**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, 2022

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 (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).
☑ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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. ☐

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

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

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

The aggregate market value of the shares of the registrant’s common stock held by non-affiliates on June 30, 2022, the last day of the registrant’s most recently completed second fiscal quarter, was approximately $53.0 million based on the closing price quoted on The Nasdaq Capital Market.

At March 28, 2023, 99,628,245 shares of common stock were outstanding, net of treasury shares.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the definitive proxy statement relating to the registrant’s 2023 Annual Meeting of Stockholders are incorporated by reference in Part III of this Form 10-K.

**TABLE OF CONTENTS**

## 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.

## Forward-Looking Statements

This Annual Report on Form 10-K (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,” “believe,” “anticipate,” “estimate,” or “continue,” or variations thereon or comparable terminology, include but are not limited to, statements about our future development plans and growth strategy, including plans and objectives relating to the future operations, products and performance of our, projections as to when certain key business milestones may be achieved; the potential of our products or technology; projections of future demand for our products; the growth of the market in which the Company operates; our estimates as to the size of our market opportunity and potential pricing, our competitive position and estimates of time reduction to results; our continued investment in new product development to both enhance our existing products and bring new ones to market; our expectations regarding research and development expenditures; the anticipated impacts from the COVID-19 pandemic on the Company, including to its business, results of operations, cash flows and financial position, as well as its future responses to the COVID-19 pandemic; and the Company’s expectations relating to current supply chain impacts and inflationary pressures, including our belief that we currently have sufficient inventory of Accelerate Pheno® system instruments to limit the impact of cost increases on such devices; our expectations regarding our commercial partnership with Becton, Dickinson and Company (“BD”), including anticipated benefits from such collaboration; our expectations and plans relating to regulatory approvals, including with respect to the U.S. Food and Drug Administration (“FDA”) and 510(k) clearance for our Accelerate Arc Products (as defined in the this Form 10-K); our plans to continue marketing and distributing the Accelerate Arc Products in Europe pursuant to its existing CE In Vitro Diagnostic Regulation (IVDR) registration; and our liquidity and capital requirements, including, without limitation, as to our ability to continue as a going concern, our belief that we do not currently have adequate financial resources to pay our outstanding debt obligation under our 2.50% Senior Convertible Notes due 2023 (the “Notes”) and to fund our forecasted operating costs for at least twelve months from the filing of this Form 10-K, and our belief that it will be necessary for us to secure additional funds to continue our existing business operations and to fund our obligations. 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.

Future events and actual results could differ materially from those set forth in, contemplated or suggested by, or underlying the forward-looking statements. There can be no assurances that results described in forward-looking statements will be achieved, and actual results could differ materially from those suggested by the forward-looking statements. The forward-looking statements included herein are based on current expectations that involve a number of risks and uncertainties, including the duration and severity of the ongoing COVID-19 pandemic, including any new variants that may become predominant; government and other third-party responses to it and the consequences for the global economy and the businesses of our suppliers and customers; such as the possibility of customer demand fluctuations, supply chain constraints and inflationary pressures and its ultimate effect on the Company’s business, results of operations, cash flows and financial position, as well as our ability (or inability) to execute on its plans to respond to the COVID-19 pandemic; and difficulties in resolving our continuing financial condition and ability to obtain additional capital to meet our financial obligations, including, without limitation, difficulties in obtaining adequate capital resources to fund our operations and address our debt obligations, including under the Notes. Other important factors that could cause the Company’s actual results to differ materially from those in its forward-looking statements include those discussed in the section entitled “Risk Factors” in this Form 10-K and in our subsequent filings with the U.S. Securities and Exchange Commission (the “SEC”). These forward-looking statements are also based on assumptions, including but not limited to, we will be successful in obtaining marketing authorization for our products from the FDA and other regulatory agencies and governing bodies; we will be successful in the commercialization of its products, the Company will obtain sufficient capital to commercialize its products and continue development of complementary products that the Company will be able to protect its intellectual property, our ability to respond to technological change, the Company will accurately anticipate market demand for our products and that there will be no material adverse change in our operations or business and general market and industry conditions. 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 we believe 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. Any forward-looking statements made by us in this Form 10-K speak only as of the date on which they are made. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

## Risk Factors Summary

We are subject to a variety of risks and uncertainties, including risks related to our financial condition, liquidity and indebtedness; risks related to our business and strategy; risks related to our intellectual property; risks related to our research and development activities; risks related to government regulation; risks related to our common stock; risks related to our convertible senior notes; 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:

- Our financial condition, including our substantial indebtedness, raises substantial doubt regarding our ability to continue as a going concern.
- We are in default of payment obligations under the terms of our Notes, which matured on March 15, 2023 and became due and payable.
- We may seek the protection of the United States Bankruptcy Court (the “Bankruptcy Court”), which may harm our business, adversely affect our ability to retain key personnel, and result in a significant loss of value for our stockholders.
- We have limited revenues from our products and no assurance of future revenues.
- We have a history of losses and expect to continue to incur losses in the future, and 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, the Accelerate Arc system and future products.
- We have entered into a sales and marketing agreement with BD and will substantially depend on BD for the successful commercialization of our products.
- Our future product candidates have not obtained marketing authorization from the FDA, and they may never obtain such marketing authorization or other regulatory clearance.
- 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.
- The failure of our current 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 had, and could continue to adversely impact our commercial operations and also expose our business to other risks.
- 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 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 commercial products 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 have and may continue to trade below $1 per share which could adversely affect our ability to continue to meet the listing requirements of Nasdaq.
- We are likely to require additional capital in the future, and you may incur dilution to your stock holdings.

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, is indicated as an aid, in conjunction with other clinical and laboratory findings, in the diagnosis of bacteremia and fungemia, both life-threatening conditions with high morbidity and mortality risk. The device provides identification (“ID”) results followed by antibiotic susceptibility testing (“AST”) for certain pathogenic bacteria commonly associated with or causing bacteremia. This test kit utilizes genotypic technology to identify infectious pathogens and phenotypic technology to conduct AST, which determines whether live bacterial cells are resistant or susceptible to a particular antimicrobial. This information can be used by physicians 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 FDA granted our de novo classification 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 our “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 July 2021, we launched our second test for use on the Accelerate Pheno system, the PhenoTest BC Kit, AST configuration. This test kit runs antibiotic susceptibility testing following the input of an ID result from another system or methodology. We believe this new AST only configuration may be attractive to prospective customers who already have a rapid ID system but still need fast susceptibility results to support getting patients on an optimal antibiotic therapy as soon as possible.

In March and May 2022, we announced the launch and commercialization of the Accelerate Arc™ system and BC Kit (“Accelerate Arc Products”). This instrument and associated one-time-use test kit automates the clean-up and concentration of microbial cells from positive blood culture samples. In May 2022, we announced IVD registration of the Accelerate Arc system and BC Kit with the FDA as a Class I device exempt from FDA clearance requirements, and in June 2022 we received CE In Vitro Diagnostic Regulation (IVDR) registration for use in Europe.

On October 21, 2022, the Company announced it has been in recent discussions with the FDA regarding its Accelerate Arc Products. Pursuant to such discussions, the FDA has challenged the Company’s commercialization of the Accelerate Arc Products in the United States as a Class I device exempt from 510(k) clearance requirements. The Company is in active dialogue with the FDA to determine the appropriate regulatory pathway. While these discussions are ongoing, the Company has put on hold in the United States its sales and marketing efforts of the Accelerate Arc Products. The Company has continued to market the Accelerate Arc Products in Europe pursuant to its existing CE IVDR registration.

In August 2022, we entered into a sales and marketing agreement (the “Sales and Marketing Agreement”) with BD. We entered into the Sales and Marketing Agreement in order to leverage BD’s expansive global sales team, benefit from natural synergies between BD’s existing products and those from us, and reduce our sales and marketing expenses. See “Sales, Marketing, and Distribution” for additional information.

We remain focused on expanding our product portfolio with solutions that reduce the time to result, improve workflow, enhance accuracy and positively impact patient care. We continue to invest in new product development to both enhance our existing products and bring new ones to market.

**History**

We were incorporated in 1982 in Colorado under the name Sage Resources Corp., and through a series of subsequent transactions, we became Accelerate Diagnostics, Inc., a Delaware corporation, in December 2012. 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 a publicly marketed common stock offering that raised 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 and September 2021, the Company executed certain securities purchase agreements in connection with certain private placement offerings of the Company’s equity securities that provided the Company aggregate gross proceeds of $32.0 million in 2021.
- In May 2021, the Company established a $50 million “at-the-market” equity offering program (the “ATM Program”) under which the Company raised gross proceeds of $10.9 million in 2021.
- In March 2022, the Company entered into a securities purchase agreement which is anticipated to close in April 2023, for gross proceeds of $4.0 million.
- In August 2022, the Company completed a publicly marketed common stock offering that raised additional gross proceeds of $35.0 million.

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 and systems, including the development of the Accelerate Arc BC kit, as well as 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. 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 is used to determine 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 AST is particularly important in improving sepsis patient outcomes. Sepsis is responsible for approximately 270,000 deaths in the United States 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, we believe that the Accelerate Pheno system can play a significant role in allowing physicians to provide timely, effective therapy to sepsis patients.

**Market Opportunity**

Across North America, Europe and Asia Pacific geographies, we estimate there are over 300 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, has the potential to address the over four million blood culture samples tested each year in North America and Europe, if authorized by the FDA for expanded indications to cover all such ID and AST testing.

In addition, there is a substantial existing installed base of legacy automated AST systems. Principally, these systems are the bioMerieux Vitek 2®, Danaher Corporation (“Danaher”) Microscan® system, and Becton, Dickinson and Company (“BD”) Phoenix. These competitors’ AST products are developed to 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 potentially complement and potentially replace existing laboratory workflows with the Accelerate Pheno system and our next generation rapid testing solutions.

Certain government initiatives are complementary to the Accelerate Pheno system. For example, effective October 1, 2008, hospitals no longer receive additional payment for cases in which a hospital-acquired condition, as determined by the Centers for Medicare and Medicaid Services, the federal agency responsible for administering the Medicare program (“CMS”), occurred but was not present on admission, thereby incentivizing providers to enhance infection-management protocols. Similarly, effective October 1, 2012, CMS implemented the Hospital Readmissions Reduction Program, which reduces payments to hospitals for excess readmissions. 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 identified 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. In October 2020, the Federal Task Force on Combating Antibiotic-Resistant Bacteria released a new National Action Plan for 2020-2025, which establishes new objectives and targets. This plan prioritizes infection prevention and control to slow the spread of resistant infections and reduce the need for antibiotic use. This plan also focuses on collecting and using data to better understand where resistance is occurring, support the development of new diagnostics and treatment options, and advance international coordination.

**Products**

The Accelerate Pheno system is the Company's first *in vitro* diagnostic platform and is intended for the ID and AST 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 ID 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. ID 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 ID 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 ID and AST testing.
- *ID 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 ID 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 ID 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 ID 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. None of the information contained on our website is part of this report or incorporated in this report by reference.

Current product development programs include the development of the Accelerate Arc system, an instrument and consumable aimed to improve the workflow and reduce the time to result associated with matrix-assisted laser desorption/ionization (MALDI) ID systems, and the development of our next generation rapid AST system, which is intended to have lower costs, higher throughput, and capable of testing a broader set of sample types compared to the current Accelerate Pheno system.

**Research and Development**

We plan 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, we have focused on product improvements and the development of additional test kits. This includes the PhenoTest BC kit, AST configuration launched in 2021 which provides our customers the ability to use the input of an ID result from another system or methodology but still benefit from rapid AST results using the Accelerate Pheno system. Our 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.

Our research activity also includes the evaluation and development of (i) technologies to reduce the cost and increase the throughput of AST, (ii) improved AST technologies, (iii) improved ID technologies, and (iv) other platform technologies potentially useful in addressing other parts of the infectious disease laboratory testing workflow. Two such programs are the development of the Accelerate Arc system, which is a sample preparation device for rapid MALDI identification results, including the development of the associated Accelerate Arc BC kit, and the development of our next generation AST platform discussed above.

The Company's research and development expenses for the years ended December 31, 2022, 2021 and 2020, 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 applied for patents related to our next generation AST system and methods, and is, thus, critical 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 ID and antibiotic susceptibility from tests on individual immobilized bacterial cells. As of December 31, 2022, we had 52 issued patents worldwide, including 22 patents issued in the United States and 30 issued outside the United States. Our patents are set to expire on various dates in 2022 through 2035. Additionally, as of December 31, 2022, we had 5 patent applications pending worldwide, including eight U.S. applications and four applications outside the United States. The Company believes that its patent suite would make it difficult for any other company to conduct rapid AST 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 ID and AST. On August 15, 2022, the Company entered into the Sales and Marketing Agreement with BD pursuant to which BD will perform certain sales, tactical marketing, technical service call forwarding, order preparation, research and development support and/or regulatory activities on the Company’s behalf as its worldwide exclusive sales agent for certain of the Company’s products, including the Accelerate Pheno and Accelerate Arc Products. An existing team of Accelerate sales and service specialists will partner with BD personnel in the United States and select international countries to market, sell, and support the Accelerate Pheno system and Accelerate Arc Products.

The Sales and Marketing Agreement also grants to BD certain other rights to certain of the Company's future products, including the Company's next generation rapid AST system. BD has an exclusive right of first negotiation to be the exclusive sales agent to commercialize the Company's next generation rapid AST system, which will be triggered if the Company proposes to license its next generation rapid AST system or sell its rights to such system, or if the Company and BD mutually agree that the related clinical data is ready to be submitted to the FDA for 510(k) clearance. In accordance with the BD Agreement, the terms of such subsequent agreement would have to be negotiated by the parties.

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, 2022, 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 BD, bioMerieux, 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 ID products which provide a component of the clinical diagnostics solution but lack rapid AST functionality.

Potential competitors for rapid AST have made announcements at various trade shows and in press releases, including - but not limited to; Quantamatrix, Q-Linea, Specific Diagnostics, Lifescale, and Gradientech. While we do not have visibility into all of these companies' respective stages of development, none have yet obtained FDA marketing authorization or commercialized their products in the United States. In 2022, bioMerieux acquired Specific Diagnostics for over $400 million. We believe this acquisition reflects both the industry leader's recognition of the importance of rapid AST testing and enhanced competition.

In addition to existing and emerging companies, there are manual methods which could be validated by individual hospitals to deliver rapid ID 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 ID 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 ID 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 ID 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 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 and the Vitek MS from bioMerieux. Bruker Corporation has agreements with a number of companies for distribution, including BD, TREK, and Siemens. 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.

**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 Regulations (“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.

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 sometimes 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, including, but not limited to the Health Insurance Portability and Accountability Act (“HIPAA”) Privacy Rule (45 CFR Part 160 and Subparts A and E of Part 164) and the Security Rule (45 CFR Part 160 and Subparts A and C of Part 164). 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;
- 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 27 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 for the Accelerate Pheno system and the Accelerate PhenoTest BC Kit.

***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 (including state and federal Stark law), 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 U.S. federal Physician Self-Referral Law, commonly referred to as the Stark law, prohibits physicians from referring patients to receive “designated health services” payable by Medicare or Medicaid from entities with which the physician or an immediate family member has a financial relationship, unless an exception applies. Financial relationships include both ownership/investment interests and compensation arrangements. The Stark law is a strict liability statute, meaning that proof of specific intent to violate the law is not required. The Stark law prohibits the submission, or causing the submission, of claims in violation of the law’s restrictions on referrals. Penalties for physicians who violate the Stark law include fines as well as exclusion from participation in Federal health care programs.

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 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***

In most cases, 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, ID/AST configuration. While the majority of testing remains with the hospital inpatient setting, these reimbursement codes provide opportunities to offset a portion of the cost of their testing for outpatient and observation bed patients.

***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 arrangements are included in Item 8, Note 16, Leases to the audited consolidated financial statements included elsewhere in this report.

We assemble instruments and formulate, fill, and assemble the kits in our facilities in Tucson, Arizona. Our instruments and kits require 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 our products.

**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 and also review relevant sources for compliance with conflict minerals requirements. 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. However, we are currently experiencing unprecedented cost increases from many of our suppliers, primarily as a result of the ongoing COVID-19 pandemic, labor and supply disruptions and increased inflation. The areas of cost increases include raw materials, components, and value-add supplier labor. We believe that we currently have sufficient inventory of Accelerate Pheno system instruments to limit the impact of cost increases on such devices. See *"Risk Factors—Risks Related to Our Business and Strategy-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, 2022, we had approximately 179 full-time employees worldwide, with approximately 166 employees in the United States and approximately 13 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 amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act. 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 Financial Condition, Liquidity and Indebtedness**

***Our financial condition, including our substantial indebtedness, raises substantial doubt regarding our ability to continue as a going concern.***

Since inception, we have not achieved profitable operations or positive cash flows from operations. Our accumulated deficit totaled $607.2 million as of December 31, 2022. During the year ended December 31, 2022, we had a net loss of $62.5 million and negative cash flows from operations of $48.7 million. As of December 31, 2022, we had $45.6 million in cash and cash equivalents. Additionally, we have a substantial amount of indebtedness primarily comprised of $56.6 million aggregate principal amount of Notes and a secured promissory note in an aggregate principal amount of $34.9 million (the "Secured Note").

As a result of our financial condition, we have determined that, as of the date of this Form 10-K filing, there is substantial doubt about our ability to continue as a going concern, as we do not currently have adequate financial resources to pay our outstanding debt obligation under the Notes and to fund our forecasted operating costs for at least twelve months from the filing of this Form 10-K. The report of our independent registered public accountant on our financial statements as of and for the years ended December 31, 2022 and 2021 also includes explanatory language describing the existence of substantial doubt about our ability to continue as a going concern. The presence of this going concern explanatory language could adversely affect our ability to raise additional debt or equity financing, as well as to further develop and market our products, all of which could have a material adverse impact on our business, results of operations and financial condition. See Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations - Capital Resources and Liquidity" of this Form 10-K and Note 1, Organization and Nature of Business; Basis of Presentation; Principles of Consolidation for additional information.

Management currently believes that it will be necessary for us to secure additional funds to continue our existing business operations and to fund our obligations. We may choose to raise additional funds during 2023 through a variety of equity and/or debt financing arrangements; however, there are currently no commitments in place for future financing and there can be no assurance that we will be able to obtain funds on commercially acceptable terms, if at all.

***We are in default of payment obligations under the terms of our Notes, which matured on March 15, 2023 and became due and payable.***

The Notes matured on March 15, 2023 and became due and payable. On March 9, 2023, the Company entered into a Forbearance Agreement (the “Forbearance Agreement”), which became effective on March 13, 2023, with the holders of approximately 85% of the Company’s outstanding Notes (collectively, the “Ad Hoc Noteholder Group”) and, the trustee for the Notes (the “Trustee”). Other holders of the Notes may become a party to the Forbearance Agreement by executing and delivering to the Company a joinder to the Forbearance Agreement. Pursuant to the Forbearance Agreement, the members of the Ad Hoc Noteholder Group have agreed, and have directed the Trustee, to forbear from exercising their rights and remedies under the indenture governing the Notes (the “Indenture”) in connection with certain events of default under the Indenture, including, but not limited to, the failure to timely pay in full the principal of any Note when due and payable on March 15, 2023 and the failure to pay any interest on any Note when due and payable. The Forbearance Agreement is effective for the period commencing on March 13, 2023 and ending on March 29, 2023. On March 29, 2023, the Company and the Ad Hoc Noteholder Group agreed to further extend the forbearance period under the Forbearance Agreement to April 5, 2023. See Part II, Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Capital Resources and Liquidity - Convertible Notes” of this Form 10-K for additional information regarding the Forbearance Agreement.

As discussed in this Form 10-K, there is substantial doubt about our ability to continue as a going concern, as we do not currently have adequate financial resources to pay our outstanding debt obligations under the Notes and to fund our forecasted operating costs for at least twelve months from the filing of this Form 10-K. While the Company continues to explore additional funding, there can be no assurance the necessary financing will be available on terms acceptable to the Company, or at all. If the Company raises funds by issuing equity securities, dilution to stockholders may result. Any equity securities issued may also provide for rights, preferences or privileges senior to those of holders of common stock. If the Company raises funds by issuing debt securities, these debt securities would have rights, preferences and privileges senior to those of preferred and common stockholders. The terms of debt securities or borrowings could impose significant restrictions on our operations. Similarly, there can be no assurance that market conditions and refinancing alternatives will be sufficient to settle or refinance the Notes. The capital markets have in the past, and may in the future, experience periods of upheaval that could impact the availability and cost of equity and debt financing. Financial market instability or disruptions to the banking system due to bank failures, particularly in light of the recent events that have occurred with respect to Silicon Valley Bank and Signature Bank, may also adversely affect our ability to enter into financing arrangements and facilities. In addition, recent and anticipated future increases in federal fund rates set by the Federal Reserve, which serve as benchmark rates on borrowing, and other general economic conditions may impact the cost of debt financing or refinancing existing debt.

Although we are actively considering all available strategic alternatives to maximize value, if we are unable to obtain adequate capital resources to fund operations and address our outstanding debt obligations under the Notes, we would not be able to continue to operate our business pursuant to our current plans. In particular, if we are unable to address our outstanding debt obligations under the Notes, or otherwise obtain an extension under the Forbearance Agreement, prior to the expiration of the forbearance period specified in the Forbearance Agreement, then the Trustee may exercise its rights and remedies under the Indenture and declare the principal of, and all accrued and unpaid interest on, the Notes to be due and payable immediately. This may require us to, among other things, materially modify our operations to reduce spending; sell assets or operations; delay the implementation of, or revising certain aspects of, our business strategy; file a voluntary petition for relief under Chapter 11 of the United States Bankruptcy Code in order to implement a restructuring; or discontinue our operations entirely. Additionally, we cannot provide any assurance that we will be able to obtain any extensions under the Forbearance Agreement.

***We may seek the protection of the Bankruptcy Court, which may harm our business, adversely affect our ability to retain key personnel, and result in a significant loss of value for our stockholders.***

We have engaged financial and legal advisors to assist us in, among other things, analyzing various strategic alternatives to address our liquidity and capital structure. However, there can be no assurance that the strategic review will be successful, and a filing under Chapter 11 may be unavoidable. Seeking Bankruptcy Court protection could have a material adverse effect on our business, financial condition, results of operations and liquidity. So long as the process related to a Chapter 11 proceeding continues, our senior management would be required to spend a significant amount of time and effort dealing with the reorganization instead of focusing exclusively on our business operations. Bankruptcy Court protection also might make it more difficult to retain management and other key personnel necessary to the success and growth of our business. The longer a Chapter 11 proceeding continues, the more likely it is that our customers would lose confidence in our ability to reorganize our businesses successfully and would seek to establish alternative commercial relationships. Additionally, all of our indebtedness is senior to the existing common stock in our capital structure. As a result, if we seek relief under Chapter 11, existing shares of our common stock may be canceled, with a very limited recovery or no recovery for holders of our common stock. Moreover, if we execute a restructuring outside of Chapter 11, such transaction could result in substantial dilution to existing holders of our common stock. Therefore, trading in our securities is highly speculative and poses substantial risks.

**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, 2022, 2021 and 2020, we experienced losses from operations. Our future revenues are dependent on the successful commercialization of our products 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 our current and future products, we will likely continue to experience losses from operations and negative cash flow.

***We have a history of losses and expect to continue to incur losses in the future, and we cannot be certain that we will achieve or sustain profitability.***

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 currently commercializing the Accelerate Pheno system and the Accelerate Arc system outside of the United States, we have incurred significant costs in connection with the development and commercialization of our technology. There is no assurance that we will achieve sufficient revenues to offset anticipated operating costs, and we expect to continue to incur losses in the future. Our ability to achieve or sustain profitability depends on numerous factors including the market acceptance of our products, product quality, future product development and our market penetration and margins. If we are unsuccessful in generating sufficient revenues from our products, 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, the Accelerate Arc system and future products.***

Our principal business strategy involves the successful commercialization of the Accelerate Pheno system and further development and commercialization of associated test kits, the Accelerate Arc module and BC kit and future products, including our next generation AST instrument platform. 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 PhenoTest BC Kit, AST configuration, the Accelerate Arc system, including the Accelerate Arc BC kit, and future products.

Any failure to do so could lead to an impairment of certain of our intellectual property, inventory, property and equipment, and may result in our ceasing operations. We may also 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, the Accelerate Arc system or developing other products.

