., dated April 9, 2014, as amended October 14, 2016.
10.20†*	Contingent Value Rights Agreement between Biodesix, Inc. and Holders on Schedule A mentioned within, dated February 22, 2016.
10.21†*	Asset Purchase Agreement among Biodesix, Inc., Integrated Diagnostics, Inc., and the stockholders of Integrated Diagnostics, Inc., listed therein, dated June 30, 2018.
10.22†*	Asset Purchase Agreement between Oncimmune Limited and Biodesix, Inc., dated June 27, 2019, as amended to date.

Exhibit No.	Description
10.23†*	COVID-19 Testing Laboratory Services Agreement by and between Biodesix, Inc., and Centura Health Corporation, dated April 3, 2020.
10.24†*	First Amendment to COVID-19 Testing Laboratory Services Agreement by and between Biodesix, Inc. and Centura Health Corporation, dated April 23, 2020.
10.25†*	Second Amendment to COVID-19 Testing Laboratory Services Agreement by and between Biodesix, Inc. and Centura Health Corporation, dated May 27, 2020.
10.26†*	Third Amendment to COVID-19 Testing Laboratory Services Agreement by and between Biodesix, Inc. and Centura Health Corporation, dated August 7, 2020.
23.1*	Consent of independent registered public accounting firm.
23.2*	Consent of Sidley Austin LLP (included in Exhibit 5.1).
24.1*	Power of Attorney (see signature pages).

* To be filed by amendment.
† 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.

(b) Financial Statement Schedules.

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

Item 17. Undertakings.

The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this Registration Statement in reliance on Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act will be deemed to be part of this Registration Statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus will be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time will be deemed to be the initial *bona fide* offering thereof.

Table of Contents

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Boulder, State of Colorado on , 2020.

BIODESIX, INC.

By: _____
Name: Scott Hutton
Title: President, Chief Executive Officer and Director

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that 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 (i) act on, sign and file with the Securities and Exchange Commission any and all amendments (including post-effective amendments) to this registration statement together with all schedules and exhibits thereto and any subsequent registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, together with all schedules and exhibits thereto, (ii) act on, sign and file such certificates, instruments, agreements and other documents as may be necessary or appropriate in connection therewith, (iii) act on and file any supplement to any prospectus included in this registration statement or any such amendment or any subsequent registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and (iv) take any and all actions which may be 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 substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
_____ Scott Hutton	President, Chief Executive Officer and Director (*Principal Executive Officer*)	, 2020
_____ Robin Harper Cowie	Chief Financial Officer, Secretary and Treasurer (*Principal Financial and Accounting Officer*)	, 2020
_____ David Brunel	Director	, 2020
_____ Jack Schuler	Director	, 2020
_____ John Patience	Director	, 2020
_____ Robert Cawthorn	Director	, 2020
_____ Matthew Strobeck, Ph.D.	Director	, 2020

Table of Contents

Signature	Title	Date
Mark Miller	Director	, 2020
Charles Watts, M.D.	Director	, 2020
Jean Franchi	Director	, 2020
Hany Massarany	Director	, 2020