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

(Mark One)

☑ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2020.

Or

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

Commission file number: 001-31822

ACCELERATE DIAGNOSTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**84-1072256**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

3950 South Country Club Road, Suite 470
Tucson, AZ 85714
(Address of principle executive offices)(Zip Code)

Registrant's telephone number, including area code:
(520) 365-3100

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

Title of each class	Trading symbol	Name of each exchange on which registered
Common Stock, $0.001 par value per share	AXDX	The Nasdaq Stock Market LLC (The Nasdaq Capital Market)

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).
☑ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 pursuant to Section 13(a) of the Exchange Act. ☐

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

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

The aggregate market value of the shares of the registrant's common stock held by non-affiliates on June 30, 2020, the last day of the registrant's most recently completed second fiscal quarter, was approximately $480.1 million based on the closing price quoted on The Nasdaq Capital Market.

There were 59,325,578 shares of common stock of the registrant outstanding as of February 23, 2021.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement relating to the registrant's 2021 Annual Meeting of Stockholders are incorporated by reference in Part III of this Form 10-K.

TABLE OF CONTENTS

Introductory Note	4
Forward-Looking Statements	4
Industry and other data	4
PART I	6
Item 1. Business	6
Item 1A. Risk Factors	19
Item 1B. Unresolved Staff Comments	42
Item 2. Properties	42
Item 3. Legal Proceedings	42
Item 4. Mine Safety Disclosures	43
PART II	44
Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	44
Item 6. Selected Financial Data	45
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations	46
Item 7A. Quantitative and Qualitative Disclosures About Market Risk	56
Item 8. Financial Statements and Supplementary Data	57
Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	94
Item 9A. Controls and Procedures	94
Item 9B. Other Information	94
PART III	95
Item 10. Directors, Executive Officers and Corporate Governance	95
Item 11. Executive Compensation	95
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	95
Item 13. Certain Relationships and Related Transactions, and Director Independence	95
Item 14. Principal Accounting Fees and Services	95
PART IV	96
Item 15. Exhibits, Financial Statement Schedules	96
Item 16. Form 10-K Summary	96
SIGNATURES	99

Introductory Note

References herein to “we,” “us” or “our” refer to Accelerate Diagnostics, Inc. and its wholly owned subsidiaries, unless the context specifically requires otherwise.

The Accelerate Pheno® system is also generically referred to herein as the “ID/AST System” or “Accelerate ID/AST System.”

Forward-Looking Statements

This Form 10-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and the Company intends that such forward-looking statements be subject to the safe harbors created thereby. These forward-looking statements, which can be identified by the use of words such as “may,” “will,” “expect,” “anticipate,” “estimate,” or “continue,” or variations thereon or comparable terminology, include the Company’s future development plans and growth strategy, including plans and objectives relating to the products and future economic performance of the Company, projections as to when certain key business milestones may be achieved, the potential of the Company’s products or technology, the growth of the market, the Company’s estimates as to the size of the Company’s market opportunity and potential pricing, the Company’s competitive position and estimates of time reduction to results. In addition, all statements other than statements of historical facts that address activities, events, or developments the Company expects, believes, or anticipates will or may occur in the future, and other such matters, are forward-looking statements.

The forward-looking statements included herein are based on current expectations that involve a number of risks and uncertainties. These forward-looking statements are based on assumptions that the Company will retain key management personnel, that the Company will be able to protect its intellectual property, the Company’s ability to respond to technological change, that the Company will accurately anticipate market demand for the Company’s products and that there will be no material adverse change in the Company’s operations or business. Assumptions relating to the foregoing involve judgments with respect to, among other things, future economic, competitive and market conditions and future business decisions, all of which are difficult or impossible to predict accurately and many of which are beyond the control of the Company. Although the Company believes that the assumptions underlying the forward-looking statements are reasonable, any of the assumptions could prove inaccurate and, therefore, there can be no assurance that the results contemplated in forward-looking statements will be realized. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

The following discussion should be read in conjunction with the Company’s audited financial statements and related notes included elsewhere herein. The Company’s future operating results may be affected by various trends and factors which are beyond the Company's control. These include, among other factors, general public perception of issues and solutions, and other uncertain business conditions that may affect the Company’s business. The Company cautions the reader that a number of important factors discussed herein, and in other reports, filed with the Securities and Exchange Commission (the “SEC”), including but not limited to the risks in the section entitled “Risk Factors” in this Form 10-K, could affect the Company’s actual results and cause actual results to differ materially from those discussed in forward-looking statements.

Risk Factors Summary

We are subject to a variety of risks and uncertainties, including risks related to legal, regulatory, and legislative matters; risks related to our business and operations; risks related to market and financial matters; risk related to technology; risks related to the ownership of our common stock; and certain general risks, which could have a material adverse effect on our business, financial condition, results of operations and cash flows. These risks include, but are not limited to, the following principal risks:

- We have limited revenues from our products and no assurance of future revenues.
- Until we received FDA approval to market the Accelerate Pheno system, we were a development-stage company and therefore incurred significant losses in prior years. While we are in the early years of

commercializing the Accelerate Pheno system, we may continue to incur losses. We cannot be certain that we will achieve or sustain profitability.

- Our future profitability and continued existence are dependent in large part upon the successful commercialization of the Accelerate Pheno system and further development and commercialization of associated test kits and complimentary products.
- If we are not successful in the development of product improvements and additional test kits and commercialization of the Accelerate Pheno system and related new products, such failure could lead to impairment of certain of our intellectual property and may result in our ceasing operations.
- If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of our products may be delayed and, as a result, our stock price may decline.
- We may not be able to enhance the capabilities of our current and new products to keep pace with our industry's rapidly changing technology and customer requirements.
- We are developing additional uses for the Accelerate Pheno system. Any failure or delay in launching new applications may compromise our ability to achieve our growth objectives.
- The failure of the Accelerate Pheno system or any future diagnostic products to perform as expected could significantly impair our reputation and the public image of our products, and we may be subject to legal claims arising from any defects or errors.
- Our industry is highly competitive, and we may not be successful in competing with our competitors. We currently face competition from new and established competitors and expect to face competition from others in the future, including those with new products, technologies or techniques.
- The COVID-19 pandemic has had, and is expected to continue to have, a significant adverse impact on our commercial operations and also exposes our business to other risks.
- We have made and intend to make significant additional investments in research and development, but there is no guarantee that any of these investments will ultimately result in a commercial product that will generate revenues.
- The regulatory processes applicable to our products and operations are expensive, time-consuming, and uncertain and may prevent us from obtaining required approvals for the commercialization of our products.
- Our stock price has been volatile and may continue to be volatile and traded on low volumes.
- We may require additional capital in the future, and you may incur dilution to your stock holdings.
- Servicing our debt will require a significant amount of cash, and we may not have sufficient cash flow from our business to pay our debt.

For a more complete discussion of the material risk factors applicable to us, see "Risk Factors" in Part I, Item 1A of this Form 10-K.

Industry and other data

We obtained the industry, statistical and market data from our own internal estimates and research as well as from industry and general publications and research, surveys and studies conducted by third parties. Industry publications, studies and surveys generally state that they have 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 statistical, market and industry data from third-party sources. While we believe our internal Company research is reliable and the market definitions are appropriate, neither such research nor these definitions have been verified by any independent source.

PART I

Item 1. Business

Overview

Accelerate Diagnostics, Inc. (“Accelerate”) is an *in vitro* diagnostics company dedicated to providing solutions that improve patient outcomes and lower healthcare costs through the rapid diagnosis of serious infections. Microbiology laboratories need new tools to address what the U.S. Centers for Disease Control and Prevention (the “CDC”) calls one of the most serious healthcare threats of our time, antibiotic resistance. A significant contributing factor to the rise of resistance is the overuse and misuse of antibiotics, which is exacerbated by a lack of timely diagnostic results. The delay of identification and antibiotic susceptibility results is often due to the reliance by microbiology laboratories on traditional culture-based tests that often take two to three days to complete. Our technology platform is intended to address these challenges by delivering significantly faster testing of infectious pathogens in various patient sample types.

Our first system to address these challenges is the Accelerate Pheno® system. The Accelerate PhenoTest® BC kit, which is the first test kit for the system, provides ID and AST results for patients suspected of bacteremia or fungemia, both life-threatening conditions with high morbidity and mortality risk. This test kit utilizes genotypic technology to identify (ID) infectious pathogens and phenotypic technology to conduct antibiotic susceptibility testing (AST), which determines whether live bacterial cells are resistant or susceptible to a particular antimicrobial. This information is used to rapidly modify antibiotic therapy to lessen adverse events, improve clinical outcomes, and help preserve the useful life of antibiotics.

On June 30, 2015, we declared our conformity to the European In Vitro Diagnostic Directive 98/79/EC and applied a CE Mark to the Accelerate Pheno system and the Accelerate PhenoTest BC kit for *in vitro* diagnostic use. On February 23, 2017, the U.S. Food and Drug Administration (“FDA”) granted our de novo request to market our Accelerate Pheno system and Accelerate PhenoTest BC kit.

In 2017, we began selling the Accelerate Pheno system in hospitals in the United States, Europe, and the Middle East. Consistent with the Company's “razor” / “razor-blade” business model, revenues to date have principally been generated from the sale or leasing of the instruments and the sale of single use consumable test kits.

In 2019 and 2020, based upon our initial experience selling and implementing the Accelerate Pheno system, we implemented initiatives to improve and refine our commercial execution and to re-engineer our product implementation processes. Improving our commercial and implementation capabilities remains an emphasis going forward, along with geographic expansion and product innovation.

On April 13, 2020 we signed a non-exclusive agreement with BioCheck to sell MS-FAST, a fully-automated chemiluminescence immunoassay analyzer, along with BioCheck’s SARS-CoV-2 tests for the detection of IgG and IgM antibodies (together the “BioCheck COVID-19 Serology System”). We will pay BioCheck a pre-defined price for the sale of each BioCheck COVID-19 Serology System device and assay. The BioCheck COVID-19 Serology System has a CE Mark and has obtained FDA Emergency Use Authorization. The Company has commercially released this product in the U.S. and in Europe, but has not sold any BioCheck COVID-19 Serology Systems during the year ended December 31, 2020.

On July 29, 2020 we signed an exclusive product supply and collaboration agreement with Ascend to commercialize a benchtop MALDI identification platform to complement the Company's expanded product offering plans.

These are the first third-party product commercialization agreements entered into by the Company. As such, there are uncertainties regarding market demand, market acceptance, supply constraints, FDA authorization, ramp up expenditures, and other factors impacting market penetration.

History

In 2012, our Board of Directors and management team established a new strategic direction for the Company, which was (1) to focus on the internal development, manufacture, and commercialization of the Accelerate Pheno system and (2) to discontinue efforts to develop and actively market OptiChem and our other surface chemistry products. Our Board of Directors and management pursued this new strategic direction based on the belief that we could internally develop and commercialize the Accelerate Pheno system, formerly called the BacCel System.

Since the adoption of the new strategic direction in 2012, we have made significant investments in research and development personnel, facilities, equipment, and consumables to support the internal development of the Accelerate Pheno system. The Company has also invested in the hiring of regulatory, manufacturing, quality, sales, and marketing personnel experienced in the manufacture and commercialization of medical devices.

This strategic direction required the Company to raise additional capital, including through the following transactions:

- In June 2012, the Company raised $14.4 million through the sale of common stock to Abeja Ventures, LLC.
- In March 2013, the Company obtained additional capital through the exercise of warrants issued to Abeja Ventures, LLC in the aggregate amount of $20.1 million.
- In August 2013, the Company completed a rights offering that raised gross proceeds of $20.0 million.
- In April 2014, the Company completed a rights offering that raised gross proceeds of $45.0 million.
- In December 2015, the Company completed a publicly marketed common stock offering that raised gross proceeds of $109.3 million.
- In May 2017, the Company completed another publicly marketed common stock offering that raised additional gross proceeds of $89.0 million.
- In March 2018, the Company completed a convertible debt offering providing additional gross proceeds of $171.5 million.
- In December 2020, the Company executed a private investment in public equity financing agreement with five of its directors that will provide the Company gross proceeds of $32.0 million in the first half of 2021.

This strategic direction coupled with various investments permitted the development, clinical trial and FDA registration, and commercialization of the Accelerate Pheno system and the Accelerate PhenoTest BC kit. Accelerate has expanded the strategic direction it took in 2012 to include the development of additional test kits, systems, and geographic expansion to advance its mission to improve patient outcomes and lower healthcare costs through the rapid diagnosis of serious infections globally.

Clinical Need

Antibiotic resistance is a major contributing factor to the significant impact sepsis is posing to healthcare, costing the U.S. an estimated $62 billion per year in healthcare and productivity costs. Notably these costs are estimated to have doubled between 2016 and 2019. Increasing infection rates and misuse of antibiotics results in serious treatment complications. Recent studies have shown that the number of hospital-acquired infections in the United States ranges from 214,700 to 1.4 million per year, contributing to an estimated 75,000 deaths per year. According to the CDC, at least 2.8 million people get an antibiotic-resistant infection each year in the United States. Moreover, inappropriate antibiotic use is widespread. Of the approximately 35 million patients admitted to U.S. hospitals each year, 56% are put on empiric antibiotic therapy, of which more than half are on inappropriate or unnecessary antibiotics.

AST testing determines which antibiotics will be effective and which will be ineffective for treating a particular patient's infections. Accordingly, AST is ideally designed to address this challenge but previous post culture methods for obtaining AST results took 2-3 days to deliver. Studies have shown that even a modest decrease in the time it takes to deliver an AST result correlates to reduced length and cost of hospital stay per patient. One such study showed that a five hour reduction in the time to receive an AST result delivered a two-day reduction in length of stay and a reduction in patient treatment costs of $1,750 per patient. Based on our analysis, we estimate that the Accelerate Pheno system is capable of delivering clinically-actionable results in approximately 19 hours from the time a blood sample is received by the laboratory, while current solutions often require 2-3 days to deliver these results. Studies have established that results from the Accelerate Pheno System are available, on average, 29 hours earlier with respect to ID and 54 hours earlier with respect to AST, than traditional methods.

Rapid antibiotic susceptibility testing is particularly important in improving sepsis patient outcomes. Sepsis is responsible for approximately 270,000 deaths in the U.S. annually, which is one in three U.S. hospital patient deaths. Optimizing antibiotics within the first 24 hours of hospitalization is critical. It is estimated that 80% of sepsis deaths could be prevented with rapid diagnosis and treatment. By providing clinically-actionable results in hours instead of days, the Accelerate Pheno system plays a significant role in providing timely, effective therapy to sepsis patients.

Market Opportunity

Across North America, Europe and Asia Pacific geographies, we estimate there are well over 100 million ID and AST tests completed annually across various sample types. We estimate that of these tests, our current test kit, the Accelerate PhenoTest BC kit, can address the over four million blood culture samples tested each year in North America and Europe.

In addition, there is a substantial existing installed base of legacy automated AST systems. Principally, these systems are the bioMerieux Vitek 2®, Danaher Microscan® Systems, and Becton Dickensen Phoenix. These competitors' AST products require purified bacterial strains or "isolates" for analysis, which require at least overnight culturing of a sample to produce enough organisms to test. This installed base represents an attractive opportunity to both complement and replace existing laboratory workflows with the Accelerate Pheno and our next generation rapid testing solutions.

Certain government initiatives are complementary to the Accelerate Pheno system. For example, Centers for Medicare and Medicaid Services ("CMS") programs, which are designed to decrease hospital-acquired infections directly impact hospital budgets via reimbursement cuts, thereby incentivizing providers to enhance infection-management protocols. These programs include the Medicare Hospital-Acquired Condition Reduction Program and the Hospital Readmissions Reduction Program. Similarly, on March 27, 2015, the White House released the National Action Plan for Combating Antibiotic-Resistant Bacteria, which directly and indirectly promotes rapid susceptibility testing. The plan identifies several milestones to accomplish this goal, such as calling on the National Institutes of Health to fund new projects and provide prizes aimed at the development of rapid diagnostic tests that characterize antibiotic susceptibility and improve antibiotic stewardship; mandating implementation of antibiotic stewardship programs by all hospitals participating in Medicare and Medicaid; and calling on the FDA and CMS to evaluate new regulatory pathways to promote development and adoption of innovative infectious disease diagnostics.

Products

The Accelerate Pheno system is the Company's first *in vitro* diagnostic platform and is intended for the identification and antibiotic susceptibility testing of pathogens most commonly associated with serious or health care-associated infections, including Gram-positive and Gram-negative organisms. The system leverages long-accepted bacteriological testing principles enhanced by proprietary technology and automation enabling the analysis of live microbial cells. It detects and identifies pathogens directly from a single patient sample followed by antimicrobial susceptibility testing based on the identification results. Antimicrobial susceptibility is determined by morphokinetic cellular analysis ("MCA"), a process that evaluates the change of individual cells and microcolonies in response to a range of antibiotics over time. The system's combined technologies and automation dramatically reduce the need for time-consuming traditional bacterial culturing, thus eliminating the major source of delay with current testing methods. Identification results are typically available within 90 minutes of presenting the patient sample to the system, and susceptibility results, including minimum inhibitory concentrations ("MIC"), are available about five hours after identification results. In the case of the Accelerate PhenoTest BC kit for positive blood culture samples, a blood culture screening step is required, which we estimate takes an average of approximately 12 hours to complete before the sample is introduced to the Accelerate Pheno system. This combined turnaround time is a significant improvement over the multiple days currently required to obtain AST results, with MIC details, using conventional testing methods.

The Accelerate Pheno system features walk-away automation and consists of a fixed instrument and proprietary single-use test kit. The instrument consists of module(s) connected to a single analysis computer, which allows hospitals to acquire various numbers of modules to address their particular test volume. In order to run a patient sample on the Accelerate Pheno system a laboratory technician would pipette the patient sample into our system, insert the Accelerate PhenoTest BC kit, and initiate the run. In the case of our initial test, a positive blood culture sample is introduced to the system by pipetting directly from the blood culture bottle into our Accelerate

PhenoTest BC kit.

The Accelerate Pheno system is the result of over a decade of technological development and several years of instrument design and engineering. The system is comprised of custom-engineered functional components, including a robotic pipettor for fluidic manipulation, an optical system with both dark-field and fluorescent illumination, and an imaging system. These sensor components, among others, are used in the four processes that follow, each of which is a crucial component in delivering the rapid ID and AST results.

These processes include:

- *Automated specimen preparation.* The initial step in the process is the automated purification of samples through an on-board and proprietary process to separate live organisms from sample debris.

- *Live-cell immobilization.* Following preparation, the purified sample is moved to the imaging cassette where pathogens are immobilized onto the cassette surface such that they can be imaged and analyzed in a stationary position during the identification and antibiotic susceptibility testing.

- *Identification testing via fluorescent in situ hybridization (FISH).* The now immobilized cells are tested with our proprietary FISH probes to enable identification. Because the genetic sequences of bacteria are distinctive, the binding of fluorescently labeled probes indicates the presence of a specific target sequence of RNA associated with a single or group of bacterial species or yeasts. When the probe finds a targeted sequence, it binds to it—generating a fluorescent signal—which is visible by the imaging system on the Accelerate Pheno system. Positive fluorescent signals from more than one target probe indicate polymicrobial samples and a universal bacterial stain discriminates target from non-target bacteria or fungi. The identification result is presented on the Accelerate Pheno system's graphic user interface in approximately 90 minutes from the introduction of the sample into the Accelerate Pheno system.

- *Susceptibility testing via live-cell optical analysis.* With the identification of the pathogen known, the system’s software determines the antibiotic panel to be used for susceptibility testing. These antibiotics, growth media, and additional patient sample are introduced to additional channels on the optical cassette. Finally, our proprietary imaging platform and algorithms determine the minimum inhibitory concentration of the bacteria by observing which antibiotics arrested live cell growth and led to cell death and which antibiotics were ineffective in ceasing live cell growth. The susceptibility test result is presented approximately five hours after the conclusion of the identification test.

The Accelerate Pheno system has been the subject of dozens of scientific posters and studies. Recent studies and associated publications have covered subjects including time savings, performance, opportunity rates for clinical interventions, and clinical outcomes including length of stay. Published study abstracts and links to full papers are available on our website at http://acceleratediagnostics.com/updates/#publications.

Research and Development

The Company plans to continue making significant investments in the research and development of new applications for existing technologies and in the research and development of new complementary technologies.

Since the completion and launch of the Accelerate Pheno system and Accelerate PhenoTest BC kit, the Company has focused on product improvements and the development of additional test kits to address opportunities in additional sample types including, but not limited to, our next kit for bacterial pneumonia samples. Similar to the Accelerate PhenoTest BC kit, the objective is to develop test kits that work seamlessly with the Accelerate Pheno system and deliver substantial benefits to microbiology laboratories and to physicians in the treatment of serious infections. In 2020, due to pandemic-related factors, the Company placed its bacterial pneumonia test kit program on hold in preference to the development of other test kits and a next generation platform.

We anticipate seeking separate regulatory approval for each additional test kit that we develop. If and when we determine that we will pursue regulatory approvals for those applications, we would likely include the identification of the most prevalent infectious pathogens found in each specimen type and the most commonly prescribed antimicrobial agents for treatment.

Our research activity also includes the evaluation and development of (i) technologies which reduce the cost and increase the throughput of AST, (ii) improved identification technologies, and (iii) other platform technologies potentially useful in addressing other parts of the infectious disease laboratory testing workflow.

The Company's research and development expenses for the years ended December 31, 2020, 2019 and 2018, are included in the consolidated statement of operations and comprehensive loss.

Intellectual Property

We rely on a combination of patent, copyright, trademark and trade secret laws, employee and third-party non-disclosure agreements, license agreements, and other intellectual property protection methods to protect our proprietary rights. We intend to continue developing intellectual property, and we intend to aggressively protect our position in key technologies. Our patented technology covers key components of the Accelerate Pheno system and is, thus, very important to the Company. Our patents are focused on several key technologies, including our automated process for sample preparation, and methods for imaging and analysis of individual pathogen cells. The Company's first patent on the Accelerate Pheno system technology, U.S. Patent No. 7,341,841 titled "Rapid Microbial Detection and Antimicrobial Susceptibility Testing," was issued on March 11, 2008. The patent specification covers methods used to derive identification and antibiotic susceptibility from tests on individual immobilized bacterial cells. As of December 31, 2020, we had 58 issued patents worldwide, including 19 patents issued in the United States and 39 issued outside the United States. Our patents are set to expire on various dates in 2022 through 2035. Additionally, as of December 31, 2020, we had 12 patent applications pending worldwide, including 7 U.S. applications and 5 applications outside the United States. The Company believes that its patent suite would make it difficult for any other company to conduct rapid antibiotic susceptibility testing of individual pathogens utilizing our technology. From a trademark perspective, we had 41 registered marks protecting our brand and prospective products both domestically and internationally.

Sales, Marketing, and Distribution

The target customers for our products are hospital microbiology laboratories that perform identification and antibiotic susceptibility testing. In general, we utilize our own direct sales force to market the Accelerate Pheno system to our targeted customers. However, in select geographies, we use third-party distributors to market, sell and support the product.

The business, while not seasonal, is influenced by the timing of hospital budget and tender approval cycles which vary by geography. Due to the relatively long sales cycles, order back-logs are not typical, and we manage our inventory based on an estimation of demand forecasts.

For the year ended December 31, 2020, none of the Company's customers represented more than 10% of the Company's total net sales.

Competition

The leading companies with automated microbiological testing products include Becton, Dickinson and Company ("BD"), bioMerieux, Danaher Corporation ("Danaher") and Thermo Fisher Scientific's subsidiary TREK Diagnostics Systems, Inc. ("TREK"). These companies provide products for the broad-based culturing and analysis of a wide variety of bacteria. These competitors' AST products require purified bacterial strains or "isolates" for analysis, which require at least overnight culturing of a sample to produce enough organisms to test. We believe these standard culturing methods, including enrichment growth and colony isolation, cannot achieve the speed that the Accelerate Pheno system provides. These companies and other competitors, such as T2 Biosystems have automated bacterial identification products which provide a component of the clinical diagnostics solution but lack rapid AST functionality.

Potential competitors for rapid AST have recently made announcements at various trade shows, including - but not limited to; Quantamatrix, Q-Linea, Specific Technologies, and Lifescale. While we do not have visibility into all of these companies' respective stages of development, none have completed FDA registration trials, achieved FDA approval, established performance and outcome data, or commercialized their products. In addition to existing and emerging companies, there are manual methods which could be validated by individual hospitals to deliver rapid identification and susceptibility results. See *"Risk Factors-Risks Related to Our Business and Strategy-Our*

industry is highly competitive, and we may not be successful in competing with our competitors. We currently face competition from new and established competitors and expect to face competition from others in the future, including those with new products, technologies or techniques" for additional information.

Industry Developments

The clinical microbiology industry is subject to rapid technological changes, and new products are frequently introduced for rapid bacterial identification using genes or other molecular markers. Numerous acquisitions, licenses, and distribution arrangements have been announced over the last few years for such products. However, we do not believe that any of these technologies offers the advantages afforded by the Accelerate Pheno system. For example, gene detection can be highly sensitive and specific for the identification of pathogens, but very few antibiotic resistance mechanisms are simple enough to accurately guide drug selection. Even in those rare instances where there is a direct relationship between a gene and effective resistance, such as particular *Methicillin-Resistant Staphylococcus aureus* (MRSA) strains, leading literature has reported novel mutations that escape detection by recently commercialized tests.

Fundamental biological limitations arise from the complexity of the majority of drug resistance expression mechanisms. This complexity precludes direct interpretation of molecular marker presence or absence and extrapolating to prescription guidance. Accordingly, recent studies indicate that identification and resistance results alone are not consistently acted upon by clinicians. Further, many new diagnostic technologies also require prior isolation of cultured colonies in order to assure accuracy. The time required to obtain such isolates, with a minimum of overnight turnaround, prevents these technologies from serving as rapid diagnostics for treatment decision support.

Another new technology receiving wide attention is mass spectrometry, and particularly the matrix-assisted laser desorption ionization time of flight version ("MALDI-TOF"), such as the Biotyper® system from Bruker Corporation. Bruker Corporation has agreements with a number of companies for distribution, including BD, TREK, and Siemens. bioMerieux has a similar system for distribution with Shimadzu Corporation. These systems build an empiric database from protein spectra acquired from many thousands of purified bacterial and fungal strains. They require a pure strain isolate for analysis and enrichment culturing to produce enough material to analyze. Some research papers on these systems report attempts to directly analyze isolate or blood culture smears, but results are not as reliable as those from samples prepared using a cleanup process to produce crude protein extracts.

MALDI-TOF systems have a major advantage over other molecular methods in identifying a very broad range of organisms. Cost of ownership is also substantially below that of older molecular methods. But the requirement for extensive organism enrichment and purification, as well as the inability to quantify live organisms or distinguish samples derived from viable organisms, substantially limits this technology from time-critical decision support. As with the older molecular methods, MALDI-TOF systems cannot identify major drug resistance expression and face the same fundamental biological barriers as gene detection. Based on the advantages of breath of menu and cost per analysis the Company is pursuing the addition of MALDI-TOF based applications for future ID solutions.

Government Regulation

Our products under development and our operations are subject to significant government regulation. In the United States, our products are regulated as medical devices by the FDA and other federal, state, and local regulatory authorities.

FDA Regulation of Medical Devices

The FDA and other U.S. and foreign governmental agencies regulate, with respect to medical devices:

- design, development, manufacturing, and storage;
- testing, content, and language of instructions for use and storage;
- labeling;
- pre-clinical testing and clinical trials;

- product safety;
- advertising, promotion, marketing, sales, and distribution;
- pre-market clearance and approval;
- record-keeping procedures;
- advertising and promotion;
- recalls and corrective field actions;
- post-market reporting, including reporting of deaths, serious injuries, and malfunctions that, if they were to recur, could lead to death or serious injury;
- post-market studies and surveillance; and
- product import and export.

In the United States, numerous laws and regulations govern all the processes by which medical devices are brought to market and marketed. These include the Federal Food, Drug and Cosmetic Act (the “FDCA”) and the FDA's regulations implementing the law codifying the FDCA.

FDA Pre-market Clearance and Approval Requirements

Each medical device we seek to commercially distribute in the United States must first receive 510(k) clearance, approval of a reclassification petition or de novo classification request, or pre-market approval from the FDA, unless specifically exempted by the FDA. The FDA categorizes medical devices into one of three classes - Class I, II, or III - based on their risks and the regulatory controls necessary to provide a reasonable assurance of safety and effectiveness. Class I devices generally pose the lowest risk to the patient and/or user and Class III devices pose the highest risk. Regulatory control increases from Class I to Class III. The device classification regulation defines the regulatory requirements for a general device type. Generally, in order to market or commercially distribute a Class I, II, and III device intended for human use in the United States, for which a Premarket Approval application (PMA) is not required, one must submit a 510(k) to FDA unless, as noted, the device is exempt from the 510(k) pre-market notification requirements of the FDCA. Per the FDA, generally, most Class I devices are exempt from Premarket Notification 510(k); most Class II devices require Premarket Notification 510(k); and most Class III devices require a PMA.

510(k) Clearance Process

To obtain 510(k) clearance, we must submit a pre-market notification to the FDA demonstrating that the proposed device is substantially equivalent to a device that has previously obtained 510(k) clearance, a device that has been classified into Class I or II, or a device that was legally marketed before May 28, 1976 and that is not yet subject to an FDA order requiring pre-market approval. In rare cases, Class III devices may be cleared through the 510(k) process. The FDA has committed to review most 510(k) decisions within 90 days, but the review clock may be stopped due to requests for additional information. A decision may take significantly longer, and clearance is never assured. Although many 510(k) pre-market notifications are cleared without clinical data, in some cases, the FDA requires clinical data to support substantial equivalence. In reviewing a pre-market notification submission, the FDA may request additional information, including clinical data, which may significantly prolong the review process.

After a device receives 510(k) clearance, any subsequent modification of the device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or, in some cases, approval of a PMA. The FDA requires each manufacturer to make this determination initially, but the FDA may review any such decision and may disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination, the FDA may require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or approval of a PMA is obtained. Under these circumstances, the FDA may also subject a manufacturer to enforcement action and sanctions, including those described below. In addition, the FDA is currently evaluating the 510(k) process and may make substantial changes to regulatory

requirements, including changes that could affect which devices are eligible for 510(k) clearance, the FDA's ability to rescind 510(k) clearances, and additional requirements that may significantly impact the 510(k) review process.

Pre-market Approval ("PMA") Process

A PMA generally must be submitted if the medical device is in Class III or cannot be cleared through the 510(k) process. A PMA must be supported by extensive technical, preclinical, clinical, manufacturing, and labeling data to demonstrate to the FDA's satisfaction the safety and effectiveness of the device.

After a PMA is submitted and filed, the FDA begins an in-depth review of the submitted information. During this review, the FDA may request additional information or clarification of information already provided. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will conduct a pre-approval inspection of the manufacturing facility to ensure compliance with Quality System Regulation ("QSR"), which imposes elaborate development, testing, control, documentation and other quality assurance requirements on the design and manufacturing process. The FDA has committed to review most PMAs within 180 days where an advisory panel is not required and within 320 days where an advisory panel is required, but the review clock may be stopped due to requests for additional information. A decision may take significantly longer, and approval is never assured. The FDA may approve a PMA with post-approval conditions intended to ensure the safety and effectiveness of the device including restrictions on labeling, promotion, sale, and distribution and collection of safety data. Failure to comply with the conditions of approval can result in enforcement action and sanctions, including those described below. New PMAs or PMA supplements are required for significant modifications to the manufacturing process, labeling of the product, or design of a device that is approved through the PMA process. PMA supplements often require submission of the same type of information as an original PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory panel.