Additionally, our efforts to educate hospitals on the benefits of our products require significant resources, and we may experience reluctance from hospitals to purchase our products. If we fail to successfully commercialize our products, 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 our products may not expand as we anticipate or may even decline based on numerous factors, including the introduction of superior alternative product or other factors beyond our control. For example, the market for our products was adversely affected by the COVID-19 pandemic. See "*Risks Related to Our Business and Strategy—The COVID-19 pandemic has had, and may continue to have, a significant adverse impact on our commercial operations and also exposes our business to other risks*" for additional information. If we are unable to adequately expand the market for our products, this failure would have a material adverse effect on our ability to execute on our business plan and ability to generate revenue.

***We have entered into the Sales and Marketing Agreement with BD and will substantially depend on BD for the successful commercialization of our products.***

As part of our collaboration with BD pursuant to the Sales and Marketing Agreement, BD will perform certain sales, tactical marketing, technical service call forwarding, order preparation, research and development support and/or regulatory activities on our behalf as our exclusive sales agent for certain of our products, including the Accelerate Pheno system, Accelerate Arc system and related BC Kits. The successful commercialization of our products, including our ability to generate revenue from our arrangement with BD, will depend on BD's ability to successfully perform the responsibilities assigned to it pursuant to the Sales and Marketing Agreement. While BD is largely responsible for the speed and scope of sales and marketing efforts, we cannot assure you that BD will dedicate the resources necessary to successfully perform its responsibilities pursuant to the Sales and Marketing Agreement, and our ability to cause BD to increase the speed and scope of its efforts may be limited. In addition, sales and marketing efforts could be negatively impacted by the delay or failure by us to obtain additional supportive clinical trial data for our products. We cannot predict the success of our collaboration with BD, and there can be no assurance that the efforts of BD will meet our expectations or result in any significant product sales or cost savings within the anticipated time frame or at all.

In the event that BD fails to perform under the Sales and Marketing Agreement, or if the Sales and Marketing Agreement is terminated, this could delay our product commercialization efforts, which would materially and adversely affect our business, financial condition, results of operations and cash flows. The termination of the Sales and Marketing Agreement could also require us to revise our commercialization and business strategy going forward and divert management attention and resources. In addition, the termination of the Sales and Marketing Agreement could materially impact our ability to enter into additional collaboration agreements with new partners on favorable terms, if at all.

***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, including our next generation Pheno system. 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. For example, on October 21, 2022, the Company filed a Current Report on Form 8-K announcing it has been in recent discussions with the FDA regarding its Accelerate Arc Products. Pursuant to such discussions, the FDA has challenged the Company's commercialization of the Accelerate Arc Products in the United States as a Class I device exempt from 510(k) clearance requirements. The Company is in active dialogue with the FDA to determine the appropriate regulatory pathway. While these discussions are ongoing, the Company has put on hold in the United States its sales and marketing efforts of the Accelerate Arc Products. 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.

***The failure of our current 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 have also experienced customer returns of our Accelerate Pheno system, some of which related to quality issues. 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, and our ability to continue as a going concern.***

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 Accelerate Arc system, and development costs for new products;
- 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, as well as in connection with the development of new products;
- 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, the Accelerate Arc 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, the Accelerate Arc system and future products. 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 products also include software and data components. 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. Attacks on our information technology systems or products 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. There also can be no assurance that our cyber insurance will be sufficient to cover the total loss or damage caused by a cyber-attack. In addition, the costs of responding to and recovering from such incidents may not be covered by insurance.

***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. Like many companies, we have experienced an increased level of employee attrition, which is largely attributable to dislocations caused by the COVID-19 pandemic. We have various programs designed to improve employee retention, but there is no assurance that we will not continue to experience elevated employee attrition levels, which could negatively impact our ability to develop, implement, support and sell our products.

***We may not successfully manage the transitions associated with certain of our executive officers, which could have an adverse impact on us.***

On March 9, 2023, Steve Reichling notified us of his decision to resign from his role as our Chief Financial Officer, effective March 31, 2023. In connection with Mr. Reichling's resignation, we appointed David Patience to serve as our Chief Financial Officer, effective April 1, 2023. Leadership transitions may be inherently difficult to manage, and an inadequate transition to our new Chief Financial Officer may cause disruption within the Company. In addition, our financial performance and ability to meet operational goals and strategic plans may be adversely impacted. This may also impact our ability to retain and hire other key members of management.

***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, the Accelerate Arc 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, economic and social instability, including instability resulting from the ongoing war between Russia and Ukraine, as well as continued and any new sanctions against Russia;
- 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 particular, further escalation or expansion of the ongoing war between Russia and Ukraine could impact our European business operations, including disrupting our sales channels and marketing activities, as well as negatively impacting the demand for our products.

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.

***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. Any estimates and forecasts in this Form 10-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. Similarly, the recoverability of the book value of inventory could be impacted by changes in growth expectations and require a reduction in their carrying value to the lower of cost or market.

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.

***Providing instrument systems to our customers through reagent rental agreements may harm our liquidity.***

Many of our systems are provided to customers via “reagent rental” agreements, under which customers are generally afforded the right to use the instrument in return for a commitment to purchase minimum quantities of reagents and test kits over a period of time. Accordingly, we must either incur the expense of manufacturing instruments well in advance of receiving sufficient revenues from test cartridges to recover our expenses or obtain third party financing sources for the purchase of our instrument. The amount of capital required to provide instrument systems to customers depends on the number of systems placed. Our ability to generate capital to cover these costs depends on the amount of our revenues from sales of reagents and test cartridges sold through our reagent rental agreements. We do not currently sell enough reagents and test cartridges to recover all of our fixed expenses, and therefore we currently have a net loss. If we cannot sell a sufficient number of reagents and test cartridges to offset our fixed expenses, our liquidity will continue to be adversely affected.

***If we fail to estimate customer demand properly, our financial results could be harmed.***

Our products are manufactured based on estimates of customers’ future demand and our manufacturing lead times are very long. This could lead to a significant mismatch between supply and demand, giving rise to product shortages or excess inventory, and make our demand forecast more uncertain. In order to have shorter shipment lead times for our customers, we may and have built up inventory for anticipated growth which has not occurred, or may build up inventory to serve what we believe is pent-up demand. In periods with limited available capacity we may and have placed inventory orders significantly in advance of our normal lead times, which could negatively impact our financial results. Additionally, consumer behavior during the COVID-19 pandemic, has made it more difficult for us to estimate future demand, and these challenges may be more pronounced in the future. In estimating demand, we make various assumptions, any of which may and have been incorrect. If we are unable to accurately anticipate demand for our products, our business and financial results could be adversely impacted. Situations that may result in excess or obsolete inventory include:

- changes in business and economic conditions, including downturns in our target markets and/or overall economy;
- changes in consumer confidence caused by changes in market conditions, including changes in the credit market;
- a sudden and significant decrease in demand for our products;
- a higher incidence of inventory obsolescence because of rapidly changing technology or customer requirements;
- our introduction of new products resulting in lower demand for older products;
- less demand than expected for newly-introduced products; or
- increased competition, including competitive pricing actions.

The cancellation or deferral of customer purchase orders could result in our holding excess inventory, which could adversely affect our gross margins. In addition, because we often sell a substantial portion of our products in the last month of each quarter, we may not be able to reduce our inventory purchases in a timely manner in response to customer cancellations or deferrals. We could be required to write-down our inventory to the lower of cost or net realizable value, and we could experience a reduction in average selling prices if we incorrectly forecast product demand, any of which could harm our financial results.

Conversely, if we underestimate our customers’ demand for our products, our partners may not have adequate lead-time or capacity to increase production and we may not be able to obtain sufficient inventory to fill customers’ orders on a timely basis. We may also face supply constraints caused by natural disasters or other factors as discussed in this “Risk Factors” section. In such cases, even if we are able to increase production levels to meet customer demand, we may not be able to do so in a cost-effective or timely manner. If we fail to fulfill our customers’ orders on a timely basis, or at all, our customer relationships could be damaged, we could lose revenue and market share and our reputation could be damaged.

***The COVID-19 pandemic has had, and may 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, and spread globally. In March 2020, the World Health Organization declared COVID-19 a global pandemic. The COVID-19 outbreak 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. New cases and hospitalizations have risen and fallen throughout the course of this pandemic. More recently, the emergence and spread of new variants of COVID-19 that are significantly more contagious than previous strains initially led many government authorities and businesses to reimplement prior restrictions in an effort to lessen the spread of COVID-19 and its variants. While most of these restrictions have been lifted, uncertainty remains as to whether additional restrictions may be initiated or again reimplemented in response to surges in COVID-19 cases. The lingering impact of the COVID pandemic continues to create significant volatility throughout the global economy, including supply chain constraints, labor supply issues and higher inflation. Accordingly, it is unclear at this point the full impact COVID-19 and its variants will have on the global economy and on our Company.

The COVID-19 pandemic, containment measures, and downstream impacts to hospital staffing and financial stability have caused, and are continuing to cause, business slowdowns in affected areas, both regionally and worldwide, as well as disruptions to global supply chains and workforce participation. These effects have significantly impacted our business and results of operations, starting in the first quarter of 2020 and continuing through 2022, albeit to a lesser degree. For example, we have experienced diminished access to our customers, including hospitals, which has severely limited our ability to sell and, to a lesser degree, implement previously contracted Accelerate Pheno systems. More recently, hospital turnover resulting from burnout and financial challenges driven by inflation and other factors have further diverted the attention of hospital decision makers. In addition, in certain months with high rates of COVID-19 hospitalization, our Accelerate PhenoTest BC Kit orders declined as many hospitals curtailed elective surgeries to respond to COVID-19. The emergence of COVID-19 variants, vaccine hesitancy and the prevalence of breakthrough cases of infection among fully vaccinated people adds additional uncertainty regarding our access to customers and prospects, demand for our products, and ability to implement our products. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations-COVID-19 and Supply Chain Impacts Update” in Part II, Item 7 of this Form 10-K for additional information.

In addition to the negative impact on new sales and implementations of the Accelerate Pheno system and demand for our consumable test kits, our business, operations, and workforce have been and may be further impacted in several ways, including, but not limited to, the following:

- delays in product development or reductions in manufacturing production as a result of inventory and supply chain shortages;
- increased supplier costs caused by ongoing shortages and inflation in materials used in our products;
- interruptions, availability or delays in global shipping to transport our products;
- regulatory approval delays due to regulators reviewing a large volume of COVID-19 related medical devices and drugs;
- delays in obtaining grants to assist our product development efforts because granting agencies are primarily focused on 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;
- negative impact on our workforce productivity, product development, and research and development due to difficulties resulting from our personnel working remotely;

- increased employee attrition caused by employees seeking permanent remote positions or other pandemic related reasons; 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, suppliers, business partners and others. 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.

The potential direct and indirect effects of COVID-19 also may impact many of our other risk factors discussed herein. 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 not limited to, the duration and spread of the pandemic and its severity; the emergence and severity of its variants, including the Omicron variant and its subvariants; the actions to contain the virus or treat its impact, such as the availability and efficacy of vaccines (particularly with respect to emerging strains of the virus) and potential hesitancy to use them; the financial impact of COVID-19 on hospitals, including to their budget priorities; hospital staffing issues; general economic factors, such as increased inflation; global supply chain constraints and the related increase in costs; labor supply issues; and how quickly and to what extent normal economic and operating conditions can resume.

***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.

For example, we are currently experiencing unprecedented cost increases from many of our suppliers, primarily as a result of labor and supply disruptions and increased inflation. The areas of cost increases include raw materials, components, and value-add supplier labor. We currently have sufficient inventory of Accelerate Pheno system instruments to limit the impact of cost increases on such devices. However, we are being impacted by cost increases to components and raw materials necessary for the production of our consumable test kits. Our kits require these components and raw materials, and many of our supply contracts permit the supplier to pass on certain inflation increases to us. Moreover, our ability to pass on cost increases to our consumable test kit customers is limited by long-term contractual price commitments. Prolonged elevated supply costs and further cost increases may further impact our cost to manufacture our Accelerate Pheno system instruments. The supply cost increases we are experiencing and may experience in the future may materially reduce our gross profit margins, thereby negatively impact our overall financial results.

The manufacturing operations for our products 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 identified a material weakness in our internal control over financial reporting, and if we are unable to remediate such material weakness, we may not be able to accurately or timely report our financial condition or results of operations.***

In connection with the audit of our consolidated financial statements for the year ended December 31, 2022, we identified a material weakness in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

The material weakness we identified prevented us from identifying a misclassification of the Notes on our condensed consolidated balance sheets in our interim financial statements as of and for the three months ended March 31, 2022, three and six months ended June 30, 2022 and three and nine months ended September 30, 2022. Our internal control structure did not have a control to review the evaluation of the classification of its outstanding debt instruments in accordance with applicable accounting guidance at each reporting period.

If we are unable to successfully remediate our existing or any future material weaknesses in our internal control over financial reporting, or identify any additional material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports and applicable listing requirements, investors may lose confidence in our financial reporting, and the share price of our common stock may decline as a result. In addition, we could become subject to investigations by Nasdaq, the SEC or other regulatory authorities, which could require additional financial and management resources. See “Controls and Procedures - Management’s Report on Internal Control over Financial Reporting” in Part II, Item 9A of this Form 10-K for further information on the material weakness identified and our remediation plans.

### 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 22 issued U.S. patents and five pending U.S. patent applications, including provisional and non-provisional filings. We also own 30 non-U.S. patents and have four 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.

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 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, including as a result of the COVID-19 pandemic, 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 our products 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.

***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 commercial products 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 into the Accelerate Pheno system, the Accelerate Arc system and a next generation Pheno system, 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, the Accelerate Arc 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 federal Stark law, which prohibits physicians from referring patients to receive “designated health services” payable by Medicare or Medicaid from entities with which the physician or an immediate family member has a financial relationship, unless an exception applies. Financial relationships include both ownership/investment interests and compensation arrangements.
- 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.
- HIPAA, 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 and 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. The Coronavirus Aid, Relief, and Economic Security (CARES) Act, signed into law in March 2020, included critical relief from sequestration cuts as it applies to Medicare payments, exempting Medicare from the effects of sequestration from May 1, 2020, through Dec. 31, 2020. The moratorium was extended until April 1, 2022. Cuts of 1% were imposed from April 1 through June 30, 2022. As of July 1, 2022, cuts of two percent were reimposed.

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 our products, 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. Additionally, CMS has created a number of waivers that impact the provision and reimbursement of healthcare services as a result of the COVID-19 Public Health Emergency ("PHE"). It is not clear to the extent these waivers will remain in effect once the PHE has ended. We cannot predict the impact that the extension or termination of these waivers may have on our business.

***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 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.

On October 21, 2022, the Company announced it has been in recent discussions with the FDA regarding its Accelerate Arc Products. Pursuant to such discussions, the FDA has clarified that the Company must obtain a 510(k) clearance in order to continue marketing and distributing the Accelerate Arc Products in the United States. The Company had been listing the Accelerate Arc Products as a Class I device exempt from 510(k) clearance requirements. Additionally, the FDA requested that the Company promptly take certain corrective actions, including, among other things, (i) discontinuing the U.S. marketing and distribution of the Accelerate Arc Products for positive blood culture processing and subsequent identification by mass spectrometry for diagnostic use; (ii) removing and/or correcting all U.S. promotional information within the Company's control (e.g., website, labeling, social media, sales associate information, or other promotional material) regarding the diagnostic use of the Accelerate Arc Products as Class I devices or as devices intended as positive blood culture processing devices for subsequent identification of microorganisms by mass spectrometry; and (iii) revising/removing the Company's registration and listing of the Accelerate Arc Products as Class I devices. The Company intends to continue to fully cooperate with the FDA, including promptly taking the corrective actions requested by the FDA. On October 21, 2022, the Company also submitted a pre-submission package to the FDA, which is intended to obtain FDA feedback regarding the Company's contemplated submission of an application for 510(k) clearance for the Accelerate Arc

Products. The Company cannot, however, give any assurances that FDA will be satisfied with the Company's actions taken in response to the matters raised by the FDA in its discussions. The Company also cannot give any assurances as to the timing of the FDA's response to the Company's pre-submission package or whether the Company will be successful in obtaining 510(k) clearance for the Accelerate Arc Products.

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 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 our products, 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. 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:

- difficulties in resolving our continuing financial condition and our ability to obtain additional capital to meet our financial obligations;
- low trading volume currently prevailing in the market for our shares;
- concentration of our stock with one individual large shareholder who could decide to materially reduce his position;
- the substantial current short interest in our stock;
- the duration and severity of the COVID-19 pandemic and its effects on our business, financial condition, results of operations and cash flows;
- adverse regulatory decisions, including failure to receive regulatory approvals for any of our product candidates;
- our success in commercializing our product candidates, if and when approved;
- the introduction of new products or product enhancements by us or others in our industry;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, capital commitments or restructurings;
- disputes or other developments with respect to our or others' intellectual property rights;
- product liability claims or other litigation;
- quarterly variations in our results of operations or those of others in our industry;
- sales of large blocks of our common stock, including sales by our executive officers and directors;
- changes in senior management or key personnel;
- changes in laws or regulations which adversely affect our industry or us;
- changes in earnings estimates or recommendations by securities analysts; and
- changes in general market, economic, and political conditions in the U.S., and global economies or financial markets, including those resulting from natural disasters, terrorist attacks, acts of war (including the ongoing war between Russia and Ukraine), other geopolitical uncertainties, public health concerns (including health epidemics or outbreaks of communicable diseases, such as the COVID-19 pandemic), and responses to such events.

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, 2022, the sale price for our common stock ranged from $0.51 to $5.15 per share, and during the year ended December 31, 2021, the sale price for our common stock ranged from $4.27 to $15.00 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.

In addition, in the past, following periods of volatility in the market price of a company's securities, securities class-action litigation has often been instituted against that company. Any lawsuit to which we are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms. Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our product offerings or business practices. Such litigation may also cause us to incur other substantial costs to defend such claims and divert management's attention and resources. Furthermore, negative public announcements of the results of hearings, motions or other interim proceedings or developments could have a negative effect on the market price of our common stock.

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

As of December 31, 2022, 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, 2022, our directors and executive officers beneficially owned in the aggregate, approximately 34% of our outstanding common stock, including 23% 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.

In addition, Jack Schuler holds Secured Notes, which the Company may, at its option, repay in (i) cash or (ii) in the form of common stock of the Company. Repayment in shares would likely increase Jack Schuler's beneficial ownership. Jack Schuler also holds Warrants that would also increase his beneficial ownership if exercised.

***Future issuances or 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 outstanding options or warrants, the issuance of future equity awards to retain and incentivize employees, the conversion of our Series A Preferred Stock or in connection with acquisitions, and any 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 issuance and sale of equity or convertible debt securities, including shares of our common stock through our ATM Program, the issuance of such securities will result in dilution to our stockholders. Investors purchasing shares or other securities in the future may also have rights superior to existing stockholders. In addition, we have a significant number of options, warrants and restricted stock units outstanding. If the holders of these options, or warrants exercise, or the restricted stock units are released, our stockholders 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. We may require additional capital to continue to operate as a going concern in the near-term and may 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 address existing obligations, including our Notes;
- 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. 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. For example, in September 2021, we issued 3,954,546 shares as Series A Preferred Stock as discussed further below. 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.

***Our Series A Preferred Stock has rights, preferences, and privileges that are not held by, and are preferential to, the rights of holders of our common stock.***

As of December 31, 2022, we have designated 3,954,546 shares as Series A Preferred Stock, all of which are outstanding as of such date. The Company's Series A Preferred Stock ranks, with respect to the payment of dividends, senior to the Company's common stock and to any other class of securities it may issue in the future that is specifically designated as junior to the Series A Preferred Stock. The holders of Series A Preferred Stock are entitled to receive dividends, out of any assets at the time legally available therefor, prior in preference to any declaration or payment of any dividend on the Company's common stock at the rate of $0.25 per share per annum on each outstanding share of Series A Preferred Stock (as appropriately adjusted for any subsequent stock splits, stock dividends, combinations, reclassifications and the like), when, as and if declared by the Board. In the event of a voluntary or involuntary liquidation, dissolution or winding up of the Company, the holders of Series A Preferred Stock then outstanding are entitled to participate with the holders of the Company's common stock or any other junior securities then outstanding, pro rata on an as-converted basis, in the distribution of all the remaining assets and funds of the Company available for distribution to its stockholders.

***Our common stock may be delisted from The Nasdaq Capital Market, which could affect its market price and liquidity.***

We are required to continually meet Nasdaq's listing requirements, including, among other things, a minimum closing bid price requirement of $1.00 per share for 30 consecutive business days. As described in a Current Report on Form 8-K filed with the SEC on January 11, 2023, on January 5, 2023, we received a deficiency letter from Nasdaq's Listing Qualifications Department (the "Staff") notifying us that, for the last 30 consecutive business days, the bid price for our common stock had closed below the minimum $1.00 per share requirement for continued inclusion on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Requirement Rule"). In accordance with Nasdaq rules, we were provided an initial period of 180 calendar days, or until July 5, 2023 (the "Compliance Date"), to regain compliance with the Minimum Bid Price Requirement Rule. To regain compliance, the closing bid price for our common stock must remain above $1.00 for 10 consecutive business days.

If we do not regain compliance with the Minimum Bid Price Requirement by the Compliance Date, we may be eligible for an additional 180 calendar day compliance period, provided that we meet the continued listing requirement for the market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the Minimum Bid Price Requirement, and notify the Staff of our intention to cure the deficiency during the additional compliance period. If we do not regain compliance with the Minimum Bid Price Requirement by the Compliance Date and are not eligible for an additional compliance period at that time, the Staff will provide written notification to us that our common stock will be subject to delisting. At that time, we may appeal the Staff's delisting determination to a Nasdaq Hearing Panel. There can be no assurance that we will regain compliance with the Minimum Bid Price Requirement or otherwise maintain compliance with any of the other Nasdaq listing requirements.

Any delisting of our common stock from The Nasdaq Capital Market could adversely affect our ability to attract new investors, reduce the liquidity of our outstanding shares of common stock, reduce our ability to raise additional capital, reduce the price at which our common stock trades, result in negative publicity and increase the transaction costs inherent in trading such shares with overall negative effects for our stockholders. We cannot assure you that our common stock, if delisted from The Nasdaq Capital Market, will be listed on another national securities exchange or quoted on an over-the-counter quotation system. In addition, delisting of our common stock could deter broker-dealers from making a market in or otherwise seeking or generating interest in our common stock and might deter certain institutions and persons from investing in our securities at all. For these reasons and others, delisting could adversely affect our business, financial condition and liquidity.

### Risks Related to our Convertible Senior Notes

**We have substantial indebtedness in the form of convertible senior notes, which could have important consequences to our business.**

We have a substantial amount of indebtedness primarily comprised of our 2.50% Convertible Senior Notes due 2023 (the “Notes”). As of December 31, 2022, we had $56.4 million aggregate principal amount of Notes, which matured and were in forbearance as of the issuance of our consolidated financial statements. 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;
- 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;
- impact our ability to continue as a going concern;
- necessitate a restructuring under Chapter 11.

***Servicing our debt could 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.

***Should we refinance the Notes, the ownership interests of existing stockholders could be diluted and our stock price may be adversely impacted.***

A consensual or non-consensual refinancing of the Notes, could result in significant dilution to the ownership interests of existing stockholders and may depress our stock price.

### General Risk Factor

***Current macroeconomic conditions and the uncertain economic outlook may remain challenging for the foreseeable future.***

Global economic conditions may remain challenging and uncertain for the foreseeable future, including as a result of the ongoing COVID-19 pandemic, the war between Russia and Ukraine, and disruptions to the banking system due to bank failures, particularly in light of the recent events that have occurred with respect to Silicon Valley Bank and Signature Bank. This had led to market disruptions and significant volatility in credit and capital markets. These conditions not only limit our access to capital but also make it difficult for our customers, our vendors and us to accurately forecast and plan future business activities, and they could cause U.S. and foreign hospitals and other customers to slow spending on our products, which would delay and lengthen sales cycles. Some of our customers rely on government research grants to fund technology purchases. If negative trends in the economy affect the government’s allocation of funds to research, there may be less grant funding available for certain of our customers to purchase technologies from us. Certain of our customers may face challenges gaining timely access to sufficient credit or may otherwise be faced with budget constraints, which could result in decreased purchases of our products or in an impairment of their ability to make timely payments to us. If our customers do not make timely payments to us, we may be required to assume greater credit risk relating to those customers and increase our allowance for doubtful accounts, and our days sales outstanding would be negatively impacted. Although we maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments, we may not continue to experience the same loss rates that we have in the past.

## 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 both December 31, 2022 and 2021, we leased approximately 54,522 square feet of office/laboratory and manufacturing space, in Tucson, Arizona. 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 Part I, 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.

**Holders**

As of March 28, 2023, we had approximately 124 record owners of our common stock. The actual number of holders of our common stock is greater than the number of record owners and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers or other nominees.

