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

(Mark One)

☑ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2023

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, 2023, the last day of the registrant's most recently completed second fiscal quarter, was approximately $60.9 million based on the closing price quoted on The Nasdaq Capital Market.

At March 25, 2024, 21,664,387 shares of common stock were outstanding, net of treasury shares. All common share data and share-based calculations set forth in this report have been adjusted to reflect the registrant's 1-for-10 reverse stock split, which was effective July 11, 2023 ("Reverse Stock Split"), on a retroactive basis for the periods presented.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement relating to the registrant's 2024 Annual Meeting of Stockholders are incorporated by reference in Part III of this Form 10-K. Such proxy statement will be filed with the U.S. Securities and Exchange Commission not later than 120 days after the end of the fiscal year covered by this report.

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 our future operations, products, including the Accelerate Wave™ system, and performance; projections as to when certain key business milestones may be achieved; expectations regarding the potential or benefits of our products and technologies; projections of future demand for our products; the growth of the market in which we operate; 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; our 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 this Form 10-K); our plans to continue marketing and distributing the Accelerate Arc Products in Europe pursuant to our 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 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 we expect, believe, or anticipate 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, among other things, volatility throughout the global economy and the related impacts to the businesses of our suppliers and customers, such as customer demand fluctuations, supply chain constraints and inflationary pressures, as well as 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. Other important factors that could cause our actual results to differ materially from those in our 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 certain additional assumptions, including, but not limited to, that we will retain key management personnel; we will be successful in the commercialization of our products; we will obtain sufficient capital to commercialize our products and continue development of complementary products; we will be successful in obtaining marketing authorization for our products from the FDA and other regulatory agencies and governing bodies; we will be able to protect our intellectual property; our ability to respond effectively to technological change; our ability to 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 our control.

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 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 have substantial indebtedness, which could have important consequences to our business.
- Servicing our debt will require a significant amount of cash, and we may not have sufficient cash flow from our business to pay our debt.
- We are in default of payment obligations under the terms of our 2.50% convertible senior notes (the “2.50% Notes”), which matured on March 15, 2023 and became due and payable.
- Our common stock may be delisted from The Nasdaq Capital Market, which could affect its market price and liquidity.
- 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 and Accelerate Wave systems.
- 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.
- We may not be able to correctly estimate or control our future operating expenses, which could lead to cash shortfalls, and impact our ability to continue as a going concern.
- If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of our products may be delayed and, as a result, our stock price may decline.
- We may not be able to enhance the capabilities of our current and new products to keep pace with our industry’s rapidly changing technology and customer requirements.
- 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.
- If we fail to estimate customer demand properly, our financial results could be harmed.
- 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.
- To the extent we deliver shares upon conversion of our outstanding 5.00% senior secured convertible notes (the “5.00% Notes”), the ownership interests of existing stockholders could be diluted and our stock price may be adversely impacted.
- We have significantly increased the total number of authorized shares of common stock under our certificate of incorporation, which could cause significant dilution.

- We are likely to require additional capital in the future, and you may incur dilution to your stock holdings.
- Our stock price has been volatile and may continue to be volatile and traded on low volumes.
- Current macroeconomic conditions and the uncertain economic outlook may remain challenging for the foreseeable future.

For a more complete discussion of the material risk factors applicable to us, see Part I, Item 1A, Risk Factors 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 Products

Accelerate Pheno

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 uses 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.

In June, 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 the first version of 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 August 2022, we entered into a sales and marketing agreement (the “Sales and Marketing Agreement”) with Becton, Dickinson and Company (“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 our products, and reduce our sales and marketing expenses. See “Commercialization of our Products” for additional information.

Accelerate Arc

In 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 IVDR registration of the Accelerate Arc Products 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.

Since that time, we have been in discussions with the FDA regarding the commercialization of our Accelerate Arc Products in the United States as Class I devices exempt from 510(k) clearance requirements. While these discussions are ongoing, we have put our United States sales and marketing efforts of the Accelerate Arc Products on hold, and have continued to market and distribute the Accelerate Arc Products in Europe pursuant to

our existing CE IVDR registration. We are currently conducting a clinical trial related to this product in the U.S. and expect to submit to the FDA a 510(k) IVD Class II Device with approval anticipated by mid-year 2024.

A technology receiving wide attention is mass spectrometry, and particularly the matrix-assisted laser desorption ionization time of flight version ("MALDI-TOF"). 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.

MALDI-TOF systems have a major advantage over other methods in identifying a very broad range of organisms. Cost of ownership is also substantially below that of older molecular methods, although 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. Also, 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.

In November 2023, we announced a collaboration and quality agreement with Bruker Corporation ("Bruker"), the provider of the MALDI Biotyper MALDI-TOF system for microbial identification, which has agreements with a number of companies for distribution, including BD, Danaher Corporation's subsidiary Beckman Coulter, Thermo Fisher Scientific's subsidiary TREK Diagnostics Systems, Inc. ("TREK") and Siemens. This agreement allows us to partner with Bruker to validate the use of our Accelerate Arc system with Bruker's MALDI Biotyper system for subsequent registration in both the U.S. and Europe, Middle East and Africa ("EMEA") markets.

We continue to invest in product development to enhance our existing products. Our current research and development areas of focus include the potential addition, if authorized by the FDA, of new AST content for our Accelerate Pheno system and of additional applications for our Accelerate Arc Products.

Accelerate Wave

The Accelerate Wave™ system, currently in development, performs AST directly from positive blood culture ("PBC") bottles and bacterial isolate colonies ("Isolates") to report minimum inhibitory concentrations ("MICs") with a goal of delivering results within 4.5 hours. The fully automated system is based on the principle of digital holographic microscopy, which allows for simultaneous volumetric imaging of a sample suspension at a high spatial resolution, enabling direct observation of phenotypic responses of individual bacterial cells in relatively short time periods versus more traditional AST methods. The Accelerate Wave system uses a time series of holograms to provide microbial quantitation under antimicrobial stress, enabling rapid determination of minimum inhibitory concentration. Additionally, Accelerate Wave holograms provide morphological information at the level of individual cells. For some bug-drug combinations, morphology is a leading indicator of future MIC.

A key differentiator of the Accelerate Wave system to current on-market and emerging AST competitors is the system's ability to process PBC as well as Isolates for AST diagnostic results. Our initial launch of menu items is expected to include a PBC assay that can be run on the Accelerate Wave system. This is expected to be followed by development of an Isolate assay. We believe our ability to process Isolates with the Accelerate Wave system expands our addressable market today with our Accelerate Pheno system and Accelerate Arc Products with PBC samples to include a much larger sample volumes segment, Isolates, within the microbiology testing market. Based on our on-market experience with our Accelerate Pheno system, we anticipate seeing significant workflow benefits to microbiology labs by offering consolidated PBC and Isolate susceptibility testing on a single, rapid, AST diagnostic. Further, recent voice-of-customer interviews highlight the value that Accelerate Wave brings to the global marketplace with a high percentage of interviewed customers expressing interest in evaluating the Accelerate Wave system once available. The Accelerate Wave system AST modules will be able to test five PBC assays or ten Isolated Colony assays per module and can scale to have 5 modules per system, which we believe will address the vast majority of microbiology lab volumes and workflows. Additionally, the cost to produce Accelerate Wave assays is expected to be significantly lower than our standard costing for the Accelerate PhenoTest BC Kit, which could improve the Company's margin profile as we seek FDA regulatory clearance for the Accelerate Wave system and assays.

While we will continue to seek out ways to improve upon the utility of our existing products, the primary focus of our current research and development efforts is our next generation AST platform, Accelerate Wave, which is being developed with the goal to have lower cost, higher throughput, and the capability to test a broader set of sample types when compared to our Accelerate Pheno system.

Our Market and Strategy

Clinical Need

Antimicrobial resistance is a major contributing factor to the significant impact sepsis is posing to healthcare, costing the U.S. an estimated $62.0 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 routinely performed by clinical microbiology laboratories 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 comparing the Accelerate Pheno system to the standard of care methodology, showed that time to definitive therapy improved from 32.6 to 10.5 hours, the total duration of therapy shortened from 14.2 to 9.5 days and the mean hospital length of stay was shortened from 7.9 to 5.3 days[1]. 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, inclusive of hospital-acquired infection 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 positive blood culture samples tested each year in North America and Europe.

In addition, there is a substantial existing installed base of legacy automated AST systems that perform AST from Isolates. Principally, these systems are the bioMerieux Vitek 2®, Danaher Corporation (“Danaher”) Microscan® system, and BD Phoenix™. These competitors’ AST products require purified bacterial strains or Isolates for analysis, which require at least overnight culturing of a clinical specimen to produce enough organisms to test. This installed base represents an attractive opportunity to both potentially complement and replace existing laboratory workflows with the Accelerate Pheno system and our next generation Accelerate Wave system 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,

[1] Walsh et al (2021) “Impact of Antimicrobial Stewardship Program-bundled initiative utilizing Accelerate Pheno system in the management of patients with aerobic Gram-negative bacilli bacteremia” Springer Nature.

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.

Key Advantages of our Technology

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 antibiotic 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 MICs, 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.

While we will continue to seek ways to improve the utility of our existing products, the primary focus of our current research and development efforts is our next generation AST platform, the Accelerate Wave system, which is being developed with the goal to have lower cost, higher throughput, and the capability to test a broader set of sample types when compared to our Accelerate Pheno system.

Commercialization of our Products

The target customers for our products are hospital microbiology laboratories that perform ID and AST. In August 2022, the Company entered into the Sales and Marketing Agreement with BD pursuant to which BD is performing 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 the Company's sales and service specialists 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, as applicable.

The Sales and Marketing Agreement also grants to BD certain other rights to certain of the Company's future products, including a right of first negotiation to be the exclusive sales agent to commercialize the Company's next generation rapid AST system, the Accelerate Wave system. These rights to negotiate a subsequent agreement 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 Sales and Marketing Agreement was entered into to allow the Company to reduce expenses through a reduction of internal sales and marketing personnel. Under this agreement, the Company will pay BD a commission based on the level of revenue realized on a quarterly basis and BD will pay the Company a fee over the duration of the agreement based on certain criteria.

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

For the year ended December 31, 2023, none of the Company's customers represented more than 10% of the Company's net sales.

Competition

The leading companies with automated microbiological testing products include BD, bioMerieux, Danaher and 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, it has been reported that at least one of these competitors has obtained FDA marketing authorization for its product in the United States. In 2022, bioMerieux acquired Specific Diagnostics for over $400.0 million. We believe this acquisition reflects both the industry leader's recognition of the importance of rapid AST testing and enhanced competition.

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 antimicrobial resistance, such as particular *Methicillin-Resistant Staphylococcus aureus* (MRSA) strains, leading literature has reported novel mutations that escape detection by recently commercialized tests.

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.

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 ("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 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 ("DOJ"), 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 ("EEA") which comprises the 27 Member States of the European Union ("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 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

Our corporate headquarters are in 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, and details regarding our lease arrangements are included in Part II, Item 8, Note 9, Leases of this Form 10-K.

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, and certain of the components of our Accelerate Pheno system and in-development Accelerate Wave system have sole source suppliers.

The third party manufacturing supply chain for our products remains stable, despite the unprecedented cost increases that we have experienced from many of our suppliers, primarily as a result of labor and supply disruptions and increased inflation over the past several years. 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 of our suppliers to provide us with the necessary materials and services at reasonable costs and continue to seek alternative sources where appropriate. 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.

Research and Development

We plan to continue making investments in the research and development of new applications for existing technologies while focusing the largest portion of our research and development efforts on the development of our next generation Accelerate Wave technology.

Since the 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 EMEA 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 continue 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-TOF identification results, including the development of the associated Accelerate Arc BC kit, and the development of our next generation AST platform, the Accelerate Wave system, discussed above.

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 platform, the Accelerate Wave 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, 2023, we had 53 issued patents worldwide, including 23 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, 2023, we had 3 patent applications pending worldwide. 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.

Human Capital Resources

As of December 31, 2023, we had approximately 134 full-time employees worldwide, with approximately 123 employees in the United States and approximately 11 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, and 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.

Corporate History and Available Information

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.

We regularly file reports with the SEC, including Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and 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 reports, proxy and information statements, and other 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.

This report contains references to our trademarks, including Accelerate Pheno and Wave, and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this report, including logos, artwork and over visual displays, may appear without the ® or ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, or to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

We are also a "smaller reporting company" as defined in the Exchange Act and have elected to take advantage of certain of the scaled disclosures available to smaller reporting companies.

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 $668.9 million as of December 31, 2023. During the year ended December 31, 2023, we had a net loss of $61.6 million and negative cash flows from operations of $40.2 million. As of December 31, 2023, we had $13.2 million in cash and cash equivalents and working capital of $12.4 million. Additionally, we have a substantial amount of indebtedness comprised of $67.6 million aggregate principal amount of 5.00% Notes and $0.7 million aggregate principal amount of 2.50% Notes outstanding.

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 fund our forecasted operating costs for at least twelve months from the date of the filing of this Form 10-K. The report of our independent registered public accountant on our financial statements as of December 31, 2023 and 2022 and for each of the three years in the period ended December 31, 2023 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” and Part II, Item 8, Note 1, Organization and Nature of Business; Basis of Presentation; Principles of Consolidation of this Form 10-K 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. While we continue to explore additional funding in the form of potential equity and/or debt financing arrangements or similar transactions, there can be no assurance the necessary financing will be available on terms acceptable to us, or at all. If we raise 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 we raise funds by issuing additional debt, it is likely any new debt would have rights, preferences and privileges senior to common stockholders. The terms of borrowing could impose significant restrictions on our operations. 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. In addition, increases in federal fund rates set by the Federal Reserve, such as the significant increases experienced throughout 2022 and 2023, which serve as benchmark rates on borrowing, and other general economic conditions have impacted, and in the future may further impact, the cost of debt financing or refinancing existing debt.

If we are unable to obtain adequate capital resources to fund operations, we would not be able to continue to operate our business pursuant to our current plans. This may require us to, among other things, materially modify our operations to reduce spending; sell assets or operations; delay the implementation of, or revise certain aspects of, our business strategy; or discontinue our operations entirely.

We have substantial indebtedness, which could have important consequences to our business.

We have a substantial amount of indebtedness primarily comprised of our 5.00% Notes. As of December 31, 2023, we had $67.6 million aggregate principal amount of 5.00% Notes outstanding, which mature on December 15, 2026. We pay interest on the 5.00% Notes by payment-in-kind (“PIK”), through the issuance of additional 5.00% Notes (“PIK Notes”). The indenture governing the 5.00% Notes (the “5.00% Notes Indenture”) provides that we may be required to repay amounts due under the 5.00% Notes Indenture in the event that there is an event of default for the 5.00% Notes that results in the principal, premium and interest, if any, becoming due prior to the maturity date for the 5.00% Notes. There can be no assurance that we will be able to repay this indebtedness when due, or that we will be able to refinance this indebtedness on acceptable terms or at all. In addition, this indebtedness could, among other things:

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

Additionally, our failure to repurchase 5.00% Notes at a time when the repurchase is required by the 5.00% Notes Indenture (whether upon a fundamental change or otherwise under the 5.00% Notes Indenture) would constitute a default under the 5.00% Notes Indenture. A default under the 5.00% Notes Indenture or the fundamental change itself could also lead to a default under agreements governing our existing or future indebtedness. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness, repurchase the 5.00% Notes or make cash payments upon conversions thereof.