De novo Classification Process

Medical device types that the FDA has not previously classified as Class I, II, or III are automatically classified into Class III regardless of the level of risk they pose. The Food and Drug Administration Modernization Act of 1997 established a new route to market for low-to-moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the de novo classification procedure. 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. Prior to the enactment of the Food and Drug Administration Safety and Innovation Act ("FDASIA") in July 2012, a medical device could only be eligible for de novo classification if the manufacturer first submitted a 510(k) pre-market notification and received a determination from the FDA that the device was not substantially equivalent to a predicate device. FDASIA streamlined the de novo classification pathway by permitting manufacturers to also request de novo classification directly without first submitting a 510(k) pre-market notification to the FDA and receiving a not substantially equivalent determination. Under FDASIA, the FDA is required to classify the device within 120 days following receipt of such a direct de novo request; however, this time period can be extended if questions and/or requests for additional information are asked of the applicant. If the manufacturer seeks classification into Class II, the manufacturer should include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. In addition, the FDA may reject a de novo request if the FDA identifies a legally marketed predicate device that would be appropriate for a 510(k), determines that the device is not low-to-moderate risk, or determines that general controls would be inadequate to control the risks and special controls cannot be developed.

In July of 2016, we submitted a de novo request for evaluation of automatic Class III Designation to the FDA for the Accelerate Pheno system and Accelerate PhenoTest BC kit. On February 23, 2017, the FDA granted our de novo request to market the Accelerate Pheno system and Accelerate PhenoTest BC kit as a Class II medical device.

Clinical Trials

Clinical trial data is typically required to support a PMA and is usually required for a 510(k) pre-market notification. Initiation of a clinical trial generally requires submission of an application for an Investigational Device Exemption (an "IDE") to the FDA. The IDE application must be supported by appropriate data, such as animal and

laboratory testing results, showing that it is safe to test the device in humans and that the investigational protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of patients, unless the product is deemed a non-significant risk device and eligible for abbreviated IDE requirements. Clinical trials for a significant risk device may begin once the IDE application is approved by the FDA as well as the appropriate institutional review boards at the clinical trial sites and the informed consent of the patients participating in the clinical trial is obtained. After a trial begins, the FDA may place it on hold or terminate if it concludes that the clinical subjects are exposed to unacceptable risks. Any trials we conduct must be undertaken in accordance with FDA regulations as well as other federal regulations and state laws concerning human subject protection and privacy. Moreover, the results of a clinical trial may not be sufficient to obtain clearance or approval of the product.

Clinical trial sponsors may also be subject to the Medicare Secondary Payer laws, which prohibit Medicare from making a payment if payment has been made or can reasonably be expected to be made by other plans, such as liability insurance plans (including self-insurance). Section 111 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 ("MMSEA") established mandatory reporting requirements with respect to Medicare beneficiaries who receive settlements, judgments, awards, or other payment from liability insurance (including self-insurance) plans. When payments are made by sponsors of clinical trials for complications or injuries arising out of the trials, such payments are considered to be payments by liability insurance (including self-insurance) and must be reported. Section III of the MMSEA includes authority for CMS to impose civil monetary penalties against liability insurance (including self-insurance) plans that are determined to be non-compliant with the applicable reporting requirements.

Pervasive and Continuing Regulation

After a medical device is placed on the market, numerous FDA regulatory requirements apply, including the following:

- the QSR, which imposes elaborate development, testing, control, documentation, and other quality assurance requirements on the design and manufacturing process;
- establishment registration, which requires establishments involved in the production and distribution of medical devices, intended for commercial distribution in the United States, to register with the FDA;
- medical device listing, which requires manufacturers to list the devices they have in commercial distribution with the FDA;
- labeling regulations and various statutory provisions, which prohibit false or misleading labeling, as well as the promotion of products for unapproved or "off-label" uses, and impose other restrictions on labeling; and
- post-market reporting requirements, which require that manufacturers report to the FDA deaths, serious injuries, and malfunctions that, if they were to recur, could lead to death or serious injury, recalls, and corrective field actions.

In certain cases, advertising is also subject to scrutiny by the Federal Trade Commission ("FTC") in addition to the FDA. The FDA and other agencies actively enforce these and other applicable laws and regulations, accordingly. Failure to comply with applicable requirements may result in enforcement action by the FDA and/or the U.S. Department of Justice, which may include one or more of the following administrative or judicial sanctions:

- untitled letters or warning letters;
- fines, injunctions, and civil penalties;
- mandatory recall or seizure of our products;
- administrative detention or banning of our products;
- operating restrictions, partial suspension, or total shutdown of production;
- import holds;

- refusing to approve pending 510(k) notifications or PMAs;
- revocation of 510(k) clearance or pre-market approvals previously granted; and
- criminal prosecution and penalties.

International Regulation

Sales of medical devices outside the United States are subject to foreign government regulations, which vary substantially from country to country. In order to market our products in other countries, we must obtain regulatory approvals and comply with extensive safety and quality regulations in other countries. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA clearance or approval, and the requirements may differ significantly.

In the European Economic Area, or EEA, which comprises the 28 Member States of the EU plus Liechtenstein, Norway and Iceland, *in vitro* medical devices are required to conform with the essential requirements of the EU Directive on *in vitro* diagnostic medical devices (Directive 98/79/EC, as amended). To demonstrate compliance with the essential requirements, the manufacturer must undergo a conformity assessment procedure. The conformity assessment varies according to the type of medical device and its classification. For low-risk devices, the conformity assessment can be carried out internally, but for higher risk devices (self-test devices and those included in List A and B of Annex II of Directive 98/79/EC) it requires the intervention of an accredited EEA Notified Body. If successful, the conformity assessment concludes with the drawing up by the manufacturer of an EC Declaration of Conformity entitling the manufacturer to affix the CE mark to its products and to sell them throughout the EEA. The EC Declaration of Conformity was received by the Company in 2015.

Other Healthcare Laws

Following the FDA's granting of our de novo request to market the Accelerate Pheno system and Accelerate PhenoTest BC kit, we commenced active commercialization of the Accelerate Pheno system. Such business activities, including the activities of any third-party distributors that we retain, will be subject to additional healthcare laws and regulations and related enforcement by the federal government as well as the governments of states and foreign jurisdictions where we conduct our business. These laws and regulations include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security, and physician payment transparency laws and regulations. Violations of these laws or regulations can result in criminal or civil sanctions, including substantial fines and, in some cases, exclusion from participation in federal healthcare programs, such as Medicare and Medicaid. The following discussion describes certain federal and state healthcare laws and regulations that may impact our operations and the operations of our customers, but is not intended to be an exhaustive discussion of all potentially applicable federal and state health laws and regulations.

The U.S. federal Anti-Kickback Statute prohibits any person from knowingly and willfully offering, soliciting, receiving, or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in exchange for or to induce either the referral of an individual for an item or service, or the purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any good, facility, item, or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person need not have actual knowledge of the Anti-Kickback Statute or specific intent in order to commit a violation, and several courts have interpreted the intent requirement of the Anti-Kickback Statute to mean that if any one purpose of an arrangement is to induce referrals or purchases of federal healthcare program business, the Anti-Kickback Statute has been violated. In addition to criminal fines and penalties set forth under the Anti-Kickback Statute, violations of the Anti-Kickback Statute can result in exclusion or debarment from participation in the federal healthcare programs, as well as substantial penalties under the Civil Monetary Penalties Statute, which imposes penalties against any person or entity that is determined to have presented or caused to be presented a claim to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. A violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act, which, as discussed below, imposes liability on any person or entity that knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. Several states and foreign countries also have anti-kickback laws and other fraud and abuse laws that establish similar prohibitions and, in some cases, may apply to items or services reimbursed by any third-party payer, including commercial insurers.

The federal False Claims Act imposes liability on any person or entity that knowingly presents or causes to be presented a false or fraudulent claim for payment to, or approval by, the U.S. government. Liability under the False Claims Act can give rise to treble damages and civil monetary penalties. In addition to actions initiated by the government itself, the qui tam provisions of the False Claims Act authorize private individuals to bring False Claims Act actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and to share in a percentage of the recovery. In recent years, the government and qui tam relators have initiated suits resulting in multi-million and multi-billion dollar settlements under the False Claims Act in addition to criminal convictions under applicable criminal statutes. Given the significant size of actual and potential settlements, it is expected that the government and qui tam relators will continue to devote substantial resources and use the False Claims Act to investigate and prosecute healthcare companies' compliance with applicable fraud and abuse laws.

The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") created federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any healthcare benefit program, including private third-party payers or to obtain—by means of false or fraudulent pretenses, representations, or promises—any of the money or property owned by or under the custody or control of any healthcare benefit program; and knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false, fictitious, or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. The Affordable Care Act ("ACA") amended certain sections of the HIPAA criminal statutes such that a person need not have actual knowledge of the applicable statute or specific intent in order to have committed a healthcare fraud violation.

As stated above, many states and foreign countries have adopted similar fraud and abuse laws that may be broader in scope and may apply regardless of payer. Violations of any of these laws can lead to additional risk such as risk of plaintiff class actions, state attorney general actions, and investigation by agencies such as the Department of Justice ("DOJ") or the FTC.

The Physician Payment Sunshine Act, implemented by Section 6002 of the ACA, imposes transparency requirements on certain manufacturers, referred to as "applicable manufacturers," of drugs, devices, biological, or medical supplies for which payment is available under Medicare, Medicaid, the Children's Health Insurance Program ("CHIP"), or a waiver of a plan offered under CHIP. Applicable manufacturers must track and report to the CMS certain payments or "transfers of value" provided to U.S. licensed physicians and teaching hospitals during the preceding calendar year, as well as certain ownership and investment interests held by U.S. licensed physicians and their immediate family members. CMS releases the reported data on a public website on an annual basis. Failure to report as required under the Physician Payment Sunshine Act could subject applicable manufacturers to significant financial penalties, while tracking and reporting the required payments and transfers of value may result in considerable administrative expense. Several states currently have similar laws, and more states may enact similar legislation, some of which may be broader in scope. For example, certain states require the implementation of compliance programs, compliance with industry ethics codes, implementation of gift bans, and spending limits, and/or reporting of gifts, compensation, and other remuneration to healthcare professionals.

We also may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and their respective implementing regulations, including the final omnibus rule published by the Department of Health and Human Services Office for Civil Rights ("OCR") in January 2013, restrict the use and disclosure of patient-identifiable health information, mandate the adoption of standards relating to the privacy and security of patient-identifiable health information, and require us to report certain security breaches to healthcare provider customers with respect to such information where we are acting as a HIPAA business associate, as that term is defined, to that customer. In addition to HIPAA criminal penalties, HITECH created four new tiers of civil and monetary penalties and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA privacy and security laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances and impose reporting requirements for data breaches, many of which differ from each other and HIPAA in significant ways and may not have the same effect, thus complicating compliance efforts.

The use of certain diagnostic products by our potential customers is affected by the Clinical Laboratory Improvement Amendments ("CLIA") and related federal and state regulations that provide for regulation of laboratory testing. CLIA is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating specific standards in the areas of personnel qualifications, administration, and participation in proficiency testing, patient test management, quality assurance, quality control, and inspections. Current or future CLIA requirements or the promulgation of additional regulations affecting laboratory testing may prevent some laboratories, hospitals, providers, or other customers with laboratories from using some or all of our diagnostic products.

Healthcare Reform

In the United States and several foreign jurisdictions, there have been, and we expect there may continue to be, a number of legislative and regulatory changes to the healthcare system seeking to reduce healthcare costs that could affect our future results of operations as we begin to commercialize our products.

In the United States, the ACA, enacted in March 2010, made changes that are expected to have a continued and significant impact on the medical device industry and clinical laboratories, including the way healthcare is delivered and financed by governmental and private insurers. For example, the legislation provided for reductions in the Medicare clinical laboratory fee schedule. The ACA also requires CMS to reduce payments to hospitals reimbursed under Medicare's Inpatient Prospective Payment System ("IPPS") that have excess readmissions. While the ACA is intended to expand health insurance coverage to uninsured persons in the United States, other elements of this legislation that are still being developed and refined, such as Medicare provisions aimed at improving quality and decreasing costs, comparative effectiveness research, an independent payment advisory board, and pilot programs to evaluate alternative payment methodologies, make it difficult to determine the overall impact on sales of our products. In addition to uncertainty regarding the impact of implementation of the ACA, there are some continued legal challenges to the ACA that, if successful, could call into question the legitimacy of the ACA and its future applicability. See *"Risk Factors-Risks related to government regulation"* for additional information.

In addition, frequently in recent years, other legislative, regulatory, and political changes aimed at regulating healthcare delivery in general and clinical laboratories in particular have been proposed and adopted in the United States. Payment and reimbursement for the laboratory industry and hospital and other healthcare provider services have been under significant pressure. In January 2015, the Department of Health and Human Services ("HHS") announced a plan to shift the Medicare program and the healthcare system at large toward paying providers based on quality, rather than the quantity of care provided to patients.

Reimbursement

We do not believe that hospitals will specifically seek reimbursement from the government or private insurance companies for their purchase of the Accelerate Pheno system or the Accelerate PhenoTest BC kit. Instead, we believe that hospitals will recoup such costs by obtaining reimbursement from the government or private insurance companies for in-bed occupancies, which traditionally includes all testing required for admitted patients.

Hospitals, clinical laboratories, and other healthcare provider customers that may purchase our products, if approved, generally bill various third-party payers to cover all or a portion of the costs and fees associated with diagnostic tests, including the cost of the purchase of our products. We currently expect most of our diagnostic tests will be performed in a hospital inpatient setting, where governmental payers, such as Medicare, generally reimburse hospitals a single bundled payment that is based on the patient's diagnosis under a classification system known as the Medicare severity diagnosis-related groups ("MS-DRGs") classification for all items and services provided to the patient during a single hospitalization, regardless of whether our diagnostic tests are performed during such hospitalization.

In 2020, the Company received a Current Procedural Terminology ("CPT") code for the rapid diagnosis of patients in a hospital outpatient setting for the Accelerate PhenoTest BC Kit. While the majority of testing remains with the hospital inpatient setting this reimbursement provides an opportunity to offset a portion of the cost of their testing.

Environmental Laws

We use hazardous materials in some of our research, development and manufacturing processes, and our operations are subject to regulation under various federal, state, local, and foreign laws concerning the environment. We believe that our operations are in material compliance with applicable environmental laws and regulations. The costs we incur in complying with such environmental laws and regulations are presently not material to our operations, cash flows or financial condition. It is possible, however, that future developments, including changes in environmental laws and regulations, could lead to material compliance costs, and such costs may have a material adverse effect on our operations, cash flows or financial condition. See *"Risk Factors-Risks Related to Our Research and Development Activities-We use hazardous materials in some of our research, development and manufacturing processes and face the accompanying risks and regulations governing environmental safety"* for additional information.

Operations

In January 2013, we relocated our headquarters from Denver, Colorado, to Tucson, Arizona, where we currently lease approximately 54,092 square feet of office, manufacturing and laboratory space. Further information regarding our Tucson facility is included in Item 2. Properties included elsewhere in this report, and details regarding our lease arrangement are included in Item 8, Note 16, Leases to the audited consolidated financial statements included elsewhere in this report.

We assemble the Accelerate Pheno system instrument and formulate, fill, and assemble the Accelerate PhenoTest BC kit in our facilities in Tucson, Arizona. The Accelerate Pheno system requires certain components that are custom-fabricated to our specifications. Such components include injection-molded plastic components, die-cut laminates, and machined mechanical components. We own the necessary production tooling and believe that we will be able to qualify secondary sources as needed to support future demand for the Accelerate Pheno system.

Raw Materials

We purchase many different types of raw materials, including plastics, glass, metals, electronic and mechanical sub-assemblies and various biological and chemical products. We seek to ensure continuity of raw material supply by securing multiple options for sourcing. We also review relevant sources for compliance with conflict minerals requirements. However, many of our components are custom-made by only a few outside suppliers. In certain instances, we have a sole source supply for key product components of the Accelerate Pheno system. We have entered into supply agreements with most of our suppliers to help ensure component availability and flexible purchasing terms with respect to the purchase of such components. See *"Risk Factors-Risks Related to Our Research and Development Activities-Disruptions in the supply of raw materials, consumable goods or other key product components, or issues associated with their quality from our single source suppliers, could result in a significant disruption in sales and profitability"* for additional information.

Human Capital Resources

As of December 31, 2020, we had approximately 224 employees worldwide, with approximately 208 employees in the United States and approximately 16 employees outside of the United States, none of whom are represented by a labor union. We have experienced no work stoppages and believe that our employee relations are good.

Our employees are one of our most important assets and set the foundation for our ability to achieve our strategic objectives, drive operational execution, deliver strong financial performance, advance innovation and maintain our quality and compliance programs.

The success and growth of our business depends in large part on our ability to attract, retain and develop a diverse population of talented and high-performing employees at all levels of our organization. To succeed in a competitive labor market, we have recruitment and retention strategies that we focus on as part of the overall management of our business, including designing our compensation and benefits programs to be competitive and align with our strategic and stockholders' interests. Some of our key employee benefits include eligibility for health insurance, vacation time, a retirement plan, an employee assistance program, life and disability coverage. We also offer a variety of voluntary benefits that allow employees to select the options that meet their needs, including

flexible spending accounts, prepaid legal benefits, backup childcare, tuition reimbursement and a wellness program.

Available Information

We regularly file reports with the SEC, including Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any other filings required by the SEC. We make these reports available free of charge in the investor relations section of our corporate website (http://ir.axdx.com/) as soon as reasonably practicable after such material is electronically filed with or furnished to the SEC. You may also access these materials, and other information regarding issuers like us that file information electronically with the SEC, from the SEC's internet website at http://www.sec.gov. References to our corporate website address in this report are intended to be inactive textual references only, and none of the information contained on our website is part of this report or incorporated in this report by reference.

Item 1A. Risk Factors

Investing in our securities involves a high degree of risk. You should carefully consider the risks described below, in addition to the other information included or incorporated by reference in this Form 10-K, including our financial statements and the related notes. If any of the following risks materialize, our business, financial condition, results of operations or growth prospects could be materially adversely affected, and the value of an investment in our common stock may decline significantly.

Risks Related to Our Business and Strategy

We have limited revenues from our products and no assurance of future revenues.

We have received limited revenue from sales of the Accelerate Pheno system and the Accelerate PhenoTest BC kit. As a result, during the years ended December 31, 2020, 2019 and 2018, we experienced losses from operations. Our future revenues are dependent on the successful commercialization of the Accelerate Pheno system, and there can be no assurance that we will be successful at the levels necessary to cover the costs of operations. If we are unsuccessful in generating sufficient revenues from the Accelerate Pheno system or any of our other products, we will likely continue to experience losses from operations and negative cash flow.

Until we received FDA approval to market the Accelerate Pheno system, we were a development-stage company and therefore incurred significant losses in prior years. While we are in the early years of commercializing the Accelerate Pheno system, we may continue to incur losses. We cannot be certain that we will achieve or sustain profitability.

We have incurred significant costs in connection with the development and commercialization of our technology, and there is no assurance that we will achieve sufficient revenues to offset anticipated operating costs. We have incurred significant losses in recent years and expect to incur losses in the future. Although our technology is now commercial, we expect that our selling, general and administrative expenses will generally increase due to the additional costs associated with establishing and expanding a dedicated sales force and other marketing efforts for the Accelerate Pheno system. Our ability to achieve or sustain profitability depends on numerous factors including the market acceptance of our product, product quality, future product development and our market penetration and margins. If we are unsuccessful in generating sufficient revenues from the Accelerate Pheno system, we will likely continue to experience losses from operations and negative cash flow. Although we anticipate deriving revenues from the sale of our products, no assurance can be given that these products can be sold on a net profit basis. If we achieve profitability, we cannot give any assurance that we will be able to sustain or increase profitability on a quarterly or annual basis in the future.

Our future profitability and continued existence are dependent in large part upon the successful commercialization of the Accelerate Pheno system and further development and commercialization of associated test kits and complimentary products.

Our principal business strategy involves the successful commercialization of the Accelerate Pheno system, development of associated test kits and the future development and commercialization of complimentary products. On June 30, 2015, we declared our conformity to the European In Vitro Diagnostic Directive 98/79/ EC and applied

a CE Mark to the Accelerate Pheno system and the Accelerate PhenoTest BC kit for in vitro diagnostic use. On February 23, 2017, the FDA granted our de novo request to market our Accelerate Pheno system and Accelerate PhenoTest BC kit. We have and will continue to dedicate a significant amount of resources to market and sell the Accelerate Pheno system. Likewise, we plan to continue our investment in the development of additional test kits and the commercialization of the Accelerate Pheno system in the United States and other jurisdictions in which we intend to pursue marketing authorization. There can be no assurance that we will successfully commercialize the Accelerate Pheno system, any associated test kits, including the Accelerate PhenoTest BC kit, or further develop and commercialize complimentary products such as PhenoAST and PhenoPrep. We may be required to expend significantly more resources than planned in this process, and as a result we may have to cease investing in the Accelerate Pheno system or developing other products.

If we are not successful in the development of product improvements and additional test kits and commercialization of the Accelerate Pheno system and related new products, such failure could lead to impairment of certain of our intellectual property, inventory, property and equipment, and may result in our ceasing operations.

Our efforts to educate hospitals on the benefits of the Accelerate Pheno system require significant resources, and we may experience reluctance from hospitals to purchase our products. If we fail to successfully commercialize the Accelerate Pheno system, we may never receive a return on the significant investments in product development, sales and marketing, regulatory compliance, manufacturing and quality assurance we have made, and on further investments we intend to make, and may fail to generate revenue and gain economies of scale from such investments.

Furthermore, the potential market for the Accelerate Pheno system may not expand as we anticipate or may even decline based on numerous factors, including the introduction of superior alternative products or the development of new technologies. If we are unable to adequately expand the market for the Accelerate Pheno system, this failure would have a material adverse effect on our ability to execute on our business plan and ability to generate revenue.

Our future product candidates have not obtained marketing authorization from the FDA, and they may never obtain such marketing authorization or other regulatory clearance.

Our success in part depends on our ability to obtain additional product marketing authorizations from the FDA for product candidates in our pipeline. If our attempts to obtain marketing authorization or other regulatory clearance are unsuccessful, we may be unable to generate sufficient revenue to sustain and grow our business. Our future product candidates may not be sufficiently sensitive or specific to obtain, or may prove to have other characteristics that preclude our obtaining, marketing authorization from the FDA or regulatory clearance. The process of obtaining regulatory clearance is expensive and time-consuming and can vary substantially based upon, among other things, the type, complexity and novelty of our product candidates. Changes in regulatory policy, changes in or the enactment of additional statutes or regulations or changes in regulatory review for each submitted product application may cause delays in the clearance of, or receipt of marketing authorization from the FDA for, a product candidate or rejection of a regulatory application altogether. The FDA has substantial discretion in the de novo review and clearance processes and may refuse to accept any application or may decide that our data is insufficient for clearance and require additional pre-clinical, clinical or other studies. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent marketing authorization from the FDA or regulatory clearance of a product candidate. Any marketing authorization from the FDA or regulatory clearance we ultimately obtain may be limited or subject to restrictions or post-market commitments that render the product candidate not commercially viable.

If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of our products may be delayed and, as a result, our stock price may decline.

From time to time, we estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development goals. These goals may include the commencement or completion of clinical trials and the submission of regulatory filings. From time to time, we may publicly announce the expected timing of some of these goals. All of these goals are, and will be, based on a variety of assumptions. The actual timing of these goals can vary significantly compared to our estimates, in some cases for reasons beyond our control. We may experience numerous unforeseen events that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including the uncertainties and risks set forth in this Form 10-K and in our

other filings with the SEC. If we do not meet our goals as publicly announced, the commercialization of our product candidates may be delayed and, as a result, our stock price may decline.

We may not be able to enhance the capabilities of our current and new products to keep pace with our industry's rapidly changing technology and customer requirements.

Our industry is characterized by rapid technological changes, frequent new product introductions and enhancements and evolving industry standards. Our future success will depend significantly on our ability to enhance our current products and develop or acquire and market new products that keep pace with technological developments and evolving industry standards as well as respond to changes in customer needs. New technologies, techniques or products could emerge that might offer better combinations of price and performance than the products and systems that we plan to sell. It is critical to our success that we anticipate changes in technology and customer requirements and physician, hospital and healthcare provider practices and successfully introduce new, enhanced and competitive technologies to meet our prospective customers' needs on a timely and cost-effective basis. At the same time, however, we must carefully manage our introduction of new products. If potential customers believe that such new products will offer enhanced features or be sold for a more attractive price, they may delay purchases of existing products until such new products are available.

Further, there can be no assurance that we will be successful in developing or acquiring product enhancements or new products to address changing technologies and customer requirements adequately, that we can introduce such products on a timely basis or that any such products or enhancements will be successful in the marketplace. If we are unable to successfully develop or acquire new products or if the market does not accept our products, or if we experience difficulties or delays in the final development and commercialization of our products, we may be unable to attract additional customers for our products or strategic partners to license our products.

We are developing additional uses for the Accelerate Pheno system. Any failure or delay in launching new applications may compromise our ability to achieve our growth objectives.

We are developing additional uses for the Accelerate Pheno system, including the ability to deliver AST test results with the incorporation of an existing identification result. We may have problems applying our technologies to additional configurations of the test and additional specimen types, and our new applications may not be as effective in detection as our initial applications. We may also encounter difficulties obtaining regulatory approval for additional uses of the Accelerate Pheno system. Any failure or delay in launching new applications may compromise our ability to achieve our growth objectives.

The failure of the Accelerate Pheno system or any future diagnostic products to perform as expected could significantly impair our reputation and the public image of our products, and we may be subject to legal claims arising from any defects or errors.

Our success will depend on the market's confidence that our technologies can provide reliable, high-quality diagnostic results. We believe that our customers are likely to be particularly sensitive to any defects or errors in the Accelerate Pheno system. As is typical of complex diagnostic systems we occasionally experience support issues or other performance problems with the Accelerate Pheno system. We could face warranty and liability claims against us and our reputation could suffer as a result of such failures. We cannot assure you that our product liability insurance would adequately protect our assets from the financial impact of defending a product liability claim. Any product liability claim brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing insurance coverage in the future. In addition, the FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. A recall, material liability claim or other occurrence that harms our reputation or decreases market acceptance of our products could cause us to incur significant costs, divert the attention of our key personnel or cause other significant customer relations problems.

In the past, we have experienced disappointing or negative publication results regarding the efficacy of our products. Such negative publicity could diminish our reputation and future sales of our products, which could have a material impact on our financial performance.

If treatment guidelines for bacterial infections change, or the standard of care evolves, we may need to redesign and seek new marketing authorization from the FDA for our product candidates.

If treatment guidelines for bacterial infections change, or the standard of care evolves, we may need to redesign and seek new marketing authorization from the FDA or other regulatory clearance for our product candidates. If treatment guidelines change so that different treatments become desirable, the Accelerate Pheno system may no longer provide the information sought by physicians, and we could be required to seek marketing authorization from the FDA or other regulatory clearance for a revised product.

We may not be able to correctly estimate or control our future operating expenses, which could lead to cash shortfalls.

Our operating expenses may fluctuate significantly in the future as a result of a variety of factors, many of which may be outside of our control. These factors include, but are not limited to:

- the expenses we incur for research and development required to maintain and improve our technology, including the continuing development of the Accelerate Pheno system;
- the expenses we incur in connection with the development, marketing authorization and regulatory clearance of the use of the Accelerate Pheno system to test on additional specimen types;
- the costs of preparing, filing, prosecuting, defending and enforcing patent claims and other intellectual property related costs, including litigation costs and the results of such litigation;
- the expenses we incur in connection with commercialization activities, including product marketing, sales and distribution expenses;
- the costs incurred to build manufacturing capabilities;
- the expenses to implement our sales strategy;
- the costs to attract and retain personnel with the skills required for effective operations; and
- the costs associated with being a public company.

Our budgeted expense levels are based in part on our expectations concerning future revenues from sales of the Accelerate Pheno system, as well as our assessment of the future investments needed to expand our commercial organization and support research and development activities in connection with the Accelerate Pheno system. We may be unable to reduce our expenditures in a timely manner to compensate for any unexpected events or a shortfall in revenue. Accordingly, a shortfall in demand for our products or other unexpected events could have an immediate and material impact on our cash levels.

Breaches of our information technology systems could have a material adverse effect on our operations and potentially result in liability, depending on the type of breach and information compromised.

We rely on information technology systems to process, transmit and store electronic information, which may include protected health information, in our day-to-day operations. In addition, our research and development operations are highly dependent on our information technology and storage. Our information technology systems have been subjected to computer viruses or other malicious codes and phishing attacks, and we expect to be subject to similar viruses and codes in the future. These attacks could result in our intellectual property, unsecured protected health information, and other confidential information being lost or stolen, including the disclosure of our trade secrets, disruption of our operations, loss of valuable research and development data, the need to notify individuals whose information was disclosed, increased costs for security measures or remediation costs and diversion of management attention and other negative consequences. While we will continue to implement protective measures to reduce the risk of and detect future cyber incidents, cyber-attacks are becoming more sophisticated and frequent, and the techniques used in such attacks change rapidly. There can be no assurance that our protective measures will prevent future attacks that could have a significant impact on our business.

Failure to comply with a variety of U.S. and international privacy laws to which we are subject could harm the Company.

Any failure by us or our vendor or other business partners to comply with federal, state or international privacy, data protection or security laws or regulations relating to the collection, use, retention, security and transfer of personally identifiable information could result in regulatory or litigation-related actions against us, legal liability, fines, damages, ongoing audit requirements and other significant costs. A significant data privacy regulation is the General Data Protection Regulation which applies to the processing of personal information collected from individuals located in the European Union, and has created new compliance obligations and has significantly increased fines for noncompliance. Substantial expenses and operational changes may be required in connection with maintaining compliance with such laws, and in particular certain emerging privacy laws are still subject to a high degree of uncertainty as to their interpretation and application.

We are dependent on our key employees. If we are unable to recruit, train and retain qualified personnel, we may not achieve our goals.

Because of the complex and technical nature of our products and the dynamic market in which we compete, our future success depends on our ability to recruit, train and retain key personnel, including our senior management, research and development, science and engineering, manufacturing and sales and marketing personnel. In particular, we are highly dependent on the management and business expertise of Jack Phillips, our President and Chief Executive Officer. We do not maintain key person life insurance for Mr. Phillips or any of our employees. Our industry is very competitive for qualified personnel. To the extent that the services of Mr. Phillips would be unavailable to us, we may be unable to employ another qualified person with the appropriate background and expertise to replace Mr. Phillips on terms suitable to us. Our growth depends, in particular, on attracting, retaining and motivating highly trained sales personnel with the necessary scientific background and ability to understand our systems and pathogens at a technical level. In addition, we may need additional employees at our manufacturing facilities to meet demand for our products as we scale up our sales and marketing operations.

Our industry is highly competitive, and we may not be successful in competing with our competitors. We currently face competition from new and established competitors and expect to face competition from others in the future, including those with new products, technologies or techniques.

The industry in which we compete is subject to rapid technological changes, and we face and expect to continue to face strong competition for our products. Many of our competitors and potential competitors may have substantially greater research and development, financial, manufacturing, customer support, sales and marketing resources, larger customer bases, longer operating histories, greater name recognition and more established relationships in the industry than we do. In addition, some of our competitors may, individually or together with companies affiliated with them, have greater human and scientific resources than we do.

Our competitors could develop new products or technologies that are more effective than the Accelerate Pheno system and any of our other products or product candidates. Additionally, we expect to face further competitive pressure resulting from the emergence of new ID or AST techniques or tests. For example, we are aware that some hospitals have begun using manual methods created through laboratory developed tests, which have been validated for internal hospital-specific use to deliver ID and AST results. Any of these newly developed products, technologies, and techniques may offer a better combination of price and performance than our products and systems. Our failure to compete effectively could materially and adversely affect our business, financial condition and operating results.