**Dividends Paid and Dividend Policy**

Holders of the Company’s common stock are entitled to receive dividends as may be declared by the Board of Directors out of funds legally available. Additionally, the Company’s Series A Preferred Stock ranks, with respect to the payment of dividends, senior to the Company’s common stock and to any other class of securities it may issue in the future that is specifically designated as junior to the Series A Preferred Stock. The holders of Series A Preferred Stock are entitled to receive dividends, out of any assets at the time legally available therefor, prior in preference to any declaration or payment of any dividend on the Company’s common stock at the rate of $0.25 per share per annum on each outstanding share of Series A Preferred Stock (as appropriately adjusted for any subsequent stock splits, stock dividends, combinations, reclassifications and the like), when, as and if declared by the Board.

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 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.

**Purchases of Equity Securities by the Issuer and Affiliated Purchasers**

None.

**Unregistered Sales of Equity Securities**

There were no unregistered sales of equity securities during the year ended December 31, 2022 other than as reported in our Current Reports on Form 8-K filed with the SEC.

**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, 2022:

**Equity Compensation Plan**

| Plan category | Number of securities to be issued upon exercise of outstanding options and release of restricted stock units | Weighted-average exercise price of outstanding options[1] | Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in the 1st column)[3] |
|---|---|---|---|
| Equity compensation plans approved by security holders | 9,764,081 [2] | $ 14.60 | 7,021,378 |
| Equity compensation plans not approved by security holders | — | — | — |
| **Total** | **9,764,081** | **$ 14.60** | **7,021,378** |

(1) Shares of common stock issuable upon vesting of restricted stock units ("RSUs") and performance share units ("PSUs") have been excluded from the calculation of the weighted average exercise price because they have no exercise price.
(2) Represents 5,408,661 shares of common stock subject to outstanding stock options and 4,355,420 shares of common stock that may be issued upon vesting of outstanding RSUs and PSUs (assuming the maximum performance level for PSUs).
(3) Includes 6,939,117 as part of the Company's 2022 Omnibus Equity Incentive Plan and 82,261 as part of the Company's Employee Stock Purchase Plan.

## Item 6. [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 Part I, 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.

**Sales and Marketing Agreement with BD**

On August 15, 2022, the Company entered into the Sales and Marketing Agreement with BD pursuant to which BD will perform certain sales, tactical marketing, technical service call forwarding, order preparation, research and development support and/or regulatory activities on the Company's behalf as its worldwide exclusive sales agent for certain of the Company's products, including the Accelerate Pheno system and Accelerate Arc Products. An existing team of sales and service professionals will partner with BD personnel in the United States and select international countries to market, sell, and support the Accelerate Pheno system and Accelerate Arc Products.

The Sales and Marketing Agreement also grants to BD certain other rights to certain of the Company's future products, including the Company's next generation rapid AST system. BD has an exclusive right of first negotiation to be the exclusive sales agent to commercialize the Company's next generation rapid AST system, which will be triggered if the Company proposes to license its next generation rapid AST system or sell its rights to such system, or if the Company and BD mutually agree that the related clinical data is ready to be submitted to the

FDA for 510(k) clearance. In accordance with the BD Agreement, the terms of such subsequent agreement would have to be negotiated by the parties.

This Sales and Marketing Agreement should allow the Company to reduce expenses through keeping fewer sales and marketing personnel on staff. Under this agreement, the Company will pay BD a commission based on the level of revenues realized on a quarterly basis. Under this agreement, BD will pay the Company a fee over the duration of the agreement based on certain criteria.

**COVID-19 and Supply Chain Impacts Update**

In late 2019, a novel strain of coronavirus (COVID-19) was reported to have surfaced in Wuhan, China, and spread globally. In March 2020, the World Health Organization declared COVID-19 a global pandemic. The COVID-19 outbreak 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. New cases and hospitalizations have risen and fallen throughout the course of this pandemic. More recently, the emergence and spread of new variants of COVID-19 that are significantly more contagious than previous strains initially led many government authorities and businesses to reimplement prior restrictions in an effort to lessen the spread of COVID-19 and its variants. While most of these restrictions have been lifted, uncertainty remains as to whether additional restrictions may be initiated or again reimplemented in response to surges in COVID-19 cases. The lingering impact of the COVID-19 pandemic continues to create significant volatility throughout the global economy, including supply chain constraints, labor supply issues and higher inflation. Accordingly, it is unclear at this point the full impact COVID-19 and its variants will have on the global economy and on our Company.

The COVID-19 pandemic, containment measures, and downstream impacts to hospital staffing and financial stability have caused, and are continuing to cause, business slowdowns in affected areas, both regionally and worldwide, as well as disruptions to global supply chains and workforce participation. These effects have significantly impacted our business and results of operations, starting in the first quarter of 2020 and continuing through 2022, albeit to a lesser degree. For example, we have experienced diminished access to our customers, including hospitals, which has severely limited our ability to sell and, to a lesser degree, implement previously contracted Accelerate Pheno systems. Hospital turnover resulting from burnout and vaccine mandates have further diverted the attention of hospital decision makers. In addition, in certain months with high rates of COVID-19 hospitalization, our Accelerate PhenoTest BC Kit orders declined as many hospitals curtailed elective surgeries to respond to COVID-19.

The reduced new instrument sales and implementations caused by the COVID-19 pandemic lowered our realized and expected revenue growth for 2020 and 2021. In 2022, we began to see many of the detrimental effects of the pandemic on our business discussed above start to ease. For example, in recent quarters, we have seen bloodstream infection testing regain normalcy, which has in turn lessened the adverse impact of the COVID-19 pandemic on our recurring revenues through the sale of Accelerate PhenoTest BC Kits. However, with the emergence of COVID-19 variants, including the Omicron variant and its sub-variants, vaccine hesitancy and the prevalence of breakthrough cases of infection among fully vaccinated people, there remains uncertainty regarding our access to customers and prospects, demand for our products, and ability to implement our products.

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 continue to 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 despite a high-degree of unpredictability in the broader supply chain environment. However, like many industries experiencing inflationary pressures in raw materials, the direct costs to manufacture our products are increasing and delivery schedules elongating.

For example, we are currently experiencing unprecedented cost increases from many of our suppliers primarily as a result of the ongoing COVID-19 pandemic, labor and supply disruptions and increased inflation. The areas of cost increases include raw materials, components, and value-add supplier labor. We believe that we currently have sufficient inventory of Accelerate Pheno system instruments to limit the impact of cost increases on such devices. However, we are being impacted by cost increases to components and raw materials necessary for the production of our Accelerate Pheno kits. Our ability to pass increased material costs to many of our customers is limited because of long-term sales agreements with limits on price increases. Accordingly, we are closely monitoring the ability of all our suppliers to provide us with necessary materials and services at reasonable costs. See “Risk Factors-Risks Related to Our Business and Strategy-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” in Part I, Item 1A of this Form 10-K for additional information.

Additionally, the Company received loan proceeds of approximately $4.8 million under the Paycheck Protection Program (“PPP”) established under the Coronavirus Aid, Relief, and Economic Security (“CARES”) Act. During January 2021, the Company submitted its application for forgiveness to the lender, and on July 15, 2021, the Small Business Administration (“SBA”) informed the Company of its full forgiveness in the amount of $4.8 million. For additional information about the loan, refer to Part II, Item 8, Note 10, Long-Term Debt of this Form 10-K.

We continue to monitor the evolving impacts to our business caused by the COVID-19 pandemic. 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 and its severity; the emergence and severity of its variants, including the Omicron variant and its subvariants; the actions to contain the virus or treat its impact, such as the availability and efficacy of vaccines (particularly with respect to emerging strains of the virus) and potential hesitancy to use them; the financial impact of COVID-19 on hospitals, including to their budget priorities; hospital staffing issues; general economic factors, such as increased inflation; global supply chain constraints and the related increase in costs; labor supply issues; and how quickly and to what extent normal economic and operating conditions can resume.

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 Part I, Item 1A of this Form 10-K for additional risks we face due to the COVID-19 pandemic, including risks relating to our supply chain.

### Changes in Results of Operations: Comparison of fiscal years ended December 31, 2022, 2021 and 2020

The Company has provided enhanced information in a tabular format which presents some of the captions presented on the statement of operations, less inventory write-downs and non-cash equity-based compensation expense. These figures are reconciled to the statement of operations and are intended to add additional clarity on the operating performance of the business. The Company believes providing such figures less inventory write-downs and non-cash equity-based compensation expense provides helpful information for investors in understanding and evaluating our operating results in the same manner as our management and our board of directors.

| | December 31, (in thousands) | | | | December 31, (in thousands) | | | |
|---|---|---|---|---|---|---|---|---|
| | **2022** | **2021** | **$ Change** | **% Change** | **2021** | **2020** | **$ Change** | **% Change** |
| Net sales | $ 12,752 | $ 11,782 | $ 970 | 8 % | $ 11,782 | $ 11,165 | $ 617 | 6 % |

During the year ended December 31, 2022, total revenues increased primarily as a result of higher sales of Accelerate PhenoTest BC Kits and service contract revenue compared to the year ended December 31, 2021. Accelerate PhenoTest BC Kit revenue increased as customers completed their instrument verifications and began purchasing kits. Service contract revenue increased as a higher number of customers entered into multi-year service agreements following the expiration of their warranty periods.

During the year ended December 31, 2021, total revenues increased primarily as a result of higher sales of Accelerate PhenoTest BC Kits and service contract revenue compared to the year ended December 31, 2020. Accelerate PhenoTest BC Kit revenue increased as customers completed their instrument verifications and began purchasing kits. Service contract revenue increased as a higher number of customers entered into multi-year service agreements following the expiration of their warranty periods.

| | December 31, (in thousands) | | | | December 31, (in thousands) | | | |
|---|---|---|---|---|---|---|---|---|
| | **2022** | **2021** | **$ Change** | **% Change** | **2021** | **2020** | **$ Change** | **% Change** |
| Total cost of sales | 9,449 | 12,163 | (2,714) | (22)% | 12,163 | 6,706 | 5,457 | 81 % |
| Inventory write-down | — | 4,500 | (4,500) | (100)% | 4,500 | — | 4,500 | 100 % |
| Non-cash equity-based compensation as a component of cost of sales | 665 | 325 | 340 | 105 % | 325 | 351 | (26) | (7)% |
| Total cost of sales less inventory write-down and non-cash equity-based compensation | $ 8,784 | $ 7,338 | $ 1,446 | 20 % | $ 7,338 | $ 6,355 | $ 983 | 15 % |

During the year ended December 31, 2022, cost of sales decreased when compared to the year ended December 31, 2021. This decrease is due to a one-time inventory write-down of $4.5 million recorded during the year ended December 31, 2021.

During the year ended December 31, 2021, the Company took charges to cost of sales for inventory provisions primarily related to the write-down of excess quantities of instrument raw materials and work in process, whose inventory levels were higher than our updated forecasts of future demand for those products. Inventory provisions totaled $4.5 million during the year ended December 31, 2021, with no inventory provisions recorded for the years ended December 31, 2022 and 2020.

Total cost of sales less inventory write-downs and non-cash equity-based compensation during the year ended December 31, 2022, increased as a result of an increase in sales of Accelerate PhenoTest BC Kit revenue, increases to our cost of manufacturing, and other factors compared to the year ended December 31, 2021. Our cost of manufacturing has increased as we are experiencing cost increases from many of our suppliers primarily as a result of the ongoing COVID-19 pandemic, labor and supply disruptions and increased inflation. The areas of cost increases include raw materials, components, and value-add supplier labor.

During the year ended December 31, 2021, cost of sales increased when compared to the year ended December 31, 2020. This increase is due to a one-time inventory write-down of $4.5 million recorded during the year ended December 31, 2021, as described above.

Total cost of sales less inventory write-downs and non-cash equity-based compensation expense during the year ended December 31, 2021, increased as a result of an increase in Accelerate PhenoTest BC Kit revenue, increases to our cost of manufacturing, and other factors compared to the year ended December 31, 2021.

Non-cash equity-based compensation cost is a component of manufacturing overhead and service cost of sales. 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 instruments are amortized to cost of sales.

Cost of sales includes non-cash equity-based compensation expense of $0.7 million, $0.3 million and $0.4 million for the years ended December 31, 2022, 2021 and 2020, respectively. During the year ended December 31, 2022, non-cash equity-based compensation expense increased due to new awards being granted in the current year and continued amortization of prior period awards. During the year ended December 31, 2021, the change in non-cash equity-based compensation expense was not considered meaningful when compared to the year ended December 31, 2020.

| | December 31, (in thousands) | | | | December 31, (in thousands) | | | |
|---|---|---|---|---|---|---|---|---|
| | **2022** | **2021** | **$ Change** | **% Change** | **2021** | **2020** | **$ Change** | **% Change** |
| Gross profit (loss) | $ 3,303 | $ (381) | $ 3,684 | (967)% | $ (381) | $ 4,459 | $ (4,840) | (109)% |
| Inventory write-down | $ — | $ 4,500 | $ (4,500) | (100)% | $ 4,500 | $ — | $ 4,500 | 100 % |
| Non-cash equity-based compensation as a component of gross (loss) profit | 665 | 325 | 340 | 105 % | 325 | 351 | (26) | (7)% |
| Gross (loss) profit less inventory write-down and non-cash equity-based compensation | $ 3,968 | $ 4,444 | $ (476) | (11)% | $ 4,444 | $ 4,810 | $ (366) | (8)% |

During the year ended December 31, 2022, the Company recorded a gross profit, while recording a gross loss during the year ended December 31, 2021. As described above, the Company incurred a one-time inventory write-down of $4.5 million for the year ended December 31, 2021 which put the Company in a gross loss position.

Gross profit (loss) less inventory write-downs and non-cash equity-based compensation expense decreased during the year ended December 31, 2022, compared to the year ended December 31, 2021, primarily due to increases in costs to manufacture consumables due to pandemic-related inflationary factors and a decrease in our average unit sales price period over period. Our cost of manufacturing has increased as we are experiencing cost increases from many of our suppliers primarily as a result of the ongoing COVID-19 pandemic, labor and supply disruptions and increased inflation. The areas of cost increases include raw materials, components, and value-add supplier labor.

During the year ended December 31, 2021, the Company recorded a gross loss, while recording a gross profit during the year end December 31, 2020. As described above, the Company incurred a one-time inventory write-down of $4.5 million during the year ended December 31, 2021 which put the Company in a gross loss position.

Gross profit (loss) less inventory write-downs and non-cash equity-based compensation expense decreased during the year ended December 31, 2021, compared to the year ended December 31, 2020, primarily due to increases in costs to manufacture consumables due to pandemic-related inflationary factors and a decrease in our average unit sales price period over period.

Inventory without a cost basis was sold to customers for the years ended December 31, 2022, 2021 and 2020. Pre-launch inventory previously not capitalized and expensed in a previous year for the years ended December 31, 2022, 2021 and 2020 was $0.8 million, $0.2 million and $0.1 million, respectively.

| | December 31, (in thousands) | | | | December 31, (in thousands) | | | |
|---|---|---|---|---|---|---|---|---|
| | 2022 | 2021 | $ Change | % Change | 2021 | 2020 | $ Change | % Change |
| Research and development | $ 26,915 | $ 21,943 | $ 4,972 | 23 % | $ 21,943 | $ 21,255 | $ 688 | 3 % |
| Non-cash equity-based compensation as a component of research and development | 1,419 | 4,102 | (2,683) | (65)% | 4,102 | 4,035 | 67 | 2 % |
| Research and development less non-cash equity-based compensation | $ 25,496 | $ 17,841 | $ 7,655 | 43 % | $ 17,841 | $ 17,220 | $ 621 | 4 % |

Research and development expenses for the year ended December 31, 2022 increased as compared to the year ended December 31, 2021 primarily due to increased expenses to develop our next generation AST platform, partially offset by decreases in non-cash equity-based compensation expense.

Research and development expenses less non-cash equity-based compensation for the year ended December 31, 2022 increased as compared to the year ended December 31, 2021 primarily due to increased expenses to develop our next generation AST platform.

Research and development expenses for the year ended December 31, 2021 increased as compared to the year ended December 31, 2020. The increase was primarily the result of an increase in costs related to the completion of the Accelerate Arc module and associated BC kit, and development and contracted services used to develop our next generation AST platform. This increase was partially offset by decreases in employee related expenses and engineering supplies.

Research and development expenses include non-cash equity-based compensation expense of $1.4 million, $4.1 million and $4.0 million for the years ended December 31, 2022, 2021 and 2020, respectively. During the year ended December 31, 2022, non-cash equity-based compensation expense decreased due to a lower fair value of stock awards being granted, compared to the year ended December 31, 2021. This lower fair value is due to a decrease in the Company's stock price year over year. During the year ended December 31, 2021, the non-cash equity-based compensation expense change was not considered meaningful when compared to the year ended December 31, 2020.

| | December 31, (in thousands) | | | | December 31, (in thousands) | | | |
|---|---|---|---|---|---|---|---|---|
| | 2022 | 2021 | $ Change | % Change | 2021 | 2020 | $ Change | % Change |
| Sales, general and administrative | $ 39,193 | $ 49,236 | $ (10,043) | (20)% | $ 49,236 | $ 46,904 | $ 2,332 | 5 % |
| Non-cash equity-based compensation as a component of sales, general and administrative | 8,541 | 17,620 | (9,079) | (52)% | 17,620 | 12,078 | 5,542 | 46 % |
| Sales, general and administrative less non-cash equity-based compensation | $ 30,652 | $ 31,616 | $ (964) | (3)% | $ 31,616 | $ 34,826 | $ (3,210) | (9)% |

Sales, general and administrative expenses during the year ended December 31, 2022 decreased compared to the year ended December 31, 2021 primarily due to a decrease in non-cash equity-based compensation expense and other factors.

Sales, general and administrative expenses excluding non-cash equity-based compensation expense during the year ended December 31, 2022 decreased compared to the year ended December 31, 2021, primarily due to lower employee related expenses, including ordinary salaries and commissions, partially offset by one-time severance expenses. During the year ended December 31, 2022, the Company restructured its commercial sales team by reducing the number of employees in consideration of the Company's new commercial partnership with BD.

Sales, general and administrative expense for the year ended December 31, 2021 increased as compared to the year ended December 31, 2020 primarily due to increases in non-cash equity-based compensation expense resulting from an increased number of RSUs granted compared to the prior year period.

For the year ended December 31, 2021, sales, general and administrative expenses less non-cash equity-based compensation expense decreased compared to the year ended December 31, 2020. This decrease is primarily the result of the COVID-19 pandemic, as hospitals had limited access to their facilities to primarily focus on COVID-19 initiatives. These circumstances resulted in lower expenses associated with travel, trade shows, and instrument demonstration expenses. In addition, cost containment initiatives implemented in the prior year continued to realize lower expenses in areas such as services and marketing.

Sales, general and administrative expenses include non-cash equity-based compensation expense of $8.5 million, $17.6 million and $12.1 million for the years ended December 31, 2022, 2021 and 2020, respectively. The decrease of non-cash equity-based compensation expense for the year ended December 31, 2022 as compared to the year ended December 31, 2021, was primarily the result of a decrease in the fair value of stock awards being granted, compared to the year ended December 31, 2021. This lower fair value is due to a decrease in the Company's stock price year over year. The increase of non-cash equity-based compensation expense for the year ended December 31, 2021 as compared to the year ended December 31, 2020 was primarily the result of larger stock awards granted to employees for the year ended December 31, 2021.

| | December 31, (in thousands) | | | | December 31, (in thousands) | | | |
|---|---|---|---|---|---|---|---|---|
| | 2022 | 2021 | $ Change | % Change | 2021 | 2020 | $ Change | % Change |
| Loss from operations | $ (62,805) | $ (71,560) | $ 8,755 | (12)% | $ (71,560) | $ (63,700) | $ (7,860) | 12 % |
| Inventory write-down | — | 4,500 | $ (4,500) | (100)% | 4,500 | — | 4,500 | 100 % |
| Non-cash equity-based compensation as a component of loss from operations | 10,625 | 22,047 | $ (11,422) | (52)% | 22,047 | 16,464 | 5,583 | 34 % |
| Loss from operations less inventory write-down and non-cash equity-based compensation | $ (52,180) | $ (45,013) | $ (7,167) | 16 % | $ (45,013) | $ (47,236) | $ 2,223 | (5)% |

During the year ended December 31, 2022, our loss from operations decreased as compared to the year ended December 31, 2021, primarily due to lower non-cash equity-based compensation expense partially offset by higher research and development costs in 2022 and a one-time inventory write-down incurred in 2021.

Loss from operations excluding inventory write-downs and non-cash equity-based compensation expense increased during the year ended December 31, 2022, compared to the year ended December 31, 2021 primarily due to increased expenses to develop our next generation AST platform which was partially offset by higher revenues compared to the prior year period.

During the year ended December 31, 2021, our loss from operations increased as compared to the year ended December 31, 2020 primarily due to higher non-cash equity-based compensation expense, inventory provisions related to write-downs, which was partially offset by higher revenues compared to the prior year period.

Loss from operations less inventory write-downs and non-cash equity-based compensation expense decreased during the year ended December 31, 2021, compared to the year ended December 31, 2020, due to decreased sales, general and administrative expenses as hospitals had limited access to their facilities to primarily focus on COVID-19 initiatives. These circumstances resulted in lower expenses associated with travel, trade shows, and instrument demonstration expenses. In addition, cost containment initiatives implemented in the prior year continued to realize lower expenses in areas such as services and marketing.

Loss from operations includes non-cash equity-based compensation expense of $10.6 million, $22.0 million and $16.5 million for the years ended December 31, 2022, 2021 and 2020, respectively. The decrease of non-cash equity-based compensation expense for the year ended December 31, 2022 as compared to the year ended December 31, 2021 was primarily the result of stock awards having a lower fair value primarily due to a decrease in the Company's stock price year over year. The increase of non-cash equity-based compensation expense for the year ended December 31, 2021 as compared to the year ended December 31, 2020 was primarily the result of larger stock awards being granted to employees during the year ended December 31, 2021.

This loss and further losses are anticipated and are the result of our continued investments in key research and development program costs, and commercialization of the Company's products.

| | December 31, (in thousands) | | | | December 31, (in thousands) | | | |
|---|---|---|---|---|---|---|---|---|
| | 2022 | 2021 | $ Change | % Change | 2021 | 2020 | $ Change | % Change |
| Total other income (expense), net | $ 235 | $ (6,097) | $ 6,332 | (104)% | $ (6,097) | $ (14,503) | $ 8,406 | (58)% |

During the year ended December 31, 2022, other income, net, is primarily comprised of a gain on extinguishment of debt of $3.6 million, partially offset by interest expense of $2.3 million, and related party interest expense of $1.5 million.

During the year ended December 31, 2021, other expense, net, is primarily comprised of interest expense of $15.5 million partially offset by gains on extinguishment of debt of $9.8 million.

During the year ended December 31, 2020, other expense, net, is primarily comprised of interest expense of $15.5 million partially offset by interest income of $0.9 million.

The Company entered into privately negotiated exchange agreements during the years ended December 31, 2022 and 2021. Holders of the Company's Notes exchanged Notes held by them for shares of the Company's common stock. The gain on extinguishment of exchanged Notes was $3.6 million and $4.9 million during the years ended December 31, 2022 and 2021, respectively.

In addition, the Small Business Administration's, Paycheck Protection Program loan and accrued interest of $4.8 million, was forgiven and recorded as gain on extinguishment during the year ended December 31, 2021.

The Company adopted ASU 2020-06 on January 1, 2022, which simplified the accounting for convertible debt instruments by removing the beneficial conversion and cash conversion separation models for our Notes. This change in accounting principle primarily resulted in a decrease in interest expense during the year ended December 31, 2022, when compared to prior periods. Another contributing factor that reduced interest expense includes a decrease in the aggregate principal amount of the Company's Notes outstanding. Interest expense was $2.3 million, $15.5 million and $15.6 million for the years ended December 31, 2022, 2021 and 2020, respectively.

| | December 31, (in thousands) | | | | December 31, (in thousands) | | | |
|---|---|---|---|---|---|---|---|---|
| | 2022 | 2021 | $ Change | % Change | 2021 | 2020 | $ Change | % Change |
| Benefit (provision) for income taxes | $ 77 | $ (45) | $ 122 | (271)% | $ (45) | $ (5) | $ (40) | 800 % |

For the year ended December 31, 2022 the Company recorded an immaterial benefit for income taxes as the Company is anticipating a refund from prior year overpayments.

For the years ended December 31, 2022, 2021 and 2020, the Company recorded immaterial income taxes as the Company is anticipating nominal state and foreign tax expense and has significant net operating losses to offset taxable income.