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

Our ability to make scheduled payments on the principal of or to refinance our indebtedness, primarily the 5.00% 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. For example, we are in default of payment obligations under the terms of our 2.50% Notes, which matured on March 15, 2023 and became due and payable. As a result, we consummated a series of transactions to allow for the restructuring of our capital structure (the "Restructuring Transactions"), including the 2.50% Notes, a secured promissory note with the Jack W. Schuler Living Trust (the "Schuler Trust") (the "Secured Note") and the then outstanding Series A Preferred Stock, as well as an amendment to a Securities Purchase Agreement that the Company entered into with the Schuler Trust in March 2022 (the "March 2022 Securities Purchase Agreement"), which resulted in significant dilution to the ownership interests of our existing stockholders.

Our ability to repay our remaining 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.

We are in default of payment obligations under the terms of our 2.50% Notes, which matured on March 15, 2023 and became due and payable.

As discussed in 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, the principal of the 2.50% Notes was due March 15, 2023. As of December 31, 2023, approximately $0.7 million remains in default and accruing interest at 2.50%.

To the extent we deliver shares upon conversion of the 5.00% Notes, the ownership interests of existing stockholders could be diluted and our stock price may be adversely impacted.

Upon conversion of the 5.00% Notes, we will pay or deliver, as the case may be, cash, shares of our common stock or a combination of cash and shares of our common stock, at the Company's election. To the extent we choose to deliver shares upon conversion of some or all of the 5.00% Notes, this will result in a dilution to the ownership interests of existing stockholders and may depress our stock price.

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, 2023, 2022 and 2021, 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 and expect to continue to incur further costs in the development and commercialization of our future products, including the Accelerate Wave system. 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 and Accelerate Wave systems.

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 the Accelerate Wave system. 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 the PhenoTest BC Kit, AST configuration, the Accelerate Arc system, including the related BC kit, and future products, such as the Accelerate Wave system.

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, Accelerate Arc or Accelerate Wave systems, 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. 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 Accelerate Wave 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.

We may not be able to correctly estimate or control our future operating expenses, which could lead to cash shortfalls, and impact 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 and Accelerate Arc systems, and development costs for new products, including the Accelerate Wave system;
- the expenses we incur in connection with the development, marketing authorization and regulatory clearance of the use of the Accelerate Pheno system to test on additional specimen types and our Accelerate Arc system, as well as in connection with the development of new products, including the Accelerate Wave system;
- 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 and Accelerate Arc systems, as well as future products, including the Accelerate Wave system. We may be unable to reduce our expenditures in a timely manner to compensate for any unexpected events or a shortfall in revenue. Accordingly, a shortfall in demand for our products or other unexpected events could have an immediate and material impact on our cash levels.

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, including those related to the ongoing development of our Accelerate Wave system. 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 also 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 had 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. See "Risks Related to Government Regulation - The regulatory processes applicable to our products and operations are expensive, time-consuming, and uncertain and may prevent us from obtaining required authorizations for the commercialization of our products" for additional information. 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 or any future diagnostic products, including the Accelerate Wave 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.

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. For example, 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 since 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.

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 wars between Russia and Ukraine and between Israel and Hamas, 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 ongoing international wars and conflicts 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, including BD. 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, sales, 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 compliance program that includes 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 policies and practices we have put into place to identify, address, and prevent inappropriate conduct 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 instrument-related 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 rent the instrument and the rental fee is paid through a commitment by the customer 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 subject to such arrangements. 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, excess inventory or further instrument-related inventory write-downs, and make our demand forecast more uncertain. In order to have shorter shipment lead times for our customers, we 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, customer behavior changes due to significant events and economic conditions have historically made it more difficult for us to estimate future demand. 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. For example, excess inventory write-downs were recorded during the year ended December 31, 2023, as well as during the year ended December 31, 2021, as a result of excess quantities of instrument inventory on hand above and beyond our forecast of future demand for those products.

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 further 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 adversely affected our business and a resurgence of COVID-19 or the occurrence of another health epidemic or pandemic may have an adverse impact on our business in the future.

Our business, including our workforce, supply chain and customer base, has been adversely affected by COVID-19 in the past and a resurgence of COVID-19 or the occurrence of another health epidemic or pandemic may adversely affect us in the future. The COVID-19 pandemic, containment measures, and downstream impacts to hospital staffing and financial stability 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 experienced diminished access to our customers, including hospitals, which 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 continued to divert the attention of hospital decision makers and impact our ability to access capital markets on terms that are not detrimental to our business.

It is possible that a resurgence of COVID-19 or the occurrence of another health epidemic or pandemic will adversely affect our business, our workforce, our supply chains and distribution networks or otherwise impact our ability to conduct business in the future. Further, to the extent our customers’, suppliers’ or service providers’ businesses are adversely affected by such occurrences, they might delay or reduce purchases from us or impact our ability to meet customer demand or development timelines, which could adversely affect our business and results of operations. The effects of ongoing or future health epidemics or pandemics on our business remain uncertain and subject to change.

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. Certain of our components are custom-made by only a few outside suppliers and, in certain instances, we have a sole source supply for key product components. 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, meet key development milestones, 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 and Accelerate Arc systems and to develop our Accelerate Wave system. 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.

We previously identified a material weakness in our internal control over financial reporting, and if we fail to maintain an effective system of internal control, 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. During 2023, management, with oversight from the Audit and Governance Committee, completed the implementation of our previously disclosed remediation plan that included a control to review the accounting treatment of outstanding debt instruments on a quarterly basis in accordance with applicable accounting guidance. We have concluded that our internal control over financial reporting was effective as of December 31, 2023.

Completion of remediation does not provide assurance that our remediation or other controls will continue to operate properly. If we are unable to maintain effective internal control over financial reporting, 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 Part II, Item 9A, Controls and Procedures - “Management’s Report on Internal Control over Financial Reporting” of this Form 10-K for further information on the remediated material weakness.

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. As of December 31, 2023, we owned 23 issued U.S. patents and 30 non-U.S. patents and had three pending applications as well as 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, interference or derivation proceedings in the United States can be initiated by a third party to

determine who has the right to the subject matter covered by the claims of our patent applications and/or patents. We may not prevail in such proceedings. 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 products. 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, our licensees, or our customers.

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, or a derivation proceeding to determine rights to the relevant claimed subject matter. 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, or had filed applications directed to such applications before us, 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 or all 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 others' 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 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, Accelerate Arc and Accelerate Wave systems, and we intend to spend significantly more on research and development activities, including for such systems. 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 result in commercial products that will generate revenues.

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

The manufacture of components of 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 the 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.

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 FDCA, 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, a criminal law, which prohibits persons and entities from knowingly and willfully offering, paying, providing, soliciting, or receiving any remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce or reward 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. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations of the federal Anti-Kickback Statute can result in significant civil monetary penalties and criminal fines, as well as imprisonment and exclusion from participation in federal healthcare programs.

- The federal False Claims Act, which imposes significant civil penalties, treble damages and potential exclusion from participation in federal healthcare programs against any person or entity that, among other things, knowingly presents, or causes to be presented, to the federal government claims for payment that are false or fraudulent or for making a false record or statement material to an obligation to pay the federal government or for knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the federal government Further, a violation of the federal Anti-Kickback Statute can serve as a basis for liability under the federal civil False Claims Act. The qui tam provisions of the False Claims Act allow private individuals to bring actions on behalf of the federal government and to share in any monetary recovery. There is also the federal Criminal False Claims Act, which is similar to the federal Civil False Claims Act and imposes criminal liability on those that make or present a false, fictitious or fraudulent claim to the federal government.
- 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. Violation of the federal Stark law can result in significant civil monetary penalties and exclusion from participation in the federal healthcare programs.
- The Eliminating Kickbacks in Recovery Act, which makes it a federal crime to knowingly and willfully solicit or receive any remuneration (including kickbacks, bribes, or rebates) in return for referring a patient to a recovery home, clinical treatment facility, or laboratory where the services are covered by a “health care benefit program,” which includes private payers, 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. Violations of the law may result in penalties per occurrence and imprisonment.
- Federal criminal statutes created by HIPAA impose criminal liability for, among other things, knowingly and willfully (i) executing (or attempting to execute) 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 HITECH, 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 applicable manufacturers of certain medical devices that may be reimbursed by Medicare, Medicaid, or CHIP, among others, to annually track and report payments or other transfers of value provided to U.S. licensed physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse-midwives, and U.S. teaching hospitals as well as certain ownership and investment interest held in the manufacturer by physicians and their immediate family members.

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 FTC, 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;
- corrective field actions for our products;
- submission of reports to FDA or other regulatory authorities;
- total or partial suspension of production or distribution;
- withdrawal or suspension of marketing clearances or approvals;

- clinical holds for investigations;
- untitled letters or 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 our business, and we intend to market our products, to meet customer needs created by these various laws and regulations. Any significant change in these regulations could reduce demand for our products. New legislation could also be enacted, and/or governmental agencies may also impose new requirements under existing laws, regarding registration, labeling or prohibited materials that may require us to modify or re-register, or seek new approvals or clearances for, products already on the market, may otherwise adversely impact our ability to market our products, or may otherwise reduce demand for 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 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 approved products depends in part on the availability of adequate coverage and reimbursement of our products by 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 reimburse 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 the MS-DRG classification system 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 reimbursement by government and private insurance plans is central to the acceptance of our products. We may be unable to sell our approved products on a profitable basis if third-party payers refuse to cover our products or reduce their current levels of reimbursement, or if our costs of production increases 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. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular products. Further, 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 Bipartisan Budget Act of 2015, approved in November 2015, extended sequestration an additional year to 2025, Medicare reimbursements were lowered, and other changes were made to compliance measures. The Bipartisan Budget Act of 2019 signed by President Trump in August 2019 also extended sequestration for another two years to fiscal year 2029. 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 March 31, 2022. Cuts of 1% were imposed from April 1 through June 30, 2022. As of July 1, 2022, cuts of two percent were reimposed and are set to remain in effect until 2031 unless unless additional Congressional action is taken. To offset the temporary suspension during the COVID-19 pandemic, in 2030, the sequestration will be 2.25% for the first half of the year, and 3% in the second half of the year.

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.

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

Our products are regulated as medical devices by the FDA and comparable agencies of other countries. In particular, the FDCA and implementing FDA regulations govern activities for devices such as design, development, testing, manufacturing, storage, distribution, labeling, registration and listing, premarket clearance or approval, advertising, promotion, sales, and reporting for devices, including reporting of certain malfunctions, deaths, and injuries associated with the device, and reporting of certain recalls and corrective field actions. Some of our products, depending on their intended use, will require approval of a PMA application or clearance of a 510(k) notification, or granting of a request for de novo classification 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 on extensive data, including technical, preclinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for Class III devices that are deemed to pose the greatest risk, including devices for which general controls would be insufficient, and special controls cannot be developed, to provide a reasonable assurance of safety and effectiveness of the device, such as life-sustaining, life-supporting or implantable devices, or devices that otherwise present a potential unreasonable risk of illness or injury. However, some devices are automatically classified as Class III and subject to the PMA pathway regardless of the level of risk they pose, because there is no legally marketed predicate device to which the proposed device may demonstrate substantial equivalency. 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 provide a reasonable assurance of safety and effectiveness for their intended uses, or that our product candidates are substantially equivalent to a predicate device;
- the data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval, or de novo classification, 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 or de novo classification 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, approval or de novo classification, 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 important or commercially attractive uses that were not cleared, approved or de novo classified.

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 or de novo classification request 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 a demonstration of 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.

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"). In particular, on October 3, 2023, the FDA proposed to regulate LDTs as medical devices, and to phase out its historical exercise of enforcement discretion for such tests. If the proposed rule is finalized, laboratories offering LDTs would be expected to come into compliance with FDA regulation of medical devices over a period of time. Even if the proposed rule is not finalized, the FDA could seek to increase its oversight of LDTs as medical devices under existing regulations. We continue to monitor these developments and analyze how they will impact the clearance approval and classification of our products, as well as the demand for our products by customers. These and other actions proposed by the FDA's Center for Devices and Radiological Health ("CDRH") could result in significant changes to the 510(k) process, which could complicate the clearance, approval and de novo classification processes, although we cannot predict the effect of such changes and cannot ascertain if such changes will have a substantive impact on the clearance, approval or de novo classification of our products. If we fail to adequately respond to the increased scrutiny and changes to the 510(k) submission process, our business may be adversely impacted.

Failure to comply with the applicable requirements can result in, among other things, untitled letters, 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, PMA approval or de novo classification for devices, withdrawal of marketing clearances or approvals, or criminal prosecution. With regard to products for which we seek 510(k) clearance, PMA approval or de novo classification from the FDA, any failure or material delay to obtain such clearance, approval or de novo classification could harm our business. If the FDA were to disagree with our regulatory assessment and conclude that approval, clearance or de novo classification is necessary to market the devices, we could be forced to cease marketing the products and seek approval, clearance or de novo classification before continuing to market such devices. Once clearance, approval or de novo classification 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 laws or regulations could arise at any stage during our product development or marketing, which may adversely affect our ability to obtain or maintain clearance, approval or de novo classification of our products. Any delay in, or failure to receive or maintain, clearance, approval or de novo classification 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 QSRs 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 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 510(k)-cleared or de novo classified device 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, unless a predetermined change control plans (“PCCP”) for the device has been cleared. If a PCCP has been cleared for the device, then the manufacturer may make changes to the device consistent with the cleared PCCP without submitting a new 510(k), even though such changes would typically require 510(k) clearance. If the modification would result in the device becoming a different type of device, including a novel device or a Class III device, then a de novo classification request or PMA, rather than a new 510(k), may be required. Similarly, any modification to a PMA-approved device that affects the safety or effectiveness of the device, including significant modifications to the manufacturing process, labeling of the product, or design of the device, requires a PMA supplement or new PMA, unless a PCCP has been approved for the device. If a PCCP has been approved for a PMA-approved device, then changes may be made to the device consistent with the approved PCCP without submitting a PMA supplement, even though such changes would typically require a PMA supplement. The FDA requires each manufacturer to make the determination initially whether a new 510(k), de novo classification request, or PMA is required for a modification to a device, or whether the modification may be documented without further FDA premarket review, but the FDA may review any manufacturer’s decision. The FDA may not agree with our decisions regarding whether new clearances, de novo classifications, or PMA approvals are necessary. If the FDA disagrees with our determination and requires us to submit new 510(k) notifications, de novo classifications, PMA supplements or PMAs for modifications to previously cleared, de novo classified, or approved products for which we conclude that new clearances, de novo classification, 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 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 or de novo classification, either by imposing more strict requirements on when a manufacturer must submit a new 510(k) for a modification to a previously cleared or de novo classified 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 clinical 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 other regulatory authorities 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. In addition, manufacturers may, under their own initiative, recall a product for any reason, including 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 information reasonably suggests that 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, such malfunction 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. Additionally, under the FDA's regulations for corrections and removals, we are required to report to the FDA any field correction or other recall action that is initiated to reduce a risk to health, or to remedy a violation of the FDCA caused by the device which may present a risk to health. 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, clearances or de novo classification for the device before we may market or distribute the corrected device. Seeking such approvals, clearances or de novo classification 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 untitled letters, 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 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 in order to maintain the listing of our common stock on The Nasdaq Capital Market. As described in a Current Report on Form 8-K filed with the SEC on March 5, 2024, we received written notice (the "Notice") from Nasdaq's Listing Qualifications Staff (the "Staff") on March 4, 2024 notifying us that for the last 31 consecutive business days prior to the date of the Notice, our Market Value of Listed Securities (as defined under Nasdaq rules) was below the minimum of $35 million required for continued listing on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(b)(2) (the "MVLS Requirement"). In accordance with Nasdaq Listing Rule 5810(c)(3)(C), Nasdaq has provided us with 180 calendar days, or until September 3, 2024 (the "Compliance Date"), to regain compliance with the MVLS Requirement. If, at

any time before the Compliance Date, the market value of our common stock (calculated in accordance with Nasdaq rules) closes at $35 million or more for a minimum of ten consecutive business days, Nasdaq will provide written confirmation to us and close the matter.