We generate a portion of our future revenue internationally and are subject to various risks relating to our international activities which could adversely affect our operating results.

We market and sell the Accelerate Pheno system in other countries outside of the United States. In order to market our products in certain foreign jurisdictions, we, or our distributors or partners, must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements regarding safety and efficacy and governing, among other things, clinical studies and commercial sales and distribution of our products. The approval procedure varies among countries and can involve additional testing. In addition, in many countries outside the United States, a product must be approved for reimbursement before the product can be approved for sale in that country. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if

at all, which could harm our ability to expand into markets outside the United States. In addition, engaging in international business involves a number of other difficulties and risks, including:

- required compliance with existing and changing foreign healthcare and other regulatory requirements and laws, such as those relating to patient privacy or handling of bio-hazardous waste;
- required compliance with anti-bribery laws, such as the U.S. Foreign Corrupt Practices Act and the U.K. Bribery Act, data privacy requirements, labor laws and anti-competition regulations;
- export and import restrictions;
- various reimbursement and insurance regimes;
- laws and business practices favoring local companies;
- longer payment cycles and difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- political and economic instability;
- potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements and other trade barriers;
- foreign exchange controls;
- fluctuations due to changes in foreign currency exchange rates;
- difficulties and costs of staffing and managing foreign operations; and
- impediments with protecting or procuring intellectual property rights.

In addition, changes in policies and/or laws of the United States or foreign governments resulting in, among other changes, higher taxation, tariffs or similar protectionist laws, currency conversion limitations, limitations on business operations, or the nationalization of private enterprises could reduce the anticipated benefits of international operations and could have a material adverse effect on our ability to expand internationally.

Our employees, independent contractors, principal investigators, consultants, commercial partners, vendors and other agents may engage in misconduct or other improper activities, including non-compliance with legal standards and requirements.

We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, principal investigators, consultants, commercial partners, vendors and other agents. Misconduct by these parties could include intentional, reckless or negligent failures to: (i) comply with the laws and regulations of the FDA, CMS, the HHS Office of Inspector General, Office for Civil Rights and other similar foreign regulatory bodies; (ii) provide true, complete and accurate information to the FDA and other similar regulatory bodies; (iii) comply with manufacturing requirements of the FDA and other similar regulatory bodies and manufacturing standards we have established; (iv) comply with healthcare fraud and abuse laws and regulations in the United States and similar foreign fraudulent misconduct laws; or (v) report financial information or data accurately, or disclose unauthorized activities to us. These laws may impact, among other things, our activities with principal investigators and research subjects, as well as our sales, marketing and education programs. In particular, the promotion, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing, unauthorized use of protected health information and data breaches, and other abusive practices. These laws may restrict or prohibit a wide range of activities related to pricing, discounting, marketing and promotion, patient support, royalty, consulting, research and other business arrangements, as well as the improper use of patient information obtained in the course of clinical studies. We currently have a code of conduct applicable to all of our employees and foreign distributors, but it is not always possible to identify and deter employee and/or commercial partner misconduct, and our code of conduct and the other 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 comply with

these 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, damages, monetary fines, disgorgement, individual imprisonment, corporate integrity agreements, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations. Any of these actions or investigations could result in substantial costs to us, including legal fees, and divert the attention of management from operating our business.

We may be unable to successfully manage our growth.

We expect to expand our operations in the future to support the commercialization of the Accelerate Pheno system and future products. We intend to continue to develop a targeted sales force in connection with our commercialization efforts in the United States and in certain other countries. Our growth has placed and may continue to place a significant strain on our management, operating and financial systems and our sales, marketing and administrative resources. As a result of our growth, operating costs may escalate faster than planned, and some of our internal systems and processes, including those relating to manufacturing our products, may need to be enhanced, updated or replaced.

We also plan to introduce additional test kits for use on the Accelerate Pheno system and plan to invest in the development of additional instruments, tests and other microbiology solutions. If we cannot effectively manage our expanding operations, manufacturing capacity and costs, including scaling to meet increased demand, we may not be able to continue to grow or we may grow at a slower pace than expected.

Our estimates of market opportunity and forecasts of market growth may prove to be inaccurate, and even if the market in which we compete achieves the forecasted growth, our business could fail to grow at similar rates, if at all.

Market opportunity estimates and growth forecasts are subject to significant uncertainty and are based on assumptions and estimates that may not prove to be accurate. The estimates and forecasts in this Form10-K relating to the size and expected growth of our market, total available market, estimated test and placement volume and estimated pricing, may prove to be inaccurate, which may have negative consequences, such as overestimation of our potential market opportunity. Even if the market in which we compete meets our size estimates and forecasted growth, our business could fail to grow at similar rates, if at all.

We are exposed to risks associated with long-lived assets that may become impaired and result in an impairment charge.

The carrying amounts of long-lived assets are affected whenever events or changes in circumstances indicate that the carrying amount of any asset may not be recoverable. Property and equipment includes Accelerate Pheno systems (also referred to as instruments) used for sales demonstrations, instruments under rental agreements and instruments used for research and development.

Adverse events or changes in circumstances may affect the estimated discounted future cash flows expected to be derived from long-lived assets. If at any time we determine that an impairment has occurred, we will be required to reflect the impaired value as a charge, resulting in a reduction in earnings, such impairment is identified and a corresponding reduction in our net asset value. In the future we may incur, impairment charges. A material reduction in earnings resulting from such a charge could cause us to fail to meet the expectations of investors and securities analysts, which could cause the price of our stock to decline.

The COVID-19 pandemic has had, and is expected to continue to have, a significant adverse impact on our commercial operations and also exposes our business to other risks.

In late 2019, a novel strain of coronavirus (COVID-19) was reported to have surfaced in Wuhan, China, which has since spread globally. In March 2020, the World Health Organization declared COVID-19 a global pandemic. Further, the COVID-19 outbreak has resulted in government authorities around the world implementing numerous measures to try to reduce the spread of COVID-19, such as travel bans and restrictions, quarantines, shelter-in-place, stay-at-home, or total lock-down (or similar) orders and business limitations and shutdowns. For example, the State of Arizona has implemented several orders promoting physical distancing, limiting certain activities, and restricting the operations of certain businesses, including restaurants, bars, gyms, theaters and water

parks. The COVID-19 pandemic and these measures have caused, and are continuing to cause, business slowdowns or shutdowns in affected areas, both regionally and worldwide, which have significantly impacted our business and results of operations, starting in the first quarter of 2020. For example, this included diminished access to our customers, including hospitals, which has severely limited our ability to sell or implement the Accelerate Pheno systems. In addition, in April and May 2020 our Accelerate Pheno kit orders declined as many hospitals curtailed elective surgeries to respond to COVID-19. Since May 2020, our Accelerate Pheno kit orders have largely returned to more normal levels, but could decline again if COVID-19 surges cause hospitals to reduce or prohibit elective surgeries. Furthermore, our expected rate of growth of our consumable test kit sales has been reduced because of the negative impact of the COVID-19 pandemic on Accelerate Pheno system new sales and implementations.

In addition to the negative impact on new sales and implementations of the Accelerate Pheno system and demand for our consumable test kits, the pandemic exposes our business, operations, and workforce to a variety of other risks, including:

- delays in product development or reductions in manufacturing production as a result of inventory shortages, supply chain shortages, or diversion of our efforts and resources to projects related to COVID-19;
- increased expenses resulting from our COVID-19 BioCheck serology initiative in order to achieve regulatory approval, training our commercial team, and develop marketing materials;
- interruptions, availability or delays in global shipping to transport our products;
- regulatory approval delays due to regulators being overwhelmed reviewing COVID-19 related medical devices and drugs;
- delays in obtaining grants to assist our product development efforts because granting agencies are primarily focused research and development activities directly related to COVID-19;
- increased regulatory restrictions or continued market volatility could hinder our ability to execute strategic business activities, as well as negatively impact our stock price;
- significant disruption of global financial markets, which could cause fluctuations in currency exchange rates or negatively impact our ability to access capital markets;
- inability to access capital markets on terms that are not significantly detrimental to our business because our revenue growth rate has slowed due to our inability to sell and implement the Accelerate Pheno system as forecasted prior to the pandemic at a stage in our maturation when we are cash flow negative and have significant indebtedness in the form of convertible senior notes;
- negative impact on our workforce productivity, product development, and research and development due to difficulties resulting from our personnel working remotely; and
- illnesses to key employees, or a significant portion of our workforce, which may result in inefficiencies, delays, and disruptions in our business.

Any of these developments may adversely affect our business, harm our reputation, or result in legal or regulatory actions against us.

Further, the spread of COVID-19 has caused us to modify our business practices (including employee travel, employee work locations, and cancellation of physical participation in meetings, events and conferences), and we may take further actions as may be required by government authorities or that we determine are in the best interests of our employees, customers, partners, and suppliers. There is no certainty that such measures will be sufficient to mitigate the risks posed by the virus, and our ability to perform critical functions could be harmed.

Additionally, COVID-19 could affect our internal controls over financial reporting as a portion of our workforce is required to work from home and therefore new processes, procedures, and controls could be required to respond to changes in our business environment.

The potential effects of COVID-19 may also impact many of our other risk factors discussed herein. The degree to which COVID-19 ultimately impacts our business, results of operations, cash flows and financial position will depend on future developments, which are highly uncertain, continuously evolving and cannot be predicted, including, but not limited to, the duration and spread of the COVID-19 outbreak, its severity, the emergence of new COVID-19 strains that are more contagious or deadly, the effectiveness and availability of COVID-19 vaccines, the actions to contain the virus or treat its impact and how quickly and to what extent normal economic and operating conditions can resume.

Risks related to our intellectual property

If we are unable to effectively protect our intellectual property, our business would be harmed.

In addition to patent protection, we rely on trademark, copyright, trade secret protection and confidentiality agreements to protect intellectual property rights related to our proprietary technologies, both in the United States and in other countries. If we fail to protect our intellectual property, third parties may be able to compete more effectively against us and we may incur substantial litigation costs in our attempts to recover or restrict use of our intellectual property. We own 19 issued U.S. patents and six pending U.S. patent applications, including provisional and non-provisional filings. We also own 39 non-US patents and have five pending applications. We own 41 registered marks in the United States and foreign countries. In addition to our patents and trademarks, we possess an array of unpatented proprietary technology and know-how, and we license intellectual property rights to and from third parties. The strength of patents in our field involves complex legal and scientific questions. In addition, patent law continuously evolves and might change the legal framework under which our patent claims would be interpreted and adjudicated in the future. Uncertainty created by these questions and potential legal changes means that our patents may provide only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. In addition, competitors could purchase our products and attempt by reverse engineering to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of the protections provided by our intellectual property rights. If our intellectual property, including licensed intellectual property, does not adequately protect our market position against competitors' products and methods, our competitive position could be adversely affected, as could our business.

Further, if we are unable to prevent unauthorized disclosure of our non-patented intellectual property, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage. In addition, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad.

We may not be successful in our currently pending or future patent applications, and even if such applications are successful, we cannot guarantee that the resulting patents will sufficiently protect our products and proprietary technology.

We cannot assure you that any of our currently pending or future patent applications will result in issued patents with claims that adequately cover our products and technologies in the United States or in other foreign countries, and we cannot predict how long it will take for such patents to be issued. Further, issuance of a patent is not conclusive as to its inventorship or scope, and there is no guarantee that our issued patents will include claims that are sufficiently broad to cover our technologies or to provide meaningful protection from our competitors. Further, we cannot be certain that all relevant prior art relating to our patents and patent applications has been identified. Accordingly, there may be prior art that can invalidate our issued patents or prevent a patent from issuing from a pending patent application, or will preclude our ability to obtain patent claims that have a scope broad enough to provide meaningful protection from our competitors.

Even if patents do successfully issue and even if such patents cover our products and technologies, we cannot assure you that other parties will not challenge the validity, enforceability or scope of such issued patents in the United States and in foreign countries, including by proceedings such as reexamination, inter-partes review, interference, opposition, or other patent office or court proceedings. The strength of patents in our field involves complex legal and scientific questions. Moreover, we cannot assure you that if such patents were challenged in court or before a regulatory agency that the patent claims will be held valid, enforceable, to be sufficiently broad to cover our technologies or to provide meaningful protection from our competitors. Nor can we assure you that the court or agency will uphold our ownership rights in such patents. Accordingly, we cannot guarantee that we will be successful in defending challenges made against our patents and patent applications. Any successful third-party challenge to our patents could result in the unenforceability or invalidity of such patents, or narrowing of claim scope, such that we could be deprived of patent protection necessary for the successful commercialization of our products and technologies, which could adversely affect our business. To this end, we note that one of our issued European Patents, EP No. 1831692, is the subject of an Opposition proceeding within the European Patent Office. The Opposition, filed by our competitor bioMerieux, alleges that, inter alia, this issued patent claims subject matter

that lacks novelty and inventive step in view of the state of the art at the time of filing. We disagree with bioMerieux's contentions, and have vigorously defended our patent as properly issued by the European Patent Office. Should we fail in our defense against bioMerieux's allegations, the opposed patent potentially could be revoked, the claims may be amended such that they no longer cover aspects of our commercialized products, or any such amended claims potentially could be designed around by competitors.

Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our inventions, provide exclusivity for our products and technologies or prevent others from designing around our claims. Others may independently develop similar or alternative products and technologies or duplicate any of our products and technologies. These products and technologies may not be covered by claims of issued patents for which we are the right holder. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product under patent protection could be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to make the inventions covered by our pending patent applications, or that we were the first to file any patent application related to a product candidate. Furthermore, if third parties have filed such patent applications, an interference proceeding in the United States can be initiated by a third party to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. In addition, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however the life of a patent, and the protection it affords, is limited.

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

Third parties may infringe or misappropriate our intellectual property, including our existing patents and patent claims that may be allowed in the future. As a result, we may be required to file infringement claims to stop third-party infringement or unauthorized use. Further, we may not be able to prevent misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

If we file an infringement action against a third party, that party may challenge the scope, validity or enforceability of our patents, requiring us to engage in complex, lengthy and costly litigation or other proceedings. Such litigation and administrative proceedings could result in revocation of our patents or amendment of our patent claims such that they no longer cover our product candidates. They may also put our pending patent applications at risk of not issuing or issuing with limited and potentially inadequate scope to cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable.

Enforcing our intellectual property rights through litigation is very expensive and time-consuming. Some of our competitors may be able to sustain the costs of litigation more effectively than we can because of greater financial resources. Patent litigation and other proceedings may also absorb significant management time and reduce employee productivity. Furthermore, because of the substantial amount of discovery required in connection with U.S. intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

We could face claims that our proprietary technologies infringe on the intellectual property rights of others.

Due to the significant number of U.S. and foreign patents issued to, and other intellectual property rights owned by, entities operating in the industry in which we operate, we believe that there is a risk of litigation arising from allegations of infringement of these patents and other rights. Third parties may assert infringement or other intellectual property claims against us or our licensees.

In addition, patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after the earliest filing date for which a benefit is claimed. For this reason, and because publications in the scientific literature often lag behind actual discoveries, despite our best efforts we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending

applications or that we were the first to invent the technology. Another party may have filed or may in the future file patent applications covering our products or technology similar to ours. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the U.S. Patent and Trademark Office to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U.S. patent position with respect to such inventions.

We may have to pay substantial damages, including treble damages, for past infringement if it is ultimately determined that our products infringe on a third party's proprietary rights. In addition, even if such claims are without merit, defending a lawsuit may result in substantial expense to us and divert the efforts of our technical and management personnel. We may also be subject to significant damages or injunctions against development and sale of some of our products. Furthermore, claims of intellectual property infringement may require us to enter into royalty or license agreements with third parties, and we may be unable to obtain royalty or license agreements on commercially acceptable terms, if at all.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these employees or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims.

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property in the performance of their work to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing an enforceable agreement with each party who in fact develops intellectual property that we regard as our own. Relevant assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

Risks Related to our Research and Development Activities

We have a single research and development facility and we may be unable to continue to conduct our research and development activities if we lose this facility. If our facility or our equipment were damaged or destroyed, or if we experience a significant disruption in our operations for any reason, our ability to continue to operate our business could be materially harmed.

We currently conduct all of our research and development and product development activities in our existing facility in Tucson, Arizona. If this facility were to be damaged, destroyed or otherwise unable to operate, whether due to fire, floods, storms, tornadoes, other natural disasters, employee malfeasance, terrorist acts, power outages or otherwise, or if our business is disrupted for any other reason, we may not be able to continue the development of future products or test our products as promptly as our potential customers expect, or possibly not at all, and we would have no other means of conducting such activities until we were able to restore such capabilities at the current facility or develop an alternative facility. Further, in such an event, we may lose revenue and significant time during which we might otherwise have conducted research and development and product development activities and, we may not be able to maintain our relationships with our licensees or customers.

The manufacture of components of the Accelerate Pheno system involves complex processes, sophisticated equipment and strict adherence to specifications and quality systems procedures. Any unforeseen manufacturing problems, such as contamination of our facility, equipment malfunction or failure to strictly follow procedures or meet specifications, could result in delays or shortfalls in production of our products. Identifying and resolving the cause of any manufacturing issues could require substantial time and resources. If we are unable to

keep up with future demand for our products by successfully manufacturing and shipping our products in a timely manner, our revenue growth could be impaired and market acceptance of our product candidates could be adversely affected.

While we carry a nominal amount of business interruption insurance to cover lost revenue and profits, this insurance does not cover all possible situations. If we have underestimated our insurance needs with respect to an interruption, or if an interruption is not subject to coverage under our insurance policies, we may not be able to cover our losses. In addition, our business interruption insurance would not compensate us for the loss of opportunity and potential adverse impact on relations with our licensees or customers.

We use hazardous materials in some of our research, development and manufacturing processes and face the accompanying risks and regulations governing environmental safety.

Our operations are subject to complex and stringent environmental, health, safety and other governmental laws and regulations that both public officials and private individuals may seek to enforce. In particular, our research activities sometimes involve the controlled use of various hazardous materials. Although we believe that our safety procedures for handling and disposing of such materials are in material compliance with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated, and we may not be in compliance with these regulations. In addition, existing laws and regulations may also be revised or reinterpreted, or new laws and regulations may become applicable to us, whether retroactively or prospectively, causing us to incur additional compliance costs and/or change the manner in which we operate. We could be held liable for any damages that might result from any accident or release involving hazardous materials.

Disruptions in the supply of raw materials, consumable goods or other key product components, or issues associated with their quality from our single source suppliers, could result in a significant disruption in sales and profitability.

We must manufacture or engage third parties to manufacture components of our products in sufficient quantities and on a timely basis, while maintaining product quality, acceptable manufacturing costs and complying with regulatory requirements. Our components are custom-made by only a few outside suppliers. In certain instances, we have a sole source supply for key product components of the Accelerate Pheno system. We may be unable to satisfy our forecast demand from existing suppliers for our products, or we may be unable to find alternative suppliers for key product components or ancillary items at reasonably comparable prices. If this occurs, we may be unable to manufacture our products and/or meet our customers' needs in a timely manner or at all.

Additionally, we have entered into supply agreements with most of our suppliers to help ensure component availability and flexible purchasing terms with respect to the purchase of such components. If our suppliers discontinue production of a key component for one or more of our products, we may be unable to identify or secure a viable alternative on reasonable terms, or at all, which could limit our ability to manufacture our products. While we may be able to modify our product candidates to utilize a new source of components, we may need to secure marketing authorization from the FDA or other regulatory clearance for the modified product, and it could take considerable time and expense to perform the requisite tasks prior to seeking such authorization.

In determining the required quantities of our products and our manufacturing schedule, we will need to make significant judgments and estimates regarding factors such as market trends and any seasonality with respect to our sales. Because of the inherent nature of estimates, there could be significant differences between our estimates and the actual amounts of products that we require. This can result in shortages if we fail to anticipate demand, or excess inventory and write-offs if we order more than we need.

Reliance on third-party manufacturers entails risk to which we would not be subject if we manufactured these components ourselves, including:

- reliance on third parties for regulatory compliance and quality assurance;
- possible breaches of manufacturing agreements by the third parties because of factors beyond our control;
- possible regulatory violations or manufacturing problems experienced by our suppliers;

- possible termination or non-renewal of agreements by third parties, based on their own business priorities, at times that are costly or inconvenient for us;

- the potential obsolescence and/or inability of our suppliers to obtain required components;

- the potential delays and expenses of seeking alternate sources of supply or manufacturing services;

- the inability to qualify alternate sources without impacting performance claims of our products;

- reduced control over pricing, quality and timely delivery due to the difficulties in switching to alternate suppliers or assemblers; and

- increases in prices of raw materials and key components.

The manufacturing operations for the Accelerate Pheno system use highly technical processes involving unique, proprietary techniques. In addition, the manufacturing equipment we use would be costly to repair or replace and could require substantial lead time to repair or replace. Any interruption in our operations or decrease in the production capacity of our manufacturing facility or the facilities of any of our suppliers because of equipment failure, natural disasters such as earthquakes, tornadoes and fires, or otherwise, would limit our ability to meet customer demand for our products. In the event of a disruption, we may lose customers and we may be unable to regain those customers thereafter. Our insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all.

We have made and intend to make significant additional investments in research and development, but there is no guarantee that any of these investments will ultimately result in a commercial product that will generate revenues.

The Accelerate Pheno system integrates several of our component products, systems and processes. We have dedicated significant resources on research and development activities, and we intend to spend significantly more on research and development activities. Notwithstanding these investments, we anticipate that we will have to spend additional funds in the research and development of the Accelerate Pheno system and our next generation instrument platform and technologies. There can also be no assurance that we will be able to develop additional types of tests and instruments in the future nor whether these will generate revenues.

Risks Related to Government Regulation

Legislative and Administrative Action May Have an Adverse Effect on Our Company

Political, economic and regulatory influences are subjecting the health care industry in the U.S. to fundamental change. We cannot predict what other legislation relating to our business or to the health care industry may be enacted, including legislation relating to third-party reimbursement, or what effect such legislation may have on our business, prospects, operating results and financial condition. We expect federal and state legislators to continue to review and assess alternative health care delivery and payment systems, and possibly adopt legislation affecting further changes in the health care delivery system. Such laws may contain provisions that may change the operating environment for hospitals and managed care organizations. Health care industry participants may react to such legislation by curtailing or deferring expenditures and initiatives, including those relating to our products. Future legislation could result in modifications to the existing public and private health care insurance systems that would have a material adverse effect on the reimbursement policies discussed above. If enacted and implemented, any measures to restrict health care spending could result in decreased revenue from our products and decrease potential returns from our research and development initiatives. Furthermore, we may not be able to successfully neutralize any lobbying efforts against any initiatives we may have with governmental agencies.

We and our suppliers, contract manufacturers and customers are subject to various governmental laws and regulations, and we may incur significant expenses to comply with, and experience delays in our product commercialization as a result of, these laws and regulations.

Our operations are affected by various state, federal, and international healthcare, environmental, anti-corruption, fraud and abuse (including anti-kickback and false claims laws), privacy, and employment laws as well

as international political sanctions. Violations of these laws and sanctions can result in criminal or civil penalties, including substantial fines and, in some cases, exclusion from participation in federal health care programs such as Medicare and Medicaid. In some cases, the violation of such laws could potentially lead to individual liability and imprisonment.

We are also subject to extensive regulation by the FDA pursuant to the Federal Food, Drug, and Cosmetic Act, by comparable agencies in foreign countries and by other regulatory agencies and governing bodies. Following the introduction of a product, these and other government agencies will periodically review our manufacturing processes, product performance and compliance with applicable requirements.

We are also subject to various U.S. healthcare related laws regulating sales, contracting, marketing, and other business arrangements and the use and disclosure of individually identifiable health information. These include but are not limited to:

- The federal Anti-Kickback Statute, which prohibits persons from knowingly and willfully offering, providing, soliciting, or receiving any remuneration, directly or indirectly, in exchange for or to induce the referral of an individual, or the purchasing, leasing, ordering, recommending, furnishing or arranging for a good or service, for which payment may be made under a federal health care program, such as Medicare or Medicaid.

- The Eliminating Kickbacks in Recovery Act, which makes it a federal crime to knowingly and willfully solicit or receive any remuneration in return for referring a patient to a recovery home, clinical treatment facility, or laboratory, or pay or offer any remuneration to induce such a referral or in exchange for an individual using the services of a recovery home, clinical treatment facility, or laboratory.

- The Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), which prohibits knowingly and willfully (i) executing a scheme to defraud any health care benefit program, including private payers, or (ii) falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for items or services under a health care benefit program.

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, which also restricts the use and disclosure of protected health information, mandates the adoption of standards relating to the privacy and security of protected health information, and requires us to report certain security breaches to health care provider customers with respect to such information where we are acting as a HIPAA business associate to that customer.

- The federal Physician Payment Sunshine Act, which requires manufacturers of certain medical devices to track payments or other transfers of value given to U.S. licensed physicians or teaching hospitals and to report this data to CMS annually for subsequent public disclosure.

- The federal False Claims Act, which imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal health care program. The qui tam provisions of the False Claims Act allow a private individual to bring actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government and to share in any monetary recovery.

Similar requirements have been adopted by many states and foreign countries. Violations of any of these laws can lead to additional legal risk such as risk of plaintiff class actions, state Attorney General actions, and investigations by the Federal Trade Commission, among others.

Failure to comply with applicable requirements, or later discovery of previously unknown problems with our products or manufacturing processes, including our failure or the failure of one of our contract manufacturers to take satisfactory corrective action in response to an adverse inspection, can result in, among other things:

- administrative or judicially imposed sanctions;

- injunctions or the imposition of civil penalties;

- recall or seizure of our products;
- reportable events;
- total or partial suspension of production or distribution;
- withdrawal or suspension of marketing clearances or approvals;
- clinical holds;
- warning letters;
- refusal to permit the import or export of our products;
- criminal prosecution; and
- exclusion or debarment from participation in federal health care programs such as Medicare and Medicaid.

Any of these actions, in combination or alone, could prevent us from marketing, distributing and selling our products.

In addition, we have developed, configured and we intend to market our products to meet customer needs created by these various regulations. Any significant change in these regulations could reduce demand for our products. Governmental agencies may also impose new requirements regarding registration, labeling or prohibited materials that may require us to modify or re-register products already on the market or otherwise adversely impact our ability to market our products. If materials used in our products become unavailable because of new governmental regulations, substitute materials may be less effective and may require significant cost to incorporate in our product.

In addition, a product defect or regulatory violation could lead to a government-mandated or voluntary recall by us. We believe that the FDA would request that we initiate a voluntary recall if a product was defective or presented a risk of injury or gross deception. Regulatory agencies in other countries have similar authority to recall devices because of material deficiencies or defects in design or manufacture that could endanger health. Any recall would divert management attention and financial resources, could cause the price of our shares of common stock to decline, expose us to product liability or other claims (including contractual claims from parties to whom we sold products) and harm our reputation with customers.

The use of our diagnostic products by our customers is also affected by the Clinical Laboratory Improvement Amendments (“CLIA”) and related federal and state regulations that provide for regulation of laboratory testing. CLIA is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating specific standards in the areas of personnel qualifications, administration, participation in proficiency testing, patient test management, quality assurance, quality control and inspections. Current or future CLIA requirements or the promulgation of additional regulations affecting laboratory testing may prevent some laboratories, hospitals, providers or other customers with laboratories from using some or all of our diagnostic products.

Maintaining adequate sales of our product may depend on the availability of adequate reimbursement to our customers from third-party payers, including government programs such as Medicare and Medicaid, private insurance plans, and managed care programs.

Maintaining and growing sales of our product, if approved, may depend in part on the availability of adequate reimbursement to our customers from third-party payers, including government programs such as Medicare and Medicaid, private insurance plans and managed care programs. Hospitals, clinical laboratories and other healthcare provider customers that may purchase our products generally bill various third-party payers to cover all or a portion of the costs and fees associated with diagnostic tests, including the cost of the purchase of our products. We currently expect that all of our diagnostic tests will be performed in a hospital inpatient setting, where governmental payers, such as Medicare, generally reimburse hospitals a single bundled payment that is based on the patient’s diagnosis under a classification system known as the Medicare severity diagnosis-related groups (MS-

DRGs) classification for all items and services provided to the patient during a single hospitalization, regardless of whether our diagnostic tests are performed during such hospitalization. As a result, our customers' access to adequate payment by government and private insurance plans is central to the acceptance of our products. We may be unable to sell our products, if approved, on a profitable basis if third-party payers reduce their current levels of payment or if our costs of production increase faster than increases in reimbursement levels.

Additionally, third-party payers are increasingly reducing reimbursement for medical products and services. In addition, the U.S. government, state legislatures, and foreign governments have and may continue to implement cost-containment measures and more restrictive policies, including price controls and restrictions on reimbursement. For example, the Budget Control Act of 2011 (the "Budget Control Act") established a process to reduce federal budget deficits through an automatic "sequestration" process if deficit reductions targets are not otherwise reached. Under the terms of the Budget Control Act, sequestration imposes cuts to a wide range of federal programs, including Medicare, which is subject to a two percent cut. The Bipartisan Budget Act of 2013 extended the two percent sequestration cut for Medicare through fiscal year 2023, and a bill signed by President Obama on February 15, 2014 further extended this cut for an additional year, through fiscal year 2024. For fiscal year 2024, however, Medicare sequestration amounts will be realigned such that there will be a four percent sequester for the first six months and no sequester for the second six months, under the Protecting Access to Medicare Act of 2014.

While we cannot predict whether third-party reimbursement to our customers will be adequate, cost-containment measures and similar efforts by third-party payers, including government programs such as Medicare and Medicaid, could substantially impact the sales of our products and potentially limit our net revenue and results.

We may be adversely affected by healthcare policy changes, including additional healthcare reform and changes in managed healthcare.

Healthcare reform and the growth of managed care organizations have been considerable forces in the medical diagnostics industry and in recent political discussions. These forces have placed, and are expected to continue to place, constraints on the levels of overall pricing for healthcare products and services as well as the coverage available by public and private insurance and thus, could have a material adverse effect on the future profit margins of our products or the amounts that we are able to receive from third parties for the licensing of our products. Changes in the United States healthcare market could also force us to alter our approach to selling, marketing, distributing and servicing our products and customer base. In and outside the United States, changes to government reimbursement policies could reduce the funding that healthcare service providers have available for diagnostic product expenditures, which could have a material adverse impact on the use of the products we are developing and our future sales, license and royalty fees and profit margin.

For example, the ACA requires CMS to reduce payments to hospitals reimbursed under Medicare's Inpatient Prospective Payment System ("IPPS") that have excess readmissions. This and other applicable requirements set forth under the ACA and its current and future implementing regulations may significantly increase our costs, and/or reduce our customer's ability to obtain adequate reimbursement for tests performed with our products, which could adversely affect our business and financial condition. In addition to direct impacts from reimbursement cuts, sales of our products could be negatively impacted if reimbursement cuts reduce microbiology budgets. While the ACA is intended to expand health insurance coverage to uninsured persons in the United States, other elements of this legislation that are still being developed and refined, such as Medicare provisions aimed at improving quality and decreasing costs, comparative effectiveness research, an independent payment advisory board, and pilot programs to evaluate alternative payment methodologies, make it difficult to determine the overall impact on sales of our products. In addition to uncertainty regarding the impact of implementation of the ACA, there are some continued legal challenges to the ACA that, if successful, could call into question the legitimacy of the ACA and its future applicability.