**Capital Resources and Liquidity**

Since inception, the Company has not achieved profitable operations or positive cash flows from operations. The Company's accumulated deficit totaled $607.2 million as of December 31, 2022. During the year ended December 31, 2022, the Company had a net loss of $62.5 million and negative cash flows from operations of $48.7 million. As of December 31, 2022, the Company had $45.6 million in cash and cash equivalents and investments, a decrease of $18.0 million from $63.6 million at December 31, 2021, and working capital deficits. The primary reason for the decrease was due to cash used in operations during the period. The future success of the Company is dependent on its ability to successfully commercialize its products, obtain regulatory clearance for and successfully launch its future product candidates, obtain additional capital and ultimately attain profitable operations. Historically, the Company has funded its operations primarily through multiple equity raises and the issuance of debt (see below and Note 1, Organization and Nature of Business; Basis of Presentation; Principles of Consolidation, Note 9, Long-Term Debt, Note 10, Convertible Notes, Note 11, Long-Term Debt Related-Party and Note 19, Stockholders' Equity in Part II, Item 8 of this Form 10-K for additional details).

In connection with the preparation of this Form 10-K, the Company is required to evaluate its financial condition as of the date of filing this Form 10-K pursuant to the requirements of ASC 205-40, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. Management must evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. This evaluation initially does not take into consideration the potential mitigating effect of management's plans that have not been fully implemented as of the date the financial statements are issued. When substantial doubt exists under this methodology, management evaluates whether the mitigating effect of its plans sufficiently alleviates substantial doubt about the Company's ability to continue as a going concern. The mitigating effect of management's plans, however, is only considered if both (1) it is probable that the plans will be effectively implemented within one year after the date that the financial statements are issued, and (2) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued.

Based on its evaluation pursuant to ASC 205-40, the Company has determined that, as of the date of this Form 10-K filing, there is substantial doubt about its ability to continue as a going concern, as the Company does not currently have adequate financial resources to pay its outstanding debt obligation under the Notes and to fund its forecasted operating costs for at least twelve months from the issuance of our consolidated financial statements.

Our primary use of capital has been for the development and commercialization of the Accelerate Pheno system and development of complementary products. While the Company continues to explore additional funding in the form of potential equity and/or debt financing arrangements or similar transactions, as well as non-cash means to settle or refinance the Notes, there can be no assurance the necessary financing will be available on terms acceptable to the Company, or at all. If the Company raises funds by issuing equity securities, dilution to stockholders may result. Any equity securities issued may also provide for rights, preferences or privileges senior to those of holders of common stock. If the Company raises funds by issuing debt securities, these debt securities would have rights, preferences and privileges senior to those of preferred and common stockholders. The terms of debt securities or borrowings could impose significant restrictions on our operations. Similarly, there can be no assurance that market conditions and refinancing alternatives will be sufficient to settle or refinance the Notes. The capital markets have in the past, and may in the future, experience periods of upheaval that could impact the availability and cost of equity and debt financing. Financial market instability or disruptions to the banking system due to bank failures, particularly in light of the recent events that have occurred with respect to Silicon Valley Bank and Signature Bank, may also adversely affect our ability to enter into financing arrangements and facilities. In addition, recent and anticipated future increases in federal fund rates set by the Federal Reserve, which serve as benchmark rates on borrowing, and other general economic conditions may impact the cost of debt financing or refinancing existing debt.

Although we are actively considering all available strategic alternatives to maximize value, if we are unable to obtain adequate capital resources to fund operations and address our outstanding debt obligation under the Notes, we would not be able to continue to operate our business pursuant to our current plans. In particular, if we are unable to address our outstanding debt obligation under the Notes, or otherwise obtain an extension under the Forbearance Agreement, prior to the expiration of the forbearance period specified in the Forbearance Agreement, then the Trustee may exercise its rights and remedies under the Indenture and declare the principal of, and all accrued and unpaid interest on, the Notes to be due and payable immediately. This may require us to, among other things, materially modify our operations to reduce spending; sell assets or operations; delay the implementation of, or revising certain aspects of, our business strategy; file a voluntary petition for relief under Chapter 11 of the United States Bankruptcy Code in order to implement a restructuring; or discontinue our operations entirely. Additionally, we cannot provide any assurance that we will be able to obtain any extensions under the Forbearance Agreement. For additional information, see "Risk Factors—Risks Related to Our Financial Condition, Liquidity and Indebtedness" in Part I, Item 1A of this Form 10-K.

The Company is subject to Lease Agreements. The future lease obligations under the Lease Agreements are included in Item 8, Note 16, Leases in Part II, Item 8 of this Form 10-K for additional details.

***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)

| | 2022 | 2021 | 2020 |
|---|---|---|---|
| Net cash used in operating activities | $ (48,728) | $ (47,323) | $ (50,394) |
| Net cash provided by investing activities | 12,417 | 8,304 | 13,606 |
| Net cash provided by financing activities | 31,630 | 43,226 | 11,633 |

***Cash flows from operating activities***

The net cash used in operating activities was $48.7 million during the year ended December 31, 2022. Net cash used in operating activities was primarily the result of net losses and gains on extinguishment of debt. These amounts were partially offset by equity-based compensation and depreciation and amortization.

The Company adopted ASU 2020-06 on January 1, 2022, which simplified the accounting for convertible debt instruments by removing the beneficial conversion and cash conversion separation models for our Notes. This change in accounting principle primarily resulted in a decrease in interest expense during the year ended December 31, 2022, when compared to prior periods. Another contributing factor that reduced interest expense includes a decrease in the aggregate principal amount of the Company's Notes outstanding.

The net cash used in operating activities was $47.3 million during the year ended December 31, 2021. Net cash used in operating activities was primarily the result of net losses and gains on extinguishment of debt. These amounts were partially offset by equity-based compensation, amortization of debt discount and issuance costs, an inventory write-down, and depreciation and amortization.

The net cash used in operating activities was $50.4 million during the year ended December 31, 2020. Net cash used in operating activities was primarily the result of net losses. This amount was partially offset by equity-based compensation, amortization of debt discount and issuance costs, and depreciation and amortization.

These losses are the result of continued investments in research and development to further mature the Accelerate Pheno system, develop ancillary products, including the Accelerate Arc system and our next generation rapid AST system, along with other factors.

***Cash flows from investing activities***

The net cash provided by investing activities was $12.4 million for the year ended December 31, 2022. The Company had maturities of marketable securities of $40.5 million which were offset in part by purchases of marketable securities of $27.5 million.

The net cash provided by investing activities was $8.3 million for the year ended December 31, 2021. The Company had maturities of marketable securities of $38.7 million which were offset in part by purchases of marketable securities of $30.1 million.

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

***Cash flows from financing activities***

The net cash provided by financing activities was $31.6 million for the year ended December 31, 2022. The Company had proceeds from the sale of common stock of $32.9 million which were offset in part from payments on finance leases of $1.2 million.

The net cash provided by financing activities was $43.2 million for the year ended December 31, 2021. The Company had proceeds from the issuance of common and preferred shares of $42.9 million as well as proceeds from equity compensation plans of $1.9 million, which were partially offset by other less significant items.

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 equity compensation plans and long-term debt. Proceeds from equity compensation plans 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 PPP loan described below.

***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 an option to purchase additional amounts. The option was partially exercised, which resulted in $21.5 million of additional proceeds, for total proceeds of $171.5 million. After giving effect to the exchange transactions described below, the Notes had an outstanding principal amount of $56.6 million as of December 31, 2022. The Notes matured on March 15, 2023 and became due and payable.

On March 9, 2023, the Company entered into a Forbearance Agreement (the “Forbearance Agreement”), which became effective on March 13, 2023, with the holders of approximately 85% of the Company’s outstanding Notes (collectively, the “Ad Hoc Noteholder Group”) and the trustee for the Notes (the “Trustee”). Other holders of the Notes may join the Forbearance Agreement, and receive a fee equal to $5.00 per $1,000 principal amount of Notes held by such party, by executing and delivering a joinder to the Forbearance Agreement to the Company (collectively with the Trustee and Ad Hoc Noteholder Group, the “Counterparties”). Pursuant to the Forbearance Agreement, the members of the Ad Hoc Noteholder Group have agreed, and have directed the Trustee, to forbear from exercising their rights and remedies under the indenture governing the Notes (the “Indenture”) in connection with certain events of default under the Indenture, such as (i) failure to timely pay in full the principal of any Note when due and payable on March 15, 2023 (the “Maturity Date”), (ii) failure to pay any interest on any Note when due and payable, (iii) failure to convert any Notes, (iv) default under any agreement with outstanding indebtedness for money borrowed in excess of $15.0 million and (v) any other breach, default or event of default under the Indenture arising from the failure of the Company to timely pay in full the principal of any Note when due and payable on the Maturity Date. The Forbearance Agreement is effective for the period commencing on March 13, 2023 and ending on March 29, 2023. On March 29, 2023, the Company and the Ad Hoc Noteholder Group agreed to further extend the forbearance period under the Forbearance Agreement to April 5, 2023.

For additional information, see “Risk Factors-Risks Related to Our Financial Condition, Liquidity and Indebtedness-We are in default of payment obligations under the terms of our Notes, which matured on March 15, 2023 and became due and payable” in Part I, Item 1A of this Form 10-K.

***2021 Exchange Transactions***

On September 22, 2021, the Company entered into separate exchange agreements with certain holders of the Notes. Under the terms of the exchange agreements, such holders agreed to exchange Notes held by it for shares of the Company’s common stock. During the year ended December 31, 2021, $51.0 million in aggregate principal amount of Notes were exchanged for 6,602,974 shares of the Company's common stock in these exchange transactions.

***March 2022 Exchange Transaction***

On March 21, 2022, the Company entered into an exchange agreement with one holder of the Notes. Under the terms of the exchange agreement, the holder agreed to exchange Notes held by them for shares of the Company’s common stock. During the year ended December 31, 2022, $14.0 million in aggregate principal amount of Notes were exchanged for 10,798,482 shares of the Company's common stock in this exchange transaction.

***August 2022 Exchange Transaction***

On August 15, 2022, the Company entered into an exchange agreement (the “August 2022 Exchange Agreement”) with the Jack W. Schuler Living Trust (the “Schuler Trust”). Under the terms of the August 2022 Exchange Agreement, the Schuler Trust agreed to exchange with the Company $49.9 million in aggregate principal amount of Notes held by it for (a) a secured promissory note in an aggregate principal amount of $34.9 million (the “Secured Note”) and (b) a warrant (the “Warrant”) to acquire the Company’s common stock at an exercise price of $2.12 per share (the “Exercise Price”). See “Capital Resources and Liquidity-Secured Note” below for additional information regarding the Secured Note.

After giving effect to the exchange transactions described above, the Notes had an outstanding principal amount of $56.6 million as of December 31, 2022.

The Warrant may be exercised from February 15, 2023 through the earlier of (i) August 15, 2029 and (ii) the consummation of certain acquisition transactions involving the Company, as set forth in the Warrant. The Warrant is exercisable for up to 2,471,710 shares, or 15% of the principal amount of the Secured Note, divided by the Exercise Price. Such number of shares and the Exercise Price are subject to certain customary proportional adjustments for fundamental events, including stock splits and recapitalizations, as set forth in the Warrant.

***Prepaid Forward***

In connection with the offering of the Notes, 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 our common stock underlying the Prepaid Forward is approximately 1,858,500 shares (based on the sale price of $24.25). During March 2023, 1,858,500 shares of Common Stock were returned to the Company pursuant to our agreement with the counterparty. As of December 31, 2022, these 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.

See Note 10, Convertible Notes, Note 11, Long-Term Debt Related-Party, Note 19, Stockholders' Equity and Note 21, Subsequent Events in Part II, Item 8 of this Form 10-K for additional details.

***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 was to mature on April 14, 2025 and bore interest at a rate of 1% per annum. Beginning August 14, 2021, the Company was required to make 45 monthly payments of principal and interest in the amount of $0.1 million. The proceeds from the PPP Note could only be used for payroll costs (including benefits), interest on mortgage obligations, rent, utilities and interest on certain other debt obligations.

Pursuant to the terms of the CARES Act and the PPP, the Company could apply to the lender for forgiveness for the amount due on the PPP Note. The amount eligible for forgiveness was based on the amount of loan proceeds used by the Company (during the 24 week period after the lender made 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. During January 2021, the Company submitted its application for forgiveness to the lender. During July 2021, the SBA informed the Company of its full forgiveness for the entire loan amount plus accrued interest, which was $4.8 million. The SBA’s determination of loan forgiveness does not preclude further investigation by the SBA according to its rules and regulations.

***At-The-Market Equity Sales Agreement***

On May 28, 2021, the Company entered into a Sales Agreement with William Blair pursuant to which it may sell shares of the Company’s common stock having an aggregate offering price of up to $50 million, from time to time, through an “at-the-market” equity offering program under which William Blair will act as sales agent. Subject to the terms and conditions of the Sales Agreement, William Blair may sell shares by any method deemed to be an “at-the-market” offering as defined in Rule 415 under the Securities Act. The Company is not obligated to sell any shares under the Sales Agreement. William Blair is entitled to a commission of 3% of the aggregate gross proceeds from each sale of shares occurring pursuant to the Sales Agreement. During the year ended December 31, 2021, the Company sold 2,092,497 shares of common stock under the Sales Agreement for aggregate gross proceeds of $10.9 million. As of December 31, 2022, the Company had an aggregate of $39.1 million available for future sales under its at-the-market equity offering program. No shares were sold under the Sales Agreement during the year ended December 31, 2022.

***2021 Sales of Equity Securities***

On December 24, 2020, the Company entered into a securities purchase agreement (the “December 2020 Securities Purchase Agreement”) with certain purchasers for the issuance and sale by the Company of shares of its common stock. The purchasers were comprised of certain directors and officers of the Company, or entities affiliated or related to such persons. On September 17, 2021, the Company entered into a rescission agreement with certain of the purchasers (the “Schuler Purchasers”) in order to, among other things, rescind and unwind the December 2020 Securities Purchase Agreement for all legal, tax and financial purposes ab initio as if the related transactions, including the issuance and sale of the shares, had never occurred with respect to the Schuler Purchasers and the Company. During the year ended December 31, 2022, the Company issued 201,820 shares of common stock to the other purchasers and received total proceeds of approximately $1.5 million under the December 2020 Securities Purchase Agreement after giving effect to the rescission agreement.

On September 22, 2021, the Company entered into a new securities purchase agreement (the “September 2021 Securities Purchase Agreement”) with the Schuler Purchasers for the issuance and sale by the Company of the Company’s newly designated Series A Preferred Stock. During the year ended December 31, 2021, the Company issued 3,954,546 shares of Series A Preferred Stock to the Schuler Purchasers and received total proceeds of approximately $30.5 million under the September 2021 Securities Purchase Agreement.

***March 2022 Securities Purchase Agreement***

On March 24, 2022, the Company entered into a securities purchase agreement (the “March 2022 Securities Purchase Agreement”) with the Schuler Trust for the issuance and sale by the Company of an aggregate of 2,439,024 shares of the Company’s common stock to the Schuler Trust (the “Private Placement”). Jack Schuler, serves as a member of the Company’s board of directors and is the sole trustee of the Schuler Trust.

Pursuant to the March 2022 Securities Purchase Agreement, the Schuler Trust has 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 $1.64 per share, which is equal to the consolidated closing bid price reported by Nasdaq immediately preceding the time the Company entered into the March 2022 Securities Purchase Agreement, for an aggregate purchase price of $4.0 million. On June 29, 2022, the Company and the Schuler Trust agreed to extend the closing date of the Private Placement (the “Closing Date”) from June 30, 2022 to September 26, 2022, subject to the satisfaction of customary closing conditions. On September 29, 2022, the parties agreed to extend the Closing Date to December 30, 2022, effective as of September 26, 2022. On December 16, 2022, the parties agreed to extend the Closing Date to March 24, 2023. On March 23, 2023, the parties agreed to further extend the Closing Date to April 20, 2023.

***2022 Sales of Equity Securities***

On August 23, 2022, the Company completed a public offering of 17,500,000 shares of its common stock at a public offering price of $2.00 per share. The Company received net proceeds of approximately $32.9 million from the offering after deducting underwriting discounts and commissions and offering expenses paid by the Company.

See Note 19, Stockholders' Equity in Part II, Item 8 of this Form 10-K for additional details.

***Secured Note***

The Secured Note has a scheduled maturity date of August 15, 2027 and will be repayable upon written demand at any time on or after such date. The Company may, at its option, repay the note in (i) cash or (ii) in the form of common stock of the Company, in a number of shares that is obtained by dividing the total amount of such payment by $2.12. The Secured Note bears interest at a rate of 5.0% per annum, payable at the option of the

Company in the same form, at the earlier of (i) any prepayment of principal and (ii) maturity. The Company may prepay the Secured Note at any time without premium or penalty. The Secured Note is secured by substantially all of the assets of the Company, subject to customary exceptions and limitations, pursuant to a security agreement, dated as of August 15, 2022. The Secured Note does not restrict the incurrence of future indebtedness by the Company but shall become subordinated in right of payment and lien priority upon the request of any future senior lender.

See Note 11, Long-Term Debt Related-Party in Part II, Item 8 of this Form 10-K for additional details.

**Contractual Obligations**

The Company has certain contractual obligations and commercial commitments as disclosed in Part II, 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 Part I, Item 2, Properties and Part II, Item 8, Note 16, Leases. The Company has entered into Long-Term Debt as described in Part II, Item 8, Note 9, Long-Term Debt and Note 11, Long-Term Debt Related-Party. The Company has entered into the Notes as described above and in Part II, Item 8, Note 10, 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** | **2023** | **2024** | **2025** | **2026** | **2027** |
| Operating lease obligations | $ 2,608 | $ 968 | $ 1,055 | $ 585 | $ — | $ — |
| Purchase obligation [1)] | 11,900 | — | — | — | — | 11,900 |
| Finance leases | 2,161 | 992 | 976 | 193 | — | — |
| Deferred compensation | 932 | — | — | 337 | 361 | 234 |
| Convertible notes | 56,595 | 56,595 | — | — | — | — |
| Convertible notes interest | 707 | 707 | — | — | — | — |
| Related party secured note [2)] | 34,934 | — | — | — | — | 34,934 |
| Related party secured note interest [3)] | 9,863 | — | — | — | — | 9,863 |
| Total | $ 119,700 | $ 59,262 | $ 2,031 | $ 1,115 | $ 361 | $ 56,931 |

1) The Company entered into a non-cancellable purchase obligation with a supplier to acquire raw materials for a total commitment of $11.9 million. Under the terms of this agreement the Company has until March 15, 2027 to take delivery of purchased items. As of December 31, 2022 the commitment remains $11.9 million as the Company has not taken delivery of any inventory.

2) The Company may, at its option, repay the note in (i) cash or (ii) in the form of common stock of the Company. However, the amount of shares to repay the Secured Notes, shall not exceed an aggregate amount of 19.99% of the Company's outstanding shares of common stock, and any remainder amount due will be paid in cash.

3) The Company may, at its option, repay the interest in (i) cash or (ii) in the form of common stock of the Company, which is due on or after August 15, 2027. The Secured Note bears interest at a rate of 5.0% per annum and if the Company were to make a first and final interest payment on the maturity date of August 15, 2027, the interest payable amount would be $9.9 million. As of December 31, 2022, accrued interest is $0.7 million.

**Recent Accounting Pronouncements**

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

## Critical Accounting Policies and Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. ("GAAP"). The preparation of these financial statements requires us to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and accompanying notes. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates on historical experience and on various other factors that are believed to be appropriate under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 in the Notes to Consolidated Financial Statements, we believe that the following judgments are most critical to aid in fully understanding and evaluating our reported financial results.

### *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.

We charge cost of sales for inventory provisions to write-down our inventory to the lower of cost or net realizable value or for obsolete or excess inventory. Most of our inventory provisions relate to excess quantities of products, based on our inventory levels and future product purchase commitments compared to assumptions about future demand and market conditions. Once inventory has been written-off or written-down, it creates a new cost basis for the inventory that is not subsequently written-up.

See Part II, Item 8, Note 6, Inventory, for further information and related disclosures.

### *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, 2022 and 2021, 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, 2022 and 2021.

See Part II, Item 8, Note 7, Property and Equipment, for further information and related disclosures.

***Convertible Notes***

On January 1, 2022 the Company adopted Accounting Standards Update ("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). As a result, the Notes are now accounted for as a single liability measured at their amortized cost. The Notes are no longer bifurcated between debt and equity and are instead accounted for entirely as debt at face value net of any discount or premium and issuance costs. Interest expense is comprised of (1) cash interest payments, (2) amortization of any debt discounts or premiums based on the original offering, and (3) amortization of any debt issuance costs. Gain or loss on extinguishment of Notes is calculated as the difference between the (i) fair value of the consideration transferred and (ii) the sum of the carrying value of the debt at the time of repurchase.

See Part II, Item 8, Note 10, Convertible Notes, for further information and related disclosures.

***Revenue Recognition***

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

The Company determines 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 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. Payment terms vary by the type and location of the 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.

The Company's contracts with customers may include multiple performance obligations. For such arrangements, the Company allocates revenue to each performance obligation based on its relative standalone selling price. The Company generally determines relative standalone selling prices based on the price charged to customers for each individual performance obligation.

Sales commissions earned by the Company's 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, 2022.

***Leases***

The Company accounts for leases in accordance with ASC 842, Leases. The Company determines 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.

***Leases as Lessee***

Operating leases are included in right-of-use ("ROU") assets and corresponding lease liabilities, and finance leases are included in ROU assets and corresponding lease liabilities within our condensed 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.

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. Our finance leases consist of leased equipment and have three-year terms.

***Leases as 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, that 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.

Net investment in sales-type leases are included within our condensed 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 Part II, Item 8, 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). Performance-based 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 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 estimate expected term for employee awards is based on a simplified method that considers an insufficient history of employee exercises. 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 the 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 Part II, Item 8, Note 13, Employee Equity-Based Compensation for further information.

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

Not required for a smaller reporting company.

## Item 8. Financial Statements and Supplementary Data

## 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, 2022 and 2021, 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, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, in conformity with U.S. generally accepted accounting principles.

### The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations, has a working capital deficiency, and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

### 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.

**Valuation of Instrument Inventory**

*Description of the Matter*

As explained in Note 2 to the consolidated financial statements, the Company evaluates the net realizable value of instrument inventory, including finished goods, work in process and raw materials available for conversion into finished goods, and records a charge to expense to the extent that inventory costs exceed net realizable value.

Auditing management's estimate of the net realizable value of instrument inventory involved subjective auditor judgment. This is due to the estimation of the number of instruments needed to meet customer demand as of December 31, 2022, and the assumptions inherent in management’s forecasted sales of these instruments.

*How We Addressed the Matter in Our Audit*

Our audit procedures included, among others, comparing the carrying value of instrument inventory, including finished goods, work in process and raw materials available for conversion into finished goods, to management’s recoverability analysis, evaluating the forecasted sales assumption and assessing the completeness and accuracy of the underlying data used. Specifically, we (i) compared the historical accuracy of forecasted sales to current and past results, (ii) assessed the reasonableness of forecasted sales considering current and past results, including recent sales, and (iii) performed a sensitivity analysis to evaluate the impact of changes in this significant assumption to the carrying value of these instruments.

/s/ Ernst & Young LLP

We have served as the Company’s auditor since 2013.
Phoenix, Arizona
March 31, 2023

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

| | December 31, 2022 | December 31, 2021 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 34,905 | $ 39,898 |
| Investments | 10,656 | 23,720 |
| Trade accounts receivable, net | 2,416 | 2,320 |
| Inventory | 5,194 | 5,067 |
| Prepaid expenses | 818 | 768 |
| Other current assets | 2,025 | 1,558 |
| Total current assets | 56,014 | 73,331 |
| Property and equipment, net | 3,478 | 5,389 |
| Finance lease assets, net | 2,422 | — |
| Operating lease right of use assets, net | 1,859 | 2,510 |
| Other non-current assets | 1,242 | 1,817 |
| Total assets | $ 65,015 | $ 83,047 |
| | | |
| **LIABILITIES AND STOCKHOLDERS' DEFICIT** | | |
| Current liabilities: | | |
| Accounts payable | $ 4,501 | $ 1,983 |
| Accrued liabilities | 2,682 | 2,853 |
| Accrued interest | 472 | 909 |
| Deferred revenue | 547 | 451 |
| Current portion of convertible notes | 56,413 | — |
| Current portion of long-term debt | — | 80 |
| Finance lease, current | 1,113 | — |
| Operating lease, current | 829 | 669 |
| Total current liabilities | 66,557 | 6,945 |
| Finance lease, non-current | 782 | — |
| Operating lease, non-current | 1,545 | 2,381 |
| Other non-current liabilities | 874 | 808 |
| Accrued interest, related-party | 663 | — |
| Long-term, debt related-party | 16,858 | — |
| Convertible notes | — | 107,984 |
| Total liabilities | 87,279 | 118,118 |
| | | |
| Commitments and contingencies (see note 16) | | |

See accompanying notes to consolidated financial statements.