If we do not regain compliance with the MVLS Requirement prior to the Compliance Date, 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. We are evaluating potential actions to regain compliance with the MVLS Requirement and intend to actively monitor the market value of our common stock. We may also, if appropriate, consider other options to regain compliance with Nasdaq's continued listing standards. There can be no assurance that we will regain compliance with the MVLS 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.

We have significantly increased the total number of authorized shares of common stock under our certificate of incorporation, which could cause significant dilution.

Our management believes the successful achievement of our business objectives may require additional financing through one or a combination of the issuance of common stock in public or private equity offerings, debt financings, exercise of common stock warrants, collaborations, licensing arrangements, grants and government funding and strategic alliances. To effectuate that, in May 2023, we sought and obtained authorization from stockholders to increase the total number of authorized shares of common stock under our certificate of incorporation by 250,000,000 for a total of 450,000,000 shares. The future issuance of all or part of our remaining authorized common stock may result in substantial dilution to our stockholders and may adversely affect the market price of our common stock.

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 issuance of our common stock upon the conversion or exchange of our convertible notes 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 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 are likely to 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 2.50% Notes and 5.00% 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.

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;
- our failure to meet applicable Nasdaq listing standards and the possible delisting of our common stock from Nasdaq;
- 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, other geopolitical uncertainties, public health concerns (including health epidemics, pandemics or outbreaks of communicable diseases), 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, 2023, the sale price for our common stock ranged from $4.17 to $10.30 per share, and during the year ended December 31, 2022, the sale price for our common stock ranged from $5.10 to $51.50 per share. Share prices shown reflect the Company effected one-for-ten Reverse Stock Split which occurred on July 11, 2023. The market prices for securities of medical technology companies like ours 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 ownership of our common stock is highly concentrated.

As of December 31, 2023, our directors and executive officers beneficially owned in the aggregate, approximately 48% of our outstanding common stock, including 40% 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.

Provisions in our Amended and Restated Certificate of Incorporation, as amended (our "Charter") and Amended and Restated Bylaws (as amended, our "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 Charter and Bylaws, as well as provisions of the Delaware General Corporation Law ("DGCL"), 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. 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 DGCL, 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.

General Risk Factor

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

Global economic conditions, which have led to market disruptions and significant volatility in credit and capital markets, may remain challenging and uncertain for the foreseeable future, including inflation, global health crises, international wars and disputes, and disruptions to the banking system due to bank failures. 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 1C. Cybersecurity

Risk Management and Strategy

We recognize the importance of developing, implementing and maintaining robust cybersecurity measures to safeguard our information systems and protect the confidentiality, integrity, and availability of our data. As such, we have implemented cybersecurity programs designed to maintain compliance with applicable laws and regulations governing ethical business practices, including our relationships with suppliers, customers, and business partners.

We maintain formal processes for our cybersecurity program and incident response procedures, which are updated at least annually. These processes include, among other things, detailed steps on how we assess cyber risks, identify threats, and determine the materiality of cyber incidents. These processes also designate certain roles within the company to execute these policies and certain leadership roles to manage material risk escalation. These processes endeavor to follow the National Institute of Standards and Technology (NIST) Cybersecurity Framework.

Our Information Security team uses automated technology, third-party partners, and direct review of system indicators to monitor and implement the prevention, detection, mitigation, and remediation of cybersecurity incidents, and to stay current with the changing threat landscape. We also leverage encryption technologies and other measures to safeguard systems. We engage third parties as part of our cyber program, including external security firms that provide security technology, conduct regular security audits, and conduct penetration testing.

We also engage third-party service providers to assist with managing various other aspects of our business. We review SOC 1 and similar documentation from these third-party service providers annually to better understand the information security programs maintained by them.

Our employees are responsible for complying with our data security standards and are required to complete annual training to understand the behaviors and technical requirements necessary to keep data secure. We also require that cybersecurity training be part of the onboarding process for new hires.

As of December 31, 2023, cybersecurity risks have not materially affected our business strategy, results of operation, or financial condition.

Governance

Cybersecurity is an important component of our enterprise risk management program. While the full board of directors (the "Board") has primary responsibility for risk oversight, the Board utilizes its committees, as appropriate, to monitor and address the risks that may be within the scope of a particular committee's expertise or charter and receives updates at Board meetings on committee activities.

The Audit and Governance Committee has oversight over the adequacy of the Company's enterprise risk management and internal controls, including computerized information system controls and security, and regularly reviews our cybersecurity, including IT risks, controls, procedures, and plans to mitigate cybersecurity risks and respond to security incidents. Due to the importance of cybersecurity, the full Board receives a report on at least an annual basis from the IT Director, on, among other issues, our cyber risks and threats, the status of projects, management's strategies to strengthen our IT systems, assessments of our security program, third-party assessments and testing, our emerging threat landscape, and the review of our cybersecurity insurance policy. Updates will be held more frequently with the Audit and Governance Committee as deemed appropriate for significant changes to the Company's IT systems or cybersecurity processes. Pursuant to our incident response procedures, material cyber incidents will be reported to the Audit and Governance Committee upon a determination of material status.

Management is responsible for our company's day-to-day risk management activities. Our cybersecurity program is led by our IT Director, who is responsible for assessing and managing cybersecurity risks. He has 12 years of experience as a leader in both the medical and defense industries. As cybersecurity-centric manager our IT Director has also achieved high-level security clearance and held the title of Information System Security Officer for other organizations.

As cybersecurity risks arise, our IT Director executes an incident response procedure and communicates the appropriate details to management in alignment with the escalation steps in the procedure. In addition, our IT Department conducts quarterly IT systems audits which include system log audits, backup and recovery assessment, account review, and project status.

Item 2. Properties

Our headquarters and reference laboratory space is located in Tucson, Arizona, and we have other offices in Europe. As of December 31, 2023, we leased approximately 54,092 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 Part II, Item 8, Note 9, 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. 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 25, 2024, we had approximately 33 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. 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, 2023 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, 2023:

Equity Compensation Plan

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights		Weighted-average exercise price of outstanding options, warrants and rights[1]	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in the 1st column)[3]
Equity compensation plans approved by security holders	1,609,275	[2]	$ 148.40	1,288,286
Equity compensation plans not approved by security holders	—		—	—
Total	**1,609,275**		**$ 148.40**	**1,288,286**

(1) Shares of common stock issuable upon vesting of restricted stock units (“RSUs”) have been excluded from the calculation of the weighted average exercise price because they have no exercise price.
(2) Represents 369,839 shares of common stock subject to outstanding stock options and 1,239,436 shares of common stock that may be issued upon vesting of outstanding RSUs.
(3) Represents shares of common stock remaining available for issuance under the Company’s 2022 Omnibus

Equity Incentive 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.

Changes in Results of Operations: Comparison of fiscal years ended December 31, 2023, 2022 and 2021

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)			
	2023	2022	$ Change	% Change	2022	2021	$ Change	% Change
Net sales	$ 12,059	$ 12,752	$ (693)	(5)%	$ 12,752	$ 11,782	$ 970	8 %

During the year ended December 31, 2023, net sales decreased primarily due to lower sales of Accelerate Pheno instruments compared to the year ended December 31, 2022, as fewer new contracts were signed for new Accelerate Pheno instrument placements in the current year. This decrease was partially offset by an increase in net sales of Accelerate PhenoTest BC Kits as customers completed their instrument verifications and began purchasing kits.

During the year ended December 31, 2022, net sales 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 instrument service agreements following the expiration of their warranty periods.

	December 31, (in thousands)				December 31, (in thousands)			
	2023	2022	$ Change	% Change	2022	2021	$ Change	% Change
Total cost of sales	$ 9,509	$ 9,449	$ 60	1 %	$ 9,449	$ 12,163	$ (2,714)	(22)%
Inventory write-down	1,184	—	1,184	100 %	—	4,500	(4,500)	(100)%
Non-cash equity-based compensation as a component of cost of sales	300	665	(365)	(55)%	665	325	340	105 %
Total cost of sales less inventory write-down and non-cash equity-based compensation	$ 8,025	$ 8,784	$ (759)	(9)%	$ 8,784	$ 7,338	$ 1,446	20 %

During the year ended December 31, 2023, cost of sales increased slightly when compared to the year ended December 31, 2022. This increase was primarily due to an excess inventory write-down of $1.2 million recorded during the year ended December 31, 2023 partially offset by reduced non-cash equity-based compensation and reduced demand for Accelerate Pheno instruments.

During the years ended December 31, 2023 and 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 material and work in process inventory, whose inventory levels were higher than our updated forecasts of future demand for those products. Inventory provisions totaled $1.2 million during the year ended December 31, 2023 and $4.5 million during the year ended December 31, 2021, with no inventory provisions recorded for the year ended December 31, 2022.

Total cost of sales less inventory write-downs and non-cash equity-based compensation expense during the year ended December 31, 2023, decreased consistent with the decrease in sales of Accelerate Pheno instruments, compared to the year ended December 31, 2022.

During the year ended December 31, 2022, cost of sales decreased when compared to the year ended December 31, 2021. This decrease was primarily due to an 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, 2022, increased primarily as a result of an increase in Accelerate PhenoTest BC Kit revenue and increases to our cost of manufacturing compared to the year ended December 31, 2021.

Non-cash equity-based compensation expense 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 $0.3 million, $0.7 million and $0.3 million for the years ended December 31, 2023, 2022 and 2021, respectively. During the year ended December 31, 2023, non-cash equity-based compensation expense decreased due to lower labor expenses and decreases in fair value of stock awards being granted. During the year ended December 31, 2022, non-cash equity based compensation increased due to new awards being granted and continued amortization of prior periods.

	December 31, (in thousands)				December 31, (in thousands)			
	2023	2022	$ Change	% Change	2022	2021	$ Change	% Change
Gross profit (loss)	$ 2,550	$ 3,303	$ (753)	(23)%	$ 3,303	$ (381)	$ 3,684	(967)%
Inventory write-down	1,184	—	1,184	100 %	—	4,500	(4,500)	(100)%
Non-cash equity-based compensation as a component of gross profit (loss)	300	665	(365)	(55)%	665	325	340	105 %
Gross profit (loss) less inventory write-down and non-cash equity-based compensation	$ 4,034	$ 3,968	$ 66	2 %	$ 3,968	$ 4,444	$ (476)	(11)%

During the year ended December 31, 2023, gross profit decreased as a result of inventory provisions primarily related to the write-down of excess quantities of raw material and work in process instrument inventory, compared to the year ended December 31, 2022. As described above, the Company recorded an inventory write-down of $1.2 million for the year ended December 31, 2023.

Gross profit (loss) less inventory write-downs and non-cash equity-based compensation expense increased during the year ended December 31, 2023, compared to the year ended December 31, 2022, primarily due to the increase in gross margin as a result of reductions in costs to manufacture consumables.

During the year ended December 31, 2022, the Company recorded a gross profit, while recording a gross loss during the year end December 31, 2021. As described above, the Company recorded an inventory write-down of $4.5 million during the year ended December 31, 2021 resulting in a gross loss for the period.

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.

Inventory with zero cost basis was sold to customers for the years ended December 31, 2023, 2022 and 2021. Sales of pre-launch inventory previously not capitalized and expensed in a previous year for the years ended December 31, 2023, 2022 and 2021 was $0.2 million, $0.8 million and $0.2 million, respectively.

	December 31, (in thousands)				December 31, (in thousands)			
	2023	2022	$ Change	% Change	2022	2021	$ Change	% Change
Research and development	$ 25,353	$ 26,915	$ (1,562)	(6)%	$ 26,915	$ 21,943	$ 4,972	23 %
Non-cash equity-based compensation as a component of research and development	1,396	1,419	(23)	(2)%	1,419	4,102	(2,683)	(65)%
Research and development less non-cash equity-based compensation	$ 23,957	$ 25,496	$ (1,539)	(6)%	$ 25,496	$ 17,841	$ 7,655	43 %

Research and development expenses for the year ended December 31, 2023 decreased as compared to the year ended December 31, 2022 primarily due to lower employee related expenses and a decrease in third party development costs to develop our Accelerate Wave system, as we further advance the program from development to verification and validation.

Research and development expenses for the year ended December 31, 2022 increased as compared to the year ended December 31, 2021. 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 the Accelerate Wave system. This increase was partially offset by decreases in employee related expenses and engineering supplies, including a decrease in non-cash equity-based compensation expense to $1.4 million from $4.1 million for the year ended December 31, 2022 compared to 2021, primarily due to a lower fair value of stock awards being granted during the year ended December 31, 2022. This lower fair value was due to a decrease in the Company's stock price year over year.

	December 31, (in thousands)				December 31, (in thousands)			
	2023	2022	$ Change	% Change	2022	2021	$ Change	% Change
Sales, general and administrative	$ 31,225	$ 39,193	$ (7,968)	(20)%	$ 39,193	$ 49,236	$ (10,043)	(20)%
Non-cash equity-based compensation as a component of sales, general and administrative	3,691	8,541	(4,850)	(57)%	8,541	17,620	(9,079)	(52)%
Sales, general and administrative less non-cash equity-based compensation	$ 27,534	$ 30,652	$ (3,118)	(10)%	$ 30,652	$ 31,616	$ (964)	(3)%

Sales, general and administrative expenses during the year ended December 31, 2023 decreased compared to the year ended December 31, 2022, primarily due to lower employee related expenses and employee non-cash equity-based compensation expenses following the restructuring of the Company's commercial sales team subsequent to the signing of the Sales and Marketing Agreement with BD in the third quarter of 2022.

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

	December 31, (in thousands)				December 31, (in thousands)			
	2023	2022	$ Change	% Change	2022	2021	$ Change	% Change
Loss from operations	$ (54,028)	$ (62,805)	$ 8,777	(14)%	$ (62,805)	$ (71,560)	$ 8,755	(12)%
Inventory write-down	1,184	—	$ 1,184	100 %	—	4,500	(4,500)	(100)%
Non-cash equity-based compensation as a component of loss from operations	5,387	10,625	$ (5,238)	(49)%	10,625	22,047	(11,422)	(52)%
Loss from operations less inventory write-down and non-cash equity-based compensation	$ (47,457)	$ (52,180)	$ 4,723	(9)%	$ (52,180)	$ (45,013)	$ (7,167)	16 %

During the year ended December 31, 2023, our loss from operations decreased as compared to the year ended December 31, 2022, primarily due to lower employee related expenses, partially offset by the write-down of excess quantities of raw material and work in process instrument inventory.

During the year ended December 31, 2022, 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 an inventory write-down incurred in 2021, as well as higher revenue compared to the prior year period.

Loss from operations includes non-cash equity-based compensation expense of $5.4 million, $10.6 million and $22.0 million for the years ended December 31, 2023, 2022 and 2021, respectively. The decrease of non-cash equity-based compensation expense for each year 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.

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)			
	2023	2022	$ Change	% Change	2022	2021	$ Change	% Change
Total other (expense) income, net	$ (6,740)	$ 235	$ (6,975)	(2,968)%	$ 235	$ (6,097)	$ 6,332	(104)%

During the year ended December 31, 2023, other expense, net, is comprised of loss on extinguishment of debt of $6.5 million, loss on extinguishment of debt with related party of $6.8 million, both in conjunction with the Restructuring Transactions, interest expense of $5.9 million, and related party interest expense of $1.8 million. These expenses were partially offset by a $13.0 million gain on a fair-value adjustment mainly consisting of the derivative liability related to our 5.00% Notes as well as the Schuler Purchase Obligation.