In recent years, other legislative, regulatory, and political changes aimed at regulating healthcare delivery in general and clinical laboratory tests in particular have been proposed and adopted in the United States. Reimbursement for the laboratory industry is under significant pressure. In January 2015, HHS announced a plan to shift the Medicare program and the healthcare system at large, toward paying providers based on quality, rather than the quantity of care provided to patients. In 2017, Medicare's clinical laboratory reimbursement system became tied to private market rates with the start of the effective period for the Protecting Access to Medicare Act of 2014 ("PAMA"), changing the payment environment for clinical laboratory tests. The measures implemented by PAMA and ACA regulations can result in reduced prices, added costs, and decreased test utilization for our

customers, although the full impact on our business of the ACA, changes to the IPPS, PAMA, and other applicable laws, regulations, and policies is uncertain.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level or in countries outside of the United States in which we may do business, or the effect of any future legislation or regulation will have on our industry generally, our ability to successfully commercialize the Accelerate Pheno system, and our overall business operations. Continued changes in healthcare policy could substantially impact the sales of our tests, increase costs and divert management's attention from our business. For example, any expansion in the government's regulation of the United States healthcare system could result in decreased profits to us, lower reimbursements to our customers for laboratory testing or reduced medical procedure volumes.

The regulatory processes applicable to our products and operations are expensive, time-consuming, and uncertain and may prevent us from obtaining required approvals for the commercialization of our products.

Our products, including the Accelerate Pheno system, are regulated as medical device products by the FDA and comparable agencies of other countries. In particular, FDA regulations govern activities such as product development, product testing, product labeling, product storage, premarket clearance or approval, manufacturing, advertising, promotion, product sales, reporting of certain product failures and distribution. Some of our products, depending on their intended use, will require approval of a premarket approval application ("PMA") or clearance of a 510(k) notification from the FDA prior to marketing. The FDA has committed to review most 510(k) decisions within 90 days, but the review may be delayed due to requests for additional information. A decision may take significantly longer, and clearance is never assured. The PMA process is much more costly, lengthy and uncertain. The FDA has committed to review most PMAs within 180 days where an advisory panel is not required and within 320 days where an advisory panel is required, but the review may be delayed due to requests for additional information. A decision may take significantly longer, and approval is never assured. In the 510(k) clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. The PMA pathway requires an applicant to demonstrate the safety and effectiveness of the device based, in part, on extensive data, including technical, preclinical, 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. However, some devices are automatically subject to the PMA pathway regardless of the level of risk they pose, because they have not previously been classified into a lower risk class by the FDA. Manufacturers of these devices may request that the FDA review such devices in accordance with the de novo classification procedure, which allows a manufacturer whose novel device would otherwise require the submission and approval of a PMA prior to marketing to request down-classification of the device on the basis that the device presents low or moderate risk. If the FDA agrees with the down-classification, the applicant will then receive authorization to market the device. This device type can then be used as a predicate device for future 510(k) submissions.

The FDA can delay, limit or deny clearance or approval of a device for many reasons, including:

- we may not be able to demonstrate to the FDA's satisfaction that our product candidates are safe and effective, sensitive and specific diagnostic tests, for their intended users;
- the data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval, where required; and
- the manufacturing process or facilities we or our contract manufacturers use may not meet applicable requirements.

With respect to those future products where a PMA is not required, we cannot assure you that we will be able to obtain 510(k) clearances with respect to those products. The process of obtaining regulatory clearances or approvals, or completing the de novo classification process, to market a medical device can be costly and time consuming, and we may not be able to successfully obtain pre-market reviews on a timely basis, if at all. Further, even if we were to obtain regulatory clearance, it may not be for the uses we believe are important or commercially attractive, in which case we would not be permitted to market our product for those uses.

Clinical trial data is typically required to support a PMA and is sometimes required for a 510(k) pre-market notification. Although many 510(k) pre-market notifications are cleared without clinical data, in some cases, the FDA requires significant clinical data to support substantial equivalence. Clinical trials are expensive and time-consuming. In addition, the commencement or completion of any clinical trials may be delayed or halted for any number of reasons, including product performance, changes in intended use, changes in medical practice and the opinion of evaluator Institutional Review Boards.

Additionally, since 2009, the FDA has significantly increased the scrutiny applied to its oversight of companies subject to its regulations by hiring new investigators and increasing inspections of manufacturing facilities. The FDA has also undertaken initiatives related to enhancement of the 510(k) review process and has proposed significant changes to the regulation of laboratory developed tests ("LDTs"). We continue to monitor these developments and analyze how they will impact the approval of our products. These and other actions proposed by the FDA's Center for Devices and Radiological Health could result in significant changes to the 510(k) process, which could complicate the product approval process, although we cannot predict the effect of such changes and cannot ascertain if such changes will have a substantive impact on the approval of our products. If we fail to adequately respond to the increased scrutiny and streamlined 510(k) submission process, our business may be adversely impacted.

Failure to comply with the applicable requirements can result in, among other things, warning letters, administrative or judicially imposed sanctions such as injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal to grant premarket clearance or PMA for devices, withdrawal of marketing clearances or approvals, or criminal prosecution. With regard to products for which we seek 510(k) clearance or PMA approval from the FDA, any failure or material delay to obtain such clearance or approval could harm our business. If the FDA were to disagree with our regulatory assessment and conclude that approval or clearance is necessary to market the products, we could be forced to cease marketing the products and seek approval or clearance. Once clearance or approval has been obtained for a product, there is an obligation to ensure that all applicable FDA and other regulatory requirements continue to be met.

In addition, it is possible that the current regulatory framework could change or additional regulations could arise at any stage during our product development or marketing, which may adversely affect our ability to obtain or maintain approval of our products. For example, in response to industry and healthcare provider concerns regarding the predictability, consistency and rigor of the 510(k) regulatory pathway, the FDA initiated an evaluation of the program, and in January 2011, announced several proposed actions intended to reform the review process governing the clearance of medical devices. The FDA undertook these reform actions to improve the efficiency and transparency of the clearance process, as well as bolster patient safety. In addition, as part of the Food and Drug Administration Safety and Innovation Act, Congress reauthorized the Medical Device User Fee Amendments with various FDA performance goal commitments and enacted several "Medical Device Regulatory Improvements" and miscellaneous reforms that are further intended to clarify and improve medical device regulation both pre- and post-approval. Any delay in, or failure to receive or maintain, clearance or approval for our product candidates could prevent us from generating revenue from these product candidates. Additionally, the FDA and other regulatory authorities have broad enforcement powers. Regulatory enforcement or inquiries, or other increased scrutiny on us, could affect the perceived safety and efficacy of our product candidates and dissuade our customers from using our product candidates, if and when they are authorized for marketing.

Our manufacturing facility located in Tucson, Arizona, where we assemble and produce the Accelerate Pheno system, may be subject to regulatory inspections by the FDA and other federal and state and foreign regulatory agencies. For example, this facility is subject to Quality System Regulations ("QSR") of the FDA and is subject to annual inspection and licensing by the State of Arizona. If we fail to maintain this facility in accordance with the QSR requirements, international quality standards or other regulatory requirements, our manufacturing process could be suspended or terminated, which would prevent us from being able to provide products to our customers in a timely fashion.

Sales of our diagnostic product candidates outside the United States are subject to foreign regulatory requirements governing clinical studies, vigilance reporting, marketing approval, manufacturing, product licensing, pricing and reimbursement. These regulatory requirements vary greatly from country to country. As a result, the time required to obtain approvals outside the United States may differ from that required to obtain FDA marketing authorization from the FDA, and we may not be able to obtain foreign regulatory approvals on a timely basis or at all. Marketing authorization from the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure clearance or approval by regulatory authorities in other

countries or by the FDA. Foreign regulatory authorities could require additional testing. For example, we are currently seeking regulatory approval in China for our Accelerate Pheno system. Failure to comply with foreign regulatory requirements, or to obtain required clearances or approvals, could impair our ability to commercialize our diagnostic product candidates outside of the United States.

Global health crises, such as the current COVID-19 global pandemic, may divert regulatory resources and attention away from approval processes for our products. This could materially lengthen the regulatory approval process of new products, which would delay expected commercialization of such new products.

Modifications to our products, if cleared or approved, may require new 510(k) clearances or pre-market approvals, or may require us to cease marketing or recall the modified products until clearances are obtained.

Any modification to a device authorized for marketing that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, requires a new 510(k) clearance or, possibly, approval of a PMA supplement or new PMA. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. If the FDA disagrees with our determination and requires us to submit new 510(k) notifications, PMA supplements or PMAs for modifications to previously cleared or approved products for which we conclude that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties.

Furthermore, the FDA's ongoing review of the 510(k) program may make it more difficult for us to make modifications to any products for which we obtain clearance, either by imposing more strict requirements on when a manufacturer must submit a new 510(k) for a modification to a previously cleared product, or by applying more onerous review criteria to such submissions. The practical impact of the FDA's continuing scrutiny of the 510(k) program remains unclear.

We rely on third parties to conduct studies of our products that may be required by the FDA or other regulatory authorities, and those third parties may not perform satisfactorily.

We rely on third parties, including medical investigators, to conduct studies on our products. Our reliance on these third parties for clinical development activities will reduce our control over these activities. These third parties may not complete activities on schedule or conduct studies in accordance with regulatory requirements or our study design. If applicable, our reliance on third parties that we do not control will not relieve us of any applicable requirement to prepare, and ensure compliance with, various procedures required under good clinical practices. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our studies may be extended, delayed, suspended or terminated, and we may not be able to obtain marketing authorization from the FDA or regulatory clearance for our products.

A recall of our products, either voluntarily or at the direction of the FDA, or the discovery of serious safety issues with our products that leads to corrective actions, could have a significant adverse impact on us.

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Under the FDA's medical device reporting regulations, we are required to report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Repeated product malfunctions may result in a voluntary or involuntary product recall. Recalls of any of our products would divert managerial and financial resources, have an adverse effect on our reputation, and may impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide that we will need to obtain, new approvals or clearances for the device before we may market or

distribute the corrected device. Seeking such approvals or clearances may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties, or civil or criminal fines. We may also be required to bear other costs or take other actions that may have a negative impact on our sales as well as face significant adverse publicity or regulatory consequences, which could harm our ability to market our products in the future.

Any adverse event involving our products could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, would require the dedication of our time and capital, distract management from operating our business and may harm our reputation.

Risks Related to our Common Stock

Our stock price has been volatile and may continue to be volatile and traded on low volumes.

The trading price of our common stock has been, and is likely to continue to be, highly volatile. Factors that may contribute to volatility in the price of our common stock include, but are not limited to: (i) low trading volume currently prevailing in the market for our shares; (ii) concentration of our stock with one individual large shareholder who could decide to materially reduce his position; and (iii) the substantial current short interest in our stock. The market value of your investment in our common stock may rise or fall sharply at any time because of this volatility and also because of significant short positions that may be taken by investors from time to time in our common stock. During the year ended December 31, 2020, the sale price for our common stock ranged from $4.62 to $18.74 per share, and during the year ended December 31, 2019, the sale price for our common stock ranged from $11.76 to $23.92 per share. The market prices for securities of medical technology companies like us historically have been highly volatile, and the market has experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies.

The short interest in our common stock is high, which may lead to further volatility in our stock price.

As of December 31, 2020, the number of shares of our common stock shorted was high as compared to the number of shares in the public float. A significant concentration of short interest can be a contributing factor resulting in high volatility in our stock price and volume fluctuations.

The ownership of our common stock is highly concentrated.

As of December 31, 2020, our directors and executive officers, together with members of their immediate families, as a group, beneficially own, in the aggregate, approximately 44% of our outstanding capital stock, including 28% beneficially owned, directly or indirectly, by our director, Jack Schuler. As a result, these stockholders will be able to affect the outcome of, or exert significant influence over, all matters requiring stockholder approval, including the election and removal of directors and any change in control. In particular, this concentration of ownership of our common stock could have the effect of delaying or preventing a change in control of us or otherwise discouraging or preventing a potential acquirer from attempting to obtain control of us. This, in turn, could have a negative effect on the market price of our common stock. It could also prevent our stockholders from realizing a premium over the market prices for their shares of common stock. Moreover, the interests of this concentration of ownership may not always coincide with our interests or the interests of other stockholders. The concentration of ownership also contributes to the low trading volume and volatility of our common stock. Certain of our major shareholders hold their shares in certificate form, further limiting trading volume.

Future sales of shares of our common stock may depress the price of our shares and be dilutive to our existing stockholders.

We cannot predict whether future issuances of shares of our common stock or the availability of shares for resale in the open market will decrease the market price per share of our common stock. Any sales by us or by our existing stockholders of a substantial number of shares of our common stock in the public market, or the perception that such sales might occur, may cause the market price of our shares to decline. The exercise of any options or warrants, the issuance of our common stock in connection with acquisitions and other issuances of our common stock could have an adverse effect on the market price of the shares of our common stock.

To the extent that we raise additional funds through the sale of equity or convertible debt securities, the issuance of such securities will result in dilution to our stockholders. Investors purchasing shares or other securities in the future could have rights superior to existing stockholders. In addition, we have a significant number of options and warrants outstanding. If the holders of these options or warrants exercise such securities, you may incur further dilution.

We may require additional capital in the future, and you may incur dilution to your stock holdings.

We have primarily relied upon capital from the sale of our securities to fund our operations. Although we have now commercialized the Accelerate Pheno system in the United States, Europe, and certain other regions, there can be no assurance that our commercialization efforts will be successful or that we will not continue to incur operating losses. If capital requirements vary materially from those currently forecast by management, we may require additional capital sooner than expected. We may also require additional capital in the future to expand our product offerings, expand our sales and marketing infrastructure, increase our manufacturing capacity, fund our operations, and continue our research and development activities. Our future funding requirements will depend on many factors, including:

- our ability to obtain marketing authorization from the FDA or clearance from the FDA to market our product candidates;
- market acceptance of our product candidates, if cleared;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the cost of our research and development activities;
- the ability of healthcare providers to obtain coverage and adequate reimbursement by third-party payers for procedures using our products;
- the cost and timing of marketing authorization or regulatory clearances;
- the cost of goods associated with our product candidates;
- the cost of customer disruptions due to supply disruptions;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products and technologies, including entering into licensing or collaboration arrangements for product candidates.

If we require additional capital, we may attempt to raise it through a variety of strategies, including the issuance and sale of additional shares of our common stock. Issuances of additional shares of our common stock or preferred stock in the future, whether in connection with a rights offering, follow-on offering or otherwise, would dilute existing stockholders and may adversely affect the market price of our common stock.

We cannot assure you that we will be able to obtain additional funds on acceptable terms, or at all. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any debt or additional equity financing that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or our products, or grant licenses on terms that are not favorable to us. If we are unable to raise adequate funds, we may have to liquidate some or all of our assets or delay, reduce the scope of or eliminate some or all of our product development.

If we do not have, or are not able to obtain, sufficient funds, we may be required to delay additional product development or license to third parties the rights to commercialize our products or technologies that we would otherwise seek to commercialize ourselves. We also may have to reduce marketing, customer support or other resources devoted to our product candidates or cease operations. Any of these factors could harm our operating results.

Provisions in our certificate of incorporation and bylaws and Delaware law may delay or prevent acquisition of our Company, which could adversely affect the value of our common stock.

Provisions contained in our certificate of incorporation and bylaws, as well as provisions of the Delaware General Corporation Law, could delay or make it more difficult to remove incumbent directors or for a third party to acquire us, even if a takeover would benefit our stockholders. For example, our board of directors may fill any vacancy on the board of directors, whether such vacancy occurs as a result of an increase in the number of directors or otherwise. Stockholders may only take action by written consent if acting unanimously. Special meetings of the stockholders may be called only by the President, a Vice President, our board of directors or the holders of not less than one-tenth of all the shares entitled to vote at the meeting. Additionally, our board of directors has the authority to cause us to issue, without any further vote or action by the stockholders, up to 5.0 million shares of preferred stock, par value $0.001 per share, in one or more series, to fix the number of shares constituting such series and the designation of such series, the voting powers, if any, of the shares of such series, and the preferences and relative, participating, optional or other special rights, if any, and any qualifications, limitations or restrictions thereof, of the shares of such series. The issuance of shares of preferred stock may have the effect of delaying, deferring or preventing a change in control of our Company without further action by the stockholders, even where stockholders are offered a premium for their shares. Moreover, we are subject to the provisions of Section 203 of the General Corporation Law of the State of Delaware, 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.

Risks Related to our Convertible Senior Notes

We have indebtedness in the form of convertible senior notes.

On March 27, 2018, the Company issued $150.0 million aggregate principal amount of 2.50% Convertible Senior Notes due 2023 (the “Notes”). In connection with the offering of the Notes, the Company granted the initial purchasers of the Notes a 13-day option to purchase up to an additional $22.5 million aggregate principal amount of the Notes on the same terms and conditions. On April 4, 2018 the option was partially exercised, which resulted in $21.5 million of additional proceeds, for total proceeds of $171.5 million. As a result of this Notes offering, we incurred $171.5 million principal amount of indebtedness, the principal amount of which we may be required to pay at maturity in 2023. Holders of the Notes will have the right to require us to repurchase their Notes upon the occurrence of a fundamental change at a purchase price equal to 100% of the principal amount of the Notes to be purchased, plus accrued and unpaid interest, if any. In addition, the indenture for the Notes provides that we are required to repay amounts due under the indenture in the event that there is an event of default for the Notes that results in the principal, premium, if any, and interest, if any, becoming due prior to Maturity Date for the Notes. There can be no assurance that we will be able to repay this indebtedness when due, or that we will be able to refinance this indebtedness on acceptable terms or at all. In addition, this indebtedness could, among other things:

- heighten our vulnerability to adverse general economic conditions and heightened competitive pressures;
- require us to dedicate a larger portion of our cash flow from operations to interest payments, limiting the availability of cash for other purposes;
- limit our flexibility in planning for, or reacting to, changes in our business and industry; and
- impair our ability to obtain additional financing in the future for working capital, capital expenditures, acquisitions, general corporate purposes or other purposes.

Our failure to repurchase Notes at a time when the repurchase is required by the indenture (whether upon a fundamental change or otherwise under the indenture) or pay cash payable on future conversions of the Notes as required by the indenture would constitute a default under the indenture. A default under the indenture or the fundamental change itself could also lead to a default under agreements governing our existing or future indebtedness. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness, repurchase the Notes or make cash payments upon conversions thereof.

Servicing our debt will require a significant amount of cash, and we may not have sufficient cash flow from our business to pay our debt.

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness, including the Notes, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not continue to generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

To the extent we choose to deliver shares upon conversion of the Notes, the ownership interests of existing stockholders will be diluted and our stock price may be adversely impacted.

Upon conversion of the Notes, we will pay or deliver, as the case may be, cash, shares of our common stock or a combination of cash and shares of our common stock, at our election. To the extent we choose to deliver shares upon conversion of some or all of the Notes, this will result in a dilution to the ownership interests of existing stockholders and may depress our stock price.

The conditional conversion feature of the Notes, if triggered, may adversely affect our financial condition and operating results.

In the event the conditional conversion feature of the Notes is triggered, holders of the Notes will be entitled to convert the Notes at any time during specified periods at their option. If one or more holders elect to convert their Notes, unless we elect to satisfy our conversion obligation by delivering solely shares of our common stock (other than cash in lieu of any fractional share), we would be required to settle a portion or all of our conversion obligation through the payment of cash, which could adversely affect our liquidity. In addition, even if holders of the Notes do not elect to convert their Notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the Notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

The accounting method for convertible debt securities that may be settled in cash, such as the Notes, could have a material effect on our reported financial results.

Under Accounting Standards Codification 470-20, Debt with Conversion and Other Options (“ASC 470-20”), an entity must separately account for the liability and equity components of the Notes that may be settled entirely or partially in cash upon conversion in a manner that reflects the issuer’s economic interest cost. The effect of ASC 470-20 on the accounting for the Notes is that the equity component is required to be included in the additional paid-in capital section of stockholders’ deficit on our consolidated balance sheet at the issuance date and the value of the equity component would be treated as debt discount for purposes of accounting for the debt component of the Notes. As a result, we will be required to record a greater amount of non-cash interest expense as a result of the amortization of the discounted carrying value of the Notes to their face amount over the term of the Notes. We will report larger net losses (or lower net income) in our financial results because ASC 470-20 will require interest to include both the amortization of the debt discount and the instrument’s non-convertible coupon interest rate, which could adversely affect our reported or future financial results, the trading price of our common stock and the trading price of the Notes. In addition, the Notes may be settled entirely or partly in cash and may be accounted for utilizing the treasury stock method, the effect of which is that the shares issuable upon conversion of such Notes are not included in the calculation of diluted earnings per share except to the extent that the conversion value of such Notes exceeds their principal amount. Under the treasury stock method, for diluted earnings per share purposes, the transaction is accounted for as if the number of shares of common stock that would be necessary to settle such excess, if we elected to settle such excess in shares, are issued. We cannot be sure that the accounting standards in the future will continue to permit the use of the treasury stock method. If we are unable or otherwise elect not to use the treasury stock method in accounting for the shares issuable upon conversion of the Notes, then our diluted earnings per share could be adversely affected.

The prepaid forward we entered into in connection with the Notes offering may affect the value of our common stock and may result in unexpected market activity in our common stock.

In connection with the issuance of the Notes, we entered into a prepaid forward with the forward counterparty. The prepaid forward is intended to reduce the dilution to our stockholders from the issuance of our common stock (if any) upon conversion of the Notes and to allow certain investors to establish short positions that generally correspond to commercially reasonable initial hedges of their investment in the Notes. In addition, the forward counterparty (or its affiliate) may modify its hedge position by entering into or unwinding one or more derivative transactions with respect to our common stock and/or purchasing or selling our common stock or other securities of ours in secondary market transactions at any time, including following the offering of the Notes and immediately prior to or shortly after March 15, 2023, the maturity date of the Notes (and are likely to unwind their derivative transactions and/or purchase or sell our common stock in connection with any conversion or repurchase of the Notes and/or in connection with the purchase or sale of notes by certain investors). These activities could also cause or avoid an increase or a decrease in the market price of our common stock.

The prepaid forward initially facilitated privately negotiated derivative transactions relating to our common stock, including derivative transactions by which investors in the Notes established short positions relating to our common stock to hedge their investments in the Notes concurrently with, or shortly after, the placement of the Notes. Neither we nor the forward counterparty control how such investors may use such derivative transactions. In addition, such investors may enter into other transactions in connection with such derivative transactions, including the purchase or sale of our common stock, at any time. As a result, the existence of the prepaid forward, such derivative transactions, and any related market activity could cause more sales of our common stock over the term of the prepaid forward than there would have otherwise been had we not entered into the prepaid forward. Such sales could potentially affect the market price of our common stock.

We are subject to counterparty risk with respect to the prepaid forward. We will be subject to the risk that the forward counterparty might default under the prepaid forward.

We are subject to the risk that the forward counterparty might default under the prepaid forward. Our exposure to the credit risk of the forward counterparty will not be secured by any collateral. Global economic conditions have in the past resulted in, and may again result in, the actual or perceived failure or financial difficulties of many financial institutions. If the forward counterparty becomes subject to insolvency proceedings, we will become an unsecured creditor in those proceedings, with a claim equal to our exposure at that time under our transactions with the forward counterparty. Our exposure will depend on many factors, but, generally, an increase in our exposure will be correlated to an increase in the market price of our common stock. In addition, upon a default by the forward counterparty, we may suffer more dilution than we currently anticipate with respect to our common stock. We can provide no assurances as to the financial stability or viability of the forward counterparty to the prepaid forward.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

Our headquarters and reference laboratory space is located in Tucson, Arizona, and we have other offices in Europe. As of December 31, 2020 and 2019, we leased approximately 54,407 and 55,970 square feet of office/ laboratory and manufacturing space, respectively. We believe that our currently leased facilities are adequate to meet our needs for the foreseeable future. See Item 8, Note 16, Leases for additional details regarding the leases.

Item 3. Legal Proceedings

We are from time to time subject to various claims and legal actions in the ordinary course of our business. Other than the patent Opposition proceeding discussed under the heading “Risk Factors-Risks Related to Our Intellectual Property-We may not be successful in our currently pending or future patent applications, and even if such applications are successful, we cannot guarantee that the resulting patents will sufficiently protect our products and proprietary technology” in Item 1A, Risk Factors of this Form 10-K, which is incorporated herein by reference,

we believe that there are currently no claims or legal actions that would reasonably be expected to have a material adverse effect on our results of operations or financial condition.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

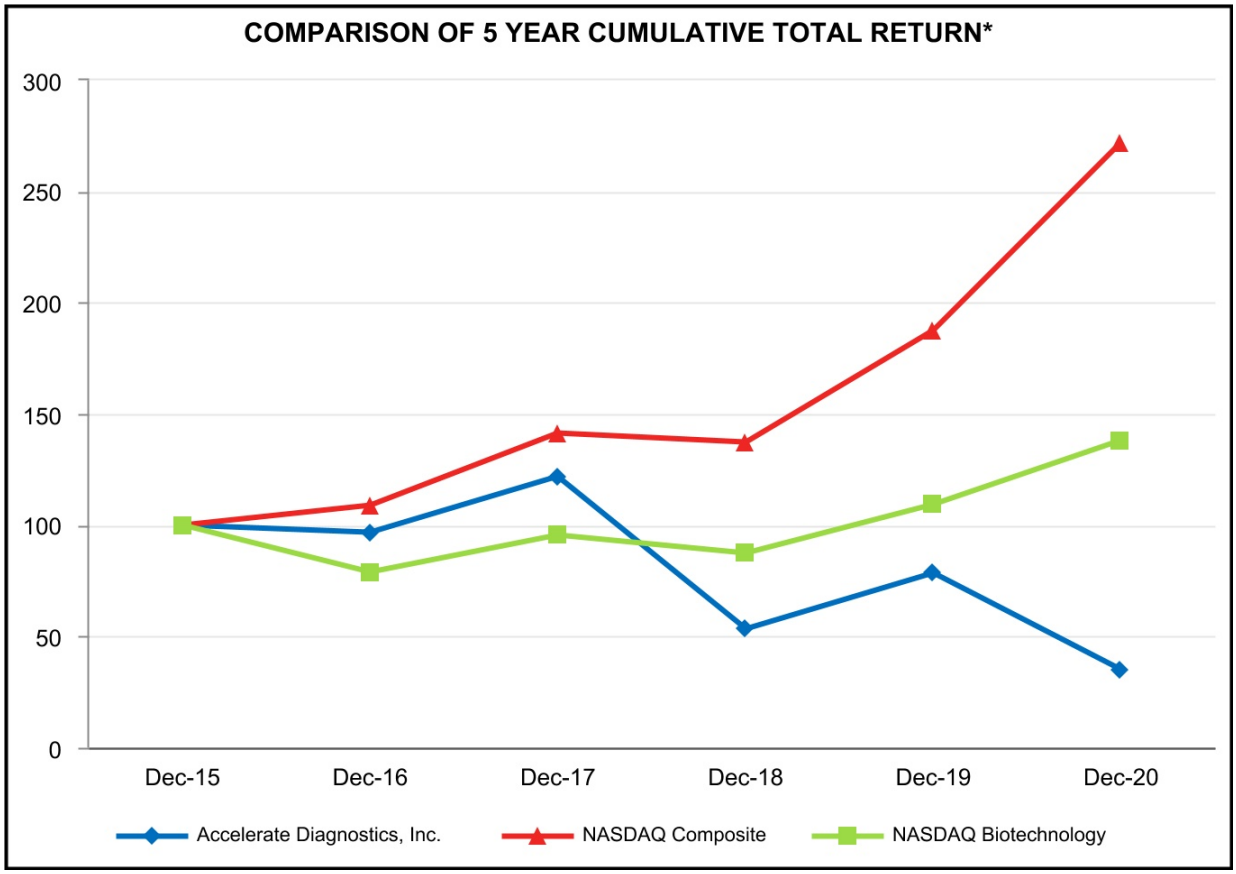
Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock trades under the symbol “AXDX” on The Nasdaq Capital Market.

Performance Graph

The following Performance Graph compares the cumulative 5-year total stockholder return on our common stock relative to the cumulative total returns of the NASDAQ Composite index (XCMP) and the NASDAQ Biotechnology index (XNBI). An investment of $100 (with reinvestment of all dividends) is assumed to have been made in our common stock and in each of the indexes on December 31, 2015 and its relative performance is tracked through December 31, 2020. The Performance Graph and related information shall not be deemed to be “soliciting material” or to be “filed” with the SEC, nor shall such information be incorporated by reference into any filing under the Securities Act or the Exchange Act except to the extent that we specifically incorporate it by reference into such filing.



	Dec-15	Dec-16	Dec-17	Dec-18	Dec-19	Dec-20
Accelerate Diagnostics, Inc.	100.00	96.56	121.92	53.51	78.64	35.27
NASDAQ Composite	100.00	108.87	141.13	137.12	187.44	271.64
NASDAQ Biotechnology	100.00	78.65	95.67	87.19	109.08	137.90

* $100 invested on 12/31/2015 in stock or index, including reinvestment of dividends.

Holders

As of February 23, 2021, we had approximately 143 record owners of our Common Stock.

Dividends Paid and Dividend Policy

Holders of Common Stock are entitled to receive dividends as may be declared by the Board of Directors out of funds legally available. To date, no dividends have been declared by the Board of Directors. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any cash dividends on our Common Stock for the foreseeable future.

Future cash dividends, if any, will be at the discretion of our Board of Directors and will depend upon our future operations and earnings, capital requirements and surplus, general financial condition, contractual restrictions and other factors as our Board of Directors may deem relevant. We do not intend to pay any cash dividends on our Common Stock in the foreseeable future.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Equity Compensation Plan Information

The table set forth below presents the securities authorized for issuance with respect to compensation plans under which equity securities are authorized for issuance as of December 31, 2020:

Equity Compensation Plan

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights[1]	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in the 1st column)
Equity compensation plans approved by security holders	8,571,875 [2]	$ 14.18	5,472,418
Equity compensation plans not approved by security holders	—	—	—
Total	**8,571,875**	**$ 14.18**	**5,472,418**

(1) Shares of common stock issuable upon vesting of RSUs and PSUs have been excluded from the calculation of the weighted average exercise price because they have no exercise price associated with them.
(2) Represents 8,045,461 shares of common stock subject to outstanding stock options and 526,414 shares of common stock that may be issued upon vesting of outstanding RSUs and PSUs (assuming the maximum performance level for PSUs).

Item 6. Selected Financial Data

Reserved.

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

The following Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") summarizes our change in fiscal year financial condition, results of operations, recent developments, the significant factors affecting our results of operations, capital resources and liquidity, off-balance sheet arrangements, and contractual obligations, and discusses recent accounting pronouncements and our critical accounting policies and estimates. You should read the following discussion and analysis together with our financial statements, including the related notes, which are included in this Form 10-K. Certain information contained in the discussion and analysis set forth below and elsewhere in this report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. See Item 1A, Risk Factors of this Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements in this report.

COVID-19 Update

In late 2019, a novel strain of coronavirus (COVID-19) was reported to have surfaced in Wuhan, China, which has since spread globally. In March 2020, the World Health Organization declared COVID-19 a global pandemic. Further, the COVID-19 outbreak has resulted in government authorities around the world implementing numerous measures to try to reduce the spread of COVID-19, such as travel bans and restrictions, quarantines, shelter-in-place, stay-at-home or total lock-down (or similar) orders and business limitations and shutdowns. For example, the State of Arizona has implemented several orders promoting physical distancing, limiting certain activities, and restricting the operations of certain businesses. The COVID-19 pandemic and these measures have caused, and are continuing to cause, business slowdowns or shutdowns in affected areas, both regionally and worldwide, which have significantly impacted our business and results of operations, starting in the first quarter of 2020. For example, this included diminished access to our customers, including hospitals, which has severely limited our ability to sell or implement the Accelerate Pheno systems. In addition, in April and May 2020 our Accelerate Pheno kit orders declined as many hospitals curtailed elective surgeries to respond to COVID-19. Since May 2020, our Accelerate Pheno kit orders have returned to more normal levels, but could decline again if COVID-19 surges cause hospitals to reduce or prohibit elective surgeries. Furthermore, our expected rate of growth of our consumable test kit sales has been reduced because of the negative impact of the COVID-19 pandemic on Accelerate Pheno system new sales and implementations.