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

| | December 31, | |
|---|---|---|
| | **2022** | **2021** |
| Stockholders' deficit: | | |
| Preferred shares, $0.001 par value; | | |
| 5,000,000 preferred shares authorized and 3,954,546 outstanding as of December 31, 2022 and 2021 | 4 | 4 |
| Common stock, $0.001 par value; | | |
| 200,000,000 common shares authorized with 97,477,546 shares issued and outstanding on December 31, 2022 and 100,000,000 common shares authorized with 67,649,018 shares issued and outstanding on December 31, 2021 | 97 | 68 |
| Contributed capital | 630,341 | 580,652 |
| Treasury stock | (45,067) | (45,067) |
| Accumulated deficit | (607,239) | (570,668) |
| Accumulated other comprehensive loss | (400) | (60) |
| Total stockholders' deficit | (22,264) | (35,071) |
| Total liabilities and stockholders' deficit | $ 65,015 | $ 83,047 |

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, | | |
|---|---|---|---|
| | **2022** | **2021** | **2020** |
| **Net sales** | $ 12,752 | $ 11,782 | $ 11,165 |
| **Cost of sales:** | | | |
| Cost of sales of products and services | 9,449 | 7,663 | 6,706 |
| Inventory write-down | — | 4,500 | — |
| Total cost of sales | 9,449 | 12,163 | 6,706 |
| Gross profit (loss) | 3,303 | (381) | 4,459 |
| **Costs and expenses:** | | | |
| Research and development | 26,915 | 21,943 | 21,255 |
| Sales, general and administrative | 39,193 | 49,236 | 46,904 |
| Total costs and expenses | 66,108 | 71,179 | 68,159 |
| Loss from operations | (62,805) | (71,560) | (63,700) |
| **Other income (expense):** | | | |
| Interest expense | (2,274) | (15,545) | (15,550) |
| Interest expense related-party | (1,497) | — | — |
| Gain on extinguishment of debt | 3,565 | 9,793 | — |
| Foreign currency exchange gain (loss) | 117 | (413) | 252 |
| Interest income | 551 | 88 | 855 |
| Other expense, net | (227) | (20) | (60) |
| Total other income (expense), net | 235 | (6,097) | (14,503) |
| Net loss before income taxes | (62,570) | (77,657) | (78,203) |
| Benefit (provision) for income taxes | 77 | (45) | (5) |
| Net loss | $ (62,493) | $ (77,702) | $ (78,208) |
| Basic and diluted net loss per share | $ (0.76) | $ (1.26) | $ (1.40) |
| Weighted average shares outstanding | 82,161 | 61,727 | 56,010 |
| **Other comprehensive loss:** | | | |
| Net loss | $ (62,493) | $ (77,702) | $ (78,208) |
| Net unrealized loss on investments | (14) | (34) | (2) |
| Foreign currency translation adjustment | (326) | (117) | 151 |
| Comprehensive loss | $ (62,833) | $ (77,853) | $ (78,059) |

See accompanying notes to consolidated financial statements.

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

| | Preferred Shares | Preferred Stock Amount | Common Shares | Common Stock Amount | Contributed Capital | Accumulated Deficit | Treasury stock | Accumulated Other Comprehensive Loss | Total Stockholders' (Deficit) Equity |
|---|---|---|---|---|---|---|---|---|---|
| Balances, December 31, 2019 | — | $ — | 54,709 | $ 55 | $ 452,344 | $ (414,653) | $ (45,067) | $ (58) | $ (7,379) |
| Cumulative impact of accounting change | — | — | — | — | — | (105) | — | — | (105) |
| 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 |
| Equity-based compensation | — | — | — | — | 16,310 | — | — | — | 16,310 |
| Balances, December 31, 2020 | — | — | 57,608 | 58 | 475,072 | (492,966) | (45,067) | 91 | (62,812) |
| Net loss | — | — | — | — | — | (77,702) | — | — | (77,702) |
| Issuance of common stock | — | — | 4,937 | 5 | 32,400 | — | — | — | 32,405 |
| Cancellation of common stock | — | — | (2,643) | (3) | (20,297) | — | — | — | (20,300) |
| Issuance of preferred stock | 3,955 | 4 | — | — | 30,446 | — | — | — | 30,450 |
| Exercise of options and restricted stock awards issued | — | — | 1,090 | 1 | 1,619 | — | — | — | 1,620 |
| Issuance of common stock under employee purchase plan | — | — | 54 | — | 326 | — | — | — | 326 |
| Unrealized loss on investments | — | — | — | — | — | — | — | (34) | (34) |
| Foreign currency translation adjustment | — | — | — | — | — | — | — | (117) | (117) |
| Issuance of shares to retire Convertible Senior Notes | — | — | 6,603 | 7 | 38,896 | — | — | — | 38,903 |
| Equity-based compensation | — | — | — | — | 22,190 | — | — | — | 22,190 |
| Balances, December 31, 2021 | 3,955 | 4 | 67,649 | 68 | 580,652 | (570,668) | (45,067) | (60) | (35,071) |

See accompanying notes to consolidated financial statements.

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

| | Preferred Shares | Preferred Stock Amount | Common Shares | Common Stock Amount | Contributed Capital | Accumulated Deficit | Treasury stock | Accumulated Other Comprehensive Loss | Total Stockholders' (Deficit) Equity |
|---|---|---|---|---|---|---|---|---|---|
| Balances, December 31, 2021 | 3,955 | 4 | 67,649 | 68 | 580,652 | (570,668) | (45,067) | (60) | (35,071) |
| Cumulative impact of accounting change | — | — | — | — | (37,438) | 25,922 | — | — | (11,516) |
| Net loss | — | — | — | — | — | (62,493) | — | — | (62,493) |
| Issuance of common stock | — | — | 17,500 | 17 | 32,855 | — | — | — | 32,872 |
| Restricted stock awards issued and exercise of options | — | — | 1,308 | 1 | 6 | — | — | — | 7 |
| Issuance of common stock under employee purchase plan | — | — | 222 | — | 224 | — | — | — | 224 |
| Unrealized loss on investments | — | — | — | — | — | — | — | (14) | (14) |
| Foreign currency translation adjustment | — | — | — | — | — | — | — | (326) | (326) |
| Issuance of shares to retire Convertible Senior Notes | — | — | 10,799 | 11 | 10,169 | — | — | — | 10,180 |
| Capital contribution from related-party in connection with exchange transaction | — | — | — | — | 29,847 | — | — | — | 29,847 |
| Warrants issued to related party | — | — | — | — | 3,753 | — | — | — | 3,753 |
| Equity-based compensation | — | — | — | — | 10,273 | — | — | — | 10,273 |
| Balances, December 31, 2022 | 3,955 | $ 4 | 97,478 | $ 97 | $ 630,341 | $ (607,239) | $ (45,067) | $ (400) | $ (22,264) |

See accompanying notes to consolidated financial statements.

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

| | Years Ended December 31, | | |
|---|---|---|---|
| | **2022** | **2021** | **2020** |
| **Cash flows from operating activities:** | | | |
| Net loss | $ (62,493) | $ (77,702) | $ (78,208) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation and amortization | 3,000 | 2,518 | 2,997 |
| Amortization of investment discount | 98 | 226 | 99 |
| Equity-based compensation expense | 10,625 | 22,047 | 16,464 |
| Amortization of debt discount and issuance costs | 474 | 11,542 | 11,168 |
| Amortization of debt discount related party | 834 | — | — |
| Realized loss on available-for-sale securities | — | — | 3 |
| Unrealized loss on equity investments | 211 | — | — |
| Loss (gain) on disposal of property and equipment | 133 | (75) | 785 |
| Gain on extinguishment of debt | (3,565) | (9,793) | — |
| Inventory write-down | — | 4,500 | — |
| (Increase) decrease in assets: | | | |
| Contributions to deferred compensation plan | (298) | (484) | (357) |
| Accounts receivable | (96) | (770) | 1,592 |
| Inventory | (236) | (415) | (1,356) |
| Prepaid expense and other assets | 138 | 1,014 | (2,087) |
| Increase (decrease) in liabilities: | | | |
| Accounts payable | 2,920 | 273 | (1,006) |
| Accrued liabilities and other | (861) | (469) | (909) |
| Accrued interest | (437) | (283) | — |
| Accrued interest from related-party | 663 | — | — |
| Deferred revenue and income | 96 | 75 | 105 |
| Deferred compensation | 66 | 473 | 316 |
| Net cash used in operating activities | (48,728) | (47,323) | (50,394) |
| **Cash flows from investing activities:** | | | |
| Purchases of equipment | (554) | (603) | (1,362) |
| Purchase of marketable securities | (27,506) | (30,081) | (46,933) |
| Proceeds from sales of marketable securities | — | 250 | — |
| Maturities of marketable securities | 40,477 | 38,738 | 61,901 |
| Net cash provided by investing activities | 12,417 | 8,304 | 13,606 |
| **Cash flows from financing activities:** | | | |
| Proceeds from issuance of common and preferred shares, net | 32,872 | 42,880 | 359 |
| Proceeds from exercise of options | 7 | 1,620 | 6,062 |
| Proceeds from issuance of common stocks under employee purchase plan | 224 | 326 | — |
| Proceeds from debt | — | — | 5,578 |
| Payment of debt | (80) | (360) | (366) |
| Payments on finance leases | (1,201) | — | — |
| Debt exchange and common stock issuance cost | (192) | (1,240) | — |
| Net cash provided by financing activities | 31,630 | 43,226 | 11,633 |

See accompanying notes to consolidated financial statements.

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

| | Years Ended December 31, | | |
|---|---|---|---|
| | **2022** | **2021** | **2020** |
| Effect of exchange rate on cash | (312) | (90) | (78) |
| | | | |
| (Decrease) increase in cash and cash equivalents | (4,993) | 4,117 | (25,233) |
| Cash and cash equivalents, beginning of period | 39,898 | 35,781 | 61,014 |
| Cash and cash equivalents, end of period | $ 34,905 | $ 39,898 | $ 35,781 |
| | | | |
| **Non-cash investing activities:** | | | |
| Net transfer of instruments from inventory to property and equipment, net | $ 168 | $ 688 | $ 1,525 |
| | | | |
| **Non-cash financing activities:** | | | |
| Extinguishment of convertible senior notes through issuance of common stock | $ 10,180 | $ 38,902 | $ — |
| Convertible notes due from related-party extinguished in connection with the exchange transaction, net of deferred issuance costs | $ 49,624 | $ — | $ — |
| Fair value of new note from related-party issued in connection with the exchange transaction | $ 16,024 | $ — | $ — |
| Fair value of common stock warrant issued to related-party in connection with exchange transaction | $ 3,753 | $ — | $ — |
| Capital contribution from related-party in connection with the exchange transaction | $ 29,847 | $ — | $ — |
| Right-of-use assets obtained in exchange for finance lease obligations | $ 3,096 | $ — | $ — |
| | | | |
| **Supplemental cash flow information:** | | | |
| Interest paid | $ 2,214 | $ 4,288 | $ 4,288 |
| Income taxes paid, net of refunds | $ — | $ — | $ 43 |

See accompanying notes to 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 U.S. 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.

***Liquidity and Going Concern***

Since inception, the Company has not achieved profitable operations or positive cash flows from operations. The Company’s accumulated deficit totaled $607.2 million as of December 31, 2022. During the year ended December 31, 2022, the Company had a net loss of $62.5 million and negative cash flows from operations of $48.7 million. As of December 31, 2022, the Company's 2.5% Convertible Senior Notes (the “Notes”) had a maturity date of March 15, 2023 and the Company had a working capital deficit. The Notes matured on March 15, 2023 and became due and payable. On March 9, 2023, the Company entered into a forbearance agreement commencing on March 13, 2023 and ending on March 29, 2023. On March 29, 2023, the Company and noteholders agreed to further extend the forbearance period under the forbearance agreement to April 5, 2023. See Note 10, Convertible Notes and Note 21, Subsequent Events for additional information. As of December 31, 2022, the Company had $45.6 million in cash and cash equivalents and investments, a decrease of $18.0 million from $63.6 million at December 31, 2021. The primary reason for the decrease was due to cash used in operations during the period. The future success of the Company is dependent on its ability to successfully commercialize its products, obtain regulatory clearance for and successfully launch its future product candidates, obtain additional capital and ultimately attain profitable operations.

The Company is subject to a number of risks similar to other early commercial stage life science companies, including, but not limited to commercially launching the Company’s products, development and market acceptance of the Company’s product candidates, development by its competitors of new technological innovations, protection of proprietary technology, and raising additional capital.

Historically, the Company has funded its operations primarily through multiple equity raises and the issuance of debt.

The Company’s primary use of capital has been for the development and commercialization of the Accelerate Pheno system and development of complementary products. While the Company continues to explore additional funding in the form of potential equity and/or debt financing arrangements or similar transactions, as well as non-cash means to settle or refinance the Notes, there can be no assurance the necessary financing will be available on terms acceptable to the Company, or at all.

Although the Company is actively considering all available strategic alternatives to maximize value, if we are unable to obtain adequate capital resources to fund operations and address the maturity of the Notes that are in forbearance, we would not be able to continue to operate our business pursuant to our current plans. This may require us to file a voluntary petition for relief under Chapter 11 of the United States Bankruptcy Code in order to implement a restructuring.

The Company is required to evaluate its financial condition as of the date of filing this Form 10-K pursuant to the requirements of ASC 205-40, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. Management must evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. This evaluation initially does not take into consideration the potential mitigating effect of management's plans that have not been fully implemented as of the date the financial statements are issued. When substantial doubt exists under this methodology, management evaluates whether the mitigating effect of its plans sufficiently alleviates substantial doubt about the Company's ability to continue as a going concern. The mitigating effect of management's plans, however, is only considered if both (1) it is probable that the plans will be effectively implemented within one year after the date that the financial statements are issued, and (2) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued.

Based on its evaluation pursuant to ASC 205-40, the Company has determined that, as of the date of this Form 10-K filing, there is substantial doubt about its ability to continue as a going concern, as the Company does not currently have adequate financial resources to pay its outstanding debt obligation under the Notes and to fund its forecasted operating costs for at least twelve months from the date of issuance of these consolidated financial statements.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of the uncertainties described above.

## 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, convertible notes, 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 10, Convertible Notes for further detail on the Company’s convertible notes.

The long-term debt with a related-party consisting of the Secured Note (as defined in Note 11) and the Warrant are instruments measured at fair value on a non-recurring basis using Level 3 inputs. See Note 11, Long-Term Debt Related-Party for further detail on the Secured Note and the Warrant.

***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 the Company’s cash management process, excess operating cash is invested in overnight repurchase agreements with its 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. The Company diversifies its cash holdings, but does have deposits at three institutions in excess of the FDIC coverage limit. Notwithstanding the possibility of bank failures, we believe that as a result of the Company’s selected banks, diversified holdings strategy, and the U.S. Government’s continued support to stabilize the banking system, such as steps taken in March 2023 as a result of bank failures, 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 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.

We charge cost of sales for inventory provisions to write-down our inventory to the lower of cost or net realizable value or for obsolete or excess inventory. Most of our inventory provisions relate to excess quantities of products, based on our inventory levels and future product purchase commitments compared to assumptions about future demand and market conditions. Once inventory has been written-off or written-down, it creates a new cost basis for the inventory that is not subsequently written-up.

See Note 6, Inventory, for further information and related disclosures.

***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 for the year ended December 31 is comprised of the following (in thousands):

| | 2022 | 2021 | 2020 |
|---|---|---|---|
| Beginning balance | $ 140 | $ 445 | $ — |
| Provisions | 204 | 123 | 684 |
| Write-offs | (20) | (428) | (239) |
| | $ 324 | $ 140 | $ 445 |

The provisions recorded during the year ended December 31, 2022, are primarily in connection with aged net investment in sales-type leases.

The write-offs and provisions recorded during the years ended December 31, 2021 and 2020, are primarily due to restructuring activity of the Company's Europe, Middle East and Africa ("EMEA") business. These credit losses were incurred as part of the Company terminating agreements with select distributors in geographies it exited and did not pursue collection of these accounts receivables.

***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, 2022 and 2021, 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, 2022 and 2021.

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):

| | 2022 | 2021 | 2020 |
|---|---|---|---|
| Beginning balance | $ 139 | $ 232 | $ 403 |
| Provisions | 389 | (22) | 13 |
| Warranty cost incurred | (303) | (71) | (184) |
| | $ 225 | $ 139 | $ 232 |

***Convertible Notes***

On January 1, 2022 the Company adopted Accounting Standards Update ("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). As a result, the Notes are now accounted for as a single liability measured at their amortized cost. The Notes are no longer bifurcated between debt and equity and are instead accounted for entirely as debt at face value net of any discount or premium and issuance costs. Interest expense is comprised of (1) cash interest payments, (2) amortization of any debt discounts or premiums based on the original offering, and (3) amortization of any debt issuance costs. Gain or loss on extinguishment of Notes is calculated as the difference between the (i) fair value of the consideration transferred and (ii) the sum of the carrying value of the debt at the time of repurchase.

See Recently Issued Accounting Pronouncements, section in this footnote and Note 10, Convertible Notes, for further information and related disclosures.

***Accounting for Government Assistance***

The Company follows ASC 832, Disclosures by Business Entities about Government Assistance, which aims to provide increased transparency by requiring business entities to disclose information about certain types of government assistance they receive in the notes to the financial statements.

The Paycheck Protection Program ("PPP") Loan, was established by the Coronavirus Aid, Relief, and Economic Security ("CARES") Act, through a significant expansion of the Small Business Administration ("SBA") 7(a) loan program. During April 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 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 remained a liability until the Company was legally released from being the primary obligor under the liability (i.e. when the PPP Note was forgiven). During July 2021, the SBA informed the Company of its full forgiveness for the entire loan amount plus accrued interest, which was $4.8 million as of the date of forgiveness.

The SBA's determination of loan forgiveness does not preclude further investigation by the SBA according to its rules and regulations. As a result of the approval of the Company's application for forgiveness the Company recorded income from the extinguishment as a gain, recorded to other income (expense), net for the year ended December 31, 2021.

See Note 9, Long-Term Debt for further detail regarding the PPP Note.

***Revenue Recognition***

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

The Company determines 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 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. Payment terms vary by the type and location of the 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.

The Company’s contracts with customers may include multiple performance obligations. For such arrangements, the Company allocates revenue to each performance obligation based on its relative standalone selling price. The Company generally determines relative standalone selling prices based on the price charged to customers for each individual performance obligation.

Sales commissions earned by the Company’s 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 years ended December 31, 2022, 2021, and 2020.

***Gross Profit (Loss) and Gross Margin***

Gross profit consists of total revenue, net of allowances, less 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.

The Company’s overall gross margin was 26%, (3)% and 40% for the years ended December 31, 2022, 2021 and 2020, respectively.

During the years ended December 31, 2022 and 2020, the Company recorded gross profit, while recording a gross loss during the year end December 31, 2021. The Company incurred a one-time inventory write-down of $4.5 million for the year ended December 31, 2021 which put the Company in a gross loss position. No write-downs of inventory were recorded for the years ended December 31, 2022 and 2020. An immaterial amount of this inventory was sold to customers for the year ended December 31, 2022.

The Company manufactures pre-launch inventory in advance of regulatory approval. This inventory is expensed before an economic benefit is probable. Pre-launch inventory sold to customers, previously not capitalized and expensed in a previous year for the years ended December 31, 2022, 2021 and 2020 was $0.6 million, $0.2 million and $0.1 million, respectively.

***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 (the “Board”) 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 expenses of $0.4 million during the year ended December 31, 2020, 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 on the consolidated statements of operations and comprehensive loss. No material restructuring liabilities were outstanding as of December 31, 2022, 2021 and 2020.

***Leases***

The Company accounts for leases in accordance with ASC 842, Leases. The Company determines 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.

***Leases as Lessee***

Operating leases are included in right-of-use (“ROU”) assets and corresponding lease liabilities, and finance leases are included in ROU assets and corresponding lease liabilities within our condensed 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.

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. Our finance leases consist of leased equipment and have three-year terms.

***Leases as 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, that 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.

Net investment in sales-type leases are included within our condensed 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). Performance-based 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 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 estimate expected term for employee awards is based on a simplified method that considers an insufficient history of employee exercises. 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 the 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, unvested RSUs and exercise of the Warrant. Potentially dilutive common shares also include common shares that would be issued upon debt conversion, exchange for Series A Preferred Stock, or in connection with a securities purchase agreement. 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 2020, the Financial Accounting Standards Board (“FASB”) issued Accounting Standard Update (“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). This update simplifies the accounting for convertible debt instruments by removing the beneficial conversion and cash conversion separation models for convertible instruments. Under the update, the embedded conversion features are no longer separated from the host contract for convertible instruments with conversion features that are not required to be accounted for as derivatives or that do not result in substantial premiums accounted for as paid-in capital. The update also amends the accounting for certain contracts in an entity’s own equity that are currently accounted for as derivatives because of specific settlement provisions. In addition, ASU 2020-06 requires the application of the if-converted method for calculating diluted earnings per share, which the Company already uses. The Company adopted the standard on January 1, 2022 through application of the modified retrospective method of transition. The Company applied the standard to the Notes outstanding as of January 1, 2022, as discussed in Note 10, Convertible Notes. As a result, the Notes are now accounted for as a single liability measured at their amortized cost. The Notes are no longer bifurcated between debt and equity and are instead accounted for entirely as debt at face value net of any discount or premium and issuance costs. Interest expense is comprised of (1) cash interest payments, (2) amortization of any debt discounts or premiums based on the original offering, and (3) amortization of any debt issuance costs. On January 1, 2022, the cumulative effect of adoption resulted in an increase in the net carrying amount of the Notes of $11.5 million, a decrease in additional-paid-in-capital of $37.4 million, and a decrease in accumulated deficit of $25.9 million.

In May 2021, the FASB issued ASU 2021-04, Earnings Per Share (Topic 260), Debt - Modifications and Extinguishments (Subtopic 470-50), Compensation - Stock Compensation (Topic 718), and Derivatives and Hedging - Contracts in Entity’s Own Equity (Topic 815 - 40). ASU 2021-04 codifies the final consensus reached by the Emerging Issues Task Force (EITF) on how an issuer should account for modifications made to equity-classified written call options (hereafter referred to as a warrant to purchase the issuer’s common stock). The guidance in the ASU requires the issuer to treat a modification of an equity-classified warrant that does not cause the warrant to become liability-classified as an exchange of the original warrant for a new warrant. This guidance applies whether the modification is structured as an amendment to the terms and conditions of the warrant or as termination of the original warrant and issuance of a new warrant. This ASU was adopted January 1, 2022, and did not impact the Company's consolidated financial statements at January 1, 2022.

In November 2021, ASU 2021-10, Government Assistance (Topic 832), Disclosures by Business Entities about Government Assistance, which aims to provide increased transparency by requiring business entities to disclose information about certain types of government assistance they receive in the notes to the financial statements. ASU 2021-10 also adds a new Topic to ASC 832, Government Assistance to the FASB’s Codification. This ASU was adopted January 1, 2022, and did not impact the Company's consolidated financial statements at January 1, 2022.

***Standards not yet adopted***

In March 2022, the FASB issued ASU 2022-01, Derivatives and Hedging (Topic 815): Fair Value Hedging - Portfolio Layer Method. ASU 2022-01 is related to the portfolio layer method of hedge accounting. The amendments in this update clarify the accounting and promote consistency in reporting for hedges where the portfolio layer method is applied. This update is effective for fiscal years beginning after December 15, 2022, and interim periods within those fiscal years. We do not expect the update to have a material effect on the consolidated financial statements.

In March 2022, the FASB issued ASU 2022-02, Financial Instruments-Credit Losses (Topic 326): Troubled Debt Restructurings and Vintage Disclosures. ASU 2022-02 relates to troubled debt restructurings (“TDRs”) and vintage disclosures for financing receivables. The amendments in this update eliminate the accounting guidance for TDRs by creditors while enhancing disclosure requirements for certain loan refinancing and restructurings by creditors made to borrowers experiencing financial difficulty. The amendments also require disclosure of current-period gross write-offs by year of origination for financing receivables. The amendments in this update are effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. We do not expect the update to have a material effect on the consolidated financial statements.

## 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, 2022, three of the Company's financial institutions held 52%, 24% and 21% of the Company’s cash and cash equivalents, respectively. As of December 31, 2021, one of the Company's financial institutions held 72% of the Company’s cash and cash equivalents.