During the year ended December 31, 2022, other income, net, was 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, was primarily comprised of interest expense of $15.5 million partially offset by gains on extinguishment of debt of $9.8 million. In addition, the Small Business Administration's, Paycheck Protection Program loan and accrued interest of $4.8 million, was forgiven and recorded as a gain on extinguishment.

The Company entered into privately negotiated exchange agreements during the years ended December 31, 2022 and 2021. Holders of certain of the 2.50% Notes exchanged 2.50% 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 year ended December 31, 2022 and 2021 respectively.

The increase in interest expense for the year ended December 31, 2023, when compared to the prior year,

was primarily the result of the Company's entry into the 5.00% Notes in 2023. The decrease in interest expense for the year ended December 31, 2022 when compared to the prior year was the result of the Company's adoption of 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) ("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 2.50% Notes. Interest expense was $5.9 million, $2.3 million and $15.5 million for the years ended December 31, 2023, 2022 and 2021, respectively.

	December 31, (in thousands)				December 31, (in thousands)			
	2023	2022	$ Change	% Change	2022	2021	$ Change	% Change
(Provision) benefit for income taxes	$ (850)	$ 77	$ (927)	(1,204)%	$ 77	$ (45)	$ 122	(271)%

For the year ended December 31, 2023 the Company recorded a tax provision of $0.9 million related to tax liabilities generated by our foreign subsidiaries. For the year ended December 31, 2022, the Company recorded an immaterial benefit for income taxes, anticipating a refund from prior year overpayments.

For the years ended December 31, 2022, and 2021, 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 $668.9 million as of December 31, 2023. During the year ended December 31, 2023, the Company had a net loss of $61.6 million and negative cash flows from operations of $40.2 million. The Company had working capital of $12.4 million as of December 31, 2023.

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 2.50% Notes (collectively, the "Ad Hoc Noteholder Group") and the trustee for the 2.50% Notes (the "Trustee"). On March 15, 2023, the 2.50% Notes matured and became due and payable. Pursuant to the Forbearance Agreement, the members of the Ad Hoc Noteholder Group agreed, and directed the Trustee, to forbear from exercising their rights and remedies under the indenture governing the 2.50% Notes (the "2.50% Notes Indenture") in connection with certain events of default under the 2.50% Notes Indenture, including, but not limited to, the failure to timely pay in full the principal of any 2.50% Note due and payable on March 15, 2023 and the failure to pay any interest on any 2.50% Note due and payable. The Forbearance Agreement was initially effective for the period commencing on March 13, 2023 and ending on March 29, 2023, which was subsequently extended by the parties to April 21, 2023. On April 21, 2023, the Company entered into a restructuring support agreement (the "Restructuring Support Agreement") with certain holders of the 2.50% Notes, the holder of the Secured Note in an aggregate principal amount of $34.9 million and the holders of the Company's Series A Preferred Stock to negotiate in good faith to effect a series of transactions to allow for the restructuring of the Company's capital structure (the "Restructuring Transactions").

On June 9, 2023, the Company completed the Restructuring Transactions contemplated by the Restructuring Support Agreement whereby the Company:

- exchanged approximately $55.9 million aggregate principal amount of 2.50% Notes for approximately $56.9 million aggregate principal amount of newly issued 5.00% Notes, which was inclusive of additional 5.00% Notes in respect of interest accrued on the 2.50% Notes from September 15, 2022, for $1.0 million;
- issued and sold an additional $10.0 million aggregate principal amount of 5.00% Notes;
- amended and repurchased the Secured Note, plus accrued interest, by issuing approximately 3.4 million shares of the Company's common stock;
- issued approximately 0.4 million shares of the Company's common stock upon conversion of all of the Company's outstanding Series A Preferred Stock;
- amended the March 2022 Securities Purchase Agreement and issued and sold approximately 0.5 million shares of the Company's common stock for proceeds of $4.0 million; and

- entered into a new securities purchase agreement with the Schuler Trust pursuant to which the Schuler Trust was required, prior to December 15, 2023 (which was subsequently amended and extended to February 15, 2024), to either purchase an aggregate of $10.0 million of the Company's common stock from the Company or to backstop an underwritten public offering by the Company of its common stock for aggregate proceeds of $10.0 million, at the Company's option (the "Schuler Purchase Obligation"). Further details regarding the Schuler Purchase Obligation and amendment are included in Part II, Item 8, Note 11, Related Party Transactions of this Form 10-K.

As of December 31, 2023, the Company had $13.2 million in cash and cash equivalents and investments, a decrease of $32.4 million from $45.6 million at December 31, 2022. The primary reason for the decrease was due to cash used in operations during the period and cash used for nonrecurring legal and professional services in connection with the Restructuring Transactions, partially offset by the proceeds from the issuance of the 5.00% Notes and the sale and issuance of common stock under the March 2022 Securities Purchase Agreement. 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's primary use of capital has been for the development and commercialization of the Accelerate Pheno system, development of complementary products and, most recently, development of its next generation technology, the Accelerate Wave system. 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. In January 2024, the Company issued and sold approximately 8.1 million units in certain underwritten public and private placement offerings, each consisting of one share of common stock and one warrant to purchase one share of common stock ("Units"), for aggregate gross proceeds of approximately $12.3 million. This includes approximately 1.2 million Units issued and sold to the Schuler Trust which satisfied the Schuler Purchase Obligation. While the Company believes that this additional funding will allow it to continue to progress its development and operational goals discussed in this report for the next several quarters, the net proceeds from these transactions are not expected to be sufficient to fund the Company's operations through twelve months from the issuance of our consolidated financial statements. See the following notes in Part II, Item 8, Financial Statements and Supplementary Data of this Form 10-K for additional details: Note 1, Organization and Nature of Business; Basis of Presentation; Principles of Consolidation, Note 10, Convertible Notes, Note 11, Related Party Transactions and Note 18, Subsequent Events.

While the Company continues to explore additional funding in the form of potential equity and/or debt financing arrangements or similar transactions, 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 additional debt, it is likely any new debt would have rights, preferences and privileges senior to common stockholders. The terms of borrowing could impose significant restrictions on the Company's operations. 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. In addition, increases in federal fund rates set by the Federal Reserve, such as the significant increases experienced throughout 2022 and 2023, which serve as benchmark rates on borrowing, and other general economic conditions have impacted, and in the future may impact, the cost of debt financing or refinancing existing debt.

Although the Company is actively considering all available strategic alternatives to maximize value, if the Company is unable to obtain adequate capital resources to fund operations, the Company would not be able to continue to operate its business pursuant to its current plans. This may require the Company to, among other things, materially modify its operations to reduce spending; sell assets or operations; delay the implementation of, or revising certain aspects of, its business strategy; or discontinue its operations entirely.

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 Accounting Standards Codification ("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 fund its forecasted operating costs for at least twelve months from the date of issuance of our 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.

For additional information, see "Risk Factors—Risks Related to Our Financial Condition, Liquidity and Indebtedness" in Part I, Item 1A, Risk Factors and Part II, Item 8, Note 1, Organization and Nature of Business; Basis of Presentation; Principles of Consolidation of this Form 10-K.

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)

	2023	2022	2021
Net cash used in operating activities	$ (40,196)	$ (48,728)	$ (47,323)
Net cash provided by investing activities	8,660	12,417	8,304
Net cash provided by financing activities	9,019	31,630	43,226

Cash flows from operating activities

The net cash used in operating activities was $40.2 million during the year ended December 31, 2023. Net cash used in operating activities was primarily the result of net losses and a gain on fair value adjustment. These amounts were partially offset by losses on extinguishment of debt, equity-based compensation, an inventory write-down, depreciation and amortization, amortization of debt discount and issuance costs, and paid-in-kind interest.

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 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.

These losses are the result of continued investments in research and development to further mature the Accelerate Pheno system, develop complementary products, including the Accelerate Arc system, as well as develop our next generation technology, the Accelerate Wave system, along with other factors.

Cash flows from investing activities

The net cash provided by investing activities was $8.7 million for the year ended December 31, 2023. The Company had maturities of marketable securities of $9.7 million which were offset in part by purchases of equipment of $1.0 million.

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.

Cash flows from financing activities

The net cash provided by financing activities was $9.0 million for the year ended December 31, 2023. The Company had proceeds from the sale of common stock of $4.0 million and proceeds from issuance of 5.00% Notes of $10.0 million, which were partially offset by debt and equity issuance costs of $3.7 million and payments on finance leases of $1.3 million.

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.

Financing Activity

Convertible Notes

On June 9, 2023, the Company issued $66.9 million aggregate principal amount of 5.00% Notes in connection with the Restructuring Transactions described above. The 5.00% Notes mature on December 15, 2026 and bear interest at a rate of 5% per annum, payable in kind. Interest is payable semi-annually in arrears June 15 and December 15 of each year, commencing on December 15, 2023. The 5.00% Notes, including any 5.00% Notes issued as a result of the payment of interest in kind, will be convertible into shares of the Company’s common stock at an initial conversion price of approximately $7.20 per share, which reflects the initial conversion rate of 138.88889 shares of common stock per $1,000 principal amount of 5.00% Notes. The initial conversion price was subject to adjustment based on the positive difference between the 31 to 90 day volume-weighted average price, subject to a cap of $8.30 per share. On October 18, 2023, the Company evaluated the conversion rate in accordance with the terms of the 5.00% Notes and determined the initial conversion rate of 138.88889 shares of common stock per $1,000 principal amount will continue to be the conversion rate through the remaining term of the 5.00% Notes. Upon conversion of the 5.00% Notes, the Company will pay or deliver, as the case may be, cash, shares of the Company’s common stock, or a combination of cash and shares of common stock, at the Company's election.

The 5.00% Notes Indenture contains customary events of default, including, but not limited to, non-payment of principal or interest, breach of certain covenants in the 5.00% Notes Indenture, defaults under or failure to pay certain other indebtedness and certain events of bankruptcy, insolvency and reorganization. If an event of default (other than certain events of bankruptcy, insolvency or reorganization involving the Company) occurs and is continuing, the Collateral Agent (as defined below), by notice to the Company, or the holders of the 5.00% Notes representing at least 25% in aggregate principal amount of the outstanding 5.00% Notes, by notice to the Company and the Collateral Agent, may declare 100% of the principal of, and all accrued and unpaid interest on, all of the then outstanding 5.00% Notes to be due and payable immediately. Upon the occurrence of certain events of bankruptcy, insolvency or reorganization involving the Company, 100% of the principal of, and all accrued and unpaid interest on, all of the then outstanding 5.00% Notes will automatically become immediately due and payable.

Additionally, the Company and certain of its subsidiaries granted U.S. Bank Trust Company, National Association, a national banking association, as collateral agent (the “Collateral Agent”), a security interest in certain

of their assets, including but not limited to certain accounts, equipment, fixtures and intellectual property, in order to secure the payment and performance of all of their Obligations (as defined in the 5.00% Notes Indenture) relating to the 5.00% Notes.

In March and April 2018, the Company issued $171.5 million aggregate principal amount of 2.50% Notes. In September 2021 and March 2022, the Company entered into exchange agreements with certain holders of 2.50% Notes pursuant to which $65.0 million aggregate principal amount of 2.50% Notes were exchanged for an aggregate of approximately 1.7 million shares of the Company's common stock. On March 15, 2023, the remaining 2.50% Notes matured and became due and payable.

In August 2022, the Company entered into an exchange agreement with the Schuler Trust pursuant to which the Schuler Trust agreed to exchange with the Company $49.9 million aggregate principal amount of 2.50% Notes held by it for (a) the Secured Note in an aggregate principal amount of $34.9 million and (b) a warrant (the "Warrant") to acquire up to approximately 0.2 million shares of the Company's common stock at an exercise price of $21.20 per share (the "Exercise Price"). 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 number of shares underlying the Warrant 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 Secured Note, plus accrued interest, was repurchased by the Company in connection with the Restructuring Transactions through the issuance of approximately 3.4 million shares of common stock.

In connection with the Restructuring Transactions, approximately $55.9 million aggregate principal amount of 2.50% Notes were exchanged for approximately $56.9 million aggregate principal amount of 5.00% Notes, which was inclusive of additional 5.00% Notes in respect of interest accrued on the 2.50% Notes from September 15, 2022.

In August and October 2023, certain holders of 5.00% Notes converted approximately $1.0 million of aggregate principal amount of 5.00% Notes held by them for approximately 0.1 million shares of the Company's common stock. In December 2023, the Company issued $1.7 million of PIK Notes to pay interest accrued on the 5.00% Notes outstanding as of that date.

As of December 31, 2023, approximately $0.7 million aggregate principal amount of 2.50% Notes remained outstanding and in default accruing interest at 2.50% per annum. As of December 31, 2023, $67.6 million aggregate principal amount of 5.00% Notes were outstanding.

See Part II, Item 8, Note 10, Convertible Notes of this Form 10-K for additional information.

Sales of Equity Securities

The Company has historically completed multiple equity raises through sales of its common and preferred stock in both public and private offerings, including the recent transactions below.

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 approximately 0.2 million shares of the Company's common stock to the Schuler Trust for an aggregate purchase price of $4.0 million. In connection with the Restructuring Transactions, the Company amended the March 2022 Securities Purchase Agreement and issued and sold approximately 0.5 million shares of the Company's common stock to the Schuler Trust for proceeds of $4.0 million.

On August 23, 2022, the Company completed a public offering of approximately 1.8 million shares of its common stock at a public offering price of $20.00 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.

On June 9, 2023, the Company entered into the Schuler Purchase Obligation with the Schuler Trust pursuant to which the Schuler Trust was required, at the Company's option, to either purchase approximately 1.4 million shares of common stock from the Company valued at $7.20 per share for an aggregate purchase price of $10.0 million or to backstop a public offering by the Company of common stock for aggregate proceeds of $10.0 million. If the Company elected to conduct a public offering of common stock and other investors purchased less

than $10.0 million of common stock by December 15, 2023, the Schuler Trust would have the obligation to purchase $10.0 million of shares of common stock, less the amount of common stock purchased by other investors, and would have the right to purchase additional shares of common stock such that the total amount of common stock purchased by the Schuler Trust equaled $10.0 million of shares of common stock. If the Company elected to conduct a public offering of common stock and other investors purchased $10.0 million of shares of common stock by December 15, 2023, the Schuler Trust would have the right, but not the obligation, to purchase up to $10.0 million of shares of common stock at the public offering price for the backstopped offering up to a maximum aggregate purchase by the Schuler Trust of $10.0 million of common stock.

In December 2023, the Company and the Schuler Trust entered into an amendment to the Schuler Purchase Obligation extending the deadline for the investment or public offering backstop through February 15, 2024 and the Schuler Trust agreed to purchase $2 million of shares at the public offering price if the aggregate gross proceeds resulting from the public offering is more than $10 million.

In January 2024, the Company completed an underwritten public offering (the “January 2024 Public Units Offering”) consisting of 6.9 million Units, each consisting of one share of common stock and one warrant to purchase one share of common stock, and for certain investors in lieu thereof, pre-funded Units, each consisting of one pre-funded warrant to purchase one share of common stock and one warrant to purchase one share of common stock. The public offering price for each Unit was $1.50 and the public offering price for each pre-funded Unit was $1.49.

The Company granted the underwriters for the January 2024 Public Units Offering a 30-day option to purchase up to an additional 1.0 million shares of common stock and/or additional warrants to purchase up to 1.0 million shares of common stock, in any combination thereof, at the public offering price, less underwriting discounts and commissions. The underwriters elected to purchase an additional 36,003 warrants from the Company under this option.