The reduced sales and implementations caused by the COVID-19 pandemic lowered our expected revenue growth for 2020. Due to this reduced revenue growth's impact on cash we furloughed certain employees and implemented salary reductions for executives and other highly compensated employees. Most of the furloughs became permanent in December 2020.

As a medical device company, we have not experienced any disruptions to our ability to manufacture our products at our Tucson, Arizona headquarters under the various State of Arizona executive orders relating to the COVID-19 pandemic because we were classified as an essential service. We currently expect that, should future orders be issued, we would be able to sustain our essential operations. Our third-party manufacturing supply chain for Accelerate Pheno systems and consumable test kits remains stable. However, the economic effects of the COVID-19 pandemic remain unpredictable, and we are closely monitoring the ability of all our suppliers to provide us with materials necessary for the manufacture of Accelerate Pheno systems and consumable test kits.

We continue to monitor the rapidly evolving situation caused by the COVID-19 pandemic, and we may take further actions required by governmental authorities or that we determine are prudent to support the well-being of our employees, customers, suppliers, business partners and others. The degree to which the COVID-19 pandemic ultimately impacts our business, results of operations, cash flows and financial position will depend on future developments, which are highly uncertain, continuously evolving and cannot be predicted. This includes, but is not limited to, the duration and spread of the pandemic, its severity, the actions to contain the virus or treat its impact, (including the efficacy of vaccines, particularly with respect to emerging strains of the virus), and how quickly and to what extent normal economic and operating conditions can resume. We currently expect to continue to have limited access to our customers and prospects for at least the first half of 2021, particularly with regard to new sales.

Accordingly, our current results and financial condition discussed herein may not be indicative of future operating results and trends. Refer to the section entitled “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2020, which is incorporated by reference herein, for additional risks we face due to the COVID-19 pandemic.

Changes in Results of Operations: Comparison of fiscal years ended December 31, 2020, 2019 and 2018

	December 31, (in thousands)				December 31, (in thousands)			
	2020	2019	$ Change	% Change	2019	2018	$ Change	% Change
Net sales	$ 11,165	$ 9,297	$ 1,868	20 %	$ 9,297	$ 5,670	$ 3,627	64 %

For the years ended December 31, 2020 and 2019, total revenues increased compared to the previous year due to increased sales of Accelerate PhenoTest BC Kits and instruments. Accelerate PhenoTest BC revenue has increased as customers complete their instrument verifications and begin purchasing kits. In addition, the Company recorded increased revenue in connection with sales-type leases of Accelerate PhenoTest Systems during the year ended December 31, 2020.

	December 31, (in thousands)				December 31, (in thousands)			
	2020	2019	$ Change	% Change	2019	2018	$ Change	% Change
Cost of sales	$ 6,706	$ 4,897	$ 1,809	37 %	$ 4,897	$ 3,187	$ 1,710	54 %
Gross profit	$ 4,459	$ 4,400	$ 59	1 %	$ 4,400	$ 2,483	$ 1,917	77 %

During the year ended December 31, 2020, cost of sales and gross profit increased as a result of an increase in sales and sales-type leases of Accelerate Pheno systems and Accelerate PhenoTest BC kits compared to the year ended December 31, 2019. This increase was primarily driven by an increase in Accelerate PhenoTest BC kits sales.

Gross profit increased at a slower rate than the increase in sales due to higher revenue from sales-type leases of Accelerate PhenoTest systems. Gross profit on sales-type leases is generally lower than gross profit from sales of Accelerate PhenoTest systems sold direct to customers.

During the year ended December 31, 2019, cost of sales and gross profit increased as a result of an increase in sales of Accelerate Pheno systems and Accelerate PhenoTest BC kits compared to the year ended December 31, 2018. This increase was primarily driven by an increase in Accelerate PhenoTest BC kits sales.

Inventory without a cost basis was sold to customers for the years ended December 31, 2020, 2019 and 2018. Pre-launch inventory previously not capitalized and expensed in a previous year for the years ended December 31, 2020, 2019 and 2018 was $0.1 million, $0.5 million and $0.4 million, respectively.

Cost of sales includes non-cash equity-based compensation of $0.4 million, $0.3 million and $0.2 million for the years ended December 31, 2020, 2019 and 2018, respectively. The increase in non-cash equity-based compensation was primarily driven by an increase in sales of Accelerate Pheno systems and Accelerate PhenoTest BC kits. Non-cash equity-based compensation cost is a component of manufacturing overhead. Manufacturing overhead is capitalized as inventory and relieved to cost of sales when consumable tests are sold to a customer, instruments are sold to a customer or when we recognize depreciation is recorded on revenue generating instruments under operating leases. Cost of sales also includes non-cash equity-based compensation of service overhead when supporting revenue generating instruments.

	December 31, (in thousands)				December 31, (in thousands)			
	2020	2019	$ Change	% Change	2019	2018	$ Change	% Change
Research and development	$ 21,255	$ 25,345	$ (4,090)	(16)%	$ 25,345	$ 27,638	$ (2,293)	(8)%

Research and development expenses for the year ended December 31, 2020 decreased as compared to the year ended December 31, 2019. The decrease was the result of a decrease in external studies spend and other cost containment measures.

Research and development expenses for the year ended December 31, 2019 decreased as compared to the year ended December 31, 2018. The decrease was primarily the result of decreases in employee non-cash equity-based compensation and employee related expenses, decreases in purchases of engineering supplies to support research and development and decreases in depreciation expense.

Research and development expenses include non-cash equity-based compensation of $4.0 million, $4.1 million and $4.8 million for the years ended December 31, 2020, 2019 and 2018, respectively.

Non-cash equity-based compensation expense for the year ended December 31, 2020 was relatively consistent with the year ended December 31, 2019. This was primarily the result of equity-based stock options becoming fully vested during the period, and new stock awards being granted and released in the same period. These two events resulted in the expense balance remaining flat for the year ended December 31, 2020 when compared to the year ended December 31, 2019.

The decrease of non-cash equity-based compensation expense for the year ended December 31, 2019 as compared to the year ended December 31, 2018 was primarily the result of equity-based stock options becoming fully vested during the period, and new equity-based stock option grants having a lower average fair value per share.

	December 31, (in thousands)				December 31, (in thousands)			
	2020	2019	$ Change	% Change	2019	2018	$ Change	% Change
Sales, general and administrative	$ 46,904	$ 51,886	$ (4,982)	(10)%	$ 51,886	$ 55,214	$ (3,328)	(6)%

Sales, general and administrative expenses for the year ended December 31, 2020 decreased as compared to the year ended December 31, 2019. This decrease is primarily the result of the COVID-19 pandemic, as hospitals have limited access to their facilities to primarily focus on COVID-19 initiatives. These circumstances resulted in decreased expenses associated with travel, trade shows, and instrument demonstration expenses. In addition management also implemented additional cost containment initiatives to reduce other expenses such as services and marketing expenses.

Sales, general and administrative expenses for the year ended December 31, 2019 decreased as compared to the year ended December 31, 2018. The decrease was primarily the result of a decrease in employee non-cash equity-based compensation, along with a reduction in expenditures with third-party vendors.

Sales, general and administrative expenses include non-cash equity-based compensation of $12.1 million, $8.2 million and $9.5 million for the years ended December 31, 2020, 2019 and 2018, respectively.

The increase of expense for the year ended December 31, 2020 as compared to the year ended December 31, 2019 was primarily the result of larger stock option and stock awards granted to employees in the current year period.

The decrease of expense for the year ended December 31, 2019 as compared to the year ended December 31, 2018 was primarily the result of new equity-based stock option grants having a lower average fair value per share, and an increase in forfeitures which offset expenses.

	December 31, (in thousands)				December 31, (in thousands)			
	2020	2019	$ Change	% Change	2019	2018	$ Change	% Change
Loss from operations	$ (63,700)	$ (72,831)	$ 9,131	(13)%	$ (72,831)	$ (80,369)	$ 7,538	(9)%

During the year ended December 31, 2020, our loss from operations decreased compared to the year ended December 31, 2019. This decrease was primarily the result of a decrease in research and development expenses, and sales, general and administrative expenses, combined with an increase in net sales as described above.

During the year ended December 31, 2019, our loss from operations decreased compared to the year ended December 31, 2018. The decrease was primarily the result of decreases in non-cash equity-based compensation, a decrease in research and development expenses, a decrease in sales, general and administrative expenses and increased sales as described above.

Loss from operations includes non-cash equity-based compensation expense of $16.5 million, $12.6 million and $14.4 million for the years ended December 31, 2020, 2019 and 2018, respectively.

This loss and further losses are anticipated and are the result of our continued investments in sales and marketing, key research and development personnel, related costs associated with product development, and commercialization of the Company's products.

	December 31, (in thousands)				December 31, (in thousands)			
	2020	2019	$ Change	% Change	2019	2018	$ Change	% Change
Total other expense, net	$ (14,503)	$ (11,585)	$ (2,918)	25 %	$ (11,585)	$ (7,746)	$ (3,839)	50 %

Other expenses for the years ended December 31, 2020 and 2019 increased compared to the previous year. The increases were primarily the result of increased interest expense partially offset by investment income. In 2018 the Company started incurring interest expense in connection with our convertible notes. For the years ended December 31, 2020, 2019 and 2018 the Company incurred interest expense of $15.5 million, $14.3 million, and $10.1 million, respectively. These amounts were partially offset by investment income of $0.9 million, $2.8 million and $2.8 million for the years ended December 31, 2020, 2019 and 2018, respectively.

	December 31, (in thousands)				December 31, (in thousands)			
	2020	2019	$ Change	% Change	2019	2018	$ Change	% Change
(Provision) benefit for income taxes	$ (5)	$ 111	$ (116)	(105)%	$ 111	$ (211)	$ 322	(153)%

For the year ended December 31, 2020, the Company recorded immaterial expense for income taxes as the Company is anticipating a small amount of state and foreign tax expense. For the year ended December 31, 2019, the Company recorded a benefit for income taxes due to an income tax refund in connection with restructuring a transfer pricing agreement of a foreign subsidiary. For the year ended December 31, 2018, the Company recorded tax provisions related to tax liabilities generated by our foreign subsidiaries for foreign income taxes.

Capital Resources and Liquidity

Our primary source of liquidity has been from sales of shares of our common stock, the issuance of our convertible notes and cash from operations. As of December 31, 2020, the Company had $68.3 million in cash and cash equivalents and marketable securities, a decrease of $40.2 million from $108.5 million at December 31, 2019. The primary reason for the decrease was due to cash used in operations during the period.

The Company is subject to Lease Agreements. The future lease obligations under the Lease Agreements

are included in Item 8, Note 16, Leases.

As of December 31, 2020, management believes that current cash balances will be more than sufficient to fund our capital and liquidity needs for the next twelve months.

Our primary use of capital has been for the commercialization and development of the Accelerate Pheno system. We believe our capital requirements will continue to be met with our existing cash balance and those provided under revenue, grants, exercises of stock options and/or additional issuance of equity or debt securities. However, if capital requirements vary materially from those currently planned, we may require additional capital sooner than expected. There can be no assurance that such capital will be available in sufficient amounts or on terms acceptable to us, if at all. Additional issuances of equity or convertible debt securities will result in dilution to our current common stockholders.

Summary of Cash Flows

The following summarizes selected items in the Company's consolidated statements of cash flows for years ended December 31 (in thousands):

Cash Flow Summary
(in thousands)

	2020	2019	2018
Net cash used in operating activities	$ (50,394)	$ (64,794)	$ (67,756)
Net cash provided by (used in) investing activities	13,606	52,811	(20,138)
Net cash provided by financing activities	11,633	6,823	125,771

Cash flows from operating activities

The net cash used in operating activities was $50.4 million, $64.8 million and $67.8 million during the years ended December 31, 2020, 2019 and 2018, respectively. Net cash used in operating activities was primarily the result of net losses offset by equity-based compensation and amortization of debt discount and issuance costs.

These losses are the result of continued investments in research and development to further mature Accelerate Pheno, develop ancillary products, and develop a next generation product, sales and marketing, along with other factors.

Cash flows from investing activities

The net cash provided by investing activities was $13.6 million for year ended December 31, 2020. The Company had maturities of $61.9 million which were offset in part by purchases of marketable securities of $46.9 million.

The net cash provided by investing activities was $52.8 million for year ended December 31, 2019. The Company purchased marketable securities of $50.2 million, offset in part by maturities of marketable securities of $88.9 million and proceeds from sales of marketable securities of $14.5 million.

The net cash used in investing activities was $20.1 million for year ended December 31, 2018. The Company purchased marketable securities of $120.6 million, offset in part by maturities of marketable securities of $98.4 million. The Company had an increase in marketable securities purchases during the year ended December 31, 2018 in connection with investing the proceeds from the Company's convertible notes offering.

Cash flows from financing activities

The net cash provided by financing activities was $11.6 million for the year ended December 31, 2020, and was primarily comprised of proceeds from exercises of options and long-term debt. Proceeds from exercises of options was $6.1 million, while the Company received $5.6 million in proceeds from long-term debt, $4.8 million of which consists of proceeds from the Paycheck Protection Program Note described below.

The net cash provided by financing activities was $6.8 million for the year ended December 31, 2019, and was primarily comprised of proceeds from exercises of options.

The net cash provided by financing activities was $125.8 million during the year ended December 31, 2018. This was primarily from proceeds received from the Notes offering during 2018, partially offset by the prepayment of a forward stock repurchase and debt issuance costs as described in Item 8, Note 11, Convertible Notes.

Convertible Notes

On March 27, 2018, the Company issued $150.0 million aggregate principal amount of 2.50% Convertible Senior Notes (the "Notes"). In connection with the offering of the Notes, the Company granted the initial purchasers of the Notes a 13-day option to purchase up to an additional $22.5 million aggregate principal amount of the Notes on the same terms and conditions. On April 4, 2018 the option was partially exercised, which resulted in $21.5 million of additional proceeds, for total proceeds of $171.5 million. The Notes mature on March 15, 2023, unless earlier repurchased or converted into shares of common stock subject to certain conditions. The Notes are convertible into shares of the Company's common stock, can be repurchased for cash, or a combination thereof, at the Company's election, at an initial conversion rate of 32.3428 shares of common stock per $1,000 principal amount of the Notes, which is equivalent to an initial conversion price of approximately $30.92 per share of common stock, subject to adjustment. We will pay interest on the Notes semi-annually in arrears on March 15 and September 15 of each year with interest payments beginning on September 15, 2018. Proceeds received from the issuance of the Notes was allocated between long-term debt (the "liability component") and contributed capital (the "equity component"), within the consolidated balance sheet. The fair value of the liability component was measured using rates determined for similar debt instruments without a conversion feature.

In connection with the offering, we entered into a prepaid forward stock repurchase transaction (the "Prepaid Forward") with a financial institution. Pursuant to the Prepaid Forward, we used approximately $45.1 million of the proceeds from the offering of the Notes to pay the prepayment amount. The aggregate number of shares of our common stock underlying the Prepaid Forward is approximately 1,858,500 shares (based on the sale price of $24.25). The expiration date for the Prepaid Forward is March 15, 2023, although it may be settled earlier in whole or in part. Upon settlement of the Prepaid Forward, at expiration or upon any early settlement, the Forward Counterparty will deliver to us the number of shares of common stock underlying the Prepaid Forward or the portion thereof being settled early. The shares purchased under the Prepaid Forward were treated as treasury stock on the consolidated balance sheet (and not outstanding for purposes of the calculation of basic and diluted earnings per share), but remain outstanding for corporate law purposes, including for purposes of any future stockholders' votes, until the Forward Counterparty delivers the shares underlying the Prepaid Forward to us. Net proceeds, less issuance cost from the offering of approximately $121.4 million, is being used for general corporate purposes.

Paycheck Protection Program ("PPP") Loan

On April 14, 2020, the Company entered into a promissory note (the "PPP Note") evidencing an unsecured loan in the amount of $4.8 million. The PPP Note matures on April 14, 2025 and bears interest at a rate of 1% per annum. Beginning August 14, 2021, the Company is required to make 45 monthly payments of principal and interest in the amount of $0.1 million. The PPP Note may be prepaid by the Company at any time prior to maturity with no prepayment penalties. The proceeds from the PPP Note were used for payroll costs (including benefits), rent and utilities.

Pursuant to the terms of the Coronavirus Aid, Relief, and Economic Security ("CARES Act") and the PPP, the Company applied to the lender for forgiveness for the amount due on the Loan. The amount eligible for forgiveness is based on the amount of loan proceeds used by the Company (during the 24 week period after the lender makes the first disbursement of loan proceeds) for the payment of certain covered costs, including payroll costs (including benefits), rent and utilities, subject to certain limitations and reductions in accordance with the CARES Act and the PPP. No assurance can be given that the Company will obtain forgiveness of the PPP Note in whole or in part. As of December 31, 2020 the Company had submitted its application for forgiveness to the Small Business Administration, which is currently under review.

Other notes payable

During the year ended December 31, 2020, the Company entered into three loan agreements with two capital asset financing companies. Loan proceeds were $0.8 million, with interest rates ranging from 9.8% to 12.4%

and maturities ranging from January 2022 through September 2022.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements as of December 31, 2020.

Contractual Obligations

The Company has certain contractual obligations and commercial commitments as disclosed in Item 8, Note 15, Commitments and Contingencies that do not meet the definition of long term debt obligations, capital leases, operating leases or purchase obligations. The Company has entered into Lease Agreements as described in Item 2, Properties and Item 8, Note 16, Leases. The Company has entered into Long-Term Debt as described in Item 8, Note 10, Long-Term Debt. The Company has entered into Convertible Senior Notes as described in Item 8, Note 11, Convertible Notes. The future expected payment obligations under our agreements over the next five years are (in thousands):

	Payments due by Period (in thousands)					
Contractual Obligations	**Total**	**2021**	**2022**	**2023**	**2024**	**2025**
Operating Lease Obligations	$ 4,220	$ 707	$ 863	$ 968	$ 1,055	$ 627
Long term debt	5,212	553	1,625	1,291	1,304	439
Convertible Notes	171,500	—	—	171,500		—
Total	$ 180,932	$ 1,260	$ 2,488	$ 173,759	$ 2,359	$ 1,066

Recent Accounting Pronouncements

A discussion relating to recent accounting pronouncements can be found in Item 8, Note 2, Summary of Significant Accounting Policies.

Critical Accounting Policies

We consider our accounting policies related to inventory, convertible notes, revenue and equity-based compensation to be critical accounting policies. A number of significant estimates, assumptions, and judgments are inherent in our calculations, which are based on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results could differ materially from these estimates.

Inventory

Inventory is stated at the lower of cost or net realizable value. The Company determines the cost of inventory using the first-in, first out method. The Company estimates the recoverability of inventory by reference to internal estimates of future demands and product life cycles, including expiration. The Company periodically analyzes its inventory levels to identify inventory that may expire prior to expected sale or has a cost basis in excess of its estimated realizable value and records a charge to expense for such inventory as appropriate.

Instruments Classified as Property and Equipment

Property and equipment includes Accelerate Pheno systems (also referred to as instruments) used for sales demonstrations, instruments under rental agreements and instruments used for research and development. Depreciation expense for instruments used for sales demonstrations is recorded as a component of sales, general and administrative expense. Depreciation expense for instruments placed at customer sites pursuant to reagent rental agreements is recorded as a component of cost of sales. Depreciation expense for instruments used in our laboratory and research is recorded as a component of research and development expense. The Company retains title to these instruments and depreciates them over five years. Losses from the retirement of returned instruments are included in costs and expenses.

The Company evaluates the recoverability of the carrying amount of its instruments whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable, and at least

annually. This evaluation is based on our estimate of future cash flows and the estimated fair value of such long-lived assets, and provides for impairment if such undiscounted cash flows or the estimated fair value are insufficient to recover the carrying amount of instruments.

For the years ended December 31, 2020 and 2019, the Company identified potential impairment indicators related to instruments installed at customer sites under rental agreement that have not yet generated revenue and the length of time from when these instruments are installed to when revenue is initially generated. The Company's evaluation for impairment included consideration of the cash flows of current revenue generating instruments, the length of time to recover the carrying value, the historical rate of returned instruments from customers and the Company's ability to resell or repurpose used instruments. As a result of the Company's evaluation, no impairment charges were recorded at December 31, 2020 and 2019.

See Note 7, Property and Equipment, for further information and related disclosures.

Convertible Notes

We account for convertible debt instruments that may be settled in cash or equity upon conversion by separating the liability and equity components of the instruments in a manner that reflects our nonconvertible debt borrowing rate. We determined the carrying amount of the liability component of the Notes by using estimates and assumptions that market participants would use in pricing a debt instrument. These estimates and assumptions are judgmental in nature and could have a significant impact on the determination of the debt component, and the associated non-cash interest expense.

The equity component is treated as a discount on the liability component of the Notes, which is amortized over the term of the Notes using the effective interest rate method. Debt issuance costs related to the Notes are allocated to the liability and equity components of the Notes based on their relative values. Debt issuance costs allocated to the liability component are amortized over the life of the Notes as additional non-cash interest expense. Transaction costs allocated to equity are netted with the equity component of the convertible debt instrument in stockholders' deficit.

Revenue Recognition

The Company recognizes revenue when control of the promised good or service is transferred to our customers, in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services. Sales taxes are excluded from revenues.

We determine revenue recognition through the following steps:

- Identification of the contract with a customer
- Identification of the performance obligations in the contract
- Determination of the transaction price
- Allocation of the transaction price to the performance obligations
- Recognition of revenue as we satisfy a performance obligation

Product revenue is derived from the sale or rental of our instruments and sales of related consumable products. When an instrument is sold, revenue is generally recognized upon installation of the unit consistent with contract terms, which do not include a right of return. When a consumable product is sold, revenue is generally recognized upon shipment. Invoices are generally issued when revenue is recognized. Our payment terms vary by the type and location of our customer and the products or services offered. The term between invoicing and when payment is due is not significant.

Service revenue is derived from the sale of extended service agreements which are generally non-cancellable. This revenue is recognized on a straight-line basis over the contract term beginning on the effective

date of the contract because the Company is standing ready to provide services. Invoices are generally issued annually and coincide with the beginning of individual service terms.

Our contracts with customers may include multiple performance obligations. For such arrangements, we allocate revenue to each performance obligation based on its relative standalone selling price. We generally determine relative standalone selling prices based on the price charged to customers for each individual performance obligation.

Sales commissions earned by our sales force are considered incremental and recoverable costs of obtaining a contract with a customer. The Company has determined these costs would have an amortization period of less than one year and has elected to recognize them as an expense when incurred. Contract asset opening and closing balances were immaterial for the year ended December 31, 2020.

Leases

The Company accounts for leases in accordance with ASC 842, Leases, which was adopted on January 1, 2019. We determine if an arrangement is or contains a lease and the type of lease at inception. The Company classifies leases as finance leases (lessee) or sales-type leases (lessor) when there is either a transfer of ownership of the underlying asset by the end of the lease term, the lease contains an option to purchase the asset that we are reasonably certain will be exercised, the lease term is for the major part of the remaining economic life of the asset, the present value of the lease payments and any residual value guarantee equals or substantially exceeds all the fair value of the asset, or the asset is of such a specialized nature that it will have no alternative use to the lessor at the end of the lease term. Payments contingent on future events (i.e. based on usage) are considered variable and excluded from lease payments for the purposes of classification and initial measurement. Several of our leases include options to renew or extend the term upon mutual agreement of the parties and others include one-year extensions exercisable by the lessee. None of our leases contain residual value guarantees, restrictions, or covenants.

To determine whether a contract contains a lease, the Company uses its judgment in assessing whether the lessor retains a material amount of economic benefit from an underlying asset, whether explicitly or implicitly identified, which party holds control over the direction and use of the asset, and whether any substantive substitution rights over the asset exist.

Lessee

Operating leases are included in right-of-use (“ROU”) assets and operating lease liabilities within our consolidated balance sheets. These assets represent our right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. ROU assets and their related liabilities are recognized at commencement date based on the present value of lease payments over the lease term. Typically, we use our incremental borrowing rate based on the information available at commencement in determining the present value of lease payments. We use the implicit rate when readily determinable. ROU assets are net of lease payments made and exclude lease incentives. Lease expense for lease payments is recognized on a straight-line basis over the lease term, which may include options to extend or terminate the lease when it is reasonably certain that we will exercise the option. As of December 31, 2020 and 2019 the Company was not party to finance lease arrangements.

Our operating leases consist primarily of leased office, factory, and laboratory space in the U.S. and office space in Europe, have between two and six-year terms, and typically contain penalizing, early-termination provisions.

Lessor

The Company leases instruments to customers under “reagent rental” agreements, whereby the customer agrees to purchase consumable products over a stated term, typically five years or less, for a volume-based price that includes an embedded rental for the instruments. When collectibility is probable, the amount is recognized as income at lease commencement for sales-type leases and as product is shipped, typically in a straight–line pattern, over the term for operating leases, which typically include a termination without cause or penalty provision given a short notice period.

Consideration is allocated between lease and non-lease components based on stand-alone selling price in accordance with ASC 606, Revenue from Contracts with Customers and ASC 842, Leases.

Net investment in sales-type leases are included within our consolidated balance sheets as a component of other current assets and other non-current assets, which include the present value of lease payments not yet received and the present value of the residual asset, which are determined using the information available at commencement, including the lease term, estimated useful life, rate implicit in the lease, and expected fair value of the instrument.

See Note 16, Leases for further information.

Equity-Based Compensation

The Company may award stock options, restricted stock units (“RSUs”), performance-based awards and other equity-based instruments to its employees, directors and consultants. Compensation cost related to equity-based instruments is based on the fair value of the instrument on the grant date, and is recognized over the requisite service period on a straight-line basis over the vesting period for each tranche (an accelerated attribution method) except for performance-based awards. Performance-based stock awards vest based on the achievement of performance targets. Compensation costs associated with performance-based awards are recognized over the requisite service period based on probability of achievement. Performance-based stock awards require management to make assumptions regarding the likelihood of achieving performance targets.

The Company estimates the fair value of service based and performance based stock option awards, including modifications of stock option awards, using the Black-Scholes option pricing model. This model derives the fair value of stock options based on certain assumptions related to expected stock price volatility, expected option life, risk-free interest rate and dividend yield.

- Volatility: The expected volatility is based on the historical volatility of the Company's stock price over the most recent period commensurate with the expected term of the stock option award.

- Expected term: The estimated expected term for employee awards is based on the calculation published by the SEC in SAB110 for use when there is not a sufficient history of employee exercise patterns. For consultant awards, the estimated expected term is the same as the life of the award.

- Risk-free interest rate: The risk-free interest rate is based on published U.S. Treasury rates for a term commensurate with the expected term.

- Dividend yield: The dividend yield is estimated as zero as the Company has not paid dividends in the past and does not have any plans to pay any dividends in the foreseeable future.

The Company records the fair value of RSUs or stock grants based on published closing market price on the day before the grant date.

The Company accounts for forfeitures as they occur rather than on an estimated basis.

The Company also has an employee stock purchase program whereby eligible employees can elect payroll deductions that are subsequently used to purchase common stock at a discounted price. There is no compensation recorded for this program as (i) the purchase discount does not exceed the issuance costs that would have been incurred to raise a significant amount of capital by a public offering, (ii) substantially all employees that meet limited employment qualifications may participate on an equitable basis, and (iii) the plan doesn't incorporate option features that would require compensation to be recorded.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

Our investment portfolio is exposed to market risk from changes in interest rates. The fair value of fixed rate securities may be adversely impacted by fluctuations in interest rates while income earned on floating rate

securities may decline as a result of decreases in interest rates. We have historically maintained a relatively short average maturity for our investment portfolio, and we believe a hypothetical 100 basis point adverse move in interest rates along the entire interest rate yield curve would change the fair value of our interest sensitive financial instruments by $0.3 million for the year ended December 31, 2019. For the year ended December 31, 2020 this hypothetical move was insignificant.

Although the Notes are based on a fixed rate, changes in interest rates could impact the fair value of the Notes. As of December 31, 2020, the fair value of the Notes was $98.7 million.

Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We attempt to ensure the safety and preservation of our invested principal funds by limiting default risk, market risk and reinvestment risk. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash and investments. We also seek to maximize income from our investments without assuming significant risk. To achieve our goals, we maintain a portfolio of cash equivalents and investments in a variety of securities that management believes to be of high credit quality. Further information regarding our investments is included in Item 8, Note 5, Investments.

Foreign Currency Risk

We operate primarily in the United States and a majority of our cost, expense and capital purchasing activities were transacted in United States dollars. As a corporation with international and domestic operations, we are exposed to changes in foreign exchange rates. Our international revenue is predominantly in Europe and the Middle East and is denominated in Euros and United States dollars. In our international operations, we pay payroll and other expenses in local currencies. Our exposures to foreign currency risks may change over time and could have a material adverse impact on our financial results.

Item 8. Financial Statements and Supplementary Data

Financial Statements of Accelerate Diagnostics, Inc.

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets as of December 31, 2020 and 2019

Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2020, 2019 and 2018

Consolidated Statements of Stockholders' Deficit for the years ended December 31, 2020, 2019 and 2018

Consolidated Statements of Cash Flow for the years ended December 31, 2020, 2019 and 2018

Notes to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Accelerate Diagnostics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Accelerate Diagnostics, Inc. (the Company) as of December 31, 2020 and 2019, the related consolidated statements of operations and comprehensive loss, stockholders' deficit and cash flows for each of the three years in the period ended December 31, 2020, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Instruments in Inventory and Property and Equipment Valuation

Description of the Matter

Instruments that are or will be available for customer use are included in work in process and finished goods inventory which totaled $4.3 million as of December 31, 2020. Instruments installed at customer sites under operating leases are classified as property and equipment and totaled $2.6 million as of December 31, 2020. As explained in Note 2 to the consolidated financial statements, the Company evaluates the net realizable value of instruments in inventory and the recoverability of the carrying amount of instruments classified as property and equipment.

Auditing management's estimate of the net realizable value of instruments in work in process and finished goods inventory and the recoverability of the carrying value of instruments installed at customer sites under operating leases classified as property and equipment by reference to the Company's forecasted ability to use such instruments to generate future revenues involved subjective auditor judgment. This is due to the increase in instruments which are not yet generating revenue during the year ended December 31, 2020 and the variability in length of time from placement of an instrument at a customer site to when the instrument either begins to generate revenue or is returned to the Company.

How We Addressed the Matter in Our Audit

Our substantive audit procedures included, among others, evaluating the significant assumptions used in management's recoverability analysis, in addition to assessing the completeness and accuracy of the underlying data used. We compared the carrying value of instruments included in work in process and finished goods inventory and instruments installed at customer sites under operating leases to management's recoverability analysis and tested key assumptions including the Company's rate of returned instruments and forecasted ability to generate revenue from these instruments. Our procedures over these assumptions included comparing the rate of returned instruments assumption to historical return rates, testing the accuracy of historical return rates, testing the accuracy of instruments currently under contract to be installed at customer sites in the future, assessing the reasonableness of forecasted demand and performing a sensitivity analysis to evaluate the impact of changes in these significant assumptions to the valuation of these instruments.