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 15% and 13% of the Company’s net accounts receivable balance as of December 31, 2022 and 2021, respectively.

The Company did not have any customers that represented 10% or more of the Company’s total revenue for the years ended December 31, 2022, 2021 and 2020.

## 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):

| | 2022 (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 | $ 7,194 | $ — | $ — | $ 7,194 |
| Total cash and cash equivalents | 7,194 | — | — | 7,194 |
| Equity investments: | | | | |
| Mutual funds | 928 | — | — | 928 |
| Total equity investments | 928 | — | — | 928 |
| Debt securities available-for-sale: | | | | |
| Certificates of deposit | — | 2,541 | — | 2,541 |
| US Treasury securities | 3,009 | — | — | 3,009 |
| Commercial paper | — | 424 | — | 424 |
| Corporate notes and bonds | — | 3,754 | — | 3,754 |
| Total debt securities available-for-sale | 3,009 | 6,719 | — | 9,728 |
| **Total assets measured at fair value** | $ 11,131 | $ 6,719 | $ — | $ 17,850 |

| | 2021 (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 | $ 5,563 | $ — | $ — | $ 5,563 |
| Commercial paper | — | 200 | — | 200 |
| Total cash and cash equivalents | 5,563 | 200 | — | 5,763 |
| Equity investments: | | | | |
| Mutual funds | 841 | — | — | 841 |
| Total equity investments | 841 | — | — | 841 |
| Debt securities available-for-sale: | | | | |
| Certificates of deposit | — | 1,351 | — | 1,351 |
| US Treasury securities | 250 | — | — | 250 |
| Commercial paper | — | 8,046 | — | 8,046 |
| Corporate notes and bonds | — | 13,232 | — | 13,232 |
| Total debt securities available-for-sale | 250 | 22,629 | — | 22,879 |
| **Total assets measured at fair value** | $ 6,654 | $ 22,829 | $ — | $ 29,483 |

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, 2022.

The Company has Notes, as described in Note 10, Convertible Notes. At December 31, 2022, the Notes had an outstanding principle of $56.6 million with a fair value of $51.9 million. At December 31, 2021, the Notes had an outstanding principle of $120.5 million with a fair value of $89.4 million. The fair value of the Notes is classified as Level 2 within the fair value hierarchy.

The Secured Note is an instrument measured at fair value on a non-recurring basis using Level 3 inputs. The estimated fair value of the Secured Note on August 15, 2022 was $16.0 million. See Note 11, Long-Term Debt Related-Party for further detail on the Secured Note.

The warrant is an instrument measured at fair value on a non-recurring basis using Level 3 inputs. The estimated fair value of the warrant on August 15, 2022 was $3.8 million. See Note 11, Long-Term Debt Related-Party for further detail on the Company's warrant with a related-party.

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**
**2022**
(in thousands)

| | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
|---|---|---|---|---|
| Certificates of deposit | $ 2,548 | $ — | $ (7) | $ 2,541 |
| U.S. Treasury securities | 3,015 | — | (6) | 3,009 |
| Commercial paper | 425 | — | (1) | 424 |
| Corporate notes and bonds | 3,769 | — | (15) | 3,754 |
| Total | $ 9,757 | $ — | $ (29) | $ 9,728 |

**AVAILABLE-FOR-SALE INVESTMENTS**
**2021**
(in thousands)

| | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
|---|---|---|---|---|
| Certificates of deposit | $ 1,351 | $ — | $ — | $ 1,351 |
| U.S. Treasury securities | 250 | — | — | 250 |
| Commercial paper | 8,048 | — | (2) | 8,046 |
| Corporate notes and bonds | 13,245 | — | (13) | 13,232 |
| Total | $ 22,894 | $ — | $ (15) | $ 22,879 |

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)

| | 2022 | | 2021 | |
|---|---|---|---|---|
| | Amortized Cost | Fair Value | Amortized Cost | Fair Value |
| Due in less than 1 year | $ 9,757 | $ 9,728 | $ 22,663 | $ 22,649 |
| Due in 1-5 years | — | — | 231 | 230 |
| Total | $ 9,757 | $ 9,728 | $ 22,894 | $ 22,879 |

Proceeds from sales of marketable securities (including principal payments) for the years ended December 31, 2022, 2021 and 2020, were $0.0 million, $0.3 million and $0.0 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, 2022, 2021 and 2020. No material balances were reclassified out of accumulated other comprehensive loss for the years ended December 31, 2022, 2021 and 2020. No unrealized losses on debt securities available-for-sale have been recognized in income for the years ended December 31, 2022, 2021 and 2020 as the issuers of such securities held by us were of high credit quality.

As of December 31, 2022 and 2021, 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, 2022 and 2021, there were no debt securities available-for-sale in a material unrealized loss position.

Equity securities are comprised of investments in mutual funds. The fair value of equity securities at December 31, 2022 and 2021 were $0.9 million and $0.8 million, respectively. Unrealized losses or gains on equity securities recorded in income during the year ended December 31, 2022, 2021 and 2020 were as follows (in thousands):

| | 2022 | 2021 | 2020 |
|---|---|---|---|
| Unrealized loss on equity investments | $ (211) | $ — | $ — |

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 during the years ended December 31, 2022, 2021 and 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):

| | 2022 | 2021 |
|---|---|---|
| Raw materials | $ 1,827 | $ 1,343 |
| Work in process | 2,115 | 1,625 |
| Finished goods | 1,252 | 2,099 |
| Inventory | $ 5,194 | $ 5,067 |

During the year ended December 31, 2021, the Company recorded a charge of $4.5 million to cost of sales to write-down excess quantities of instrument raw materials and work in process inventory. There was no write-down of inventory required in 2022.

**NOTE 7. PROPERTY AND EQUIPMENT**

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

| | 2022 | 2021 |
|---|---|---|
| Computer equipment | $ 3,551 | $ 3,181 |
| Technical equipment | 3,236 | 3,285 |
| Facilities | 3,663 | 3,675 |
| Instruments | 3,735 | 5,364 |
| Capital projects in progress | 114 | 683 |
| Total property and equipment | $ 14,299 | $ 16,188 |
| Accumulated depreciation | (10,821) | (10,799) |
| Net property and equipment | $ 3,478 | $ 5,389 |

Depreciation expense for the years ended December 31, 2022, 2021 and 2020 was $1.7 million, $2.0 million and $2.4 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):

| | 2022 | 2021 |
|---|---|---|
| Instruments at cost under operating leases | $ 2,585 | $ 3,110 |
| Accumulated depreciation under operating leases | (1,209) | (1,165) |
| Net property and equipment under operating leases | $ 1,376 | $ 1,945 |

**NOTE 8. 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):

| | 2022 | 2021 |
|---|---|---|
| Products and services not yet delivered | $ 547 | $ 451 |
| Deferred revenue | $ 547 | $ 451 |

We recognized $0.4 million, $0.3 million and $0.2 million of revenues during the years ended December 31, 2022, 2021 and 2020, respectively, 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, 2022, $8.1 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 9. LONG-TERM DEBT**

As of December 31, 2022 and 2021, long-term debt consisted of the following (in thousands):

| | 2022 | 2021 |
|---|---|---|
| Other Loans - various interest | $ — | $ 80 |
| Total debt | — | 80 |
| Current portion of long-term debt | — | 80 |
| Long-term debt | $ — | $ — |

***PPP Loan***

During April 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.

During September 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. The amended terms required 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 bore an interest at a rate of 1% per annum.

The proceeds from the PPP Note could only be used for payroll costs (including benefits), interest on mortgage obligations, rent, utilities and interest on certain other debt obligations.

Pursuant to the terms of the CARES Act and the PPP, the Company could apply to the lender for forgiveness for the amount due on the Loan. The amount eligible for forgiveness was based on the amount of Loan proceeds used by the Company (during the 24-week period after the lender made 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.

During January 2021, the Company submitted its application for forgiveness to the lender. During July 2021, the SBA informed the Company of its full forgiveness for the entire loan amount plus accrued interest, which was $4.8 million as of the date of forgiveness. The SBA’s determination of loan forgiveness does not preclude further investigation by the SBA according to its rules and regulations. With approval of the Company's application for forgiveness the Company recorded a gain on extinguishment of $4.8 million during the year ended December 31, 2021.

**NOTE 10. 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 matured on March 15, 2023.

The Company incurred issuance costs related to the issuance of the Notes which is 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 was 3.2%.

The Notes include customary terms and covenants, including certain events of default upon which the Notes may be due and payable immediately. Holders had 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 could have converted 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 (the "Indenture")) were, 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, subject to certain conditions, had 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.

As of December 31, 2022, $56.4 million aggregate principal amount of the Notes were outstanding and convertible pursuant to their original terms, none of which were converted prior to the Maturity Date. The Notes matured on March 15, 2023 and became due and payable. On March 9, 2023, the Company entered into a Forbearance Agreement (the "Forbearance Agreement"), which became effective on March 13, 2023, with certain holders of the Notes holding approximately 85% of the Company's outstanding Notes (collectively, the "Ad Hoc Noteholder Group"), the trustee for the Notes (the "Trustee") and any other owner of the Notes who executes and delivers to the Company a joinder to the Forbearance Agreement (collectively with the Trustee and Ad Hoc Noteholder Group, the "Counterparties"). Pursuant to the Forbearance Agreement, the members of the Ad Hoc Noteholder Group have agreed, and have directed the Trustee, to forbear from exercising their rights and remedies under the Indenture in connection with certain events of default under the Indenture, including, but not limited to, the failure to timely pay in full the principal of any Note when due and payable on March 15, 2023 and the failure to pay any interest on any Note when due and payable. See Note 21, Subsequent Events for additional information regarding the Forbearance Agreement.

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

| | 2022 | 2021 |
|---|---|---|
| Outstanding principal | $ 56,595 | $ 120,500 |
| Unamortized debt issuance | (182) | (729) |
| Unamortized debt discount | — | (11,787) |
| Net carrying amount | $ 56,413 | $ 107,984 |

As of December 31, 2022 the Notes were classified as follows (in thousands):

| | 2022 | 2021 |
|---|---|---|
| Current portion of convertible notes | $ 56,413 | $ — |
| Non-current portion of convertible notes | — | 107,984 |
| Total convertible notes | $ 56,413 | $ 107,984 |

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

| | 2022 | 2021 | 2020 |
|---|---|---|---|
| Contractual coupon interest | $ 1,794 | $ 3,934 | $ 4,288 |
| Amortization of the debt discount | — | 10,869 | 10,518 |
| Amortization of debt issuance costs | 474 | 672 | 651 |
| Total interest expense on convertible notes | $ 2,268 | $ 15,475 | $ 15,457 |

Net gain on extinguishment of exchanged Notes for the years ended December 31 is as follows (in thousands):

| | 2022 | 2021 | 2020 |
|---|---|---|---|
| Gain on extinguishment | $ 3,565 | $ 4,916 | $ — |

***2021 Exchange Transactions***

On September 22, 2021, the Company entered into separate exchange agreements with certain holders of the Notes. Under the terms of the exchange agreements, such holders agreed to exchange Notes held by them for shares of the Company's common stock. During the year ended December 31, 2021, $51.0 million in aggregate principal amount of Notes were exchanged for 6,602,974 shares of the Company's common stock. The carrying value of the Notes was $44.7 million while the estimated fair value of the shares was $38.9 million at the time of the exchange. The Company incurred $0.9 million of reacquisition costs, which was as an offset to gain on extinguishment of debt during the year ended December 31, 2021. This resulted in a net gain of $4.9 million reflected in other income (expense), net in the consolidated statement of operations during the year ended December 31, 2021. See Note 19, Stockholders' Equity for additional information.

***March 2022 Exchange Transaction***

On March 21, 2022, the Company entered into an exchange agreement with one holder of the Notes. Under the terms of the exchange agreement, the holder agreed to exchange Notes held by them for shares of the Company's common stock. During the year ended December 31, 2022, $14.0 million in aggregate principal amount of Notes were exchanged for 10,798,482 shares of the Company's common stock. The carrying value of the Notes was $14.0 million while the estimated fair value of the shares was $10.2 million at the time of the exchange. The Company incurred $0.2 million of reacquisition costs, which was recorded as an offset to gain on extinguishment of debt during the year ended December 31, 2022. This resulted in a net gain of $3.6 million reflected in other income (expense), net in the consolidated statement of operations during the year ended December 31, 2022. See Note 19, Stockholders' Equity for additional information.

***August 2022 Exchange Transaction***

On August 15, 2022, the Company entered into an exchange agreement (the "August 2022 Exchange Agreement") with the Jack W. Schuler Living Trust (the "Schuler Trust"). Under the terms of the August 2022 Exchange Agreement, the Schuler Trust agreed to exchange with the Company $49.9 million in aggregate principal amount of Notes held by it for (a) a secured promissory note in an aggregate principal amount of $34.9 million (the "Secured Note") and (b) a warrant to acquire the Company's common stock (the "Warrant") at an exercise price of $2.12 per share (the "Exercise Price"). The carrying value of the Notes was $49.6 million at the time of the exchange. The estimated fair value of the Secured Note and the Warrant at the time of the exchange was $16.0 million and $3.8 million, respectively, which resulted in a net gain of $29.8 million that was recorded to contributed capital.

The Secured Note includes various features that were advantageous to the Company, including a lower interest rate compared to current market rates and a share conversion feature. There were no other negotiating parties that had similar terms or economic outcomes. As such, the exchange was considered not to be an arm's length transaction, and therefore the resulting gain was accounted for as a capital transaction. See Note 11, Long-Term Debt Related-Party and Note 19, Stockholders' Equity for additional information.

***Prepaid Forward***

In 2018, in connection with the Notes, 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. During March 2023, 1,858,500 shares of Common Stock were returned to the Company pursuant to our agreement with the counterparty. As of December 31, 2022, these 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. See Note 21, Subsequent Events for additional information.

**NOTE 11. LONG-TERM DEBT RELATED-PARTY**

On August 15, 2022, the Company entered into the August 2022 Exchange Agreement with the Schuler Trust, a holder of the Notes. Jack Schuler, who serves as a member of the Company's board of directors, is the sole trustee of the Schuler Trust. Under the terms of the August 2022 Exchange Agreement, the Schuler Trust agreed to exchange with the Company $49.9 million in aggregate principal amount of Notes held by it (the "Exchanged Notes") for (a) a secured promissory note in an aggregate principal amount of $34.9 million (the "Secured Note") and (b) a Warrant to acquire the Company's common stock at an exercise price of $2.12 per share (the "Warrant").

The Secured Note has a scheduled maturity date of August 15, 2027 and is repayable upon written demand at any time on or after such date. The Company may, at its option, repay the Secured Note in (i) cash or (ii) in the form of common stock of the Company, in a number of shares that is obtained by dividing the total amount of such payment by $2.12. However, the payment in common stock is subject to certain limitations, including that the aggregate amount of common shares issued to settle the debt not exceed 19.99% of the Company's then outstanding shares of common stock. The Secured Note bears interest at a rate of 5.0% per annum, payable at the option of the Company in the same form, at the earlier of (i) any prepayment of principal and (ii) maturity. The Company may prepay the Secured Note at any time without premium or penalty. The Secured Note is secured by substantially all of the assets of the Company, subject to customary exceptions and limitations, pursuant to a security agreement, dated as of August 15, 2022. The Secured Note does not restrict the incurrence of future indebtedness by the Company but shall become subordinated in right of payment and lien priority upon the request of any future senior lender.

Under ASC 470-50-40, the transaction qualified as an extinguishment of debt. Under extinguishment accounting, the Exchanged Notes were derecognized and the new instruments, which include the Secured Note and the Warrant, were recorded at their fair values on the issuance date, August 15, 2022. See Note 10, Convertible Notes for additional information. The fair value of the Secured Note was $16.0 million and was estimated using a Monte Carlo simulation which simulated the share price of the Company over the remaining term through the Secured Note's maturity date. The simulated per-share price in a given iteration determined if the Company settled in cash or shares, and the mean present value of the iterations was concluded as the estimated fair value. The fair value of the Secured Note is a non-recurring measurement that is categorized as Level 3 within the fair value hierarchy as it is based on Level 2 and Level 3 inputs. Based on a face value of $34.9 million and fair value of $16.0 million, the Company recorded a debt issuance discount of $18.9 million, which is being amortized over the life of the Secured Note using the effective interest method. The effective interest rate on the Secured Note is 24.60%.

The table below summarizes the significant assumptions and inputs used to estimate the fair value of the Secured Note as of August 15, 2022:

| | 2022 |
|---|---|
| Stock price | $ 2.68 |
| Term (years) | 5 |
| Volatility | 84.30 % |
| Risk-free rate | 2.91 % |

The carrying value of the Secured Note at December 31, 2022 consisted of the following (in thousands):

| | 2022 |
|---|---|
| Outstanding principal | $ 34,934 |
| Unamortized debt issuance discount | (18,076) |
| Net carrying amount | $ 16,858 |

Interest expense consisted of the following for the year ended December 31 (in thousands):

| | 2022 |
|---|---|
| Contractual interest | $ 663 |
| Amortization of the debt discount | 834 |
| Total interest expense | $ 1,497 |

The Secured Note's carrying amount of $16.9 million and accrued interest expense of $0.7 million are recorded in non-current liabilities on the Company's consolidated balance sheet as of December 31, 2022. Neither the principal amount nor the accrued interest are contractually payable within twelve months of the balance sheet date of December 31, 2022. The Secured Note's interest is payable at the option of the Company in the same form as the principal, at the earlier of (i) any prepayment of principal and (ii) maturity. It is the Company's intention to pay all interest at maturity.

No principal or accrued interest have been paid or shares issued as of December 31, 2022.

The following presents maturities of future principal and accrued interest obligations of the Secured Note as of December 31, 2022 (in thousands):

| | Principal | Accrued Interest | Total |
|---|---|---|---|
| 2023 | $ — | $ — | $ — |
| 2024 | — | — | — |
| 2025 | — | — | — |
| 2026 | — | — | — |
| 2027 | 34,934 | 663 | 35,597 |
| Thereafter | — | — | — |
| Total | $ 34,934 | $ 663 | $ 35,597 |

If the Company were to make a first and final interest payment on the maturity date of August 15, 2027, the interest payable amount would be $9.9 million.

***Warrant***

The Warrant may be exercised from February 15, 2023 through the earlier of (i) August 15, 2029 and (ii) the consummation of certain acquisition transactions involving the Company (the "exercise period"), as set forth in the Warrant agreement. The Warrant is exercisable for up to 2,471,710 shares of the Company's common stock and may be exercised in whole or in part at any time during the exercise period. The Company determined that the Warrant meets the criteria for classification in stockholders' equity and was recorded in equity and initially measured at fair value on the issuance date. The fair value of the Warrant was $3.8 million and was estimated using the Black-Scholes option pricing model. The fair value of the Warrant is a non-recurring measurement that is categorized as Level 3 within the fair value hierarchy as it is based on Level 2 and Level 3 inputs. No portion of the Warrant has been exercised as of December 31, 2022.

The table below summarizes the significant assumptions and inputs used to estimate the fair value of the Warrant as of August 15, 2022:

| | | 2022 |
|---|---|---|
| Stock market price | $ | 2.12 |
| Exercise price | $ | 2.12 |
| Contractual term (in years) | | 7 |
| Volatility | | 76.10 % |
| Expected dividends | | — |
| Risk free interest rates | | 2.86 % |

**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):

| | 2022 | 2021 | 2020 |
|---|---|---|---|
| Shares issuable upon the release of restricted stock units | 4,355 | 2,090 | 526 |
| Shares issuable upon exercise of stock options | 5,409 | 7,193 | 8,045 |
| Shares issuable upon the exercise of the Warrant | 2,472 | — | — |
| | 12,236 | 9,283 | 8,571 |

As discussed in Note 10, Convertible Notes, as of December 31, 2022, $56.4 million aggregate principal amount of the Notes were outstanding and convertible pursuant to their original terms, none of which were converted prior to the Maturity Date.

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. On March 24, 2023, 1,858,500 shares of Common Stock were returned to the Company pursuant to our agreement with the counterparty.

Potentially dilutive common shares would also include common shares that would be outstanding if Series A Preferred Stock were converted into common stock. Each share of Series A Preferred Stock is convertible, at the option of the holder, at any time into one share of the Company's common stock. Additionally, each share of Series A Preferred Stock will automatically be converted into one share of the Company's common stock immediately upon a sale of all outstanding stock of the Company or a merger of the Company into another corporation where the pre-merger Company's stockholders cease to be the controlling stockholders of the post-merger corporation. The number of shares of common stock issuable upon conversion of the Series A Preferred Stock is 3,954,546 as of December 31, 2022.

As discussed in Note 19, Stockholders' Equity, the Company entered into a securities purchase agreement with the Schuler Trust for the issuance and sale by the Company of an aggregate of 2,439,024 shares of the Company's common stock. The closing of the transaction is expected to occur in 2023, subject to the satisfaction of customary closing conditions and is considered an equity forward agreement. The shares to be issued from this agreement were not included in the computation of diluted net loss per share because they would have an anti-dilutive effect due to net losses.

As discussed in Note 11, Long-Term Debt Related-Party, the Company may, at its option, repay the Secured Note in (i) cash or (ii) in the form of common stock of the Company, in a number of shares that is obtained by dividing the total amount of such payment by $2.12. The number of shares of common stock issuable upon conversion of the Secured Note and accrued interest was approximately 16,478,066 and 312,812 shares respectively, as of December 31, 2022. The shares issuable in connection with a repayment of the Secured Note were not included in the computation of diluted net loss per share because they would have an anti-dilutive effect due to net losses. The amount of shares to repay the Secured Notes, shall not exceed an aggregate amount of 19.99% of the Company's outstanding shares of common stock.

**NOTE 13. EMPLOYEE EQUITY-BASED COMPENSATION**

The Company has one equity-based compensation plan as of December 31, 2022, which is discussed below:

***2012 Omnibus Equity Incentive Plan***

The 2012 Omnibus Equity Incentive Plan (the "2012 Incentive Plan") was set to automatically expire pursuant to its terms in October 2022. Accordingly, on March 16, 2022, the Board approved, subject to the approval of our stockholders, the Accelerate Diagnostics, Inc. 2022 Omnibus Incentive Compensation Plan (the "2022 Incentive Plan") which was approved by share holders on May 12, 2022 (the "Effective Date"). The 2012 Incentive Plan was automatically replaced and superseded by the 2022 Incentive Plan on the the Effective Date. Outstanding awards granted under the 2012 Incentive Plan will remain in effect pursuant to their terms. Shares of common stock that remained authorized for grant under the 2012 Incentive Plan following the effective date was 11,458,205.

***2022 Omnibus Equity Incentive Plan***

The Company's stockholders approved the Company's 2022 Incentive Plan on the Effective Date to replace all prior plans ("Prior Plans"). The total number of shares of the Company's common stock reserved and available for grant pursuant to the 2022 Incentive Plan is 5,500,000, plus the number of shares of common stock that remain available or that otherwise become available for grant under the 2012 Incentive Plan. The total reserved shares for the 2022 Incentive Plan was 16,958,205 as of the effective date, which included 11,458,205 reserved shares from the 2012 Incentive Plan.

Total reserved shares under the 2022 Incentive Plan is 16,703,198 as of December 31, 2022, which includes 9,764,081 shares outstanding, and 6,939,117 available for grant.

Stock options granted under this plan vest in a range from immediate to 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.

The following table summarizes option activity under the plan during the years ended December 31, 2022 and 2021 and shows the exercisable shares as of December 31, 2022:

| | Number of Shares | Weighted Average Exercise Price per Share |
|---|---|---|
| **Options Outstanding January 1, 2021** | **8,045,461** | **$ 14.18** |
| Granted | 489,804 | 7.09 |
| Forfeited | (370,106) | 14.04 |
| Exercised | (426,762) | 3.79 |
| Expired | (545,857) | 19.85 |
| **Options Outstanding December 31, 2021** | **7,192,540** | **13.89** |
| Granted | 140,000 | 3.05 |
| Forfeited | (208,569) | 12.58 |
| Exercised | (6,105) | 1.04 |
| Expired | (1,709,205) | 10.96 |
| **Options Outstanding December 31, 2022** | **5,408,661** | **14.60** |
| Exercisable December 31, 2022 | 4,263,496 | 15.39 |

The cash received from the exercise of options during the year ended December 31, 2022 was immaterial. Upon exercise, shares are issued from shares authorized and held in reserve. The intrinsic value of options exercised was $0.0 million, $3.3 million and $23.5 million for the years ended December 31, 2022, 2021 and 2020, respectively.