The warrants issued to investors in the January 2024 Public Units Offering have an exercise price of $1.65 per share, were immediately exercisable upon issuance and will remain exercisable until the date that is five years after their original issuance. The pre-funded warrants have an exercise price of $0.01 per share, are immediately exercisable and will remain exercisable until exercised in full. The gross proceeds from the January 2024 Public Units Offering, before deducting underwriting discounts and commissions and other public offering expenses payable by the Company were approximately $10.3 million (excluding any proceeds that may be received upon the exercise of the warrants or the pre-funded warrants).

Concurrently with the completion of the January 2024 Public Units Offering, the Company sold 1.2 million Units at a purchase price of $1.73 per Unit to the Schuler Trust, which satisfied the Schuler Purchase Obligation and an aggregate of 33,332 Units at a purchase price of $1.50 per Unit to the Company’s Chief Executive Officer and Chief Financial Officer, in each case, in a private placement offering. In addition, the Schuler Trust agreed to purchase an additional 1.6 million Units at a purchase price of $1.73 per unit on or before May 20, 2024. The gross proceeds from the private placement offerings, before deducting private placement expenses payable by the Company, were approximately $4.7 million (excluding any proceeds that may be received upon the exercise of the warrants).

The current estimate of net proceeds after consideration of estimated transaction expenses is approximately $13.6 million.

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 9, Leases. The Company also has convertible notes outstanding as described above and in Part II, Item 8, Note 10, Convertible Notes. As of December 31, 2023, 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**	**2024**	**2025**	**2026**	**2027**	**2028**
Operating lease obligations	$ 1,638	$ 1,055	$ 583	$ —	$ —	$ —
Purchase obligation [1)]	11,858	—	—	—	11,858	—
Finance leases	900	784	86	30	—	—
Deferred compensation	1,081	—	393	421	267	—
2.50% Notes	726	726	—	—	—	—
5.00% Notes [2)]	67,634	—	—	67,634	—	—
5.00% Notes interest [3)]	10,801	—	—	10,801	—	—
Total	$ 94,638	$ 2,565	$ 1,062	$ 78,886	$ 12,125	$ —

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, 2023 the commitment remains $11.9 million as the Company has not taken delivery of any inventory.

2) The amount shown here is the 5.00% Notes outstanding principal at par including payment-in-kind (“PIK”) Notes. Each holder of the 5.00% Notes has the right at their option, to convert any portion of the 5.00% Notes at an initial conversion rate of 138.88889 shares of common stock per $1,000 principal amount of the 5.00% Notes. Effective October 18, 2023, the initial conversion rate was to be adjusted to a conversion rate calculated based on a conversion price of $7.20 per share of common stock plus 50% of the difference between the Post-Closing VWAP (as defined in the 5.00% Notes Indenture) and $7.20 (if such difference is a positive number), provided that in no event will the adjusted conversion rate be lower than 120.48193 per $1,000 principal amount of the 5.00% Notes, based on a conversion price of $8.30 per share of common stock. The Company cannot require the holder of the 5.00% Notes to convert at any time. On October 18, 2023, the Company evaluated the conversion rate per the terms outlined above and determined the initial conversion rate of 138.88889 shares of common stock per $1,000 principal amount will continue to be the conversion rate through the remaining term of the 5.00% Notes.

3) The 5.00% Notes bear interest at a rate of 5.00% per annum. The Company will pay interest on the 5.00% Notes by PIK issuance of additional 5.00% Notes. The amount will be payable to holders by increasing the principal amount of each outstanding 5.00% Note by an amount equal to the interest payable for the applicable interest period. The amount shown here relates to interest for which the PIK Notes have not yet been issued.

Until such time as we can generate substantial product revenue, we expect to finance our cash requirements, beyond what is currently available or on hand, through a combination of equity offerings and debt financings, or collection of the exclusivity fee from BD in accordance with the Sales and Marketing Agreement with BD.

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. ("U.S. GAAP"). The preparation of these financial statements in conformity with U.S. GAAP 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 Part II, Item 8, Note 2, Summary of Significant Accounting Policies, we believe that the following judgments are most critical to aid in fully understanding and evaluating our reported financial results.

Inventory Valuation

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.

The Company manufactures pre-launch inventory in advance of regulatory approval. This inventory is expensed before an economic benefit is probable.

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 and Accelerate Arc systems (also referred to as instruments) used for sales demonstrations, instruments under rental agreements and instruments used for research and development. Depreciation expense and losses from retirement of instruments used for sales demonstrations is recorded as a component of sales, general and administrative expense. Depreciation expense and losses from retirement of instruments placed at customer sites pursuant to reagent rental agreements is recorded as a component of cost of sales. Depreciation expense and losses from retirement of 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.

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, 2023, 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 material impairment charges were recorded at December 31, 2023, 2022, and 2021.

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

Convertible Notes

The Company follows 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) in accounting for its outstanding convertible notes. The convertible notes are accounted for as a liability measured at their amortized cost. 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, conversion or settlement.

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 years ended December 31, 2023 and 2022.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not required for a smaller reporting company.

Item 8. Financial Statements and Supplementary Data

Financial Statements of Accelerate Diagnostics, Inc.

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, 2023 and 2022, 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, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023, 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 and negative cash flows from operations, 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 disclosed 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 cost of sales 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, 2023, 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 28, 2024

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

	December 31,	
	2023	**2022**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 12,138	$ 34,905
Investments	1,081	10,656
Trade accounts receivable, net	2,622	2,416
Inventory	3,310	5,194
Prepaid expenses	380	818
Purchase obligation put option asset	3,419	—
Other current assets	1,516	2,025
Total current assets	24,466	56,014
Property and equipment, net	2,389	3,478
Finance lease assets, net	1,518	2,422
Operating lease right of use assets, net	1,177	1,859
Other non-current assets	1,816	1,242
Total assets	$ 31,366	$ 65,015
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 4,796	$ 4,501
Accrued liabilities	3,243	2,682
Accrued interest	164	472
Deferred revenue and income, current	1,545	547
Current portion of convertible notes	726	56,413
Finance lease, current	583	1,113
Operating lease, current	977	829
Total current liabilities	12,034	66,557
Finance lease, non-current	262	782
Operating lease, non-current	570	1,545
Deferred income, non-current	1,122	—
Other non-current liabilities	1,164	874
Accrued interest, related-party	—	663
Long-term debt, related-party	—	16,858
Convertible notes, non-current	36,102	—
Total liabilities	51,254	87,279
Commitments and contingencies (see Note 15)		

See accompanying notes to consolidated financial statements.

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

	December 31,	
	2023	**2022**
Stockholders' deficit:		
Preferred shares, $0.001 par value;		
5,000,000 preferred shares authorized with no shares issued and outstanding as of December 31, 2023 and 3,954,546 issued and outstanding on December 31, 2022	—	4
Common stock, $0.001 par value;		
450,000,000 common shares authorized with 14,569,500 shares issued and outstanding on December 31, 2023 and 200,000,000 common shares authorized with 9,747,755 shares issued and outstanding on December 31, 2022	14	10
Contributed capital	694,634	630,428
Treasury stock	(45,067)	(45,067)
Accumulated deficit	(668,857)	(607,239)
Accumulated other comprehensive loss	(612)	(400)
Total stockholders' deficit	(19,888)	(22,264)
Total liabilities and stockholders' deficit	$ 31,366	$ 65,015

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,		
	2023	**2022**	**2021**
Net sales	$ 12,059	$ 12,752	$ 11,782
Cost of sales:			
Cost of sales of products and services	8,325	9,449	7,663
Inventory write-down	1,184	—	4,500
Total cost of sales	9,509	9,449	12,163
Gross profit (loss)	2,550	3,303	(381)
Costs and expenses:			
Research and development	25,353	26,915	21,943
Sales, general and administrative	31,225	39,193	49,236
Total costs and expenses	56,578	66,108	71,179
Loss from operations	(54,028)	(62,805)	(71,560)
Other (expense) income:			
Interest expense	(5,926)	(2,274)	(15,545)
Interest expense related-party	(1,817)	(1,497)	—
(Loss) gain on extinguishment of debt	(6,499)	3,565	9,793
(Loss) on extinguishment of debt related party	(6,755)	—	—
Gain on fair value adjustment	12,955	—	—
Foreign currency exchange gain (loss)	71	117	(413)
Interest income	1,123	551	88
Other expense, net	108	(227)	(20)
Total other (expense) income, net	(6,740)	235	(6,097)
Net loss before income taxes	(60,768)	(62,570)	(77,657)
(Provision) benefit for income taxes	(850)	77	(45)
Net loss	$ (61,618)	$ (62,493)	$ (77,702)
Basic and diluted net loss per share	$ (4.94)	$ (7.61)	$ (12.59)
Weighted average shares outstanding	12,477	8,216	6,173
Other comprehensive loss:			
Net loss	$ (61,618)	$ (62,493)	$ (77,702)
Net unrealized gain (loss) on available-for-sale investments	29	(14)	(34)
Foreign currency translation adjustment	(241)	(326)	(117)
Comprehensive loss	$ (61,830)	$ (62,833)	$ (77,853)

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
Balances, December 31, 2020	—	$ —	5,761	$ 6	$ 475,072	$ (492,966)	$ (45,067)	$ 91	$ (62,864)
Net loss	—	—	—	—	—	(77,702)	—	—	(77,702)
Issuance of common stock	—	—	494	—	32,400	—	—	—	32,400
Cancellation of common stock	—	—	—	—	(20,297)	—	—	—	(20,297)
Issuance of preferred stock	3,955	4	(264)	—	30,446	—	—	—	30,450
Exercise of options and restricted stock awards issued	—	—	109	—	1,619	—	—	—	1,619
Issuance of common stock under employee purchase plan	—	—	6	—	326	—	—	—	326
Unrealized loss on investments	—	—	—	—	—	—	—	(34)	(34)
Foreign currency translation adjustment	—	—	—	—	—	—	—	(117)	(117)
Issuance of shares to retire 2.50% Notes	—	—	661	1	38,896	—	—	—	38,897
Equity-based compensation	—	—	—	—	22,190	—	—	—	22,190
Reclassification of common stock par value due to reverse stock split	—	—	—	—	61	—	—	—	61
Balances, December 31, 2021	3,955	4	6,767	7	580,713	(570,668)	(45,067)	(60)	(35,071)
Net loss	—	—	—	—	—	(62,493)	—	—	(62,493)
Issuance of common stock	—	—	1,750	2	32,855	—	—	—	32,857
Restricted stock awards issued and exercise of options	—	—	130	—	6	—	—	—	6
Issuance of common stock under employee purchase plan	—	—	22	—	224	—	—	—	224
Foreign currency translation adjustment	—	—	—	—	—	—	—	(326)	(326)
Unrealized loss on investments	—	—	—	—	—	—	—	(14)	(14)
Cumulative impact of accounting change	—	—	—	—	(37,438)	25,922	—	—	(11,516)
Issuance of shares to retire 2.50% Notes	—	—	1,079	1	10,169	—	—	—	10,170
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
Reclassification of common stock par value due to reverse stock split	—	—	—	—	26	—	—	—	26
Balances, December 31, 2022	3,955	4	9,748	10	630,428	(607,239)	(45,067)	(400)	(22,264)

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
Balances, December 31, 2022	3,955	$ 4	9,748	$ 10	$ 630,428	$ (607,239)	$ (45,067)	$ (400)	$ (22,264)
Net loss	—	—	—	—	—	(61,618)	—	—	(61,618)
Issuance of common stock to related party	—	—	488	1	3,996	—	—	—	3,997
Capital contribution from modification of securities purchase agreement with related party	—	—	—	—	1,805	—	—	—	1,805
Conversion of preferred stock into common stock with related party	(3,955)	(4)	396	—	—	—	—	—	(4)
Restricted stock awards issued	—	—	373	—	—	—	—	—	—
Unrealized gain on investments	—	—	—	—	—	—	—	29	29
Foreign currency translation adjustment	—	—	—	—	—	—	—	(241)	(241)
Issuance of shares to retire secured promissory note with related party	—	—	3,432	3	25,363	—	—	—	25,366
Reclassification of derivative liability to contributed capital	—	—	—	—	26,908	—	—	—	26,908
Issuance of shares to retire convertible notes and derivative	—	—	133	—	819	—	—	—	819
Equity-based compensation	—	—	—	—	5,274	—	—	—	5,274
Reclassification of common stock par value due to reverse stock split	—	—	—	—	41	—	—	—	41
Balances, December 31, 2023	—	$ —	14,570	$ 14	$ 694,634	$ (668,857)	$ (45,067)	$ (612)	$ (19,888)

See accompanying notes to consolidated financial statements.

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

	Years Ended December 31,		
	2023	**2022**	**2021**
Cash flows from operating activities:			
Net loss	$ (61,618)	$ (62,493)	$ (77,702)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	3,254	3,000	2,518
Provision for bad debts	301	204	123
Amortization of investment discount	—	98	226
Equity-based compensation expense	5,387	10,625	22,047
Amortization of debt discount and issuance costs	3,278	474	11,542
Amortization of debt discount related party	1,033	834	—
Unrealized (gain) loss on equity investments	(114)	211	—
Loss (gain) on disposal of property and equipment	150	133	(75)
Loss (gain) on extinguishment of debt	6,499	(3,565)	(9,793)
Loss on extinguishment of debt with related party	6,755	—	—
Gain on fair value adjustments	(12,955)	—	—
Paid-in-kind interest	1,718	—	—
Inventory write-down	1,184	—	4,500
(Increase) decrease in assets:			
Deferred compensation plan	(39)	(298)	(484)
Accounts receivable	(234)	(100)	(893)
Inventory	446	(236)	(415)
Prepaid expense and other assets	965	(62)	1,014
Increase (decrease) in liabilities:			
Accounts payable	295	2,920	273
Accrued liabilities and other	(411)	(861)	(469)
Accrued interest	716	(437)	(283)
Accrued interest from related-party	784	663	—
Deferred revenue and income	2,120	96	75
Deferred compensation	290	66	473
Net cash used in operating activities	(40,196)	(48,728)	(47,323)
Cash flows from investing activities:			
Purchases of equipment	(1,035)	(554)	(603)
Purchase of marketable securities	—	(27,506)	(30,081)
Proceeds from sales of marketable securities	—	—	250
Maturities of marketable securities	9,695	40,477	38,738
Net cash provided by investing activities	8,660	12,417	8,304
Cash flows from financing activities:			
Proceeds from issuance of common stock to related party	4,000	—	—
Proceeds from issuance of common and preferred stock, net	—	32,872	42,880
Proceeds from exercise of options	—	7	1,620
Proceeds from issuance of common stocks under employee purchase plan	—	224	326
Proceeds from issuance of 5.00% Notes	10,000	—	—
Payment of debt	—	(80)	(360)
Payments on finance leases	(1,250)	(1,201)	—
Transaction costs related to debt	(3,731)	(192)	(1,240)
Net cash provided by financing activities	9,019	31,630	43,226

See accompanying notes to consolidated financial statements.