[Ernst & Young LLP signature or /s/ Ernst & Young LLP]

We have served as the Company's auditor since 2013.
Phoenix, Arizona
March 1, 2021

ACCELERATE DIAGNOSTICS, INC.
CONSOLIDATED
BALANCE SHEETS
(in thousands, except share data)

	December 31,	
	2020	**2019**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 35,781	$ 61,014
Investments	32,488	47,437
Trade accounts receivable	1,550	3,222
Inventory	9,216	8,059
Prepaid expenses	1,172	955
Other current assets	1,780	1,165
Total current assets	81,987	121,852
Property and equipment, net	6,135	7,905
Right of use assets	3,183	3,917
Other non-current assets	2,120	750
Total assets	$ 93,425	$ 134,424
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 1,290	$ 2,351
Accrued liabilities	2,991	3,828
Accrued interest	1,262	1,262
Deferred revenue	376	271
Current portion of long-term debt	553	—
Current operating lease liability	497	450
Total current liabilities	6,969	8,162
Non-current operating lease liability	3,063	3,579
Other non-current liabilities	335	19
Long-term debt	4,659	—
Convertible notes	141,211	130,043
Total liabilities	156,237	141,803
Commitments and contingencies		
Stockholders' deficit:		
Preferred shares, $0.001 par value;		
5,000,000 preferred shares authorized and none outstanding as of December 31, 2020 and 2019	—	—
Common stock, $0.001 par value;		
85,000,000 common shares authorized with 57,607,939 shares issued and outstanding on December 31, 2020 and 85,000,000 common shares authorized with 54,708,792 shares issued and outstanding on December 31, 2019	58	55
Contributed capital	475,072	452,344
Treasury stock	(45,067)	(45,067)
Accumulated deficit	(492,966)	(414,653)
Accumulated other comprehensive loss	91	(58)
Total stockholders' deficit	(62,812)	(7,379)
Total liabilities and stockholders' deficit	$ 93,425	$ 134,424

See accompanying notes to consolidated financial statements.

ACCELERATE DIAGNOSTICS, INC.
CONSOLIDATED
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except per share data)

	Years Ended December 31,		
	2020	**2019**	**2018**
Net sales	$ 11,165	$ 9,297	$ 5,670
Cost of sales	6,706	4,897	3,187
Gross profit	4,459	4,400	2,483
Costs and expenses:			
Research and development	21,255	25,345	27,638
Sales, general and administrative	46,904	51,886	55,214
Total costs and expenses	68,159	77,231	82,852
Loss from operations	(63,700)	(72,831)	(80,369)
Other income (expense):			
Interest expense	(15,550)	(14,256)	(10,113)
Foreign currency exchange gain (loss)	252	(124)	(450)
Interest and dividend income	855	2,809	2,845
Other expense, net	(60)	(14)	(28)
Total other expense, net	(14,503)	(11,585)	(7,746)
Net loss before income taxes	(78,203)	(84,416)	(88,115)
(Provision) benefit for income taxes	(5)	111	(211)
Net loss	$ (78,208)	$ (84,305)	$ (88,326)
Basic and diluted net loss per share	$ (1.40)	$ (1.55)	$ (1.62)
Weighted average shares outstanding	56,010	54,506	54,494
Other comprehensive loss:			
Net loss	$ (78,208)	$ (84,305)	$ (88,326)
Net unrealized (loss) gain on investments	(2)	193	23
Foreign currency translation adjustment	151	(102)	(172)
Comprehensive loss	$ (78,059)	$ (84,214)	$ (88,475)

See accompanying notes to consolidated financial statements.

ACCELERATE DIAGNOSTICS, INC.
CONSOLIDATED
STATEMENTS OF STOCKHOLDERS' DEFICIT
(in thousands)

	Shares	Common Stock Amount	Contributed Capital	Accumulated Deficit	Treasury stock	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity (Deficit)
Balances, January 1, 2018	55,674	$ 56	$ 360,620	$ (241,972)	$ —	$ —	$ 118,704
Net loss	—	—	—	(88,326)	—	—	(88,326)
Exercise of options and restricted stock awards issued	382	—	3,749	—	—	—	3,749
Issuance of common stock under employee purchase plan	35	—	583	—	—	—	583
Unrealized gain on investments	—	—	—	—	—	23	23
Foreign currency translation adjustment	—	—	—	—	—	(172)	(172)
Repurchase of common stock under Prepaid Forward contract	(1,859)	(2)	—	—	(45,067)	—	(45,069)
Issuance of convertible note	—	—	53,283	—	—	—	53,283
Cumulative impact of accounting change	—	—	—	(50)	—	—	(50)
Equity-based compensation	—	—	14,650	—	—	—	14,650
Balances, December 31, 2018	54,232	54	432,885	(330,348)	(45,067)	(149)	57,375
Net loss	—	—	—	(84,305)	—	—	(84,305)
Issuance of common stock	56	—	1,000	—	—	—	1,000
Exercise of options and restricted stock awards issued	396	1	5,364	—	—	—	5,365
Issuance of common stock under employee purchase plan	25	—	458	—	—	—	458
Unrealized gain on investments	—	—	—	—	—	193	193
Foreign currency translation adjustment	—	—	—	—	—	(102)	(102)
Equity-based compensation	—	—	12,637	—	—	—	12,637
Balances, December 31, 2019	54,709	55	452,344	(414,653)	(45,067)	(58)	(7,379)
Net loss	—	—	—	(78,208)	—	—	(78,208)
Exercise of options and restricted stock awards issued	2,858	3	6,059	—	—	—	6,062
Issuance of common stock under employee purchase plan	41	—	359	—	—	—	359
Unrealized loss on investments	—	—	—	—	—	(2)	(2)
Foreign currency translation adjustment	—	—	—	—	—	151	151
Cumulative impact of accounting change	—	—	—	(105)	—	—	(105)
Equity-based compensation	—	—	16,310	—	—	—	16,310
Balances, December 31, 2020	$ 57,608	$ 58	$ 475,072	$ (492,966)	$ (45,067)	$ 91	$ (62,812)

See accompanying notes to consolidated financial statements.

ACCELERATE DIAGNOSTICS, INC.
CONSOLIDATED
STATEMENT OF CASH FLOWS
(in thousands)

	Years Ended December 31,		
	2020	**2019**	**2018**
Cash flows from operating activities:			
Net loss	$ (78,208)	$ (84,305)	$ (88,326)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	2,997	2,602	2,561
Amortization of investment discount	99	(427)	(621)
Equity-based compensation expense	16,464	12,618	14,422
Amortization of debt discount and issuance costs	11,168	9,969	6,849
Realized loss on available-for-sale securities	3	—	—
Loss on disposal of property and equipment	785	837	678
(Increase) decrease in assets:			
Contributions to deferred compensation plan	(357)	—	—
Accounts receivable	1,592	(1,362)	86
Inventory	(1,356)	(3,655)	(4,223)
Prepaid expense and other assets	(2,087)	(752)	(250)
Increase (decrease) in liabilities:			
Accounts payable	(1,006)	988	(748)
Accrued liabilities	(909)	(1,327)	1,426
Accrued interest	—	—	1,262
Deferred revenue and income	105	54	(904)
Deferred compensation	316	(34)	32
Net cash used in operating activities	(50,394)	(64,794)	(67,756)
Cash flows from investing activities:			
Purchases of equipment	(1,362)	(330)	(998)
Purchase of marketable securities	(46,933)	(50,226)	(120,556)
Proceeds from sales of marketable securities	—	14,500	3,000
Maturities of marketable securities	61,901	88,867	98,416
Net cash provided by (used in) investing activities	13,606	52,811	(20,138)
Cash flows from financing activities:			
Proceeds from issuance of common stock	359	1,458	583
Proceeds from exercise of options and warrants	6,062	5,365	3,749
Proceeds from issuance of convertible note	—	—	171,500
Proceeds from debt	5,578	—	—
Payment of debt	(366)	—	—
Prepayment of forward stock repurchase transaction	—	—	(45,069)
Payment of debt issuance costs	—	—	(4,992)
Net cash provided by financing activities	11,633	6,823	125,771
Effect of exchange rate on cash	(78)	(86)	(130)
(Decrease) increase in cash and cash equivalents	(25,233)	(5,246)	37,747
Cash and cash equivalents, beginning of period	61,014	66,260	28,513
Cash and cash equivalents, end of period	$ 35,781	$ 61,014	$ 66,260

See accompanying notes to consolidated financial statements.

ACCELERATE DIAGNOSTICS, INC.
CONSOLIDATED
STATEMENT OF CASH FLOWS (CONTINUED)
(in thousands)

	Years Ended December 31,		
	2020	**2019**	**2018**
Non-cash investing activities:			
Net transfer of instruments from inventory to property and equipment	$ 1,525	$ 3,361	$ 4,767
Supplemental cash flow information:			
Interest paid	$ 4,288	$ 4,288	$ 2,001
Income taxes paid, net of refunds	$ 43	$ 41	$ 651

See accompanying notes to consolidated financial statements.

ACCELERATE DIAGNOSTICS, INC.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1. ORGANIZATION AND NATURE OF BUSINESS; BASIS OF PRESENTATION; PRINCIPLES OF CONSOLIDATION

Accelerate Diagnostics, Inc. ("we" or "us" or "our" or "Accelerate" or "the Company") is an *in vitro* diagnostics company dedicated to providing solutions that improve patient outcomes and lower healthcare costs through the rapid diagnosis of serious infections.

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles, ("U.S. GAAP"), and applicable rules and regulations of the United States Securities and Exchange Commission ("SEC"), regarding annual financial reporting.

All amounts are rounded to the nearest thousand dollars unless otherwise indicated.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries after elimination of intercompany transactions and balances.

Reclassification

Certain prior year amounts have been reclassified for consistency with the current year presentation and had no effect on our net income, stockholders' deficit or cash flows.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

The preparation of the Company's consolidated financial statements requires the Company to make estimates and assumptions that affect the reported amounts of assets and liabilities and the related disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. The more significant areas requiring the use of management estimates and assumptions relate to accounts receivable, inventory, property and equipment, accrued liabilities, warranty liabilities, tax valuation accounts, equity–based compensation, revenue and leases. Actual results could differ materially from those estimates.

Estimated Fair Value of Financial Instruments

The Company follows ASC 820*,* Fair Value Measurement*,* which has defined fair value and requires the Company to establish a framework for measuring fair value and disclose fair value measurements. The framework requires the valuation of assets and liabilities subject to fair value measurements using a three tiered approach and fair value measurement be classified and disclosed in one of the following three categories:

- Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

- Level 2: Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs that are observable, either directly or indirectly, for substantially the full term of the asset or liability;

- Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e. supported by little or no market activity).

The carrying amounts of financial instruments such as cash and cash equivalents, trade accounts receivable, prepaid expenses, other current assets, accounts payable, accrued liabilities, and other current liabilities approximate the related fair values due to the short-term maturities of these instruments.

See Note 4, Fair Value of Financial Instruments, for further information and related disclosures regarding the Company's fair value measurements.

The estimated fair value of the Company's convertible notes represents a Level 2 measurement. See Note 11, Convertible Notes for further detail on the Company's convertible notes.

The estimated fair value of the Company's long-term debt represents a Level 3 measurement. The promissory notes issued under the Paycheck Protection Program ("PPP") and other long-term debt is privately held with no public market. The carrying amount of the long-term debt approximates fair value. See Note 10, Long-Term Debt for further detail on the Company's long-term debt.

Cash and Cash Equivalents

All highly liquid investments with an original maturity of three months or less at time of purchase are considered to be cash equivalents. Cash and cash equivalents include overnight repurchase agreement accounts and other investments. As part of our cash management process, excess operating cash is invested in overnight repurchase agreements with our bank. Repurchase agreements and other investments classified as cash and cash equivalents are not deposits and are not insured by the U.S. Government, the FDIC or any other government agency and involve investment risk including possible loss of principal. We believe however, that the market risk arising from holding these financial instruments is minimal.

Investments

The Company invests in various debt and equity securities which are primarily held in the custody of major financial institutions. Debt securities consist of certificates of deposit, U.S. government and agency securities, commercial paper, and corporate notes and bonds. Equity securities consist of mutual funds. The Company records these investments in the consolidated balance sheet at fair value. Unrealized gains or losses for debt securities available-for-sale and are included in accumulated other comprehensive income (loss), a component of stockholders' deficit. Unrealized gains or losses for equity securities are included in other income (expense), net, a component of statements of operations and comprehensive loss. The Company considers all debt securities available-for-sale, including those with maturity dates beyond 12 months, as available to support current operational liquidity needs. The Company classifies its investments as current based on the nature of the investments and their availability for use in current operations.

We perform an assessment to determine whether there have been any events or economic circumstances to indicate that a debt security available-for-sale in an unrealized loss position has suffered impairment as a result of credit loss or other factors. A debt security is considered impaired if its fair value is less than its amortized cost basis at the reporting date.

If we intend to sell the debt security or if it is more-likely-than-not that we will be required to sell the debt security before the recovery of its amortized cost basis, the impairment is recognized and the unrealized loss is recorded as a direct write-down of the security's amortized cost basis with an offsetting entry to earnings. If we do not intend to sell the debt security or believe we will not be required to sell the debt security before the recovery of its amortized cost basis, the impairment is assessed to determine if a credit loss component exists. We use a discounted cash flow method to determine the credit loss component. In the event a credit loss exists, an allowance for credit losses is recorded in earnings for the credit loss component of the impairment while the remaining portion of the impairment attributable to factors other than credit loss is recognized, net of tax, in accumulated other comprehensive income (loss). The amount of impairment recognized due to credit factors is limited to the excess of the amortized cost basis over the fair value of the security.

Inventory

Inventory is stated at the lower of cost or net realizable value. The Company determines the cost of inventory using the first-in, first out method. The Company estimates the recoverability of inventory by reference to internal estimates of future demands and product life cycles, including expiration. The Company periodically

analyzes its inventory levels to identify inventory that may expire prior to expected sale or has a cost basis in excess of its estimated realizable value and records a charge to expense for such inventory as appropriate.

Accounts Receivable

Accounts receivable consist of amounts due to the Company for sales to customers and are based on what we expect to collect in exchange for goods and services. Receivables are considered past due based on the contractual payment terms and are written off if reasonable collection efforts prove unsuccessful.

We maintain an allowance for credit losses for expected uncollectible accounts receivable, which is recorded as an offset to accounts receivable and changes in such are classified as general and administrative expense in the consolidated statements of operations. We assess collectibility by reviewing accounts receivable on a collective basis where similar characteristics exist and on an individual basis when we identify specific customers with known disputes or collectibility issues. In determining the amount of the allowance for credit losses, we consider historical collectibility and make judgments about the creditworthiness of customers based on credit evaluations. Our customers typically have good credit quality. We also consider customer-specific information, current market conditions and reasonable and supportable forecasts of future economic conditions to inform adjustments to historical loss data. The allowance for credit losses as of December 31, 2020 was $0.4 million.

The allowance for credit losses for the year ended December 31 is comprised of the following (in thousands):

	2020
Beginning balance	$ —
Provisions	129
Write-offs	316
Recoveries	—
	$ 445

Property and Equipment

Property and equipment are recorded at cost. Maintenance and repairs are charged to expense as incurred and expenditures for major improvements are capitalized. Gains and losses from retirement or replacement are included in costs and expenses. Depreciation of property and equipment is computed using the straight-line method over the estimated useful life of the assets, ranging from one to seven years. Leasehold improvements are depreciated over the remaining life of the lease or the life of the asset, whichever is less.

Instruments Classified as Property and Equipment

Property and equipment includes Accelerate Pheno systems (also referred to as instruments) used for sales demonstrations, instruments under rental agreements and instruments used for research and development. Depreciation expense for instruments used for sales demonstrations is recorded as a component of sales, general and administrative expense. Depreciation expense for instruments placed at customer sites pursuant to reagent rental agreements is recorded as a component of cost of sales. Depreciation expense for instruments used in our laboratory and research is recorded as a component of research and development expense. The Company retains title to these instruments and depreciates them over five years. Losses from the retirement of returned instruments are included in costs and expenses.

The Company evaluates the recoverability of the carrying amount of its instruments whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable, and at least annually. This evaluation is based on our estimate of future cash flows and the estimated fair value of such long-lived assets, and provides for impairment if such undiscounted cash flows or the estimated fair value are insufficient to recover the carrying amount of instruments.

For the years ended December 31, 2020 and 2019, the Company identified potential impairment indicators related to instruments installed at customer sites under rental agreement that have not yet generated revenue and

the length of time from when these instruments are installed to when revenue is initially generated. The Company's evaluation for impairment included consideration of the cash flows of current revenue generating instruments, the length of time to recover the carrying value, the historical rate of returned instruments from customers and the Company's ability to resell or repurpose used instruments. As a result of the Company's evaluation, no impairment charges were recorded at December 31, 2020 and 2019.

See Note 7, Property and Equipment, for further information and related disclosures.

Long-lived Assets

Long-lived assets and certain identifiable intangibles to be held and used by the Company are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The Company continuously evaluates the recoverability of its long-lived assets based on estimated future cash flows from and the estimated fair value of such long-lived assets, and provides for impairment if such undiscounted cash flows or the estimated fair value are insufficient to recover the carrying amount of the long-lived asset.

Warranty Reserve

Instruments are typically sold with a one year limited warranty, while kits and accessories are typically sold with a sixty days limited warranty. Accordingly, a provision for the estimated cost of the limited warranty repair is recorded at the time revenue is recognized. Our estimated warranty provision is based on our estimate of future repair events and the related estimated cost of repairs. The Company periodically assesses the adequacy of the warranty reserve and adjusts the amount as necessary. The cost incurred for these provisions is included in cost of sales on the consolidated statements of operations and comprehensive loss.

Product warranty reserve activity for the years ended December 31 is as follows (in thousands):

	2020	2019	2018
Beginning balance	$ 403	$ 215	$ 192
Provisions	13	411	420
Warranty cost incurred	(184)	(223)	(397)
	$ 232	$ 403	$ 215

Paycheck Protection Program ("PPP") Loan

The PPP was established by the CARES Act, through a significant expansion of the Small Business Administration ("SBA") 7(a) loan program. On April 14, 2020, the Company entered into a promissory note (the "PPP Note") evidencing an unsecured loan in the amount of $4.8 million.

The Company elected to account for the PPP Note in accordance with ASC 470, Debt, with interest accrued in accordance with the interest method under ASC 835-30, Imputation of Interest. The Company recognized the entire PPP Note amount as a liability on the consolidated balance sheet, with interest accrued and expensed over the term of the loan. The Company did not impute additional interest at a market rate because transactions where interest rates are prescribed by governmental agencies are excluded from the scope of ASC 835-30.

The PPP Note will remain a liability until either of the following criteria are met:

- the Company has been legally released from being the primary obligor under the liability (i.e. the PPP Note is forgiven); or
- the Company pays the lender and is relieved of its obligation for the liability.

See Note 10, Long-Term Debt for further detail regarding the PPP Note.

Convertible Notes

We account for convertible debt instruments that may be settled in cash or equity upon conversion by separating the liability and equity components of the instruments in a manner that reflects our nonconvertible debt borrowing rate. We determined the carrying amount of the liability component of the Notes by using estimates and assumptions that market participants would use in pricing a debt instrument. These estimates and assumptions are judgmental in nature and could have a significant impact on the determination of the debt component, and the associated non-cash interest expense.

The equity component is treated as a discount on the liability component of the Notes, which is amortized over the term of the Notes using the effective interest rate method. Debt issuance costs related to the Notes are allocated to the liability and equity components of the Notes based on their relative values. Debt issuance costs allocated to the liability component are amortized over the life of the Notes as additional non-cash interest expense. Transaction costs allocated to equity are netted with the equity component of the convertible debt instrument in stockholders' deficit.

Revenue Recognition

The Company recognizes revenue when control of the promised good or service is transferred to our customers, in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services. Sales taxes are excluded from revenues.

We determine revenue recognition through the following steps:

- Identification of the contract with a customer
- Identification of the performance obligations in the contract
- Determination of the transaction price
- Allocation of the transaction price to the performance obligations
- Recognition of revenue as we satisfy a performance obligation

Product revenue is derived from the sale or rental of our instruments and sales of related consumable products. When an instrument is sold, revenue is generally recognized upon installation of the unit consistent with contract terms, which do not include a right of return. When a consumable product is sold, revenue is generally recognized upon shipment. Invoices are generally issued when revenue is recognized. Our payment terms vary by the type and location of our customer and the products or services offered. The term between invoicing and when payment is due is not significant.

Service revenue is derived from the sale of extended service agreements which are generally non-cancellable. This revenue is recognized on a straight-line basis over the contract term beginning on the effective date of the contract because the Company is standing ready to provide services. Invoices are generally issued annually and coincide with the beginning of individual service terms.

Our contracts with customers may include multiple performance obligations. For such arrangements, we allocate revenue to each performance obligation based on its relative standalone selling price. We generally determine relative standalone selling prices based on the price charged to customers for each individual performance obligation.

Sales commissions earned by our sales force are considered incremental and recoverable costs of obtaining a contract with a customer. The Company has determined these costs would have an amortization period of less than one year and has elected to recognize them as an expense when incurred. Contract asset opening and closing balances were immaterial for the year ended December 31, 2020.

Cost of Sales

Cost of sales includes cost of materials, direct labor, equity-based compensation, facility and other manufacturing overhead costs for consumable tests and instruments sold to customers. Cost of sales for instruments also includes depreciation on revenue generating instruments that have been placed with our customers under a reagent rental agreement. Cost of sales includes repair and maintenance cost for instruments covered by a service agreement or instruments covered by a reagent rental agreement. Cost of sales also includes warranty related costs.

Shipping and Handling

Shipping and handling costs billed to customers are included as a component of revenue. The corresponding expense incurred with third party carriers is included as a component of sales, general and administrative costs on the consolidated statements of operations and comprehensive loss.

Restructure Activity

During the year ended December 31, 2020, following the completion of a strategic review of the Company's Europe, Middle East and Africa (“EMEA”) business, the Company's board of directors approved a plan to reduce its workforce, focus the geographies it plans to operate in, and terminate agreements with some distributors in geographies it plans on exiting (collectively, the “EMEA Restructuring Plan”). As of December 31, 2020, the Company substantially completed the workforce reduction portion of the EMEA Restructuring Plan. Restructuring charges are primarily comprised of employee severance and other post-employment benefits. The Company evaluates the nature of these costs to determine if they relate to on-going benefit arrangements which are accounted for under ASC 712, Compensation - Nonretirement Postemployment Benefits, or one-time benefit arrangements which are accounted for under ASC 420, Exit or Disposal Cost Obligations. The Company incurred expense of $0.4 million in connection with the EMEA Restructuring Plan which was primarily a component of ASC 712. These expenses were recorded as a component of sales, general and administrative costs costs on the consolidated statements of operations and comprehensive loss. No material restructuring liabilities were outstanding as of December 31, 2020.

Leases

The Company accounts for leases in accordance with ASC 842, Leases, which was adopted on January 1, 2019. We determine if an arrangement is or contains a lease and the type of lease at inception. The Company classifies leases as finance leases (lessee) or sales-type leases (lessor) when there is either a transfer of ownership of the underlying asset by the end of the lease term, the lease contains an option to purchase the asset that we are reasonably certain will be exercised, the lease term is for the major part of the remaining economic life of the asset, the present value of the lease payments and any residual value guarantee equals or substantially exceeds all the fair value of the asset, or the asset is of such a specialized nature that it will have no alternative use to the lessor at the end of the lease term. Payments contingent on future events (i.e. based on usage) are considered variable and excluded from lease payments for the purposes of classification and initial measurement. Several of our leases include options to renew or extend the term upon mutual agreement of the parties and others include one-year extensions exercisable by the lessee. None of our leases contain residual value guarantees, restrictions, or covenants.

To determine whether a contract contains a lease, the Company uses its judgment in assessing whether the lessor retains a material amount of economic benefit from an underlying asset, whether explicitly or implicitly identified, which party holds control over the direction and use of the asset, and whether any substantive substitution rights over the asset exist.

Lessee

Operating leases are included in right-of-use (“ROU”) assets and operating lease liabilities within our consolidated balance sheets. These assets represent our right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. ROU assets and their related liabilities are recognized at commencement date based on the present value of lease payments over the lease term. Typically, we use our incremental borrowing rate based on the information available at commencement in determining the present value of lease payments. We use the implicit rate when readily determinable. ROU

assets are net of lease payments made and exclude lease incentives. We elect not to separate the lease components from the non-lease components for all classes of underlying assets. Lease expense for lease payments is recognized on a straight-line basis over the lease term, which may include options to extend or terminate the lease when it is reasonably certain that we will exercise the option. As of December 31, 2020 and 2019 the Company was not party to finance lease arrangements.

Our operating leases consist primarily of leased office, factory, and laboratory space in the U.S. and office space in Europe, have between two and six-year terms, and typically contain penalizing, early-termination provisions.

Lessor

The Company leases instruments to customers under “reagent rental” agreements, whereby the customer agrees to purchase consumable products over a stated term, typically five years or less, for a volume-based price that includes an embedded rental for the instruments. When collectibility is probable, the amount is recognized as income at lease commencement for sales-type leases and as product is shipped, typically in a straight–line pattern, over the term for operating leases, which typically include a termination without cause or penalty provision given a short notice period.

Consideration is allocated between lease and non-lease components based on stand-alone selling price in accordance with ASC 606, Revenue from Contracts with Customers and ASC 842, Leases.

Net investment in sales-type leases are included within our consolidated balance sheets as a component of other current assets and other non-current assets, which include the present value of lease payments not yet received and the present value of the residual asset, which are determined using the information available at commencement, including the lease term, estimated useful life, rate implicit in the lease, and expected fair value of the instrument.

See Note 16, Leases for further information.

Nonqualified Cash Deferral Plan

The Company's Cash Deferral Plan (the “Deferral Plan”), provides certain key employees, with an opportunity to defer the receipt of such participant's base salary. The Deferral Plan is intended to be a nonqualified deferred compensation plan that complies with the provisions of Section 409A of the Internal Revenue Code. All of the investments held in the Deferral Plan are equity securities consisting of mutual funds and recorded at fair value with changes in the investments' fair value recognized as earnings in the period they occur. The corresponding liability for the Deferral Plan is included in other non-current liabilities in the consolidated balance sheet.

Equity-Based Compensation

The Company may award stock options, restricted stock units (“RSUs”), performance-based awards and other equity-based instruments to its employees, directors and consultants. Compensation cost related to equity-based instruments is based on the fair value of the instrument on the grant date, and is recognized over the requisite service period on a straight-line basis over the vesting period for each tranche (an accelerated attribution method) except for performance-based awards. Performance-based stock awards vest based on the achievement of performance targets. Compensation costs associated with performance-based awards are recognized over the requisite service period based on probability of achievement. Performance-based stock awards require management to make assumptions regarding the likelihood of achieving performance targets.

The Company estimates the fair value of service based and performance based stock option awards, including modifications of stock option awards, using the Black-Scholes option pricing model. This model derives the fair value of stock options based on certain assumptions related to expected stock price volatility, expected option life, risk-free interest rate and dividend yield.

- Volatility: The expected volatility is based on the historical volatility of the Company's stock price over the most recent period commensurate with the expected term of the stock option award.

- Expected term: The estimated expected term for employee awards is based on the calculation

published by the SEC in SAB110 for use when there is not a sufficient history of employee exercise patterns. For consultant awards, the estimated expected term is the same as the life of the award.

- Risk-free interest rate: The risk-free interest rate is based on published U.S. Treasury rates for a term commensurate with the expected term.

- Dividend yield: The dividend yield is estimated as zero as the Company has not paid dividends in the past and does not have any plans to pay any dividends in the foreseeable future.

The Company records the fair value of RSUs or stock grants based on published closing market price on the day before the grant date.

The Company accounts for forfeitures as they occur rather than on an estimated basis.

The Company also has an employee stock purchase program whereby eligible employees can elect payroll deductions that are subsequently used to purchase common stock at a discounted price. There is no compensation recorded for this program as (i) the purchase discount does not exceed the issuance costs that would have been incurred to raise a significant amount of capital by a public offering, (ii) substantially all employees that meet limited employment qualifications may participate on an equitable basis, and (iii) the plan doesn't incorporate option features that would require compensation to be recorded.

See Note 13, Employee Equity-Based Compensation for further information.

Deferred Tax Assets

Deferred tax assets and liabilities are recorded for the estimated future tax effects of temporary differences between the tax basis of assets and liabilities and amounts reported in the accompanying balance sheets. The change in deferred tax assets and liabilities for the period represents the deferred tax provision or benefit for the period. Effects of changes in enacted tax laws in deferred tax assets and liabilities are reflected as an adjustment to the tax provision or benefit in the period of enactment.

The Company follows the provisions of ASC 740, Income Taxes, to account for any uncertainty in income taxes with respect to the accounting for all tax positions taken (or expected to be taken) on any income tax return. This guidance applies to all open tax periods in all tax jurisdictions in which the Company is required to file an income tax return. Under U.S. GAAP, in order to recognize an uncertain tax benefit the taxpayer must be more likely than not certain of sustaining the position, and the measurement of the benefit is calculated as the largest amount that is more likely than not to be realized upon resolution of the position. Interest and penalties, if any, would be recorded within tax expense.

Foreign Currency Translation and Foreign Currency Transactions

Adjustments resulting from translating foreign functional currency financial statements into U.S. Dollars are included in the foreign currency translation adjustment, a component of accumulated other comprehensive loss in the consolidated statements of stockholders' deficit.

The Company has assets and liabilities, including receivables and payables, which are denominated in currencies other than their functional currency. These balance sheet items are subject to re-measurement, the impact of which is recorded in foreign currency exchange gain and loss, within the consolidated statement of operations and comprehensive loss.

Loss Per Share

Basic loss per share includes no dilution and is computed by dividing loss available to common stockholders by the weighted average number of common shares outstanding for the period. Potentially dilutive common shares consist of shares issuable from stock options and unvested RSUs. Potentially dilutive common shares would also include common shares that would have been outstanding if notes convertible at the balance sheet date were converted. Diluted earnings are not presented when the effect of adding such additional common shares is antidilutive.

See Note 12, Loss Per Share, for further information.

Comprehensive Loss

In addition to net loss, comprehensive loss includes all changes in equity during a period, except those resulting from investments by and distributions to owners. The Company holds debt securities as available-for-sale and records the change in fair market value as a component of comprehensive loss. The Company also has adjustments resulting from translating foreign functional currency financial statements into U.S. Dollars which is included as a component of comprehensive loss.

Recent Accounting Pronouncements

Standards that were recently adopted

In August 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2018-13, Fair Value Measurement (Topic 820); Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement. ASU 2018-13 modifies, among other things, the disclosures required for Level 3 fair value measurements, including the range and weighted average of significant unobservable inputs. The guidance removes, among other things, the disclosure requirement to disclose transfers between Levels 1 and 2. Level 3 fair value measurement disclosures should be applied prospectively while all other amendments should be applied retrospectively. The Company adopted ASU 2018-13 on January 1, 2020, which had no impact to our consolidated financial statements as the Company did not carry Level 3 fair value items upon implementing this ASU on January 1, 2020.

In June 2016, the FASB issued ASU 2016-13, Financial Instruments-Credit Losses (Topic 326); Measurement of Credit Losses on Financial Instruments. In November 2018, ASU 2018-19 was issued which amended the standard to clarify that receivables arising from operating leases are within the scope of lease accounting standards. Further, the FASB issued ASU 2019-04, 2019-05, 2019-10, ASU 2019-11, 2020-02 and 2020-03 to provide additional guidance on the credit losses standard. ASU 2016-13 amends the guidance on measuring credit losses on financial assets (including trade accounts receivable and available for sale debt securities) held at amortized cost. Previously, an "incurred loss" methodology was used for recognizing credit losses which delays recognition until it is probable a loss has been incurred. This amendment requires assets valued at amortized cost to be presented at the net amount expected to be collected using an allowance for credit losses. Reversal of credit losses on available for sale debt securities are now recorded in current period net income. The Company adopted ASU 2016-13 on January 1, 2020. We adopted this standard using a modified-retrospective approach, and recorded a $0.1 million cumulative-effect adjustment to the opening balance of accumulated deficit in connection with the adoption. This adjustment was recorded to establish an allowance for trade account receivables and investment in leases. No cumulative-effect adjustment was recorded for unrealized losses on debt securities available-for-sale as the issuers of such securities held by us were of high credit quality. As a result, the consolidated financial statements for the current periods are presented under the new standard, while the comparative prior year period is not adjusted and continues to be reported in accordance with our historical accounting policy.