The total fair value of options vesting during the period was $7.2 million, $11.1 million, and $9.0 million for the years ended December 31, 2022, 2021 and 2020, 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:

| | 2022 | 2021 | 2020 |
|---|---|---|---|
| Expected term (in years) | 6.30 | 5.79 | 5.94 |
| Volatility | 66 % | 65 % | 58 % |
| Expected dividends | — | — | — |
| Risk free interest rates | 2.1 % | 1.1 % | 0.6 % |
| Estimated forfeitures | — % | — % | — % |
| Weighted average fair value | $ 1.88 | $ 4.09 | $ 4.49 |

The following table shows summary information for outstanding options and options that are exercisable (vested) as of December 31, 2022:

| | Options Outstanding | Options Exercisable |
|---|---|---|
| Number of options | 5,408,661 | 4,263,496 |
| Weighted average remaining contractual term (in years) | 5.25 | 4.82 |
| Weighted average exercise price | $ 14.60 | $ 15.39 |
| Weighted average fair value | $ 9.08 | $ 9.46 |
| Aggregate intrinsic value (in millions) | $ — | $ — |

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 $0.71 on the last trading day of 2022 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, 2022 and 2021:

| | Number of Shares | Weighted Average Grant Date Fair Value per Share |
|---|---|---|
| **RSUs & Stock Grants Outstanding January 1, 2021** | **526,414** | **$ 11.17** |
| Granted | 2,704,948 | 11.23 |
| Forfeited | (479,472) | 11.01 |
| Vested/released | (661,708) | 12.23 |
| **RSUs & Stock Grants outstanding December 31, 2021** | **2,090,182** | **10.77** |
| Granted | 4,227,921 | 1.53 |
| Forfeited | (662,038) | 8.28 |
| Vested/released | (1,300,645) | 3.70 |
| **RSUs & Stock Grants outstanding December 31, 2022** | **4,355,420** | **4.29** |

The total fair value of RSUs and stock grants vested and released during the period was $4.8 million, $8.1 million, and $2.7 million for the years ended December 31, 2022, 2021 and 2020, 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 ended December 31:

| | 2022 | 2021 | 2020 |
|---|---|---|---|
| Weighted average fair value | $ 1.53 | $ 11.23 | $ 11.44 |

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:

| | 2022 | 2021 | 2020 |
|---|---|---|---|
| Cost of Sales | $ 665 | $ 325 | $ 351 |
| Research and development | 1,419 | 4,102 | 4,035 |
| Sales, general and administrative | 8,541 | 17,620 | 12,078 |
| Total equity-based compensation expense | $ 10,625 | $ 22,047 | $ 16,464 |
| 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:

| | 2022 | 2021 | 2020 |
|---|---|---|---|
| Cost capitalized to inventory | $ 254 | $ 401 | $ 253 |

As of December 31, 2022, unrecognized equity-based compensation cost related to unvested stock options, and unvested RSUs was $1.7 million and $5.7 million, respectively. This is expected to be recognized over the years 2023 through 2027.

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.

During 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 due to the performance targets not being achieved in prior periods. During the year ended December 31, 2021, 75,000 performance-based stock options expired as they weren't exercised. Of these performance-based stock options, none were outstanding as of December 31, 2021.

During 2020, the Company granted another 105,000 performance-based stock options. Of these performance-based stock options, performance obligations had been met for 90,000 options which became exercisable. This included 45,000 performance-based stock options which vested during the year ended December 31, 2021, and the remaining 45,000 performance-based stock options vesting during the prior year. During the year ended December 31, 2021, 15,000 performance-based stock options were forfeited due to the performance targets not being achieved. During the year ended December 31, 2022, 90,000 performance-based stock options expired as they weren't exercised. Of these performance-based stock options, none were outstanding as of December 31, 2022.

As of December 31, 2022 no performance-based stock options were outstanding.

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

| | 2022 | 2021 | 2020 |
|---|---|---|---|
| Performance-based stock option expense | $ — | $ 230 | $ 215 |

Included in the above-noted RSU outstanding amount are performance-based RSUs which vest only upon the achievement of certain targets. Performance-based RSUs 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 2020, the Company granted 364,338 performance-based RSUs. During the year ended December 31, 2021, 84,000, of these performance-based RSUs were released due to the performance obligations being achieved with an additional 81,000 being released in prior periods. During the year ended December 31, 2022, 2021 and 2020, 165,974, 9,369, 23,995 of these performance-based RSUs were forfeited, respectively, due to performance obligations not being achieved or employees separating from the Company. Of these performance-based RSUs, none were outstanding as of December 31, 2022.

During 2021, the Company granted 233,472 performance-based RSUs. None of these performance-based RSUs have been released. During the year ended December 31, 2022 and 2021, 8,507 and 121,666 of these performance-based RSUs were forfeited, respectively, due to performance obligations not being achieved or employees separating from the Company. Of these performance-based RSUs, 103,299 of these were outstanding as of December 31, 2022.

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

| | 2022 | 2021 | 2020 |
|---|---|---|---|
| Performance-based RSU expense | $ — | $ 818 | $ 810 |

**NOTE 14. INCOME TAXES**

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

| | 2022 | 2021 | 2020 |
|---|---|---|---|
| U.S. Domestic | $ (54,099) | $ (68,131) | $ (66,482) |
| Foreign | (8,471) | (9,526) | (11,721) |
| Net loss before income taxes | $ (62,570) | $ (77,657) | $ (78,203) |

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

| | 2022 | 2021 | 2020 |
|---|---|---|---|
| Current: | | | |
| Federal | $ — | $ — | $ — |
| State | (19) | (18) | (1) |
| Foreign | 96 | (27) | (4) |
| Total benefit (provision) | 77 | (45) | (5) |
| Deferred: | | | |
| Federal | — | — | — |
| State | — | — | — |
| Foreign | — | — | — |
| Total deferred provision | — | — | — |
| Total benefit (provision) | $ 77 | $ (45) | $ (5) |

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 as of December 31 are as follows (in thousands):

| | 2022 | 2021 |
|---|---|---|
| Deferred tax assets: | | |
| Net operating loss carryforward | $ 94,003 | $ 93,056 |
| General business credit | 17,293 | 16,364 |
| Stock options | 12,809 | 14,851 |
| Intangible assets, definite-lived | 7,239 | 8,047 |
| Section 174 research & development | 4,840 | — |
| Inventory | 2,145 | 1,790 |
| Operating lease liability | 568 | 734 |
| Property & equipment | 137 | 284 |
| Other | 310 | 339 |
| Total deferred tax assets | 139,344 | 135,465 |
| Valuation allowance | (138,710) | (131,839) |
| Deferred tax assets | $ 634 | $ 3,626 |
| | | |
| Deferred tax liabilities: | | |
| Debt amortization | $ (24) | $ (2,933) |
| Right of use asset | (527) | (693) |
| Finance lease liability | $ (83) | $ — |
| Total deferred tax liabilities | $ (634) | $ (3,626) |
| | | |
| Net deferred taxes | $ — | $ — |

As of December 31, 2022, the Company generated regular tax federal net operating losses (“NOLs”) of approximately $383.7 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. Of the Company's total federal net operating loss of $383.7 million, $169.8 million will begin to expire in 2023 and $213.9 million will not expire but will only offset 80% of taxable income generated in tax years after 2020.

As of December 31, 2022, the Company has generated state net operating losses of approximately $369.6 million. The Company's state net operating losses will begin to expire in 2033.

As of December 31, 2022, the Company has generated $14.5 million of federal research and development (“R&D”) tax credits which begin to expire in 2032.

As of December 31, 2022, the Company has generated $12.4 million of state R&D tax credits which begin to expire in 2032.

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 $138.7 million as of December 31, 2022, compared to $131.8 million as of December 31, 2021. 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 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 has 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 would be recorded as a component of income tax expense or benefit.

The Company adopted ASU 2020-06 on January 1, 2022, as discussed in Note 2, Summary of Significant Accounting Policies - Recent Accounting Pronouncements. This update simplifies the accounting for convertible debt instruments by removing the beneficial conversion and cash conversion separation models for convertible instruments. As a result, the Notes are no longer bifurcated between debt and equity and are accounted for entirely as debt at face value net of any discount or premium and issuance costs. On January 1, 2022, the cumulative effect of adoption resulted in an increase in the net carrying amount of the Notes of $11.5 million.

The deferred tax liability recognized upon the issuance of the Notes of $3.0 million was also reversed from additional-paid-in-capital, with a corresponding adjustment to the valuation allowance, as of January 1, 2022.

As discussed in Note 11, Long-Term Debt Related-Party, the Company entered into the August 2022 Exchange Agreement with the Schuler Trust on August 15, 2022 to exchange $49.9 million in Notes for the Secured Notes of $34.9 million and warrants valued at $3.8 million to acquire the Company’s common stock. The gain from the partial extinguishment of the Notes was treated as a capital transaction and was recorded to contributed capital for $29.8 million. For the year ended December 31, 2022, the Company recorded the current and deferred tax impact of the transaction to additional paid in capital, with a corresponding adjustment to the valuation allowance, having no net impact on the Company’s financial statements.

The Company began commercialization of its products in Europe in 2016 and has subsidiaries in the Netherlands, France, Germany, Italy, Spain 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 the suspension of 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 were 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. This did not have a material impact to the Company.

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:

| | 2022 | 2021 | 2020 |
|---|---|---|---|
| U.S. federal statutory income tax rate | (21.00)% | (21.00)% | (21.00)% |
| State taxes, net of federal tax benefit | (2.55)% | (4.26)% | (4.95)% |
| Permanent and other differences | 1.74 % | (9.01)% | 2.35 % |
| Loan forgiveness | — % | (1.31)% | — % |
| Change in tax rates | 0.26 % | 0.02 % | (0.05)% |
| Tax rate differential | (0.52)% | 2.30 % | 3.09 % |
| Unrecognized tax benefits | 1.01 % | 2.64 % | 1.34 % |
| Nondeductible equity and other compensation | 5.44 % | 1.72 % | (3.38)% |
| Credit for increased research activities | (2.80)% | (6.19)% | (6.29)% |
| Change in valuation allowance | 18.30 % | 35.15 % | 28.89 % |
| | (0.12)% | 0.06 % | — % |

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

| | 2022 | 2021 | 2020 |
|---|---|---|---|
| Balance at beginning of year | $ 7,556 | $ 4,866 | $ 3,712 |
| Increases for prior positions | 380 | 2,359 | — |
| Increases for current year positions | 5,660 | 1,746 | 1,154 |
| Decreases due to settlements | — | (1,415) | — |
| Other increases | — | — | — |
| Balance at end of year | $ 13,596 | $ 7,556 | $ 4,866 |

These uncertain positions are not expected to change within the next twelve months. Of the $13.6 million of uncertain tax positions, $0.1 million would impact the effective tax rate, if reversed. The Company accounts for interest and penalties on uncertain tax positions within tax expense. The Company's foreign subsidiaries are generally 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 currently 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 substantially completed the IRS audit of the 2018 tax year during 2021. The IRS assessed an adjustment reducing the Company's 2018 R&D tax credit. The IRS assessed an adjustment reducing the Company's 2018 NOL. The Company has removed the associated reserve for uncertain tax benefits during the year ended December 31, 2022 and adjusted the deferred tax asset for the NOL and R&D credit carryforwards as a result of the audit settlement. During the year ended December 31, 2022, the Company increased its reserve for uncertain tax positions in connection with the exchange of debt. No cash taxes, interest or penalties were paid in connection with this settlement. The Company’s foreign income tax filings are subject to examination by the appropriate foreign tax authorities. The Company is not otherwise currently under examination by tax authorities.

**NOTE 15. COMMITMENTS AND CONTINGENCIES**

During April 2022, the Company entered into a non-cancellable purchase obligation with a supplier to acquire raw materials for a total commitment of $11.9 million. Under the terms of this agreement the Company has until March 15, 2027 to take delivery of purchased items. This commitment was entered into to ensure proper material quantities to develop and commercialize our next generation AST platform.

As of December 31, 2022 the commitment remains $11.9 million as the Company has not taken delivery of any inventory.

**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):

| | 2022 | 2021 |
|---|---|---|
| **Cash paid for amounts included in lease liabilities** | | |
| Operating cash flows from operating leases | $ 850 | $ 680 |
| Operating cash flows from finance leases | 1,201 | — |
| **ROU assets obtained in exchange for lease obligations** | | |
| Operating leases | — | — |
| Finance leases | 3,096 | — |
| **Lease Cost** | | |
| Operating leases | 1,114 | 1,095 |
| Finance leases | 673 | — |
| Short-term leases | $ 82 | $ 80 |

The weighted average remaining lease term on our operating leases is 2.6 years. The weighted average discount rate on those leases is 7.1%. The weighted average remaining lease term on our finance leases is 2.2 years. The weighted average discount rate on those leases is 6.2%.

The following presents maturities of operating lease liabilities in which we are the lessee as of December 31, 2022 (in thousands):

| | 2022 |
|---|---|
| 2023 | $ 968 |
| 2024 | 1,055 |
| 2025 | 585 |
| 2026 | — |
| 2027 | — |
| Thereafter | — |
| Total lease payments | 2,608 |
| Less imputed interest | (234) |
| | $ 2,374 |

The following presents maturities of finance lease liabilities in which we are the lessee as of December 31, 2022 (in thousands):

| | 2022 |
|---|---|
| 2023 | $ 992 |
| 2024 | 976 |
| 2025 | 193 |
| 2026 | — |
| 2027 | — |
| Thereafter | — |
| Total lease payments | 2,161 |
| Less imputed interest | (266) |
| | $ 1,895 |

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, 2022, the total net investment in these leases was $2.7 million. The following presents maturities of lease receivables under sales-type leases as of December 31, 2022 (in thousands):

| | 2022 |
|---|---|
| 2023 | $ 1,429 |
| 2024 | 824 |
| 2025 | 266 |
| 2026 | 123 |
| 2027 | 41 |
| Thereafter | — |
| | 2,683 |

## NOTE 17. GEOGRAPHIC AND REVENUE DISAGGREGATION

The Company operates as one operating segment. Sales to customers outside the U.S. represented 14%, 14% and 8% of total revenue for the years ended December 31, 2022, 2021 and 2020, respectively. As of December 31, 2022 and 2021, balances due from foreign customers, in U.S. dollars, were $0.6 million and $0.7 million, respectively.

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

| | 2022 | 2021 |
|---|---|---|
| Domestic | $ 3,120 | $ 5,014 |
| Foreign | 358 | 375 |
| | $ 3,478 | $ 5,389 |

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

| | 2022 | 2021 | 2020 |
|---|---|---|---|
| Domestic | $ 10,921 | $ 10,121 | $ 10,305 |
| Foreign | 1,831 | 1,661 | 860 |
| Net sales | $ 12,752 | $ 11,782 | $ 11,165 |

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

| | 2022 | 2021 | 2020 |
|---|---|---|---|
| Accelerate Pheno revenue | $ 12,598 | $ 11,628 | $ 11,025 |
| Other revenue | 154 | 154 | 140 |
| Net sales | $ 12,752 | $ 11,782 | $ 11,165 |

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

| | 2022 | 2021 | 2020 |
|---|---|---|---|
| Products | $ 11,107 | $ 10,430 | $ 10,336 |
| Services | 1,645 | 1,352 | 829 |
| Net sales | $ 12,752 | $ 11,782 | $ 11,165 |

Lease income included in net sales was $1.4 million, $1.9 million and $3.6 million for the years ended December 31, 2022, 2021 and 2020, respectively, and was recorded in accordance with ASC 842, which does not represent revenues recognized from contracts with customers in accordance with ASC 606.

## NOTE 18. SUPPLEMENTAL DATA (UNAUDITED)

The following is a summary of unaudited selected quarterly financial information for the three months ended 2022 (in thousands, except per share data):

| | December 31, | September 30, | June 30, | March 31, |
|---|---|---|---|---|
| Net sales | $ 2,973 | $ 2,960 | $ 3,861 | $ 2,958 |
| Gross profit | $ 842 | $ 579 | $ 1,080 | $ 802 |
| Loss from operations | $ (13,960) | $ (14,961) | $ (17,989) | $ (15,895) |
| Net loss | $ (14,609) | $ (15,896) | $ (18,523) | $ (13,465) |
| Basic and diluted net loss per share | $ (0.14) | $ (0.18) | $ (0.24) | $ (0.20) |

The following is a summary of unaudited selected quarterly financial information for the three months ended 2021 (in thousands, except per share data):

| | December 31, | September 30, | June 30, | March 31, |
|---|---|---|---|---|
| Net sales | $ 3,344 | $ 3,122 | $ 2,798 | $ 2,518 |
| Gross (loss) profit | $ (3,317) | $ 986 | $ 1,053 | $ 897 |
| Loss from operations | $ (19,411) | $ (14,532) | $ (17,590) | $ (20,027) |
| Net loss | $ (22,803) | $ (8,986) | $ (21,674) | $ (24,239) |
| Basic and diluted net loss per share | $ (0.34) | $ (0.15) | $ (0.36) | $ (0.41) |

## NOTE 19. STOCKHOLDERS' EQUITY

***At-The-Market Equity Sales Agreement***

During May 2021, the Company entered into an Equity Sales Agreement (the “ATM Sales Agreement”) with William Blair & Company, L.L.C. (“William Blair”) pursuant to which the Company may sell shares of its common stock having an aggregate offering price of up to $50 million, from time to time, through an “at-the-market” equity offering program under which William Blair will act as sales agent. Subject to the terms and conditions of the ATM Sales Agreement, William Blair may sell shares by any method deemed to be an “at-the-market” offering as defined in Rule 415 under the U.S. Securities Act of 1933, as amended (the “Securities Act”). The Company is not obligated to sell any shares under the ATM Sales Agreement. The Board has authorized management to sell up to a specified number of shares under the Sales Agreement within certain share price levels. The Board may choose to change such share number and share price authorizations at any time. William Blair is entitled to a commission of 3% of the aggregate gross proceeds from each sale of shares occurring pursuant to the Sales Agreement. During the year ended December 31, 2021, the Company sold 2,092,497 shares of common stock under the ATM Sales Agreement for aggregate gross proceeds of $10.9 million, which was recorded to contributed capital. No shares were sold under the ATM Sales Agreement during the year ended December 31, 2022. As of December 31, 2022, the Company had an aggregate of $39.1 million available for future sales under its at-the-market equity offering program.

***December 2020 Securities Purchase Agreement***

During December 2020, the Company entered into a securities purchase agreement (the “December 2020 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 “Original 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 Original 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 was a member of the Board at the time of the transaction. Mr. Phillips also serves as the Company’s President and Chief Executive Officer. Additionally, during December 2020, the Company entered into a registration rights agreement (the “Registration Rights Agreement”) with the Original Purchasers in connection with the December 2020 Securities Purchase Agreement pursuant to which the Company agreed to register the resale of the Shares pursuant to the terms set forth therein.

The Jack W. Schuler Living Trust (the “Schuler Trust”), which was the entity affiliated with Jack W. Schuler that originally entered into the December 2020 Securities Purchase Agreement for the purchase of 3,964,843 Shares for an aggregate purchase price of approximately $30.5 million, subsequently entered into an assignment and assumption agreement whereby it assigned all of its rights and obligations as an Original Purchaser to three other entities under the December 2020 Securities Purchase Agreement (collectively, the “Schuler Purchasers”). These three entities are related to Jack W. Schuler but are not affiliates of his.

Pursuant to the December 2020 Securities Purchase Agreement, the Original Purchasers 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 was equal to the consolidated closing bid price reported by Nasdaq immediately preceding the time the Company entered into the December 2020 Securities Purchase Agreement, for an aggregate purchase price of approximately $32 million.

The December 2020 Securities Purchase Agreement contemplated that the closing of the purchase and sale of the Shares would occur in three approximately equal tranches on the dates specified in the agreement or such other dates as the parties may agree, with the first and second tranches having closed on February 19, 2021 and April 9, 2021, respectively, whereby the Company received total proceeds of approximately $21.3 million which were recorded to contributed capital.

On September 17, 2021, the Company entered into a rescission agreement (the “Rescission Agreement”) with the Schuler Purchasers and the Schuler Trust pursuant to which, effective as of January 29, 2021, the Company and the Schuler Purchasers agreed to rescind and unwind the December 2020 Securities Purchase Agreement and the Registration Rights Agreement for all legal, tax and financial purposes ab initio as if the related transactions, including the issuance and sale of an aggregate of 2,643,228 Shares in the first two tranche closings and the third tranche (as discussed below) under the December 2020 Purchase Agreement, had never occurred with respect to the Schuler Purchasers and the Company. The Rescission Agreement was entered into due to the unanticipated legal, tax and/or financial consequences that may have otherwise resulted from the December 2020 Purchase Agreement and the Registration Rights Agreement. The 2,643,228 Shares re-acquired by the Company from the Schuler Purchasers as a result of the Rescission Agreement are treated as a reduction to contributed capital and are not outstanding for purposes of the calculation of basic and diluted earnings per share.

On September 30, 2021, the Company closed the final third tranche in connection with the December 2020 Securities Purchase Agreement and received total proceeds of approximately $0.5 million. In accordance with the Rescission Agreement, the Schuler Purchasers did not participate in the third tranche. During the year ended December 31, 2021, the Company issued 201,820 Shares and received total proceeds of approximately $1.5 million under the December 2020 Securities Purchase Agreement, which were recorded to contributed capital, after giving effect to the Rescission Agreement.

***September 2021 Securities Purchase Agreement***

During September 2021, the Company entered into a new securities purchase agreement (the “September 2021 Securities Purchase Agreement”) with the Schuler Purchasers for the issuance and sale by the Company of an aggregate of 3,954,546 shares of the Company’s newly designated Series A Preferred Stock, par value $0.001 per share (the “Series A Preferred Shares”), to the Schuler Purchasers in an offering exempt from registration pursuant to Section 4(a)(2) of the Securities Act and Rule 506 promulgated thereunder.

Pursuant to the September 2021 Securities Purchase Agreement, the Schuler Purchasers agreed to purchase the Series A Preferred Shares at a purchase price of $7.70 per share for an aggregate purchase price of approximately $30.5 million.

The September 2021 Securities Purchase Agreement contemplated that the closing of the purchase and sale of the Series A Preferred Shares would occur in two tranches. The first tranche closed on the date of the execution of the September 2021 Securities Purchase Agreement whereby an aggregate of 2,636,364 Series A Preferred Shares were issued and sold to the Schuler Purchasers. On October 29, 2021, the Company closed the final second tranche in connection with the September 2021 Securities Purchase Agreement for an aggregate of 1,318,182 Series A Preferred Shares. During the year ended December 31, 2021, the Company issued 3,954,546 shares of Series A Preferred Stock to the Schuler Purchasers and received total proceeds of approximately $30.5 million under the September 2021 Securities Purchase Agreement, which were recorded to contributed capital.

The Company’s Series A Preferred Stock ranks, with respect to the payment of dividends, senior to the Company’s common stock and to any other class of securities it may issue in the future that is specifically designated as junior to the Series A Preferred Stock. The holders of Series A Preferred Stock are entitled to receive dividends, out of any assets at the time legally available therefor, prior in preference to any declaration or payment of any dividend on the Company’s common stock at the rate of $0.25 per share per annum on each outstanding share of Series A Preferred Stock (as appropriately adjusted for any subsequent stock splits, stock dividends, combinations, reclassifications and the like), when, as and if declared by the Board.

In the event of a voluntary or involuntary liquidation, dissolution or winding up of the Company, the holders of Series A Preferred Stock then outstanding are entitled to participate with the holders of the Company’s common stock or any other junior securities then outstanding, pro rata on an as-converted basis, in the distribution of all the remaining assets and funds of the Company available for distribution to its stockholders.

The holders of Series A Preferred Stock generally have no voting rights with respect to their shares of Series A Preferred Stock, except as provided by law or to amend, modify or waive any provision of the certificate of designation of the Series A Preferred Stock.

Each share of Series A Preferred Stock is convertible, at the option of the holder, at any time into one share of the Company’s common stock. Additionally, each share of Series A Preferred Stock will automatically be converted into one share of the Company’s common stock immediately upon a sale of all outstanding stock of the Company or a merger of the Company into another corporation where the pre-merger Company’s stockholders cease to be the controlling stockholders of the post-merger corporation.

***2021 Exchange Transactions***

During the year ended December 31, 2021, the Company entered into separate exchange agreements with certain holders of the Notes pursuant to which, such holders exchanged $51.0 million in aggregate principal amount of Notes for 6,602,974 shares with a value of $38.9 million which was recorded to contributed capital. See Note 10, Convertible Notes, for additional information.