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

	Years Ended December 31,		
	2023	**2022**	**2021**
Effect of exchange rate on cash	(250)	(312)	(90)
(Decrease) increase in cash and cash equivalents	(22,767)	(4,993)	4,117
Cash and cash equivalents, beginning of period	34,905	39,898	35,781
Cash and cash equivalents, end of period	$ 12,138	$ 34,905	$ 39,898
Non-cash investing activities:			
Net transfer of instruments from inventory to property and equipment, net	$ 401	$ 168	$ 688
Non-cash financing activities:			
Exchange of 2.50% Notes and accrued interest for 5.00% Notes	$ 56,893	$ —	$ —
Debt premium on issuance of 5.00% Notes	$ 6,023	$ —	$ —
Derivative liability associated with the bifurcated conversion option	$ 38,160	$ —	$ —
Reclassification of bifurcated conversion option to contributed capital	$ 26,908	$ —	$ —
Extinguishment of derivative liability in connection with extinguishment of 5.00% Notes	$ 380	$ —	$ —
Issuance of common stock in connection with extinguishment of 5.00% Notes	$ 819	$ —	$ —
Capital contribution from the exchange of secured note and accrued interest through the issuance of common stock with related party	$ 25,366	$ 29,847	$ —
Extinguishment of 2.50% Notes through issuance of common stock	$ —	$ 10,180	$ 38,902
2.50% Notes extinguished in connection with exchange transaction	$ —	$ 49,624	$ —
Fair value of new note issued in connection with the exchange transaction	$ —	$ 16,024	$ —
Fair value of common stock warrant issued in connection with the exchange transaction	$ —	$ 3,753	$ —
Right-of-use assets obtained in exchange for finance lease obligations	$ 200	$ 3,096	$ —
Supplemental cash flow information:			
Interest paid	$ 122	$ 2,214	$ 4,288
Income taxes paid, net of refunds	$ 363	$ —	$ —

See accompanying notes to consolidated financial statements.

ACCELERATE DIAGNOSTICS, INC.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

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

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

Basis of Presentation

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

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

On July 11, 2023, the Company effected a one-for-ten reverse stock split ("Reverse Stock Split"). Consequently, on the Company's consolidated balance sheets, the aggregate par value of the issued common stock was reduced by reclassifying the par value amount of the eliminated shares of common stock to additional paid-in capital. All per share amounts and outstanding shares, including all common stock equivalents, have been retroactively restated in the consolidated financial statements and in the notes to the consolidated financial statements for all periods presented to reflect the Reverse Stock Split.

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 $668.9 million as of December 31, 2023. During the year ended December 31, 2023, the Company had a net loss of $61.6 million and negative cash flows from operations of $40.2 million. The Company had working capital of $12.4 million as of December 31, 2023.

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 2.50% convertible senior notes (the "2.50% Notes") (collectively, the "Ad Hoc Noteholder Group") and the trustee for the 2.50% Notes (the "Trustee"). On March 15, 2023, the 2.50% Notes matured and became due and payable. Pursuant to the Forbearance Agreement, the members of the Ad Hoc Noteholder Group agreed, and directed the Trustee, to forbear from exercising their rights and remedies under the indenture governing the 2.50% Notes (the "2.50% Notes Indenture") in connection with certain events of default under the 2.50% Notes Indenture, including, but not limited to, the failure to timely pay in full the principal of any 2.50% Note due and payable on March 15, 2023 and the failure to pay any interest on any 2.50% Note due and payable. The Forbearance Agreement was initially effective for the period commencing on March 13, 2023 and ending on March 29, 2023, which was subsequently extended by the parties to April 21, 2023. On April 21, 2023, the Company entered into a restructuring support agreement (the "Restructuring Support Agreement") with certain holders of the 2.50% Notes, the holder of a secured promissory note with the Jack W. Schuler Living Trust (the "Schuler Trust") (the "Secured Note") in an aggregate principal amount of $34.9 million and the holders of the Company's Series A Preferred Stock to negotiate in good faith to effect a series of transactions to allow for the restructuring of the Company's capital structure (the "Restructuring Transactions").

On June 9, 2023, the Company completed the Restructuring Transactions contemplated by the Restructuring Support Agreement whereby the Company:

- exchanged approximately $55.9 million aggregate principal amount of 2.50% Notes for approximately $56.9 million aggregate principal amount of newly issued 5.00% senior secured convertible notes due 2026

(the “5.00% Notes”), which was inclusive of additional 5.00% Notes in respect of interest accrued on the 2.50% Notes from September 15, 2022, for $1.0 million;
- issued and sold an additional $10.0 million aggregate principal amount of 5.00% Notes;
- amended and repurchased the Secured Note, plus accrued interest, by issuing approximately 3.4 million shares of the Company’s common stock;
- issued approximately 0.4 million shares of the Company’s common stock upon conversion of all of the Company’s outstanding Series A Preferred Stock;
- amended the securities purchase agreement that the Company entered into with the Schuler Trust in March 2022 (the “March 2022 Securities Purchase Agreement”) and issued and sold approximately 0.5 million shares of the Company’s common stock for proceeds of $4.0 million; and
- entered into a new securities purchase agreement with the Schuler Trust pursuant to which the Schuler Trust was required, prior to December 15, 2023 (which was subsequently amended and extended to February 15, 2024), to either purchase an aggregate of $10.0 million of the Company’s common stock from the Company or to backstop an underwritten public offering by the Company of its common stock for aggregate proceeds of $10.0 million, at the Company’s option (the “Schuler Purchase Obligation”). Further details regarding the Schuler Purchase Obligation and amendment are included in Note 11, Related Party Transactions.

As of December 31, 2023, the Company had $13.2 million in cash and cash equivalents and investments, a decrease of $32.4 million from $45.6 million at December 31, 2022. The primary reason for the decrease was due to cash used in operations during the period and cash used for nonrecurring legal and professional services in connection with the Restructuring Transactions, partially offset by the proceeds from the issuance of the 5.00% Notes and the sale and issuance of common stock under the March 2022 Securities Purchase Agreement. 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’s primary use of capital has been for the development and commercialization of the Accelerate Pheno system, development of complementary products and, most recently, development of its next generation technology, the Accelerate Wave system. 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. In January 2024, the Company issued and sold approximately 8.1 million units in certain underwritten public and private placement offerings, each consisting of one share of common stock and one warrant to purchase one share of common stock (“Units”), for aggregate gross proceeds of approximately $12.3 million. This includes approximately 1.2 million Units issued and sold to the Schuler Trust, which satisfied the Schuler Purchase Obligation. While the Company believes that this additional funding will allow it to continue to progress its development and operational goals discussed in this report for the next several quarters, the net proceeds from these transactions are not expected to be sufficient to fund the Company’s operations through twelve months from the issuance of these financial statements. See Note 10, Convertible Notes, Note 11, Related Party Transactions and Note 18, Subsequent Events for additional detail.

While the Company continues to explore additional funding in the form of potential equity and/or debt financing arrangements or similar transactions, 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 additional debt, it is likely any new debt would have rights, preferences and privileges senior to common stockholders. The terms of borrowing could impose significant restrictions on the Company’s operations. 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. In addition, increases in federal fund rates set by the Federal Reserve, such as the significant increases experienced throughout 2022 and 2023, which serve as benchmark rates on borrowing, and other general economic conditions have impacted, and in the future may impact, the cost of debt financing or refinancing existing debt.

Although the Company is actively considering all available strategic alternatives to maximize value, if the Company is unable to obtain adequate capital resources to fund operations, the Company would not be able to

continue to operate its business pursuant to its current plans. This may require the Company to, among other things, materially modify its operations to reduce spending; sell assets or operations; delay the implementation of, or revising certain aspects of, its business strategy; or discontinue its operations entirely.

The Company is required to evaluate its financial condition as of the date of filing this Annual Report on Form 10-K ("Form 10-K") pursuant to the requirements of Accounting Standards Codification ("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 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, bifurcated derivatives, fair value instruments, tax valuation accounts and uncertain tax positions, 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 and disclosing fair value. 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.

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 Federal Deposit Insurance Corporation (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, the Company believes that as a result of the 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 certain bank failures, 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 sheets at fair value. Unrealized gains or losses for debt securities available-for-sale 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 to be available-for-sale, including those with maturity dates beyond 12 months, as they are 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 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.

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 over trade receivables and net investment in sales-type leases for the years ended December 31, are comprised of the following (in thousands):

	2023	2022	2021
Beginning balance	$ 324	$ 140	$ 445
Provisions	301	204	123
Write-offs	(35)	(20)	(428)
	$ 590	$ 324	$ 140

The provisions recorded during the years ended December 31, 2023 and 2022, are primarily in connection with aged net investment in sales-type leases. See Note 9, Leases for further information.

The write-offs and provisions recorded during the year ended December 31, 2021, were 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.

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, has a cost basis in excess of its estimated realizable value, or is considered in excess of demand. These types of inventory events could result in a change to expense 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.

The Company manufactures pre-launch inventory in advance of regulatory approval. This inventory is expensed before an economic benefit is probable.

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

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. 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 and Accelerate Arc systems (also referred to as instruments) used for sales demonstrations, instruments under rental agreements and instruments used for

research and development. Depreciation expense and losses from retirement of instruments used for sales demonstrations are recorded as a component of sales, general and administrative expenses. Depreciation expense and losses from retirement of instruments placed at customer sites pursuant to reagent rental agreements are recorded as a component of cost of sales. Depreciation expense and losses from retirement of instruments used in our laboratory and research are recorded as a component of research and development expense. The Company retains title to these instruments and depreciates them over five years.

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, 2023, 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 material impairment charges were recorded at December 31, 2023, 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-day 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):

	2023	2022	2021
Beginning balance	$ 225	$ 139	$ 232
Provisions	160	389	(22)
Warranty cost incurred	(191)	(303)	(71)
	$ 194	$ 225	$ 139

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Convertible Notes

The Company follows 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) in accounting for its outstanding convertible notes. The convertible notes are accounted for as a liability measured at their amortized cost. 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, conversion or settlement.

Accounting for Derivatives

Upon issuance of the 5.00% Notes, each holder has the right, at their option, to convert any portion to common stock ("Conversion Option"). The conversion price initially was not fixed and therefore, the Conversion Option represented a derivative financial instrument and was recorded at its estimated fair value as a derivative liability in the consolidated balance sheets through October 17, 2023, the date at which the conversion price was fixed. Changes in the fair value of the derivative financial instrument were recognized in gain on fair value adjustment within the consolidated statements of operations and comprehensive loss. The derivative liability was derecognized and reclassified to equity as of October 17, 2023 once the conversion price was fixed and after completion of the final mark-to-market fair value adjustment as of that date. See Note 10, Convertible Notes for further information regarding the Conversion Option.

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 or transfer of control in sales to third party distributors 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 and external sales agents 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, 2023 and 2022.

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.

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 and finance leases are included in right-of-use (“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.

Short-term leases have a lease term of twelve months or less and do not include an option to purchase the underlying asset that the Company is reasonably certain to exercise. Lease payments for short-term leases are recognized within the statements of operations and comprehensive loss in the period in which the obligation is incurred.

Our operating leases consist primarily of leased office, factory, and laboratory space in the U.S. and office space in Europe, have between one and six-year terms, and typically contain penalizing, early-termination provisions. Our finance leases consist of leased equipment and have three-year terms. Short-term leases consist of rental cars and copier leases.

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. In some of these contracts, the customer has an option to purchase the underlying asset at a specified price.

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 is 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. These amounts are determined using the information available at commencement, including the lease term, estimated useful life, rate implicit in the lease, purchase options (if any and if such option is reasonably certain to be exercised), and expected fair value of the instrument.

See Note 9, 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 sheets.

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. Annual bonus equity-based awards are typically granted based upon meeting goals and objectives for a given year as determined in the following year after the Company’s financials are prepared, final results are reasonably certain, and the compensation committee has authorized the awards. Given the compensation committee has unilateral authority to modify the amount of the awards, the criteria for payout, vesting terms, etc., the Company has elected a narrow approach to determining the grant date and, as such, the grant date is based on compensation committee approval. 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 estimated 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 accounts for forfeitures as they occur rather than on an estimated basis.

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.

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

Deferred Tax Assets and Liabilities

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 statements 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 warrants, as well as shares that would be outstanding if the 5.00% Notes were converted and shares that would be outstanding if the Schuler Purchase Obligation was exercised. 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 March 2022, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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 ASU was adopted January 1, 2023, and did not impact the Company's consolidated financial statements in any of the periods reported.

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. This ASU was adopted January 1, 2023, and did not impact the Company's consolidated financial statements in any of the periods reported.

In July 2023, the FASB issued ASU 2023-03, Presentation of Financial Statements (Topic 205), Income Statement - Reporting Comprehensive Income (Topic 220), Distinguishing Liabilities from Equity (Topic 480), Equity (Topic 505), and Compensation - Stock Compensation (Topic 718): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 120, SEC Staff Announcement at the March 24, 2022 EITF Meeting, and Staff Accounting Bulletin Topic 6.B, Accounting Series Release 280 - General Revision of Regulation S-X: Income or Loss Applicable to Common Stock. The SEC staff issued Staff Accounting Bulletin (SAB) 120 to provide guidance on the measurement and disclosure of share-based payment awards granted when a company is in possession of material nonpublic information to which the market is likely to react positively when it is announced. Such awards are commonly referred to as spring-loaded awards. This ASU was effective for the Company upon issuance, which was on July 14, 2023, and did not impact the Company's consolidated financial statements in any of the periods reported.

Standards not yet adopted

In December 2023, the FASB issued ASU 2023-09 (Topic 740): Income Taxes: Improvements to Income Tax Disclosures which expands the existing rules on income tax disclosures. This update requires entities to disclose specific categories in the tax rate reconciliation, provide additional information for reconciling items that meet a quantitative threshold and disclose additional information about income taxes paid on an annual basis. The new disclosure requirements are effective for fiscal years beginning after December 15, 2024. Early adoption is permitted. We are currently evaluating these new expanded disclosure requirements.

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures which expands disclosure requirements to require entities to disclose significant segment expenses that are regularly provided to or easily computed from information regularly provided to the chief operating decision maker. This update also requires all annual disclosures currently required by Topic 280 to be disclosed in interim periods. The new disclosure requirements are effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. We are currently evaluating these new expanded disclosure requirements.

NOTE 3. CONCENTRATION OF CREDIT RISK

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and 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, 2023, two of the Company's financial institutions held 61% and 25% of the Company's cash and cash equivalents, respectively. 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.

The Company grants credit to domestic and international customers in various industries. Exposure to losses on accounts receivable is principally dependent on each customer's financial position. The Company had one customer that accounted for 13% and 15% of the Company's net accounts receivable balance as of December 31, 2023 and 2022, respectively.

The Company did not have any customers that represented 10% or more of the Company's net sales for the years ended December 31, 2023, 2022 and 2021.

NOTE 4. FAIR VALUE OF FINANCIAL INSTRUMENTS

The following tables represent the financial instruments measured at fair value on a recurring basis in the financial statements of the Company and the valuation approach applied to each class of financial instruments as of the dates indicated:

	December 31, 2023 (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	$ 7,406	$ —	$ —	$ 7,406
Total cash and cash equivalents	7,406	—	—	7,406
Equity investments:				
Mutual funds	1,081	—	—	1,081
Total equity investments	1,081	—	—	1,081
Total assets measured at fair value	$ 8,487	$ —	$ —	$ 8,487

	December 31, 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
U.S. 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

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 sheets.

Level 1 assets are priced using quoted prices in active markets for identical assets which include money market funds, U.S. Treasury securities and mutual funds 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 years ended December 31, 2023, 2022, and 2021.

As of December 31, 2023, the Schuler Purchase Obligation, which is classified as a financial instrument asset and included in purchase obligation put option asset on the consolidated balance sheets, has a fair value of $3.4 million, using Level 3 measurement assumptions. See Note 11, Related Party Transactions for further detail on the Schuler Purchase Obligation.

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.

Liabilities for which Fair Value is only Disclosed

At December 31, 2023, the Company's 5.00% Notes, issued in June 2023, had an outstanding principal balance of $67.6 million and a fair value of $50.8 million, using Level 3 measurement assumptions.

The 2.50% Notes matured on March 15, 2023 and became due and payable on such date. The amortized carrying amount of the 2.50% Notes is $0.7 million as of December 31, 2023 and approximates the related fair value due to the instrument being fully matured and payable. As of December 31, 2022, the 2.50% Notes represented a Level 2 measurement with an outstanding principal balance of $56.6 million with a fair value of $51.9 million.