Standards not yet adopted

In August 2020, the FASB issued ASU 2020-06, Debt - Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40). ASU 2020-06 reduces the complexity associated with applying U.S. GAAP for certain financial instruments with characteristics of liabilities and equity. In addressing the complexity, this ASU amends the guidance on convertible instruments and the guidance on the derivatives scope exception for contracts in an entity's own equity. This ASU will reduce the number of accounting models for convertible debt instruments and convertible preferred stock. Limiting the accounting models results in fewer embedded conversion features being separately recognized from the host contract as compared with current U.S. GAAP standards. Convertible instruments that continue to be subject to separation models are (1) those with embedded conversion features that are not clearly and closely related to the host contract, that meet the definition of a derivative, and that do not qualify for a scope exception from derivative accounting and (2) convertible debt instruments issued with substantial premiums for which the premiums are recorded as paid-in capital. This ASU is effective for us on January 1, 2022, with early adoption permitted. We are currently assessing the impact this will have on our consolidated financial statements.

In January 2020, the FASB issued ASU 2020-01, Investments-Equity Securities (Topic 321), Investments-Equity Method and Joint Ventures (Topic 323), and Derivatives and Hedging (Topic 815), Clarifying the Interactions between Topic 321, Topic 323, and Topic 815 (a consensus of the FASB Emerging Issues Task Force). ASU 2020-01 clarifies the interaction of the accounting for equity securities under Topic 321, the accounting for the equity method investments in Topic 323 and the accounting for certain forward contracts and purchased options in Topic 815. This ASU is effective for us on January 1, 2021, with early adoption permitted. We are currently assessing the impact this will have on our consolidated financial statements, and believe it will not have a material impact on the Company's consolidated financial statements at January 1, 2021.

In December 2019, the FASB issued ASU 2019-12, Income Taxes (Topic 740); Simplifying the Accounting for Income Taxes. ASU 2019-12 reduces complexity in the accounting standard. This ASU is effective for us on January 1, 2021, with early adoption permitted. We are currently assessing the impact this will have on our consolidated financial statements, and believe it will not have a material impact on the Company's consolidated financial statements at January 1, 2021.

NOTE 3. CONCENTRATION OF CREDIT RISK

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash equivalents, short-term investments and accounts receivable, including receivables from major customers.

The Company has financial institutions for banking operations that hold 10% or more of the Company’s cash and cash equivalents. As of December 31, 2020, three of the Company's financial institutions held 53%, 16% and 14% of the Company’s cash and cash equivalents, respectively. As of December 31, 2019, two of the Company's financial institutions held 73% and 18% of the Company’s cash and cash equivalents, respectively.

The Company grants credit to domestic and international clients in various industries. Exposure to losses on accounts receivable is principally dependent on each client's financial position. The Company had one customer that accounted for 11% of the Company's net accounts receivable balance as of December 31, 2019. None of the Company's customers accounted for 10% or more of the net accounts receivable balance as of December 31, 2020.

The Company did not have any customers who represented 10% or more of the Company’s total revenue for the years ended December 31, 2020, 2019 and 2018.

NOTE 4. FAIR VALUE OF FINANCIAL INSTRUMENTS

The following tables represent the financial instruments measured at fair value on a recurring basis on the financial statements of the Company and the valuation approach applied to each class of financial instruments at December 31 (see Note 2, Summary of Significant Accounting Policies for further information):

	2020 (in thousands)			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Cash and cash equivalents:				
Money market funds	$ 19,276	$ —	$ —	$ 19,276
Commercial paper	—	885	—	885
Total cash and cash equivalents	19,276	885	—	20,161
Equity investments:				
Mutual funds	357	—	—	357
Total equity investments	357	—	—	357
Debt securities available-for-sale:				
Certificates of deposit	—	5,825	—	5,825
US Treasury securities	5,923	—	—	5,923
Commercial paper	—	10,604	—	10,604
Corporate notes and bonds	—	9,779	—	9,779
Debt securities available-for-sale	5,923	26,208	—	32,131
Total assets measured at fair value	$ 25,556	$ 27,093	$ —	$ 52,649

	2019 (in thousands)			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Cash and cash equivalents:				
Money market funds	$ 43,745	$ —	$ —	$ 43,745
Commercial paper	—	1,993	—	1,993
Corporate notes and bonds	—	1,006	—	1,006
Total cash and cash equivalents	43,745	2,999	—	46,744
Debt securities available-for-sale:				
Certificates of deposit	—	5,663	—	5,663
US Treasury securities	12,579	—	—	12,579
US Agency securities	—	3,998	—	3,998
Commercial paper	—	2,491	—	2,491
Corporate notes and bonds	—	22,706	—	22,706
Debt securities available-for-sale	12,579	34,858	—	47,437
Total assets measured at fair value	$ 56,324	$ 37,857	$ —	$ 94,181

Highly liquid investments with an original maturity of three months or less at time of purchase are included in cash and cash equivalents on the consolidated balance sheet.

Level 1 assets are priced using quoted prices in active markets for identical assets which include money market funds and U.S. Treasury securities as these specific assets are liquid.

Level 2 available-for-sale securities are priced using quoted market prices for similar instruments or nonbinding market prices that are corroborated by observable market data. The Company uses inputs such as actual trade data, benchmark yields, broker/dealer quotes, and other similar data, which are obtained from quoted market prices, independent pricing vendors, or other sources, to determine the ultimate fair value of these assets and liabilities. The Company uses such pricing data as the primary input to make its assessments and determinations as to the ultimate valuation of its investment portfolio and has not made, during the periods presented, any material adjustments to such inputs. There were no transfers between levels during the year ended December 31, 2020.

In 2018, the Company issued the Notes, for total proceeds of $171.5 million, as described in Note 11, Convertible Notes. As of December 31, 2020 and 2019, the calculated fair value of the Notes were $98.7 million and $133.8 million, respectively. The Notes are highly correlated to the Company's stock price and as a result, significant changes to the Company's stock price will have a significant impact on the calculated fair value of the Notes. The fair value of the Notes are classified as Level 2 within the fair value hierarchy.

The Company's PPP Note along with its other long-term notes, cumulatively $5.6 million, approximate their fair value. The estimated fair value of the Company's long-term debt represents a Level 3 measurement. See Note 10, Long-Term Debt for further detail on the Company's long-term debt.

For certain other financial assets and liabilities, including accounts receivable, accounts payable and other current liabilities, the carrying amounts approximate their fair value due to the relatively short maturity of these balances.

NOTE 5. INVESTMENTS

The following tables summarize the Company's debt securities classified as available-for-sale at December 31 (in thousands):

AVAILABLE-FOR-SALE INVESTMENTS
2020
(in thousands)

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Certificates of deposit	$ 5,820	$ 5	$ —	$ 5,825
US Treasury securities	5,908	15	—	5,923
Commercial paper	10,603	1	—	10,604
Corporate notes and bonds	9,779	1	(1)	9,779
Total	$ 32,110	$ 22	$ (1)	$ 32,131

AVAILABLE-FOR-SALE INVESTMENTS
2019
(in thousands)

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Certificates of deposit	$ 5,646	$ 17	$ —	$ 5,663
US Treasury securities	12,564	16	(1)	12,579
US Agency securities	4,002	—	(4)	3,998
Commercial paper	2,492	—	(1)	2,491
Corporate notes and bonds	22,711	6	(11)	22,706
Total	$ 47,415	$ 39	$ (17)	$ 47,437

The following table summarizes the maturities of the Company's debt securities classified as available-for-sale at December 31 (in thousands):

AVAILABLE-FOR-SALE INVESTMENT MATURITIES
(in thousands)

	2020		2019	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
Due in less than 1 year	$ 32,110	$ 32,131	$ 43,627	$ 43,650
Due in 1-5 years	—	—	3,788	3,787
Total	$ 32,110	$ 32,131	$ 47,415	$ 47,437

Proceeds from sales of marketable securities (including principal payments) for the years ended December 31, 2020 and 2019 were zero and $14.5 million, respectively. The Company determines gains and losses of marketable securities based on specific identification of the securities sold. There were no material realized gains or losses from sales of marketable securities for the years ended December 31, 2020, 2019 and 2018. No material balances were reclassified out of accumulated other comprehensive loss for the years ended December 31, 2020, 2019 and 2018. Unrealized losses on debt securities available-for-sale have not been recognized in income for the year ended December 31, 2020 because the issuers of such securities held by us were of high credit quality.

As of December 31, 2020, there were no holdings of debt securities available-for-sale of any one issuer, other than the U.S. government, in an amount greater than 10%. As of December 31, 2020 there were no debt securities available-for-sale in a material unrealized loss position.

As of December 31, 2020 the Company carried debt securities available-for-sale that were certificates of deposits, which were not covered by a rating agency or the credit rating was below the Company's minimum credit rating. As of December 31, 2020 all of the Company's certificate deposits were below the FDIC's insurance limit of $250,000 per depositor which mitigated the Company's investment risk. All other debt securities available-for-sale had a credit rating of A- or better as of December 31, 2020.

Equity securities are comprised of investments in mutual funds. The fair value of equity securities at December 31, 2020 was $0.4 million. There were no material unrealized gains or losses on equity securities recorded in income for the year ended December 31, 2020. These unrealized gains or losses are recorded as a component of other income (expense), net. There were no realized gains or losses from equity securities for the year December 31, 2020.

Additional information regarding the fair value of our financial instruments is included in Note 4, Fair Value of Financial Instruments.

NOTE 6. INVENTORY

Inventories consisted of the following at December 31 (in thousands):

	2020	2019
Raw materials	$ 4,891	$ 4,854
Work in process	1,942	1,561
Finished goods	2,383	1,644
Inventory	$ 9,216	$ 8,059

NOTE 7. PROPERTY AND EQUIPMENT

Property and equipment are recorded at cost and consisted of the following at December 31 (in thousands).

	2020	2019
Computer equipment	$ 3,608	$ 2,477
Technical equipment	3,789	3,681
Facilities	3,693	3,883
Instruments	5,880	7,491
Capital projects in progress	—	238
Total property and equipment	$ 16,970	$ 17,770
Accumulated depreciation	(10,835)	(9,865)
Net property and equipment	$ 6,135	$ 7,905

Depreciation expense for the years ended December 31, 2020, 2019 and 2018 was $2.4 million, $2.3 million and $2.5 million, respectively.

Instruments at cost and accumulated depreciation where the Company is the lessor under operating leases consisted of the following at December 31 (in thousands).

	2020	2019
Instruments at cost under operating leases	$ 3,750	$ 4,604
Accumulated depreciation under operating leases	(1,120)	(808)
Net property and equipment under operating leases	$ 2,630	$ 3,796

NOTE 8. LICENSE AGREEMENTS AND GRANTS

National Institute of Health Grant

In February 2015, the National Institute of Health awarded Denver Health and the Company a five-year, $5.0 million grant to develop a fast and reliable identification and categorical susceptibility test for carbapenem-resistant Enterobacteriaceae directly from whole blood. The cumulative award amount under these subawards is $1.5 million. The amounts invoiced for the years ended December 31, 2020, 2019 and 2018 was $0.1 million, $0.3 million and $0.2 million, respectively. Subsequent to the original term of the grant the National Institute of Health has provided incremental annual extensions that have allowed the Company to provide additional services.

Arizona Commerce Authority Grant

In August 2012, the Company entered into a Grant Agreement (the "Grant Agreement") with the Arizona Commerce Authority, an agency of the State of Arizona (the "Authority"), pursuant to which the Authority provided certain state and county sponsored incentives for the Company to relocate its corporate headquarters to, and expand its business within, the State of Arizona (the "Project"). Pursuant to the Grant Agreement, the Authority agreed to provide a total grant in the amount of $1.0 million (the "Grant") for the use by the Company in the advancement of the Project. The Grant is payable out of an escrow account in four installments, upon the achievement of the following milestones:

- Milestone 1 – Relocation of Company's operations and corporate headquarters to Arizona and creation of 15 Qualified Jobs (as defined below).
- Milestone 2 – Creation of 30 Qualified Jobs (including Qualified Jobs under Milestone 1).
- Milestone 3 – Creation of 40 Qualified Jobs (including Qualified Jobs under Milestones 1 and 2).
- Milestone 4 – Creation of 65 Qualified Jobs (including Qualified Jobs under Milestones 1, 2 and 3) and capital investment of at least $4.5 million.

For purposes of the Grant Agreement, a "Qualified Job" is a job that is permanent, full-time, new to Arizona, and for which the Company pays average (across all Qualified Jobs identified by the Company in its discretion) annual wages of at least $63,000 and offers health insurance benefits and pays at least 65% of the premiums associated with such benefits. The amount of each installment payment will be determined in accordance with a formula specified in the Grant Agreement. The Grant Agreement also contains other customary provisions, including representations, warranties and covenants of both parties. As of December 31, 2018, the full amount was collected and recorded in current deferred revenue and income.

In January 2018, the full amount was recognized due to the economic development provisions of the grant being satisfied in full, with the "claw-back" provisions expiring. The $1.0 million was recognized as an offset to expense.

NOTE 9. DEFERRED REVENUE AND REMAINING PERFORMANCE OBLIGATIONS

Deferred revenue consists of amounts received for products or services not yet delivered or earned. Deferred income consists of amounts received for commitments not yet fulfilled. If we anticipate that the revenue or income will not be earned within the following twelve months, the amount is reported as long-term deferred income. A summary of the balances as of December 31 follows (in thousands):

	2020	2019
Products and services not yet delivered	$ 376	$ 271
Deferred revenue	$ 376	$ 271

We recognized $0.2 million and $0.2 million of revenues during the years ended December 31, 2020 and December 31, 2019, respectively, and no material amount of revenue during the year ended December 31, 2018, that were included in the contract liabilities balances at the beginning of the period. No material amount of revenue recognized during the current period was from performance obligations satisfied in prior periods.

Transaction Price Allocated to Remaining Performance Obligations

As of December 31, 2020, $10.6 million of revenue is expected to be recognized from remaining performance obligations under existing customer contracts. This balance primarily relates to product shipments for reagents sold to customers under sales-type lease agreements. These agreements have between two and four year terms and revenue is recognized as product is shipped, typically on a straight-line basis. The remaining balance relates to executed service contracts that begin as warranty periods expire. These service contracts typically provide for four-year terms and revenue is recognized on a straight-line basis.

The Company elects not to disclose the value of unsatisfied performance obligations for (i) contracts with an expected length of one year or less and (ii) contracts for which we recognize revenue at the amount to which we have the right to invoice for services performed.

NOTE 10. LONG-TERM DEBT

As of December 31, 2020 and December 31, 2019, long-term debt consisted of the following (in thousands):

	2020	2019
PPP Loan - 1% interest	$ 4,812	$ —
Other Loans - various interest	400	—
Total debt	5,212	—
Current portion of long-term debt	553	—
Long-term debt	$ 4,659	$ —

The following presents maturities of future principal obligations of long-term debt as of December 31, 2020 (in thousands):

2021	$ 553
2022	1,625
2023	1,291
2024	1,304
Thereafter	439
Total	$ 5,212

Other notes payable

During the year ended December 31, 2020, the Company entered into three loan agreements with two capital asset financing companies. Loan proceeds were $0.8 million, with interest rates ranging from 9.8% to 12.4% and maturities ranging from January 1, 2022 to September 2022. As of December 31, 2020, the current portion of long-term debt was $0.1 million and long-term debt was $0.3 million.

PPP Loan

On April 14, 2020, the Company entered into the PPP Note evidencing an unsecured loan in the amount of $4.8 million made to the Company under the PPP. The PPP was established under the CARES Act and is administered by the SBA.

On September 3, 2020 the Company's loan provider amended the PPP Note per the Paycheck Protection Program Flexibility Act (“PPP Flexibility Act”), which was enacted after the PPP Note was approved and funded. The PPP Flexibility Act amended the CARES Act to require that all PPP Notes made prior to June 5, 2020 be extended to a 5-year term. In accordance with this amendment the PPP Notes' original maturity date of April 14, 2022 was amended to April 14, 2025. The original terms of the loan required 18 monthly payments of principal and interest in the amount of $0.3 million starting November 14, 2020. These amended terms now require 45 monthly payments of principal and interest in the amount of $0.1 million starting August 14, 2021. The PPP Note's interest rate was unchanged and bears interest at a rate of 1% per annum.

The PPP Note may be prepaid by the Company at any time prior to maturity with no prepayment penalties. The proceeds from the PPP Note may only be used for payroll costs (including benefits), interest on mortgage obligations, rent, utilities and interest on certain other debt obligations.

The PPP Note contains customary events of default relating to, among other things, payment defaults, making materially false and misleading representations to the lender or breaching the terms of the PPP Note documents. The occurrence of an event of default will result in an increase in the interest rate to 18% per annum

and provides the lender with customary remedies, including the right to require immediate payment of all amounts owed under the PPP Note.

Pursuant to the terms of the CARES Act and the PPP, the Company applied to the lender for forgiveness for the amount due on the PPP Note. The amount eligible for forgiveness is based on the amount of PPP Note proceeds used by the Company (during the 24 week period after the lender makes the first disbursement of PPP Note proceeds) for the payment of certain covered costs, including payroll costs (including benefits), rent and utilities, subject to certain limitations and reductions in accordance with the CARES Act and the PPP. No assurance can be given that the Company will obtain forgiveness of the PPP Note in whole or in part. As of December 31, 2020 the Company had submitted its application for forgiveness to the SBA, which is currently under review.

NOTE 11. CONVERTIBLE NOTES

On March 27, 2018, the Company issued $150.0 million aggregate principal amount of 2.50% Senior Convertible Notes due 2023. In connection with the offering of the Notes, the Company granted the initial purchasers of the Notes a 13-day option to purchase up to an additional $22.5 million aggregate principal amount of the Notes on the same terms and conditions. On April 4, 2018 the option was partially exercised, which resulted in $21.5 million of additional proceeds, for total proceeds of $171.5 million. The Notes are the Company's senior unsecured obligations and mature on March 15, 2023 (the “Maturity Date”), unless earlier repurchased or converted into shares of common stock under certain circumstances described below. The Notes are convertible into shares of the Company’s common stock, can be repurchased for cash, or a combination thereof, at the Company’s election, at an initial conversion rate of 32.3428 shares of common stock per $1,000 principal amount of the Notes, which is equivalent to an initial conversion price of approximately $30.92 per share of common stock, subject to adjustment. The Company will pay interest on the Notes semi-annually in arrears on March 15 and September 15 of each year.

The $171.5 million of proceeds received from the issuance of the Notes were allocated between long-term debt (the “liability component”) of $116.6 million and contributed capital (the “equity component”) of $54.9 million. The fair value of the liability component was measured using rates determined for similar debt instruments without a conversion feature. The carrying amount of the equity component, representing the conversion option, was determined by deducting the fair value of the liability component from the aggregate face value of the Notes. The liability component will be accreted up to the face value of the Notes of $171.5 million, which will result in additional non-cash interest expense being recognized through the Maturity Date. The equity component will not be remeasured as long as it continues to meet the conditions for equity classification.

The Company incurred approximately $5.0 million of issuance costs related to the issuance of the Notes, of which $3.4 million and $1.6 million were recorded to long-term debt and contributed capital, respectively. The $3.4 million of issuance costs recorded as long-term debt on the consolidated balance sheet are being amortized over the five-year contractual term of the Notes using the effective interest method. The effective interest rate on the Notes, including accretion of the Notes to par and debt issuance cost amortization, is 11.52%.

The Notes include customary terms and covenants, including certain events of default upon which the Notes may be due and payable immediately. Holders have the option to convert the Notes in multiples of $1,000 principal amount at any time prior to December 15, 2022, but only in the following circumstances:

- if the Company’s stock price exceeds 130% of the conversion price for 20 of the last 30 trading days of any calendar quarter after June 30, 2018;
- during the 5 business day period after any 5 consecutive trading day period in which the Notes’ trading price is less than 98% of the product of the common stock price times the conversion rate; or
- the occurrence of certain corporate events, such as a change of control, merger or liquidation.

At any time on or after December 15, 2022, a holder may convert its Notes in multiples of $1,000 principal amount. Holders of the Notes who convert their Notes in connection with a make-whole fundamental change (as defined in the Indenture pursuant to which the Notes were issued) are, under certain circumstances, entitled to an increase in the conversion rate. In addition, in the event of a fundamental change or event of default prior to the Maturity Date, holders will, subject to certain conditions, have the right, at their option, to require the Company to repurchase for cash all or part of the Notes at a repurchase price equal to 100% of the principal amount of the

Notes to be repurchased, plus accrued and unpaid interest up to, but excluding, the repurchase date.

The Notes consisted of the following at December 31 (in thousands):

	2020	2019
Outstanding principal	$ 171,500	$ 171,500
Unamortized debt discount	(28,524)	(39,042)
Unamortized debt issuance	(1,765)	(2,415)
Net carrying amount of the liability component	$ 141,211	$ 130,043

Interest expense consisted of the following at December 31 (in thousands):

	2020	2019	2018
Contractual coupon interest	$ 4,288	$ 4,288	$ 3,264
Amortization of the debt discount	10,518	9,388	6,450
Amortization of debt issuance costs	651	581	399
Total interest expense on convertible notes	$ 15,457	$ 14,257	$ 10,113

As of December 31, 2020, no Notes were convertible pursuant to their terms.

In connection with the debt issuance, the Company entered into a prepaid forward stock repurchase transaction (“Prepaid Forward”) with a financial institution (“Forward Counterparty”). Pursuant to the Prepaid Forward, the Company used approximately $45.1 million of the net proceeds from its issuance of the Notes to fund the Prepaid Forward. The aggregate number of shares of the Company’s common stock underlying the Prepaid Forward was approximately 1,858,500. The expiration date for the Prepaid Forward is March 15, 2023, although it may be settled earlier in whole or in part. Upon settlement of the Prepaid Forward, at expiration or upon any early settlement, the Forward Counterparty will deliver to the Company the number of shares of common stock underlying the Prepaid Forward or the portion thereof being settled early. The shares purchased under the Prepaid Forward are treated as treasury stock and not outstanding for purposes of the calculation of basic and diluted earnings per share, but will remain outstanding for corporate law purposes, including for purposes of any future stockholders’ votes, until the Forward Counterparty delivers the shares underlying the Prepaid Forward to the Company. The Company’s Prepaid Forward hedge transaction exposes the Company to credit risk to the extent that its counterparty may be unable to meet the terms of the transaction. The Company mitigates this risk by limiting its counterparty to a major financial institution.

NOTE 12. LOSS PER SHARE

Basic net loss per common share was determined by dividing net loss applicable to common stockholders by the weighted average common shares outstanding during the period. Basic and diluted net loss per share are the same because all outstanding common stock equivalents have been excluded, as they are anti-dilutive due to the Company’s losses.

The following potentially issuable common shares were not included in the computation of diluted net loss per share because they would have an anti-dilutive effect due to net losses at of the following at December 31 (in thousands):

	2020	2019	2018
Shares issuable upon the release of restricted stock awards	526	14	76
Shares issuable upon exercise of stock options	8,045	10,133	8,091
	8,571	10,147	8,167

Potentially dilutive common shares would include common shares that would be outstanding if Notes convertible at the balance sheet date were converted. As discussed in Note 11, Convertible Notes, the Company issued $171.5 million of Notes due 2023. The Notes are convertible into shares of the Company’s common stock,

can be repurchased for cash, or a combination thereof, at the Company's election, at an initial conversion rate of 32.3428 shares of common stock per $1,000 principal amount of the Notes. As of December 31, 2020, no Notes were convertible pursuant to their terms. The maximum number of shares issuable upon conversion of the Notes is 5.5 million shares.

In connection with the Notes, the Company entered into a prepaid forward stock repurchase transaction. The aggregate number of shares of the Company's common stock underlying the Prepaid Forward was approximately 1,858,500. The shares purchased under the Prepaid Forward are treated as treasury stock and not outstanding for purposes of the calculation of basic and diluted earnings per share, but will remain outstanding for corporate law purposes, including for purposes of any future stockholders' votes, until the Forward Counterparty delivers the shares underlying the Prepaid Forward to the Company.

As discussed in Note 19, Securities Purchase Agreement, the Company entered into a securities purchase agreement (the "Securities Purchase Agreement") with Jack W. Schuler, John Patience, Matthew Strobeck, Mark C. Miller, Thomas D. Brown and Jack Phillips, or entities affiliated with such persons (collectively, the "Purchasers"), for the issuance and sale by the Company of an aggregate of 4,166,663 shares of the Company's common stock. The closing of the purchase and sale of the Shares is expected to occur in three approximately equal tranches, with the first tranche having closed on February 19, 2021 and the next two tranches expected to close on March 31, 2021 and June 30, 2021, respectively, or such other dates as the parties may agree. The potentially issuable common shares were not included in the computation of diluted net loss per share because they would have an anti-dilutive effect due to net losses.

NOTE 13. EMPLOYEE EQUITY-BASED COMPENSATION

The Company has three equity based compensation plans, which are discussed below:

Non-Qualified Stock Option Plan

The Non-Qualified Stock Option Plan was a stockholder-approved plan. As of December 31, 2020, there were 280,000 options exercised during the life of the plan and 0 that remain outstanding. The Non-Qualified Stock Option Plan has been replaced by the 2012 Omnibus Equity Incentive Plan, so no further options are available for grant.

2004 Omnibus Stock Option Plan

In December 2004, the Company's stockholders approved the Omnibus Stock Option Plan. Authorized shares in this plan were 5,500,000. As of December 31, 2020, there were 3,188,174 options exercised during the life of the plan and 751,826 options remain outstanding. The 2004 Omnibus Stock Option Plan has been replaced by the 2012 Omnibus Equity Incentive Plan, so no further options are available for grant.

2012 Omnibus Equity Incentive Plan

In December 2012, the Company's stockholders approved the Company's 2012 Omnibus Equity Incentive Plan to replace all prior plans ("Prior Plans"). The Prior Plans remain in effect until all awards granted under those plans have been exercised, forfeited, canceled, expired or otherwise terminated. In connection with the approval of such plan, all stock options, totaling 1,677,500 formerly available for new awards under the Prior Plans were transferred to the 2012 Omnibus Equity Incentive Plan.

During the Company's Annual Meeting of Stockholders, stockholders approved amendments to the Company's 2012 Omnibus Equity Incentive Plan increasing the number of shares of Common Stock reserved and available for grant by 4,000,000 in May 2014, 2,000,000 in May 2017, 3,000,000 in March 2019 and 4,000,000 in May 2020, resulting in a total of 14,677,500 reserved shares.

Stock options granted under this plan vest in a range from immediate to five years while generally stock options under this plan vest over five years. RSUs granted under this plan vest in a range from immediate to five years while generally RSUs under this plan vest over three years. Stock grants granted under this plan vest immediately.

As of December 31, 2020, there were 1,464,663 options exercised and 281,245 RSUs, performance awards and stock grants issued, during the life of the plan. There were 7,820,049 shares remaining outstanding, leaving 5,111,543 available for grant.

Combined Stock Option Plans

The following table summarizes option activity under all plans during the years ended December 31, 2020 and 2019 and shows the exercisable shares as of December 31, 2020:

	Number of Shares	Weighted Average Exercise Price per Share
Options Outstanding January 1, 2019	**8,090,636**	**$ 12.22**
Granted	3,067,888	14.52
Forfeited	(533,503)	20.65
Exercised	(383,319)	13.99
Expired	(109,140)	23.86
Options Outstanding December 31, 2019	**10,132,562**	**12.28**
Granted	1,738,083	8.53
Forfeited	(713,070)	14.23
Exercised	(2,631,935)	2.30
Expired	(480,179)	18.62
Options Outstanding December 31, 2020	**8,045,461**	**14.18**
Exercisable December 31, 2020	4,174,813	13.89

The cash received from the exercise of options during the year ended December 31, 2020 was $6.1 million and the tax benefit realized was zero for the same period. Upon exercise, shares are issued from shares authorized and held in reserve. The intrinsic value of options exercised was $23.5 million, $2.3 million and $4.6 million for the years ended December 31, 2020, 2019 and 2018, respectively.

The total fair value of options vesting during the period was $9.0 million, $9.9 million, and $13.4 million for the years ended December 31, 2020, 2019 and 2018, respectively.

The Company accounts for all option grants using the Black-Scholes option pricing model. The table below summarizes the inputs used to calculate the estimated fair value of options awarded for the years ended December 31:

	2020	2019	2018
Expected term (in years)	5.94	6.28	6.01
Volatility	58 %	60 %	66 %
Expected dividends	—	—	—
Risk free interest rates	0.6 %	2.1 %	2.7 %
Estimated forfeitures	— %	— %	— %
Weighted average fair value	$ 4.49	$ 8.33	$ 14.87

The following table shows summary information for outstanding options and options that are exercisable (vested) as of December 31, 2020:

	Options Outstanding	Options Exercisable
Number of options	8,045,461	4,174,813
Weighted average remaining contractual term (in years)	6.55	4.92
Weighted average exercise price	$ 14.18	$ 13.89
Weighted average fair value	$ 8.88	$ 8.92
Aggregate intrinsic value (in millions)	$ 6.1	$ 5.2

The aggregate intrinsic value in the table above represents the total pretax intrinsic value that would have been received by the option holders had all option holders exercised their options on that date. It is calculated as the difference between the Company's closing stock price of $7.58 on the last trading day of 2020 and the exercise price multiplied by the number of shares for options where the exercise price is below the closing stock price. This amount changes based on the fair value of the Company's stock.

The following table summarizes RSU and stock grant activity during the years ended December 31, 2020 and 2019:

	Number of Shares	Weighted Average Grant Date Fair Value per Share
RSUs & Stock Grants Outstanding January 1, 2019	**76,000**	**$ 18.70**
Granted	11,000	20.32
Forfeited	(60,500)	19.74
Vested/released	(12,168)	17.43
RSUs & Stock Grants outstanding December 31, 2019	**14,332**	**16.66**
Granted	813,256	11.44
Forfeited	(98,398)	11.66
Vested/released	(202,776)	12.41
RSUs & Stock Grants outstanding December 31, 2020	**526,414**	**11.17**

The total fair value of RSUs and stock grants vested and released during the period was $2.7 million, $0.2 million, and $0.4 million for the years ending December 31, 2020, 2019 and 2018, respectively.

The Company records compensation cost based on the fair value of the award. The table below summarizes the weighted average fair value of RSUs and stock grants awarded for the years ending December 31:

	2020	2019	2018
Weighted average fair value	$ 11.44	$ 20.32	$ 17.33

The expense and tax benefits recognized on the Company's consolidated statements of operations and comprehensive loss related to share-based compensation for the years ended December 31 (in thousands) is as follows:

	2020	2019	2018
Cost of Sales	$ 351	$ 277	$ 189
Research and development	4,035	4,115	4,760
Sales, general and administrative	12,078	8,226	9,473
Total equity-based compensation expense	$ 16,464	$ 12,618	$ 14,422
Recognized tax benefit	$ —	$ —	$ —

The share-based compensation cost capitalized to inventory or inventory transferred to property and equipment (also referred to as instruments) for the years ended December 31 (in thousands) is as follows:

	2020	2019	2018
Cost capitalized to inventory	$ 253	$ 409	$ 463

As of December 31, 2020, unrecognized equity-based compensation cost related to unvested stock options, and unvested RSUs was $13.0 million and $2.3 million, respectively. This is expected to be recognized over the years 2021 through 2025.

Included in the above-noted stock options outstanding and stock compensation expense are performance-based stock options which vest only upon the achievement of certain targets. Performance-based stock options are generally granted at-the-money, contingently vest over a period of 1 to 2 years, depending on the nature of the performance goal, and have contractual lives of 10 years. These options were valued in the same manner as the time-based options, with the assumption that performance goals will be achieved. The inputs for expected volatility, expected dividends, and risk-free rate used in estimating those options' fair value are the same as the time-based options issued under the plan. The expected term for performance-based stock options is 5 to 7 years. However, the Company only recognizes stock compensation expense to the extent that the targets are determined to be probable of being achieved, which triggers the vesting of the performance options.