*March 2022 Exchange Transaction*

During the year ended December 31, 2022, a holder of the Notes exchanged $14.0 million in aggregate principal amount of Notes held by it for 10,798,482 shares of the Company's common stock. The 10,798,482 shares of the Company's common stock were determined to have a value of $10.8 million, which was recorded to contributed capital during the year ended December 31, 2022. See Note 10, Convertible Notes, for additional information.

*March 2022 Securities Purchase Agreement*

On March 24, 2022, the Company entered into a securities purchase agreement (the "March 2022 Securities Purchase Agreement") with the Schuler Trust for the issuance and sale by the Company of an aggregate of 2,439,024 shares of the Company's common stock to the Schuler Trust in an offering (the "Private Placement") exempt from registration pursuant to Section 4(a)(2) of the Securities Act, and Rule 506 promulgated thereunder. Pursuant to the March 2022 Securities Purchase Agreement, the Schuler Trust 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 $1.64 per share, for an aggregate purchase price of $4.0 million. The Company and the Schuler Trust have subsequently agreed to extend the closing date of the Private Placement from March 24, 2023 to April 20, 2023.

This equity forward agreement meets the definition of a freestanding financial instrument which is classified in stockholders' equity. The value of this equity forward agreement as December 31, 2022 is immaterial.

*August 2022 Exchange Transaction*

On August 15, 2022, the Company entered into the August 2022 Exchange Agreement with the Schuler Trust. Under the terms of the August 2022 Exchange Agreement, the Schuler Trust agreed to exchange with the Company $49.9 million in aggregate principal amount of Notes held by it for (a) the Secured Note in an aggregate principal amount of $34.9 million and (b) the Warrant to acquire the Company's common stock at an exercise price of $2.12. The gain from the extinguishment of the Notes was treated as a capital transaction. The net gain on extinguishment was $29.8 million during the year ended December 31, 2022, and was recorded to contributed capital. See Note 10, Convertible Notes and Note 11, Long-Term Debt Related-Party for additional information.

The Warrant may be exercised from February 15, 2023 through the earlier of (i) August 15, 2029 and (ii) the consummation of certain acquisition transactions involving the Company, as set forth in the Warrant. The Warrant is exercisable for up to 2,471,710 shares, or 15% of the principal amount of the Secured Note, divided by the Exercise Price. Such number of shares and the Exercise Price are subject to certain customary proportional adjustments for fundamental events, including stock splits and recapitalizations, as set forth in the Warrant. The Warrant meets the criteria for classification in stockholders' equity and was recorded in contributed capital at fair value of $3.8 million on August 15, 2022.

*August 2022 Public Offering*

On August 23, 2022, the Company completed a public offering 17,500,000 shares of its common stock at a public offering price of $2.00 per share. The Company received net proceeds of approximately $32.9 million from the offering after deducting underwriting discounts and commissions and offering expenses paid by the Company.

## NOTE 20. RELATED PARTY TRANSACTIONS

*Convertible notes*

As discussed in Note 10, Convertible Notes, the Company issued Notes in March 2018. The Schuler Family Foundation (the "Foundation") purchased an aggregate of $30.0 million of the Notes in the March 2018 offering on the same terms as those under which other investors purchased the Notes, although no discount or commission in respect of such notes purchased by the Foundation was paid by the Company to the initial purchasers of the Notes. During 2019, the Foundation purchased an additional $12.0 million of Notes on the open market. Jack W. Schuler, a member of our Board, is the President of the Foundation.

During the year ended December 31, 2021, the Foundation transferred by gift the $42.0 million aggregate principal amount of Notes held by the Foundation to the Schuler Initiative Supporting Charitable Trust (the “Supporting Organization”), a tax-exempt organization that is not an affiliate of Jack W. Schuler.

In connection with the exchange transactions discussed in Note 19, Stockholders' Equity, during the year ended December 31, 2021, the Supporting Organization exchanged $42.0 million in aggregate principal amount of Notes held by it for 5,428,699 shares of the Company's common stock. Using the closing stock price on September 22, 2021 of $5.81, the 5,428,699 shares of the Company's common stock were determined to have a value of $31.5 million which was recorded to contributed capital during the year ended December 31, 2021.

The Supporting Organization had the same or similar terms as the other holders of Notes that participated in the Exchange Transactions. The Company determined the Exchange Transactions were in accordance with extinguishment accounting and were accounted for as an extinguishment of debt opposed to a capital transaction.

See Note 10, Convertible Notes and Note 19, Stockholders' Equity, for additional information.

***December 2020 Securities Purchase Agreement***

On December 24, 2020, the Company entered into the December 2020 Securities Purchase Agreement with the Original Purchasers for the issuance and sale by the Company of the Shares. Additionally, on December 24, 2020, the Company entered into the Registration Rights Agreement with the Original Purchasers pursuant to which the Company agreed to register the resale of the Shares pursuant to the terms set forth therein. The Original Purchasers are comprised of certain directors and officers of the Company, or entities affiliated or related to such persons. See Note 19, Stockholders' Equity, for further information.

On September 17, 2021, the Company entered into the Rescission Agreement with the Schuler Purchasers and the Schuler Trust, an entity affiliated with Jack W. Schuler, pursuant to which, effective as of January 29, 2021, the Company and the Schuler Purchasers agreed to rescind and unwind the December 2020 Securities Purchase Agreement and the Registration Rights Agreement for all legal, tax and financial purposes ab initio as if the related transactions, including the issuance and sale of an aggregate of 2,636,364 Shares in the first two tranche closings and the third tranche under the December 2020 Purchase Agreement, had never occurred with respect to the Schuler Purchasers and the Company. The Schuler Purchasers are related to Jack W. Schuler but are not affiliates of his. See Note 19, Stockholders' Equity, for further information.

During the year ended December 31, 2021, the Company issued 201,820 Shares and received total proceeds of approximately $1.5 million under the December 2020 Securities Purchase Agreement after giving effect to the Rescission Agreement.

***September 2021 Rescission Agreement***

On September 22, 2021, the Company entered into the September 2021 Securities Purchase Agreement with the Schuler Purchasers for the issuance and sale by the Company of the Series A Preferred Shares. The Schuler Purchasers are related to Jack W. Schuler but are not affiliates of his. For the year ended December 31, 2021, the Company issued 3,954,546 Series A Preferred Shares and received total proceeds of approximately $30.5 million under the September 2021 Securities Purchase Agreement. See Note 19, Stockholders' Equity, for further information.

***March 2022 Securities Purchase Agreement***

On March 24, 2022, the Company entered into the March 2022 Securities Purchase Agreement with the Schuler Trust for the issuance and sale by the Company of 2,439,024 shares of the Company’s common stock. Jack Schuler serves as a member of the Company’s board of directors and is the sole trustee of the Schuler Trust. Pursuant to the March 2022 Securities Purchase Agreement, the Schuler Trust agreed to purchase the shares at a purchase price of $1.64 per share, for an aggregate purchase price of $4.0 million. The Company and the Schuler Trust have subsequently agreed to extend the closing date of the Private Placement from March 24, 2023 to April 20, 2023. See Note 19, Stockholders' Equity, for further information.

### *August 2022 Exchange Transaction*

On August 15, 2022, the Company entered into the August 2022 Exchange Agreement with the Schuler Trust. Under the terms of the August 2022 Exchange Agreement, the Schuler Trust agreed to exchange with the Company $49.9 million in aggregate principal amount of Notes held by it for the Secured Note in an aggregate principal amount of $34.9 million and the Warrant. The net gain on extinguishment was $29.8 million during the year ended December 31, 2022, and was recorded as contributed capital. See Note 10, Convertible Notes and Note 11, Long-Term Debt Related-Party for additional information.

## NOTE 21. SUBSEQUENT EVENTS

### *Nasdaq de-listing notice*

On January 5, 2023, the Company received a deficiency letter from the Listing Qualifications Department of The Nasdaq Stock Market LLC notifying the Company that, for the last 30 consecutive business days, the closing bid price for the Company's common stock had closed below the minimum $1.00 per share requirement for continued inclusion on The Nasdaq Capital Market. In accordance with Nasdaq rules, the Company has been provided an initial period of 180 calendar days, or until July 5, 2023, to regain compliance with the Minimum Bid Price Requirement. If, at any time before this date, the closing bid price for the Company's common stock is at least $1.00 for a minimum of ten consecutive business days, the Staff will provide the Company written confirmation of compliance with the Minimum Bid Price Requirement. The Company may be eligible for an additional 180 calendar day compliance period. If the Company's share price does not meet the minimum listing requirements in the initial or extended periods, it may seek shareholder approval to execute a reverse stock split.

### *Forbearance of remedies upon maturity of the Notes*

On March 9, 2023, the Company entered into the Forbearance Agreement, which became effective on March 13, 2023, with the Ad Hoc Noteholder Group holding approximately 85% of the Company's outstanding Notes, the Trustee and any other owner of the Notes who executes and delivers to the Company a joinder to the Forbearance Agreement (collectively with the Trustee and Ad Hoc Noteholder Group, the "Counterparties"). Pursuant to the Forbearance Agreement, the members of the Ad Hoc Noteholder Group have agreed, and have directed the Trustee, to forbear from exercising their rights and remedies under the Indenture in connection with certain events of default under the Indenture, such as (i) failure to timely pay in full the principal of any Note when due and payable on March 15, 2023, (ii) failure to pay any interest on any Note when due and payable, (iii) failure to convert any Notes, (iv) default under any agreement with outstanding indebtedness for money borrowed in excess of $15.0 million and (v) any other breach, default or event of default under the Indenture arising from the failure of the Company to timely pay in full the principal of any Note when due and payable on the Maturity Date. The Forbearance Agreement is effective for the period commencing on March 13, 2023 and ending on March 29, 2023. On March 29, 2023, the Company and the Ad Hoc Noteholder Group agreed to further extend the forbearance period under the Forbearance Agreement to April 5, 2023.

Other holders of the Notes may join the Forbearance Agreement, and receive a fee equal to $5.00 per $1,000 principal amount of Notes held by such party, by executing and delivering a joinder to the Forbearance Agreement to the Company. See Note 10, Convertible Notes for additional information.

### *Closing of prepaid forward in connection with the maturity of the Notes*

In connection with the offering of the Notes, 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 our common stock underlying the Prepaid Forward is approximately 1,858,500 shares (based on the sale price of $24.25). On March 24, 2023, 1,858,500 shares of Common Stock were returned to the Company pursuant to our agreement with the counterparty. As of December 31, 2022, these 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. See Note 10, Convertible Notes for additional information.

***Extension of Schuler Forward Purchase Arrangement***

On March 23, 2023, the Company further amended the Securities Purchase Agreement with the Jack W. Schuler Living Trust for the purchase of gross proceeds of $4.0 million of its common stock to close on or before April 20, 2023. See Note 19, Stockholders' Equity for additional information.

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

None.

## Item 9A. Controls and Procedures

**Management's 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 not effective, as a result of a material weakness in our internal control over financial reporting discussed below, as of December 31, 2022, 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 that evaluation, due to a material weakness in internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) described below, the Principal Executive Officer and the Principal Financial Officer have concluded that our disclosure controls and procedures, were not effective as of December 31, 2022.

This Form 10-K does not include an attestation report of our independent registered public accounting firm because, as a "smaller reporting company" and non-accelerated filer, our independent registered public accounting firm is not required to issue such an attestation report.

**Material Weakness in Internal Control Over Financial Reporting**

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Management identified a material weakness in our internal control over financial reporting as of December 31, 2022 that prevented us from identifying a misclassification of the Notes in the Consolidated Balance Sheet, which has been corrected herein. The Company's internal control structure did not have a control to review the evaluation of the classification of its outstanding debt instruments in accordance with applicable accounting guidance.

### Remediation Plan

With oversight from the Audit Committee and input from management, the Company has begun designing and implementing changes in processes and controls to remediate the material weakness described above and to enhance our internal control over financial reporting, including a control to review the accounting treatment of outstanding debt instruments on a quarterly basis in accordance with applicable accounting guidance.

### 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) and 15d-15(d) under the Exchange Act during the quarter ended December 31, 2022, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## Item 9B. Other Information

Not Applicable.

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

Not Applicable.

**PART III**

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 2023 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 Accountant 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, and Financial Statement Schedules

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



**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 |
| 3.1.4 | 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 May 13, 2021 |
| 3.1.5 | Certificate of Designation of the Series A Preferred Stock of Registrant | Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on September 23, 2021 |
| 3.1.6 | 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 May 17, 2022 |
| 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 |
| 3.2.1 | Amendment No. 1 to the Amended and Restated Bylaws of Registrant | Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on February 3, 2022 |
| 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 Securities Exchange Act of 1934 | Filed herewith |
| 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 | 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 |

| | | |
|---|---|---|
| 10.6 | 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 |
| 10.7 | 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 |
| 10.8* | 2019 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 December 28, 2018 |
| 10.8.1* | Form of 2019 Salary Waiver Agreement | Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on December 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 | Rescission Agreement, dated September 17, 2021, by and among Registrant, the Tanya Eva Schuler Trust, the Therese Heidi Schuler Trust, Schuler Grandchildren LLC and the Jack W. Schuler Living Trust | Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on September 23, 2021 |
| 10.12 | Securities Purchase Agreement, dated September 22, 2021, by and among Registrant, the Tanya Eva Schuler Trust, the Therese Heidi Schuler Trust and Schuler Grandchildren LLC | Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on September 23, 2021 |
| 10.13 | Form of Exchange Agreement | Incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed on September 23, 2021 |
| 10.14 | Securities Purchase Agreement, dated March 24, 2022, by and between the Registrant and the Jack W. Schuler Living Trust | Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on March 25, 2022 |
| 10.15* | Accelerate Diagnostics, Inc. 2022 Omnibus Equity Incentive Plan | Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on May 17, 2022 |
| 10.16 | Exchange Agreement, dated as of August 15, 2022, by and between the Registrant and the Jack W. Schuler Living Trust | Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on August 15, 2022 |
| 10.17 | Secured Promissory Note, dated as of August 15, 2022, by the Registrant in favor of the Jack W. Schuler Living Trust | Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on August 15, 2022 |
| 10.18 | Warrant, dated as of August 15, 2022, issued to the Jack W. Schuler Living Trust | Incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed on August 15, 2022 |
| 10.19 | Security Agreement, dated as of August 15, 2022, by and between the Registrant and the Jack W. Schuler Living Trust | Incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K filed on August 15, 2022 |
| 10.20+ | Sales and Marketing Agreement, dated as of August 15, 2022, by and between the Registrant and Becton, Dickinson and Company | Incorporated by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q filed on November 14, 2022 |
| 10.21* | Separation Agreement and Release, dated December 8, 2022, by and between the Registrant and Ron Price | Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on December 13, 2022 |
| 10.22 | Forbearance Agreement, dated as of March 9, 2023, by and among the Registrant, the Ad Hoc Noteholder Group and the Trustee | Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on March 14, 2023 |
| 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.

\+ Portions of this exhibit have been redacted pursuant to Item 601(b)(10)(iv) of Regulation S-K. An unredacted copy of this exhibit will be furnished supplementally to the SEC upon request.

## 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 31, 2023

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 Jack Phillips, as his or her attorney-in-fact, with the power of substitution, for him or her in any and all capacities, to sign any amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, 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<br>Jack Phillips | President, Chief Executive Officer and Director (Principal Executive Officer) | March 31, 2023 |
| /s/ Steve Reichling<br>Steve Reichling | Chief Financial Officer (Principal Financial and Accounting Officer) | March 31, 2023 |
| /s/ Hany Massarany<br>Hany Massarany | Chairman of the Board of Directors | March 31, 2023 |
| /s/ Tom Brown<br>Tom Brown | Director | March 31, 2023 |
| /s/ Wayne Burris<br>Wayne Burris | Director | March 31, 2023 |
| /s/ Louise Francesconi<br>Louise Francesconi | Director | March 31, 2023 |
| /s/ John Patience<br>John Patience | Director | March 31, 2023 |
| /s/ Jack Schuler<br>Jack Schuler | Director | March 31, 2023 |
| /s/ Matthew W. Strobeck, Ph.D.<br>Matthew W. Strobeck, Ph.D. | Director | March 31, 2023 |
| /s/ Charles Watts, M.D.<br>Charles Watts, M.D. | Director | March 31, 2023 |

**EXHIBIT 4.4**

DESCRIPTION OF OUR CAPITAL STOCK
REGISTERED PURSUANT TO SECTION 12
OF THE SECURITIES EXCHANGE ACT OF 1934

**General**

As of December 31, 2022, Accelerate Diagnostics, Inc. (“we”, “us” or “our”) had one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended: our common stock, par value $0.001 per share.

Our authorized capital stock consists of 205,000,000 shares with a par value of $0.001 per share, comprised of 200,000,000 authorized shares of common stock and 5,000,000 authorized shares of preferred stock. As of March 28, 2023, there were 99,628,245 shares of our common stock, net of treasury shares, and 3,954,546 shares of our Series A Preferred Stock issued and outstanding.

The following summary description is based on the material provisions of our certificate of incorporation, our bylaws and the applicable provisions of the Delaware General Corporation Law (the “DGCL”). This description is not complete and is subject to, and qualified in its entirety by reference to, our certificate of incorporation and our bylaws, each of which is incorporated by reference as an exhibit to our Annual Report on Form 10-K of which this Exhibit 4.4 is a part, and the DGCL. You should read our certificate of incorporation, our bylaws and the applicable provisions of the DGCL for a complete statement of the provisions described below and for other provisions that may be important to you.

**Common Stock**

The holders of our common stock are entitled to one vote per share on all matters to be voted on by the stockholders. Subject to preferences that may be applicable to any outstanding shares of preferred stock, holders of common stock are entitled to receive ratably such dividends as may be declared by the board of directors out of funds legally available therefor. If we liquidate, dissolve or wind up, holders of common stock are entitled to share ratably in all assets remaining after payment of liabilities and the liquidation preferences of any outstanding shares of preferred stock. Holders of common stock have no preemptive, conversion or subscription rights. There are no redemption or sinking fund provisions applicable to the common stock. All outstanding shares of common stock are fully paid and nonassessable.

Our common stock is listed on The Nasdaq Capital Market under the symbol “AXDX.” The transfer agent for our common stock is Broadridge Corporate Issuer Solutions, Inc. Its address is 1717 Arch Street, Suite 1300, Philadelphia, Pennsylvania 19103, and its telephone number is (800) 733-1121.

**Preferred Stock**

Under the terms of our certificate of incorporation, our board of directors has the authority, without further action by the stockholders, to issue from time to time the preferred stock 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. Preferred stock will be fully paid and nonassessable upon issuance.

The issuance of preferred stock will affect, and may adversely affect, the rights of holders of common stock. It is not possible to state the actual effect of the issuance of any shares of preferred stock on the rights of holders of common stock until our board of directors determines the specific rights attached to that preferred stock. The effects of issuing preferred stock could include one or more of the following:

- restricting dividends on the common stock;
- diluting the voting power of the common stock;
- impairing the liquidation rights of the common stock; or
- delaying or preventing changes in control or management of our company.

***Series A Preferred Stock***

Our Series A Preferred Stock ranks, with respect to the payment of dividends, senior to our common stock and to any other class of securities we may issue in the future that is specifically designated as junior to the Series A Preferred Stock. The holders of Series A Preferred Stock are entitled to receive dividends, out of any assets at the time legally available therefor, prior in preference to any declaration or payment of any dividend on our common stock at the rate of $0.25 per share per annum on each outstanding share of Series A Preferred Stock (as appropriately adjusted for any subsequent stock splits, stock dividends, combinations, reclassifications and the like), when, as and if declared by our board of directors.

In the event of a voluntary or involuntary liquidation, dissolution or winding up of the Company, the holders of Series A Preferred Stock then outstanding are entitled to participate with the holders of our common stock or any other junior securities then outstanding, pro rata on an as-converted basis, in the distribution of all the remaining assets and funds of the Company available for distribution to its stockholders.

The holders of Series A Preferred Stock generally have no voting rights with respect to their shares of Series A Preferred Stock, except as provided by law or to amend, modify or waive any provision of the certificate of designation of the Series A Preferred Stock.

Each share of Series A Preferred Stock is convertible, at the option of the holder, at any time into one share of our common stock. Additionally, each share of Series A Preferred Stock will automatically be converted into one share of our common stock immediately upon a sale of all outstanding stock of the Company or a merger of the Company into another corporation where the pre-merger Company's stockholders cease to be the controlling stockholders of the post-merger corporation.

**Anti-Takeover Effects of Delaware Law and Certificate of Incorporation and Bylaws**

***Delaware Law***

We are subject to the Delaware anti-takeover laws regulating corporate takeovers, including Section 203 of the DGCL. In general, Section 203 of the DGCL prohibits a publicly held Delaware corporation from engaging in any business combinations with any interested stockholder for a period of three years following the time that such person became an interested stockholder, unless (1) the business combination or the transaction which resulted in the stockholder becoming an interested stockholder is approved by our board of directors prior to the time the interested stockholder obtained such status; (2) upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding shares owned by directors who are also officers of the corporation and shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or (3) at or subsequent to such time the business combination is approved by our board of directors and authorized at an annual or special meeting of stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

A "business combination" is defined to include mergers, asset sales, and other transactions resulting in financial benefit to an "interested stockholder." In general, an "interested stockholder" is a person who owns (or is an affiliate or associate of the corporation and, within the prior three years, did own) 15% or more of the corporation's voting stock.

***Certificate of Incorporation***

Our certificate of incorporation provides our board of directors with the express authority to issue up to 5,000,000 shares of serial preferred stock and to determine the price, rights, preferences and privileges of such preferred stock without stockholder approval. In addition, the certificate of incorporation does not provide for cumulative voting. These rights may deter or impede a hostile takeover or change of control or management.

***Bylaws***

In addition, our bylaws include a number of provisions that may deter or impede hostile takeovers or changes of control or management.

*Vacancies in our Board of Directors*

Our bylaws provide that any vacancy occurring in our board of directors may be filled by the affirmative vote of a majority of the remaining members of the board of directors. Each director so elected shall hold office until his or her successor is duly elected and qualified or until the director's earlier death, resignation, disqualification or removal.

*Special Meetings of Stockholders*

Under our bylaws, special meetings of stockholders may only be called by the President or a Vice President or the board of directors. Our bylaws further provide that the Secretary shall call a special meeting following receipt of one or more written requests to call a special meeting from stockholders of record who own at least 10% of the voting power of our outstanding shares then entitled to vote on the matter or matters to be brought before the proposed special meeting.

*Stockholder Action by Written Consent without a Meeting*

Under our bylaws, any action to be taken at any annual or special meeting of stockholders may be taken without a meeting, without prior notice and without a vote, if a consent or consents in writing, setting forth the action to be so taken, is signed by the holders of outstanding stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted, is delivered to the Company. Every written consent shall bear the date of signature of each stockholder who signs the consent, and no written consent shall be effective to take the action referred to therein unless, within 60 days of the earliest dated consent delivered, written consents are delivered signed by a sufficient number of holders to take action.

*Requirements for Notice of Stockholder Director Nominations and Stockholder Business*

Under our bylaws, nominations for the election of directors may be made by the board of directors or by any stockholder of record who complies with the applicable notice and other requirements set forth in our bylaws.

If a stockholder wishes to bring any business before an annual or special meeting or nominate a person for election to our board of directors, our bylaws contain certain procedures that must be followed for the advance timing required for delivery of stockholder notice of such nomination or other business and the information that such notice must contain.

These provisions of Delaware law and our certificate of incorporation and bylaws could prohibit or delay mergers or other takeovers or changes of control of the Company and may discourage attempts by other companies to acquire us, even if such a transaction would be beneficial to the Company's stockholders.

**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 Pty Ltd | Australia |
| Accelerate Diagnostics B.V. | Netherlands |
| Accelerate Diagnostics Holdings, LLC | United States |

**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-3 No. 333-262494) of Accelerate Diagnostics, Inc.,

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

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

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

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

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

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

(9) Registration Statement (Form S-8 No. 333-265126) pertaining to the 2022 Omnibus Equity Incentive Plan of Accelerate Diagnostics, Inc.;

of our report dated March 31, 2023, with respect to the consolidated financial statements of Accelerate Diagnostics, Inc., included in this Annual Report (Form 10-K) of Accelerate Diagnostics, Inc. for the year ended December 31, 2022.

/s/ Ernst & Young LLP

Phoenix, Arizona
March 31, 2023

**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 31, 2023 | /s/ Jack Phillips |
| | Jack Phillips<br>President and Chief Executive Officer<br>(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 31, 2023

/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, 2022 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 31, 2023 | /s/ Jack Phillips<br>Jack Phillips<br>President and Chief Executive Officer<br>(Principal Executive Officer) |
| March 31, 2023 | */s/ Steve Reichling*<br>Steve Reichling<br>Chief Financial Officer<br>(Principal Financial and Accounting Officer) |