As of December 31, 2022, the Secured Note had an outstanding principal balance of $34.9 million, and a fair value of $16.0 million, using Level 3 measurement assumptions. The Secured Note was not outstanding as of December 31, 2023.

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 See Note 11, Related Party Transactions for further detail on the Company's warrant with a related-party.

See Note 10, Convertible Notes for further detail on the 5.00% Notes and the 2.50% Notes and see Note 11, Related Party Transactions for further detail on the Secured Note.

NOTE 5. INVESTMENTS

The Company did not have any debt securities classified as available-for-sale investments at December 31, 2023.

The following table summarizes the Company's debt securities classified as available-for-sale at December 31, 2022, all which had maturities of less than one year as of that date (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
	$ 9,757	$ —	$ (29)	$ 9,728

There were no material proceeds (including principal paydowns) or realized gains or losses from sales of debt securities available-for-sale for the years ended December 31, 2023, 2022 and 2021. The Company determines gains and losses on marketable securities based on specific identification of the securities sold. No

material balances were reclassified out of accumulated other comprehensive loss and no losses on debt securities available-for-sale have been recognized in income for the years ended December 31, 2023, 2022 and 2021. As of December 31, 2023 and 2022, 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, 2023 and 2022 were $1.1 million and $0.9 million, respectively. Unrealized losses or gains on equity securities recorded in income during the year ended December 31, 2023, 2022 and 2021 were as follows (in thousands):

	2023	2022	2021
Unrealized gain (loss) on equity investments	$ 114	$ (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, 2023, 2022 and 2021.

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):

	2023	2022
Raw materials	$ 1,268	$ 1,827
Work in process	648	2,115
Finished goods	1,394	1,252
	$ 3,310	$ 5,194

During the year ended December 31, 2023, the Company recorded a charge of $1.2 million to write-down excess quantities of instrument inventory on hand above and beyond our forecast of future demand for those products. This write-down primarily impacted work in process inventory for the period. There was no write-down of inventory required in 2022.

NOTE 7. PROPERTY AND EQUIPMENT

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

	2023	2022
Computer equipment	$ 3,464	$ 3,551
Technical equipment	3,135	3,236
Facilities	3,688	3,663
Instruments	3,004	3,735
Capital projects in progress	109	114
Total property and equipment	$ 13,400	$ 14,299
Accumulated depreciation	(11,011)	(10,821)
Net property and equipment	$ 2,389	$ 3,478

Depreciation expense for the years ended December 31, 2023, 2022 and 2021 was $1.3 million, $1.7 million and $2.0 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):

	2023	2022
Instruments at cost under operating leases	$ 2,010	$ 2,585
Accumulated depreciation under operating leases	(1,194)	(1,209)
Net property and equipment under operating leases	$ 816	$ 1,376

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. When products or services are delivered to customers and as service commitments are fulfilled, these contract liabilities are recognized as earned. Deferred revenue or income that the Company does not expect will be earned within the following twelve months is reported in the consolidated balance sheets as deferred income, non-current.

Contract liabilities consisted of the following as of December 31 (in thousands):

	2023	2022
Products and services not yet delivered	$ 540	$ 547
BD deferred exclusivity fee	1,005	
Deferred revenue and income, current	$ 1,545	$ 547
Australia R&D tax incentive	$ 1,122	$ —
Deferred income, non-current	$ 1,122	$ —

The Company recognized $0.5 million, $0.4 million, and $0.3 million of revenue that was included in the beginning contract liabilities for the years ended December 31, 2023, 2022, and 2021 respectively. No material amount of revenue recognized during the period was from performance obligations satisfied in prior periods.

Transaction Price Allocated to Remaining Performance Obligations

As of December 31, 2023, $5.2 million of revenue is expected to be recognized from remaining performance obligations. This balance primarily relates to product shipments for reagents sold to customers under sales-type lease agreements. These agreements have between one and six year terms and revenue is recognized as reagents are 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 a one to five year term 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.

Commercial Agent Relationship with Becton, Dickinson and Company (“BD”)

The Company has entered into an exclusive commercial agreement with BD to act as the Company’s agent and representative. The purpose of this agreement is to establish an on-going commercialization of the Company’s products. The Company is classified as the principal and BD as the agent. In accordance with the terms of this agreement, BD will pay the Company an exclusivity fee in multiple installments for exclusive rights, while the Company will pay BD an agent fee based on the Company’s revenue.

The Company accounts for agent fees consistent with how it accounts for sales commissions as described above in Note 2, Summary of Significant Accounting Policies. As such, agent fees paid to BD correspond with periodic sales and are expensed to sales, general and administrative expense.

The Company accounts for the exclusivity fee from BD as a deferred income when the cash is received. The Company uses forecasted revenue to estimate the amount of deferred income to amortize within the period as an offset to sales, general and administrative expense.

The following table presents the activity related to the BD commercial agreement for the year ended December 31, 2023 (in thousands).

	2023
Exclusivity fees received	$ 2,000
Amortized exclusivity fees	$ (995)
Agent fees incurred	998
Net expense	$ 3

Australia R&D Tax Incentive

As discussed further in Note 14, Income Taxes, in 2023, the Company received a research and development tax incentive from Australia ("Australia R&D Tax Incentive") totaling $1.1 million from the Australian government which is fully reserved as the sustainability of the amount upon potential examination by the Australian tax authority is uncertain. This amount is recorded as deferred income, non-current in the consolidated balance sheets as of December 31, 2023.

NOTE 9: LEASES

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

	2023	2022
Cash paid for amounts included in lease liabilities		
Operating cash flows from operating leases	$ 913	$ 850
Operating cash flows from finance leases	1,250	1,201
ROU assets obtained in exchange for lease obligations		
Operating leases	—	—
Finance leases	200	3,096
Lease Cost		
Operating leases	1,041	1,114
Finance leases	1,104	673
Short-term leases	$ 77	$ 82

For the Company's operating leases, the weighted average remaining lease term is 1.6 years with a weighted average discount rate of 7.1%. For the Company's finance leases, the weighted average remaining lease term is 1.6 years with a weighted average discount rate of 6.6%.

The following presents maturities of operating lease liabilities in which the Company is the lessee as of December 31, 2023 (in thousands):

	2023
2024	$ 1,055
2025	583
2026	—
2027	—
2028	—
Thereafter	—
Total operating lease payments	1,638
Less imputed interest	(91)
	$ 1,547

The following presents maturities of finance lease liabilities in which the Company is the lessee as of December 31, 2023 (in thousands):

	2023
2024	$ 784
2025	86
2026	30
2027	—
2028	—
Thereafter	—
Total finance lease payments	900
Less imputed interest	(55)
	$ 845

The net investment in sales-type leases, where the Company is the lessor, is a component of other current assets and other non-current assets in the consolidated balance sheets. As of December 31, 2023, the total net investment in these leases is $2.4 million. Lease income is a component of net sales in the statements of operations and comprehensive loss. The following presents maturities of lease receivables under sales-type leases as of December 31, 2023 (in thousands):

	2023
2024	$ 1,299
2025	684
2026	393
2027	47
2028	—
Thereafter	—
Net investment in sales-type leases	$ 2,423
Allowances	(522)
Net investment in sales-type leases, net of allowances	$ 1,901

For more information on leases, see Note 2, Summary of Significant Accounting Policies.

NOTE 10: CONVERTIBLE NOTES

The Company's convertible notes consisted of the 2.50% Notes and the 5.00% Notes as of December 31, 2023, and the 2.50% Notes as of December 31, 2022. As of December 31, 2023 and 2022, the convertible note obligations were classified as follows in the consolidated balance sheets (in thousands):

	2023	2022
2.50% Notes	$ 726	$ 56,413
5.00% Notes	$ 36,102	$ —
Total convertible notes	$ 36,828	$ 56,413
Current portion of convertible notes	$ 726	$ 56,413
Convertible notes, non-current	$ 36,102	$ —

Interest expense related to the Company's convertible note obligations consisted of the following for the years ended December 31 (in thousands):

	2023	2022	2021
Contractual coupon interest	$ 2,425	$ 1,794	$ 3,934
Amortization of premium, discount and issuance costs, net	3,278	474	11,542
Total interest expense on convertible notes	$ 5,703	$ 2,268	$ 15,476

Gain (loss) on extinguishment of exchanged convertible notes were as follows for the years ended December 31 (in thousands):

	2023	2022	2021
(Loss) gain on extinguishment	$ (6,499)	$ 3,565	$ 4,916

2.50% Notes

The carrying value of the 2.50% Notes was included in current portion of convertible notes and consisted of the following at December 31 (in thousands):

	2023	2022
Outstanding principal	$ 726	$ 56,595
Unamortized debt issuance	—	(182)
Net carrying amount	$ 726	$ 56,413

In March 2018, the Company issued $150.0 million aggregate principal amount of 2.50% Notes. In connection with the offering of the 2.50% 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 2.50% 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 Company incurred issuance costs related to the issuance of the 2.50% Notes which were amortized over the five-year contractual term of the 2.50% Notes using the effective interest method until the maturity date of the 2.50% Notes. The 2.50% Notes matured on March 15, 2023 and became due and payable.

In September 2021 and March 2022, the Company entered into separate exchange agreements with certain holders of 2.50% Notes, pursuant to which $65.0 million aggregate principal amount of 2.50% Notes were exchanged for an aggregate of approximately 1.7 million shares of the Company's common stock. For the year ended December 31, 2021, the Company incurred $0.9 million of reacquisition costs associated with these transactions, which were recorded as an offset to the gain on extinguishment of debt, resulting in a net gain $4.9 million. For the year ended December 31, 2022, the Company incurred $0.2 million of reacquisition costs, which were recorded as an offset to the gain on extinguishment of debt, resulting in a net gain of $3.6 million. The net gain on extinguishment of debt for the years ended December 31, 2022 and 2021 are reflected in other income (expense), net in the consolidated statements of operations.

In August 2022, the Company entered into an exchange agreement (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 2.50% Notes held by it for (a) the Secured Note with an aggregate principal amount of $34.9 million and (b) a warrant to acquire the Company's common stock (the "Warrant") at an exercise price of $21.20 per share (the "Exercise Price"). 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, resulting in a net gain of $29.8 million recorded to contributed capital for the year ended December 31, 2022. See Note 11, Related Party Transactions for additional information.

As of December 31, 2022, $56.4 million aggregate principal amount of the 2.50% Notes were outstanding and convertible pursuant to their original terms, none of which were converted prior to the March 15, 2023 maturity date. In March 2023, the Company entered into the Forbearance Agreement with the Ad Hoc Noteholder Group holding approximately 85% of the Company's outstanding 2.50% Notes, the "Trustee" and any other owner of the 2.50% Notes who executed and delivered 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 agreed, and directed the Trustee, to forbear from exercising their rights and remedies under the 2.50% Notes Indenture in connection with certain events of default under the 2.50% Notes Indenture, such as (i) failure to timely pay in full the principal of any 2.50% Note when due and payable on March 15, 2023, (ii) failure to pay any interest on any 2.50% Note when due and payable, (iii) failure to convert any 2.50% 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 2.50% Notes Indenture arising from the failure of the Company to timely pay in full the principal of any 2.50% Note when due and payable on the maturity date for the 2.50% Notes. The Forbearance Agreement was initially effective for the period commencing on March 13, 2023 and ending on April 21, 2023, the date of the Restructuring Support Agreement.

The holders of the 2.50% Notes that joined the Forbearance Agreement received a fee (the "Forbearance Premium") equal to $5.00 per $1,000 principal amount of the 2.50% Notes held by such party, by executing and delivering a joinder to the Forbearance Agreement to the Company. During the year ended December 31, 2023, the Ad Hoc Noteholder Group received $0.2 million in Forbearance Premiums, which were capitalized and amortized as interest expense during the period commencing on March 13, 2023 through March 31, 2023.

Restructuring Support Agreement and June 2023 Exchange Transactions

In April 2023, the Company entered into the Restructuring Support Agreement with certain holders of the 2.50% Notes, the holder of the Secured Note and the holders of the Company's Series A Preferred Stock to negotiate in good faith to effect the restructuring of the Company's capital structure. In June 2023, the Company completed the Restructuring Transactions, contemplated by the Restructuring Support Agreement whereby the Company:

- exchanged approximately $55.9 million, aggregate principal amount of the 2.50% Notes for approximately $56.9 million aggregate principal amount of newly issued 5.00% Notes, which was inclusive of an additional 5.00% Notes in respect of interest accrued on the 2.50% Notes from September 15, 2022, for $1.0 million;
- issued and sold an additional $10.0 million aggregate principal amount of 5.00% Notes;
- amended and repurchased the Secured Note, plus accrued interest, by issuing approximately 3.4 million shares of the Company's common stock;
- issued approximately 0.4 million shares of the Company's common stock upon conversion of all of the Company's outstanding Series A Preferred Stock;
- amended the March 2022 Securities Purchase Agreement and issued and sold approximately 0.5 million shares of the Company's common stock for proceeds of $4.0 million; and

- entered into the Schuler Purchase Obligation, a new securities purchase agreement with the Schuler Trust pursuant to which the Schuler Trust was required, prior to December 15, 2023 (which was subsequently amended and extended to February 15, 2024), to either purchase an aggregate $10.0 million of the Company's common stock from the Company or to backstop an underwritten public offering by the Company of its common stock for aggregate proceeds of $10.0 million, at the Company's option. Further details regarding the Schuler Purchase Obligation and amendment are included in Note 11, Related Party Transactions.

The convertible note exchange transaction which resulted in a portion of the 2.50% Notes being exchanged for 5.00% Notes, as described above, and associated accrued interest was accounted for as an extinguishment of debt under ASC 470-50-40. Under extinguishment accounting, the 2.50% Notes were derecognized and the new instruments, which included the 5.00% Notes and a bifurcated Conversion Option were recorded at their respective fair values. The extinguishment of the 2.50% Notes resulted in a loss of $6.6 million for the year ended December 31, 2023. See further discussion of the 5.00% Notes below.

As of December 31, 2023, approximately $0.7 million aggregate principal amount of the 2.50% Notes remained outstanding and in default, accruing interest at 2.50% per annum. None of the remaining 2.50% Notes outstanding as of December 31, 2023 are convertible pursuant to their original terms. As of December 31, 2023, the amount of accrued interest on these notes is immaterial.

5.00% Notes

The carrying value of the 5.00% Notes consisted of the following at December 31 (in thousands):

	2023	2022
Outstanding principal at par	$ 67,634	$ —
Unamortized debt premium	5,408	—
Unamortized debt discount	(34,267)	—
Unamortized debt issuance costs	(2,673)	—
Net carrying amount	$ 36,102	$ —

As a result of the Restructuring Transactions, the Company recorded at fair value approximately $56.9 million aggregate principal amount of newly issued 5.00% Notes in its consolidated balance sheets in June 2023. In addition, the Company issued an additional $10.0 million aggregate principal amount of 5.00% Notes, for cash proceeds with certain existing note holders as part of the Restructuring Transactions. Following the Restructuring Transactions and the issuance of additional 5.00% Notes, the 5.00% Notes had a total aggregate principal amount of $66.9 million. On the December 15, 2026 maturity date, outstanding principal will be due for all remaining outstanding 5.00% Notes.

The 5.00% Notes bear interest at a rate of 5.00% per annum. The Company pays interest on the 5.00% Notes by payment-in-kind ("PIK"), through the issuance of additional 5.00% Notes ("PIK Notes"). The amount is paid to holders by increasing the principal amount of each outstanding 5.00% Note by an amount equal to the interest payable for the applicable interest period. The Company calculates PIK interest semi-annually on June 15 and December 15, on a compound basis based on the stated rate of 5.00%.