In August 2018, the Company granted 225,000 performance-based stock options. Of these performance-based stock options performance obligations had been met for 75,000 options which became exercisable in a prior period. The remaining 150,000 options were forfeited for the performance targets not being achieved. Of the total options forfeited, 50,000 of those options were forfeited during the year ended December 31, 2020. No stock compensation expense for the forfeited performance-based stock options was recognized. The stock compensation expense for the vested options was recorded in prior periods.

During the year ended December 31, 2020, the Company granted another 105,000 performance-based stock options. During the year ended December 31, 2020, 45,000 performance-based stock options vested due to the performance obligations being achieved. None of these options have been forfeited as of December 31, 2020.

The table below summarizes share-based compensation cost in connection with performance-based stock options for the years ending December 31 (in thousands):

	2020	2019	2018
Performance-based stock option expense	$ 215	$ 107	$ 717

Included in the above-noted RSU outstanding amount are performance-based RSU's which vest only upon the achievement of certain targets. Performance-based RSU's contingently vest over a period of 1 to 3 years, depending on the nature of the performance goal, and have contractual lives of 10 years. These units were valued in the same manner as other RSUs, based on the published closing market price on the day before the grant date. However, the Company only recognizes stock compensation expense to the extent that the targets are determined to be probable of being achieved, which triggers the vesting of the performance options.

During the year ended December 31, 2020, the Company granted 364,338 performance-based RSU's. During the year ended December 31, 2020, 81,000 performance-based RSU's were released due to the performance obligations being achieved. At December 31, 2020 259,343 performance-based RSU's were outstanding. None of these performance-based RSU have been forfeited due to performance obligations not being achieved, while 23,995 performance-based RSU were forfeited for the employees separating from the Company.

The table below summarizes share-based compensation cost in connection with performance-based stock options for the years ending December 31 (in thousands):

	2020	2019	2018
Performance-based RSU expense	$ 810	$ —	$ —

NOTE 14. INCOME TAXES

The components of the pretax loss from operations for the years ended December 31 are as follows (in thousands):

	2020	2019	2018
U.S. Domestic	$ (66,482)	$ (70,452)	$ (67,508)
Foreign	(11,721)	(13,964)	(20,607)
Net loss before income taxes	$ (78,203)	$ (84,416)	$ (88,115)

The components of the provision for income taxes for the years ended December 31 is presented in the following table:

	2020	2019	2018
Current:			
Federal	$ —	$ —	$ —
State	(1)	(8)	(14)
Foreign	(4)	119	(197)
Total (provision) benefit	(5)	111	(211)
Deferred:			
Federal	—	—	—
State	—	—	—
Foreign	—	—	—
Total deferred provision	—	—	—
Total (provision) benefit	$ (5)	$ 111	$ (211)

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's net deferred income taxes for the years ended December 31 are as follows (in thousands):

	2020	2019
Deferred tax assets:		
Net operating loss carryforward	$ 81,733	$ 66,319
General business credit	15,484	11,306
Stock options	13,366	13,217
Operating lease liability	846	908
Property & equipment	206	403
Inventory	588	397
Intangible assets, definite-lived	55	38
Other	284	30
Total deferred tax assets	112,562	92,618
Valuation allowance	(104,585)	(81,946)
Deferred tax assets	$ 7,977	$ 10,672
Deferred tax liabilities:		
Debt amortization	$ (7,229)	$ (9,793)
Right of use asset	$ (748)	$ (879)
Total deferred tax liabilities	$ (7,977)	$ (10,672)
Net deferred taxes	$ —	$ —

As of December 31, 2020, the Company has generated regular tax federal net operating losses ("NOLs") of approximately $335.0 million. As a result of the Tax and Jobs Act ("the TCJA"), for U.S. income tax purposes, NOLs generated prior to December 31, 2017 can be carried forward for up to 20 years. NOLs generated after December 31, 2017 carry forward indefinitely, but are limited to 80% utilization against taxable income generated in tax years after 2020. Of the Company's total federal net operating loss of $335.0 million, $170.6 million will begin to expire in 2023 and $164.4 million will not expire but will only offset 80% of taxable income generated in tax years after 2020.

As of December 31, 2020, the Company has generated state net operating losses of approximately $315.1 million. The Company's state net operating losses will begin to expire in 2033.

As of December 31, 2020, the Company has generated $11.3 million of federal research and development ("R&D") tax credits which begin to expire in 2032.

As of December 31, 2020, the Company has generated $8.7 million of state R&D tax credits which begin to expire in 2031.

Pursuant to Sections 382 and 383 of the Internal Revenue Code, utilization of the Company's NOLs and R&D tax credits may be subject to substantial annual limitation if certain ownership changes occur during a three-year testing period as defined by the Internal Revenue Code.

The net deferred tax asset valuation allowance is $104.6 million as of December 31, 2020, compared to $81.9 million as of December 31, 2019. The valuation allowance is based on management's assessment that it is more likely than not that the Company will not have taxable income in the foreseeable future. Due to the Company's consolidated loss position, the Company maintains a valuation allowance against its net deferred tax assets.

During 2018, the Company recognized $14.0 million of the initial deferred tax liability related to the 2018 convertible debt with an adjustment to equity in accordance with ASC 740. The establishment of the deferred tax

liability resulted in the reduction of the Company's valuation allowance on existing deferred tax assets. The Company recorded the reduction of the valuation allowance as an offsetting adjustment in equity. As a result, no net entry to equity was recorded for the 2018 convertible debt in 2018. Subsequent changes in the deferred tax liability related to the convertible debt are recorded as a component of income tax expense or benefit.

The Company began commercialization of its products in Europe in 2016 and has subsidiaries in the Netherlands, France, Germany, Italy, Spain, Russia, and the United Kingdom. The Company intends to treat earnings from its foreign subsidiaries as permanently reinvested.

On March 27, 2020, the United States enacted the CARES Act. The CARES Act is an emergency economic stimulus package that includes spending and tax breaks to strengthen the United States economy and fund a nationwide effort to curtail the effect of COVID-19. While the CARES Act provides sweeping tax changes in response to the COVID-19 pandemic, some of the more significant provisions are the extension of the carryback period of certain losses to five years, and suspended the 80 percent limitation imposed by the TCJA on utilization of NOLs generated in 2018, 2019 and 2020 to offset taxable income generated in tax years prior to 2021. The CARES Act also increased the ability to deduct interest expense from 30 percent, as imposed by the TCJA, to 50 percent of modified taxable income. The CARES Act also provides for a credit against employee wages, the opportunity to defer payment of a portion of federal payroll taxes to December 2021 and December 2022 and enhanced small business loans to assist business impacted by the pandemic. The Company’s tax provision and financial position was not materially impacted by the CARES Act.

On December 27, 2020, the United States enacted the Consolidated Appropriations Act which extended and modified many of the tax related provisions of the CARES Act. The Company does not anticipate a material impact of the Consolidated Appropriations Act on its tax provision or financial position.

The difference between the U.S. federal statutory income tax rate and the Company’s effective tax rate for years ending December 31 is as follows:

	2020	2019	2018
U.S. federal statutory income tax rate	(21.00)%	(21.00)%	(21.00)%
State taxes, net of federal tax benefit	(4.95)	(3.83)	(3.07)
Permanent and other differences	2.35	(0.25)	(0.26)
Change in tax rates	(0.05)	0.16	(0.41)
Tax rate differential	3.09	3.28	4.92
Unrecognized tax benefits	1.34	0.79	0.81
Nondeductible equity and other compensation	(3.38)	1.12	(0.17)
Credit for increased research activities	(6.29)	(2.80)	(3.12)
Change in valuation allowance	28.89	22.40	22.54
	— %	(0.13)%	0.24 %

The Company's uncertain tax positions at December 31 as follows (in thousands):

	2020	2019	2018
Balance at beginning of year	$ 3,712	$ 2,983	$ 2,141
Increases for prior positions	—	7	70
Increases for current year positions	1,154	724	775
Other decreases	—	(2)	(3)
Balance at end of year	$ 4,866	$ 3,712	$ 2,983

These uncertain positions are not expected to change within the next twelve months. Of the $4.9 million of uncertain tax positions, $0.1 million would impact the effective tax rate, if reversed. The Company accounts for interest on uncertain tax positions within tax expense. The Company's foreign subsidiaries are subject to applicable jurisdiction examination for all years of operations. The Company has adequate tax attributes available to utilize

against its uncertain tax positions in a given year. As a result the Company does not accrue interest or penalties against its uncertain tax positions.

The Company incurred net operating losses since inception that are subject to adjustment under Internal Revenue Service ("IRS") and state examination. In the first quarter of 2021, the Company was informed by the IRS that they would begin an examination of the Company's 2018 tax year. The Company's foreign income tax filings are subject to examination by the appropriate foreign tax authorities. The Company is not currently under examination by tax authorities other than the IRS and is not aware of any material proposed adjustments to its income tax filings.

NOTE 15. COMMITMENTS AND CONTINGENCIES

Clinical Trial & Study Agreements

The Company has entered into master agreements with clinical trial and study sites in which we typically pay a set amount for start-up costs and then pay for work performed. These agreements typically indemnify the clinical trial sites from any and all losses arising from third party claims as a result of the Company's negligence, willful misconduct or misrepresentation. The expenses for start-up costs and work performed for these trials and studies is recorded as research and development or sales, general and administrative expenses on the Company's consolidated statements of operations and comprehensive loss. No commitments were recorded in connection with indemnifying these sites for losses.

NOTE 16. LEASES

The following presents supplemental information related to our leases in which we are the lessee for the years ended December 31 (in thousands):

	2020	2019
Cash paid for amounts included in lease liabilities		
Operating cash flows from operating leases	$ 712	$ 333
ROU assets obtained in exchange for lease obligations		
Operating leases	17	3,639
Lease Cost		
Operating leases	1,052	378
Short-term leases	$ 66	$ 697

The weighted average remaining lease term on our operating leases is 4.5 years. The weighted average discount rate on those leases is 7.0%. Rent expense including common area charges was $1.4 million for the year ended December 31, 2018.

The following presents maturities of operating lease liabilities in which we are the lessee as of December 31, 2020 (in thousands):

	2020
2021	$ 707
2022	863
2023	968
2024	1,055
2025	627
Thereafter	—
Total lease payments	4,220
Less imputed interest	(659)
	$ 3,561

The net investment in sales-type leases, where we are the lessor, is a component of other current assets and other non-current assets in our consolidated balance sheet. As of December 31, 2020, the total net investment in these leases was $3.2 million. The following presents maturities of lease receivables under sales-type leases as of December 31, 2020 (in thousands):

	2020
2021	$ 1,094
2022	1,037
2023	666
2024	255
2025	46
Thereafter	150
	3,248

NOTE 17. INDUSTRY, GEOGRAPHIC, AND REVENUE DISAGGREGATION

The Company operates as one operating segment. Sales to customers outside the U.S. represented 8%, 28% and 27% of total revenue for the years ended December 31, 2020, 2019 and 2018, respectively. As of December 31, 2020 and 2019, balances due from foreign customers, in U.S. dollars, were $0.3 million and $2.1 million, respectively.

The following presents long-lived assets (excluding intangible assets) by geographic territory at December 31 (in thousands):

	2020	2019
Domestic	$ 5,658	$ 7,244
Foreign	477	661
	$ 6,135	$ 7,905

The following presents total net sales by geographic territory for the years ended December 31 (in thousands):

	2020	2019	2018
Domestic	$ 10,305	$ 6,705	$ 4,153
Foreign	860	2,592	1,517
Net sales	$ 11,165	$ 9,297	$ 5,670

The following presents total net sales by line of business for the years ended December 31 (in thousands):

	2020	2019	2018
Accelerate Pheno revenue	$ 11,025	$ 9,132	$ 5,547
Other revenue	140	165	123
Net sales	$ 11,165	$ 9,297	$ 5,670

The following presents total net sales by products and services for the years ended December 31 (in thousands):

	2020	2019	2018
Products	$ 10,336	$ 8,839	$ 5,576
Services	829	458	94
Net sales	$ 11,165	$ 9,297	$ 5,670

Lease income included in net sales was $3.6 million and $1.3 million for the years ended December 31, 2020 and December 31, 2019, respectively, which does not represent revenues recognized from contracts with customers. Lease income included in net sales for the year ended 2018 is immaterial.

NOTE 18. SUPPLEMENTAL DATA (UNAUDITED)

The following is a summary of unaudited selected quarterly financial information for the three months ended 2020 (in thousands, except per share data):

	December 31,	September 30,	June 30,	March 31,
Net sales	$ 3,110	$ 3,588	$ 2,125	$ 2,342
Gross profit	$ 1,149	$ 1,301	$ 954	$ 1,055
Loss from operations	$ (15,080)	$ (15,165)	$ (15,725)	$ (17,730)
Net loss	$ (18,912)	$ (18,757)	$ (19,230)	$ (21,309)
Basic and diluted net loss per share	$ (0.33)	$ (0.33)	$ (0.35)	$ (0.39)

The following is a summary of unaudited selected quarterly financial information for the three months ended 2019 (in thousands, except per share data):

	December 31,	September 30,	June 30,	March 31,
Net sales	$ 3,470	$ 2,271	$ 1,806	$ 1,750
Gross profit	$ 1,513	$ 1,154	$ 899	$ 834
Loss from operations	$ (18,269)	$ (17,653)	$ (18,087)	$ (18,822)
Net loss	$ (21,335)	$ (20,434)	$ (20,815)	$ (21,721)
Basic and diluted net loss per share	$ (0.40)	$ (0.37)	$ (0.38)	$ (0.40)

NOTE 19. SECURITIES PURCHASE AGREEMENT

On December 24, 2020, the Company entered into a securities purchase agreement (the “Securities Purchase Agreement”) with Jack W. Schuler, John Patience, Matthew Strobeck, Mark C. Miller, Thomas D. Brown and Jack Phillips, or entities affiliated with such persons (collectively, the “Purchasers”), for the issuance and sale by the Company of an aggregate of 4,166,663 shares of the Company’s common stock (the “Shares”), to the Purchasers in an offering exempt from registration pursuant to Section 4(a)(2) of the Securities Act, and Rule 506 promulgated thereunder. Each of Jack W. Schuler, John Patience, Matthew Strobeck, Mark C. Miller, Thomas D. Brown and Jack Phillips is a member of the Company’s board of directors. Mr. Phillips also serves as the Company’s President and Chief Executive Officer. The entity affiliated with Jack W. Schuler that originally entered into the Securities Purchase Agreement subsequently entered into an assignment and assumption agreement whereby it assigned all of its rights and obligations as a Purchaser to three other entities that became Purchasers under the Securities Purchase Agreement. These three entities are related to Jack W. Schuler but are not affiliates of his.

Pursuant to the Securities Purchase Agreement, the Purchasers have agreed to purchase the Shares at a purchase price (determined in accordance with Nasdaq rules relating to the “market value” of the Company’s common stock) of $7.68 per share, which is equal to the consolidated closing bid price reported by Nasdaq immediately preceding the time the Company entered into the Securities Purchase Agreement for an aggregate purchase price of approximately $32 million. The closing of the purchase and sale of the Shares is expected to

occur in three approximately equal tranches, with the first tranche having closed on February 19, 2021 and the next two tranches expected to close on March 31, 2021 and June 30, 2021, respectively, or such other dates as the parties may agree.

Additionally, on December 24, 2020, the Company entered into a registration rights agreement with the Purchasers pursuant to which the Company has agreed to register the resale of the Shares pursuant to the terms set forth therein.

NOTE 20. RELATED PARTY TRANSACTION

Convertible notes

As discussed in Note 11, Convertible Notes, the Company issued Notes in March 2018. As part of this issuance, an entity controlled by one member of the Company's board of directors purchased an aggregate of $30.0 million of the Notes. In 2019, this affiliate purchased an additional $12.0 million of Notes on the open market. The affiliated entity is a Qualified Institutional Buyer which purchased and holds an aggregate of $42.0 million of the Notes at December 31, 2020.

Purchase Agreement 2019

On August 20, 2019, the Company and an entity affiliated with the Chief Operating Officer of the Company entered into a securities purchase agreement (the “Purchase Agreement”) for the issuance and sale by the Company of an aggregate of 55,586 shares of the Company’s common stock (the “Shares”) in an offering exempt from registration pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder. The Shares were sold at a purchase price (determined in accordance with Nasdaq rules relating to the “market value” of the shares) of $17.99 per share, which was equal to the consolidated closing bid price reported by Nasdaq immediately preceding the time the Company entered into the Purchase Agreement. The $1.0 million of proceeds were recorded to contributed capital.

Security Purchase Agreement 2020

On December 24, 2020, the Company entered into a Securities Purchase Agreement with Jack W. Schuler, John Patience, Matthew Strobeck, Mark C. Miller, Thomas D. Brown and Jack Phillips, or entities affiliated with such persons, for the issuance and sale by the Company of an aggregate of 4,166,663 Shares, to the Purchasers in an offering exempt from registration pursuant to Section 4(a)(2) of the Securities Act, and Rule 506 promulgated thereunder. Each of Jack W. Schuler, John Patience, Matthew Strobeck, Mark C. Miller, Thomas D. Brown and Jack Phillips is a member of the Company’s board of directors. Mr. Phillips also serves as the Company’s President and Chief Executive Officer. The entity affiliated with Jack W. Schuler that originally entered into the Securities Purchase Agreement subsequently entered into an assignment and assumption agreement whereby it assigned all of its rights and obligations as a Purchaser to three other entities that became Purchasers under the Securities Purchase Agreement. These three entities are related to Jack W. Schuler but are not affiliates of his. See Note 19, Securities Purchase Agreement, for further information.

NOTE 21. SUBSEQUENT EVENTS

The Company evaluates events that have occurred after the balance sheet date but before the financial statements are issued. Based upon the evaluation, the Company did not identify any recognized or non-recognized subsequent events that would have required adjustment or disclosure in the financial statements, except as disclosed. On February 15, 2021, the Company received gross proceeds of $10.7 million from the first tranche closing of the Securities Purchase Agreement. The Company expects the remaining two tranches of the Securities Purchase Agreement to close in the first half of 2021 and the total expected gross proceeds including the first tranche to be $32.0 million.

The Company and the purchasers subject to the Securities Purchase Agreement are obligated to fulfill their obligations set forth in the Securities Purchase Agreement upon the closure of the first tranche. The remaining tranches represent freestanding equity-classified instruments that will be fair valued upon closure of the first tranche and the corresponding fair value for each subsequent tranche will be recorded to APIC. At the time of the filing of the Company’s Form 10-K, the valuation for these instruments was not available. The accounting for the second

and third tranches were predicated on the first tranche closing, the Company concluded these transaction would not require adjustment to the Company's financial results for the year ending December 31, 2020.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Based on an evaluation under the supervision and with the participation of the Company's management, the Company's Principal Executive Officer and Principal Financial Officer have concluded that the Company's disclosure controls and procedures, as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, were effective as of December 31, 2020, to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to the Company's management, including its Principal Executive Officer and Principal Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external purposes in accordance with U.S. GAAP. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Under the supervision and with the participation of our management, including the Company's Principal Executive Officer and Principal Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control-Integrated Framework (2013), issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2020.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) under the Exchange Act during the quarter ended December 31, 2020, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Not Applicable.

PART III

Certain information required by Part III is omitted from this Form 10-K because the required information will be incorporated by reference to our definitive proxy statement for our 2021 Annual Meeting of Stockholders, to be filed with the SEC pursuant to Regulation 14A of the Exchange Act (the “Proxy Statement”) not later than 120 days after the end of the fiscal year covered by this Form 10-K.

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item will be disclosed in the Proxy Statement and is incorporated by reference to the Proxy Statement.

Item 11. Executive Compensation

The information required by this Item will be disclosed in the Proxy Statement and is incorporated by reference to the Proxy Statement.

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

The information required by this Item will be disclosed in the Proxy Statement and is incorporated by reference to the Proxy Statement.

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

The information required by this Item will be disclosed in the Proxy Statement and is incorporated by reference to the Proxy Statement.

Item 14. Principal Accounting Fees and Services

The information required by this Item will be disclosed in the Proxy Statement and is incorporated by reference to the Proxy Statement.

PART IV

Item 15. Exhibits, Financial Statement Schedules

a) Documents filed as part of this report
1) All financial statements

	Page
Report of Independent Registered Public Accounting Firm	58
Consolidated Balance Sheets as of December 31, 2020 and 2019	60
Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2020, 2019 and 2018	61
Consolidated Statements of Stockholders' Deficit for the years ended December 31, 2020, 2019 and 2018	62
Consolidated Statements of Cash Flow for the years ended December 31, 2020, 2019 and 2018	63
Notes to Consolidated Financial Statements	65

2) Financial Statement Schedules

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

b) Exhibits required by Item 601 of Registration S-K

The information required by this Item is set forth on the exhibit index preceding the signature page of this report.

Item 16. Form 10-K Summary

None.

EXHIBIT INDEX

Exhibit No.	Description	Filing Information
3.1	Certificate of Incorporation of Registrant	Incorporated by reference to Appendix B of the Registrant's Definitive Proxy Statement on Schedule 14A filed on November 13, 2012
3.1.1	Certificate of Amendment to Certificate of Incorporation of Registrant	Incorporated by reference to Exhibit A to the Registrant's Definitive Information Statement on Schedule 14C filed on July 12, 2013
3.1.2	Certificate of Amendment to Certificate of Incorporation of Registrant	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on March 15, 2016
3.1.3	Certificate of Amendment to Certificate of Incorporation of Registrant	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on March 15, 2019
3.2	Amended and Restated Bylaws of Registrant	Incorporated by reference to Exhibit 3.1 filed with the Registrant's Annual Report on Form 8-K for the fiscal year ended August 8, 2019
4.1	Specimen Common Stock Certificate	Incorporated by reference to Exhibit 4.1 filed with the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2018
4.2	Indenture, dated March 27, 2018 between Registrant and U.S. Bank National Association, as trustee	Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on March 28, 2018
4.3	Form of 2.50% Convertible Senior Note due 2023 (included in Exhibit 4.2)	Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed on March 28, 2018
4.4	Description of our Capital Stock Registered Pursuant to Section 12 of the Securties Exchange Act of 1934	Incorporated by reference to Exhibit 4.4 to the Registrant's Annual Report on Form 10-K filed on February 28, 2020
10.1*	Registrant's 2004 Omnibus Stock Option Plan	Incorporated by reference to Appendix A of the Registrant's Definitive Proxy Statement on Schedule 14A filed on November 15, 2004
10.1.1*	Amendment to Registrant's 2004 Omnibus Stock Option Plan	Incorporated by reference to Annex C of the Registrant's Definitive Proxy Statement on Schedule 14A filed on May 17, 2012
10.1.2*	Form of Stock Option Award Agreement under Registrant's 2004 Omnibus Stock Option Plan	Incorporated by reference to Exhibit 4.4 filed with the Registrant's Form S-8 Registration Statement (No. 333-182930) on July 30, 2012
10.2	Registration Rights Agreement between Registrant and Abeja Ventures, LLC, dated as of June 26, 2012	Incorporated by reference to Exhibit 10.5 filed with the Registrant's Annual Report on Form 10-K for the fiscal year ended July 31, 2012
10.3*	CFO Offer Letter between Registrant and Steve Reichling, dated as of August 8, 2012	Incorporated by reference to Exhibit 10.10 filed with the Registrant's Annual Report on Form 10-K for the fiscal year ended July 31, 2012
10.4*	Accelerate Diagnostics, Inc. 2012 Omnibus Equity Incentive Plan (as amended by the First Amendment to the Accelr8 Technology Corporation 2012 Omnibus Equity Incentive Plan and the Second Amendment to the Accelerate Diagnostics, Inc. 2012 Omnibus Equity Incentive Plan)	Incorporated by reference to Appendix A of the Registrant's Definitive Proxy Statement on Schedule 14A filed on April 10, 2017
10.4.1*	Third Amendment to the Accelerate Diagnostics, Inc. 2012 Omnibus Equity Incentive Plan	Incorporated by reference to Appendix A of the Registrant's Definitive Proxy Statement on Schedule 14A filed on April 10, 2017
10.4.2*	Fourth Amendment to the Accelerate Diagnostics, Inc. 2012 Omnibus Equity Incentive Plan	Incorporated by reference to Exhibit 10.9.6 filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2018
10.4.3*	Fifth Amendment to the Accelerate Diagnostics, Inc. 2012 Omnibus Equity Incentive Plan	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on May 15, 2019
10.4.4*	Sixth Amendment to the Accelerate Diagnostics, Inc. 2012 Omnibus Equity Incentive Plan	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on May 14, 2020
10.4.5*	Form of Nonqualified Stock Option Award Agreement under the Accelerate Diagnostics, Inc. 2012 Omnibus Equity Incentive Plan	Incorporated by reference to Exhibit 99.3 to the Form S-8 Registration Statement (No. 333-187439) filed by the Registrant on March 22, 2013
10.4.6*	Form of Incentive Stock Option Award Agreement under the Accelerate Diagnostics, Inc. 2012 Omnibus Equity Incentive Plan	Incorporated by reference to Exhibit 99.4 to the Form S-8 Registration Statement (No. 333-187439) filed by the Registrant on March 22, 2013
10.4.7*	UK Sub-Plan under the Accelerate Diagnostics, Inc. 2012 Omnibus Equity Incentive Plan	Incorporated by reference to Exhibit 10.9.7 filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2018
10.5	Promissory Note, dated April 14, 2020, by and between Registrant and Zions Bancorporation, N.A. dba National Bank of Arizona	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on April 20, 2020

10.5.1	Addendum A to Promissory Note, dated April 14, 2020, by and between Registrant and Zions Bancorporation, N.A. dba National Bank of Arizona	Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020
10.6	Securities Purchase Agreement, dated December 24, 2020 by and among Registrant and the purchasers party thereto	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on December 28, 2020
10.7	Registration Rights Agreement, dated December 24, 2020 by and among Registrant and the purchasers party thereto	Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on December 28, 2020
10.8	Forward Stock Purchase Transaction, dated March 22, 2018, between Registrant and JPMorgan Chase Bank, National Association, London Branch	Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on March 28, 2018
10.9*	2020 Salary Waiver and Nonqualified Stock Option Grant Plan	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on April 8, 2020
10.9.1*	Form of 2020 Salary Waiver Agreement	Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on form 8-K filed on April 8, 2020
10.10*	Agreement between Registrant and Jack Phillips, dated as of January 31, 2020	Incorporated by reference to Exhibit 10.8 to the Registrant's Annual Report on Form 10-K filed on February 28, 2020
10.11*	Transition Agreement, Part-Time Employment Agreement, and General Release of Claims between Registrant and Lawrence Mehren, dated December 1, 2019	Incorporated by reference to Exhibit 10.7 to the Registrant's Annual Report on Form 10-K filed on February 28, 2020
21	List of Subsidiaries	Filed herewith
23.1	Consent of Independent Registered Public Accounting Firm	Filed herewith
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith
32	Certificate of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Furnished herewith
101.INS	XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document	Filed herewith
101.SCH	Inline XBRL Taxonomy Extension Schema Document	Filed herewith
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	Filed herewith
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	Filed herewith
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	Filed herewith
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	Filed herewith
104	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibits 101)	Filed herewith

* Management contract or compensatory plan or arrangement.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

ACCELERATE DIAGNOSTICS, INC.

March 1, 2021

By: /s/ Jack Phillips
Jack Phillips
President and Chief Executive Officer

Power of Attorney

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Steve Reichling, as his attorney-in-fact, with the power of substitution, for him in any and all capacities, to sign any amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that said attorney-in-fact, or his substitute or substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the registrant and in the capacities and on the date indicated.

Signature	Title	Date
/s/ Jack Phillips Jack Phillips	President, Chief Executive Officer and Director (Principal Executive Officer)	March 1, 2021
/s/ Steve Reichling Steve Reichling	Corporate Secretary, Chief Financial Officer and Chief Accounting Officer (Principal Financial and Accounting Officer)	March 1, 2021
/s/ John Patience John Patience	Chairman of the Board of Directors	March 1, 2021
/s/ Jack Schuler Jack Schuler	Director	March 1, 2021
/s/ Matthew W. Strobeck, Ph.D. Matthew W. Strobeck, Ph.D.	Director	March 1, 2021
/s/ Frank ten Brink Frank ten Brink	Director	March 1, 2021
/s/ Mark Miller Mark Miller	Director	March 1, 2021
/s/ Charles Watts, M.D. Charles Watts	Director	March 1, 2021
/s/ Tom Brown Tom Brown	Director	March 1, 2021
/s/ Roland D Diggelmann Roland D Diggelmann	Director	March 1, 2021
/s/ Louise Francesconi Louise Francesconi	Director	March 1, 2021

EXHIBIT 21

ACCELERATE DIAGNOSTICS, INC.
LIST OF SUBSIDIARIES

Legal Entity	Jurisdiction/Domicile
Accelerate Diagnostics UK Limited	England
Accelerate Diagnostics S.L.	Spain
Accelerate Diagnostics GmbH	Germany
Accelerate Diagnostics SARL	France
Accelerate Diagnostics S.r.l	Italy
Accelerate Diagnostics B.V.	Netherlands
AX Diagnostics C.V.	Netherlands
Accelerate Diagnostics Holdings, LLC	United States
Accelerate Diagnostics RUS Limited Liability Company	Russia

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-3 No. 333-252470) of Accelerate Diagnostics, Inc.,

(2) Registration Statement (Form S-8 No. 333-187439) pertaining to the 2012 Omnibus Equity Incentive Plan of Accelerate Diagnostics, Inc.,

(3) Registration Statement (Form S-8 No. 333-199992) pertaining to the 2012 Omnibus Equity Incentive Plan of Accelerate Diagnostics, Inc.,

(4) Registration Statement (Form S-8 No. 333-213072) pertaining to the 2016 Employee Stock Purchase Plan of Accelerate Diagnostics, Inc.,

(5) Registration Statement (Form S-8 No. 333-225585) pertaining to the 2012 Omnibus Equity Incentive Plan of Accelerate Diagnostics, Inc.,

(6) Registration Statement (Form S-8 No. 333-233185) pertaining to the 2012 Omnibus Equity Incentive Plan of Accelerate Diagnostics, Inc., and

(7) Registration Statement (Form S-8 No. 333-239052) pertaining to the 2012 Omnibus Equity Incentive Plan of Accelerate Diagnostics, Inc.

of our report dated March 1, 2021, with respect to the consolidated financial statements of Accelerate Diagnostics, Inc., included in this Annual Report (Form 10-K) for the year ended December 31, 2020.

/s/ Ernst & Young LLP

Phoenix, Arizona
March 1, 2021

EXHIBIT 31.1

CERTIFICATION PURSUANT TO
RULE 13a-14 OF THE SECURITIES EXCHANGE ACT OF 1934
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jack Phillips, certify that:

1. I have reviewed this Annual Report on Form 10-K of Accelerate Diagnostics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 1, 2021

/s/ Jack Phillips

Jack Phillips
President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION PURSUANT TO
RULE 13a-14 OF THE SECURITIES EXCHANGE ACT OF 1934
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Steve Reichling, certify that:

1. I have reviewed this Annual Report on Form 10-K of Accelerate Diagnostics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 1, 2021

/s/ Steve Reichling

Steve Reichling
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Each of the undersigned officers of Accelerate Diagnostics, Inc. (the "Company") hereby certifies that, to his knowledge, the Company's Annual Report on Form 10-K for the period ended December 31, 2020 to which this certification is attached (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 1, 2021

/s/ Jack Phillips

Jack Phillips
President and Chief Executive Officer
(Principal Executive Officer)

March 1, 2021

/s/ Steve Reichling

Steve Reichling
Chief Financial Officer
(Principal Financial and Accounting Officer)