The 5.00% Notes are secured by substantially all of the assets of the Company and its subsidiaries.

Redeeming the 5.00% Notes before June 15, 2025 could trigger a "Make-Whole Fundamental Change" as defined in the indenture governing the 5.00% Notes (the "5.00% Notes Indenture"). On or after June 15, 2025, the Company may, at its option, redeem for cash all or a portion of the 5.00% Notes.

Upon issuance of the 5.00% Notes, each holder has a Conversion Option, which represented the right at their option, to convert any portion at an initial conversion rate of 138.88889 shares of common stock per $1,000 of principal amount. Effective October 18, 2023, the initial conversion rate was to be adjusted to a conversion rate calculated based on a conversion price of $7.20 per share of common stock plus 50% of the difference between the Post-Closing VWAP (as defined in the 5.00% Notes Indenture) and $7.20 (if such difference is a positive number), provided that in no event will the adjusted conversion rate be lower than 120.48193 per $1,000 principal amount of

the 5.00% Notes, based on a conversion price of $8.30 per share of common stock. The Company evaluated the conversion rate per the terms outlined above and determined the initial conversion rate of 138.88889 shares of common stock per $1,000 principal amount will continue to be the conversion rate through the remaining term of the 5.00% Notes. The Company cannot require the holders of the 5.00% Notes to convert at any time but when a holder exercises their Conversion Option, the Company can settle in cash, shares of common stock or a combination of cash and shares of common stock, at the Company's election.

As of December 31, 2023, the number of shares of common stock issuable upon conversion of the 5.00% Notes was 9.4 million shares, based on the conversion rate which was fixed on October 18, 2023.

Management determined the Conversion Option met the derivative bifurcation criteria under ASC 815 at inception through October 17, 2023, the date at which the conversion rate became fixed. During that period the derivative instrument was bifurcated and adjusted to fair value through earnings, using Level 3 inputs, at each reporting date with a final mark-to-market adjustment once the Conversion Option became fixed at the end of the day on October 17, 2023 and no longer met the bifurcation criteria. The fair value of the Conversion Option and a derivative liability of $38.2 million as of the transaction date was recorded as a debt issuance discount at inception. The Company also incurred issuance costs of $3.0 million. The debt premium, debt discount and debt issuance costs are being amortized using the effective interest method over the 3.5 year contractual term of the 5.00% Notes. The effective interest rate on the 5.00% Notes is 27.30%.

Holders of the 5.00% Notes who convert in connection with the Make-Whole Fundamental Change are, under certain circumstances, entitled to an increase in the conversion rate. If a fundamental change occurs at any time prior to the Maturity Date, each holder will have the right, at such holder's option, to require the Company to repurchase for cash all of such holder's 5.00% Notes, at a repurchase price equal to 100% of the principal amount thereof, plus accrued and unpaid interest.

During the period from inception through October 17, 2023, the bifurcated Conversion Option was adjusted to fair value through earnings within Gain on fair value adjustment on the statement of operations and the statement of cash flows, using Level 3 inputs, at each reporting date with a final mark-to-market adjustment once the Conversion Option became fixed at the end of the day on October 17, 2023 and no longer met the bifurcation criteria. The derivative financial instrument activity for the year ended December 31, 2023 is comprised of the following (in thousands):

	2023
Beginning balance	$ —
Initial measurement	38,160
Reduction as a result of conversion of 5.00% Notes	(380)
Change in value - gain	(10,872)
Reclassification to contributed capital	(26,908)
Ending balance	$ —

The derivative financial instrument was derecognized as of October 17, 2023, and the fair value of the instrument as of that date was moved to contributed capital in the consolidated balance sheet.

In August 2023 and October 2023, certain holders of 5.00% Notes converted portions of their aggregate principal amount for shares of common stock (the "August 2023 Conversions", the "October 2023 Conversions", and collectively, the "Conversions"). Per the terms described above as part of the Conversion Option, the note holders opted to convert portions of their 5.00% Notes, at a conversion rate of 138.88889 shares of common stock per $1,000 principal amount. Through the August 2023 Conversions, the holders of the 5.00% Notes converted approximately $0.7 million of aggregate principal for approximately 94,000 shares of the Company's common stock. Through the October 2023 Conversions, the holders of the 5.00% Notes converted an additional $0.3 million of aggregate principal for approximately 39,000 shares of the Company's common stock.

As described above, the Conversion Option was bifurcated which resulted in the Conversions qualifying as extinguishments of debt. The August 2023 Conversions included the bifurcated Conversion Option classified as a derivative liability, and both the converted 5.00% Notes and the associated derivative liability, where applicable,

were derecognized at their carrying amounts and the common stock was measured at its then-current fair value, with the difference recorded as a gain on the extinguishment of the applicable liability. The value of the shares of common stock issued in connection with the October 2023 Conversions was recorded to contributed capital.

The net carrying value of the 5.00% Notes derecognized as part of the August 2023 and October 2023 Conversions was $0.3 million and $0.1 million, respectively. The carrying amount of the derivative liability, which was carried at fair value, derecognized as part of the August 2023 Conversions was $0.4 million. The August 2023 Conversions resulted in a gain on extinguishment of debt of $0.1 million, for the year ended December 31, 2023.

The 5.00% Notes represent an instrument measured at fair value on a non-recurring basis using Level 3 inputs. The estimated fair value of the 5.00% Notes on June 9, 2023, the initial measurement, date was $38.2 million, which included a $6.0 million debt premium.

As of December 31, 2023, the 5.00% Notes are carried at amortized cost with an estimated fair value of $50.8 million. The table below summarizes the significant inputs used to estimate the fair value of the 5.00% Notes as of December 31, 2023 and the June 9, 2023 issuance date:

	December 31, 2023	June 09, 2023
Coupon rate	5.00%	5.00%
Term (years)	3.0	3.5
Volatility	55.00%	55.00%
Risk-free rate	4.02 %	4.15 %
Discount yield	25.00 %	25.00 %
Discount factor	50.00%	44.00%

The volatility used to estimate the fair value of the 5.00% Notes is an unobservable input. As volatility is an estimate, there is a range of values that could be considered appropriate. Changes to this input could impact the fair value reported.

On December 15, 2023, the Company issued $1.7 million of PIK Notes to pay interest accrued on the 5.00% Notes outstanding as of that date. As of December 31, 2023, the Company has recorded $0.1 million of accrued interest related to the 5.00% Notes.

Fair Value of Conversion Option

The Company's Conversion Option was classified as a derivative financial instrument and carried at fair value using Level 3 inputs from the date of inception until the conversion price became fixed on October 17, 2023. To determine the fair value of the Conversion Option, the Company calculated the difference in the value of the 5.00% Notes with and without the Conversion Option. The estimated fair value of the Conversion Option as of October 17, 2023 was $26.9 million. The fair value of the Conversion Option was estimated using a Monte Carlo simulation. For each path, the Company simulated the stock price over time such that:

- The Company determined the 60-day average stock price to calculate the conversion price.
- At each date after the call option start date, the Company used a Tsiveriotis and Fernandes model to determine the continuation value and compare it to a call price. If the continuation value exceeds the call price, the Company assumed exercise of the call option. When the call option is exercised, the holders will receive the maximum of the conversion value or the call price.
- The valuation also considered the reset conversion price as well as the accrued PIK, the Company determined whether the holder elects to convert the 5.00% Notes at the Maturity Date for the simulation paths where the 5.00% Notes has not been called prior to such date.

The table below summarizes the significant inputs used to estimate the fair value of the Conversion Option as of October 17, 2023 and June 9, 2023:

	October 17 2023	June 09, 2023
Stock price	$ 5.94	$ 7.40
Initial conversion price	$ 7.20	$ 7.20
Conversion cap	$ 8.30	$ 8.30
Term (years)	3.2	3.5
Time to call (years)	1.7	2.0
Volatility	55.00 %	55.00 %
Risk-free rate	5.00 %	4.15 %
Discount yield	25.00 %	25.00 %

The volatility used to estimate the fair value of the Conversion Option is an unobservable input and, because volatility is an estimate, there is a range of values that could be considered appropriate. Changes to this input could impact the fair value reported.

See Note 4, Fair Value of Financial Instruments for additional information.

NOTE 11. RELATED PARTY TRANSACTIONS

March 2022 Securities Purchase Agreement

In March 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 approximately 0.2 million 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 of 1933, as amended, 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 $16.40 per share, for an aggregate purchase price of $4.0 million. In March 2022, the Company classified the March 2022 Securities Purchase Agreement as an equity forward agreement that met the definition of a freestanding derivative financial instrument initially classified in stockholders' deficit. The value of this equity forward agreement was considered immaterial at inception.

The Company and the Schuler Trust agreed to extend the closing date of the March 2022 Securities Purchase Agreement several times under the original terms of the Private Placement. As discussed in Note 10, Convertible Notes, in June 2023, the Company and the Schuler Trust amended the March 2022 Securities Purchase Agreement, which changed the terms of settlement. The amendment changed the closing date to June 9, 2023, amended the price per share from $16.40 to $8.20, upon which the Company issued approximately 0.5 million shares of common stock to the Schuler Trust for the same proceeds of $4.0 million.

The Company determined the amendment was a modification of a freestanding equity classified instrument financial instrument. The share price change from $16.40 to $8.20, with no changes to the total proceeds of $4.0 million, resulted in the Schuler Trust receiving approximately 0.2 million more shares than the Schuler Trust would have received prior to the modification. The closing price of the Company's common stock on June 9, 2023, the date of the modification was $7.40 and was used to estimate the fair value of the additional common stock issued. The fair value of the additional shares issued was $1.8 million, which was recorded to loss on extinguishment of debt with related party on the condensed consolidated statements of operations.

August 2022 Exchange Agreement

In August 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 2.50% Notes held by it for the Secured Note and the Warrant. See Note 10, Convertible Notes for additional information regarding the 2.50% Notes.

The Secured Note had a scheduled maturity date of August 15, 2027 and was repayable upon written demand any time on or after such date. The Company could, 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 $21.20.

The Warrant may be exercised 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 247,171 shares of the Company's common stock and may be exercised in whole or in part at any time during the exercise period. 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 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 at issuance 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, 2023.

The Secured Note included various features that were advantageous to the Company, including a lower interest rate compared to 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 not considered to be an arm's length transaction, and therefore, the resulting gain was accounted for as a capital transaction. The carrying value of the 2.50% 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 during the year ended December 31, 2022.

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

	December 3 2022
Outstanding principal	$ 3
Unamortized debt issuance discount	(1
Net carrying amount	$ 1

Interest expense related to the Secured Note consisted of $0.7 million of contractual interest and $0.8 million of amortization of the debt discount for the year ended December 31, 2022. The Secured Note's carrying amount of $16.9 million and accrued interest expense of $0.7 million were recorded in non-current liabilities on the Company's consolidated balance sheet as of December 31, 2022. As noted under "Secured Note Amendment and Exchange" below, the Secured Note was extinguished in June 2023, resulting in a carrying value of the Secured Note of $0 as of December 31, 2023.

Conversion of Series A Preferred Stock to Common Stock

In September 2021, the Company entered into a securities purchase agreement with the Tanya Eva Schuler Trust, the Therese Heidi Schuler Trust and Schuler Grandchildren LLC (collectively, the ""Schuler Purchasers") for the issuance and sale by the Company of an aggregate of approximately 4.0 million shares of the Company's Series A Preferred Stock, par value $0.001 per share (the "Series A Preferred Shares") at a purchase price of $7.70 per share for an aggregate purchase price of approximately $30.5 million, which was recorded to contributed capital when it was received in 2022. Each share of Series A Preferred Shares was convertible, at the option of the holder, into one share of the Company's common stock.

As discussed in Note 10, Convertible Notes, the Schuler Purchasers exercised their right to convert a total of approximately 4.0 million shares of Series A Preferred Shares to approximately 0.4 million shares of the Company's common stock. All of the Company's Series A Preferred Shares were converted into common stock as part of the Restructuring Transactions, and no Series A Preferred Shares remained outstanding as of December 31, 2023. During the year ended December 31, 2023, the amounts associated with the Series A Preferred Shares were reclassified to common stock and contributed capital as presented in the statements of stockholders' deficit.

Secured Note Amendment and Exchange

As discussed in Note 10, Convertible Notes, as part of the Restructuring Transactions, the Company and the Schuler Trust amended the Secured Note (the "Secured Note Amendment"), which changed the settlement provisions of the Secured Note. Pursuant to the Secured Note Amendment, the share conversion price was changed from $21.20 to $10.60, and the Secured note was contemporaneously settled through the Company's issuance of approximately 3.4 million shares of its common stock.

The transaction qualified as an extinguishment of debt, and the reacquisition price of the extinguished debt was determined to be the fair value of the common stock issued in the transaction. The closing price of the Company's common stock on June 9, 2023, the date of the extinguishment, was $7.40 and was used to estimate the fair value of the common stock issued as $25.4 million. The carrying amount of the Secured Note and associated accrued interest being extinguished was determined to be $19.3 million. This resulted in a net loss on extinguishment of $6.1 million, which was recorded to loss on extinguishment of debt with related party in the consolidated statements of operations for the year ended December 31, 2023.

Schuler Purchase Obligation

In June 2023, the Company entered into the Schuler Purchase Obligation with the Schuler Trust pursuant to which the Schuler Trust was required, at the Company's option, to either purchase approximately 1.4 million shares of common stock from the Company valued at $7.20 per share for an aggregate purchase price of $10.0 million or to backstop a public offering by the Company of common stock for aggregate proceeds of $10.0 million. If the Company elected to conduct a public offering of common stock and other investors purchased less than $10.0 million of common stock by December 15, 2023, the Schuler Trust would have the obligation to purchase $10.0 million of shares of common stock, less the amount of common stock purchased by other investors, and would have the right to purchase additional shares of common stock such that the total amount of common stock purchased by the Schuler Trust's equaled $10.0 million of shares of common stock. If the Company elected to conduct a public offering of common stock and other investors purchased $10.0 million of shares of common stock by December 15, 2023, the Schuler Trust would have the right, but not the obligation, to purchase up to $10.0 million of shares of common stock at the public offering price for the backstopped offering up to a maximum aggregate purchase by the Schuler Trust of $10.0 million of common stock.

In December 2023, the Company and the Schuler Trust entered into an amendment to the Schuler Purchase Obligation extending the deadline for the investment or public offering backstop through February 15, 2024 and the Schuler Trust agreed to purchase $2 million at the public offering price if the aggregate gross proceeds to the Company resulting from the public offering is more than $10.0 million. Additional information regarding the public offering is included in Note 18, Subsequent Events.

Management determined the Schuler Purchase Obligation met the criteria of a freestanding financial instrument at inception. The Schuler Purchase Obligation was recorded as an asset at fair value to be marked to market at each reporting period. At inception, the value of the Schuler Purchase Obligation was $1.3 million, which was recorded as an offset to loss on extinguishment of debt with related party on the consolidated statements of operations.

At December 31, 2023, it was determined that the fair value of the Schuler Purchase Obligation financial instrument was $3.4 million. Changes in the fair value of the Schuler Purchase Obligation are recognized in Gain on fair value adjustment, within the consolidated statements of operations and comprehensive loss. The recognized gain on fair value adjustment on financial instruments related to the Schuler Purchase Obligation for the year ended December 31, 2023 was $2.1 million.

To determine the fair value of the Schuler Purchase Obligation, the Company used a Cox-Ross-Rubinstein binomial tree model to value the American put option. The table below summarizes the significant inputs used to estimate the fair value of the Schuler Purchase Obligation as of December 31, 2023 and June 9, 2023:

	December 31, 2023	June 9, 2023
Stock price	$ 3.92	$ 7.40
Exercise price	$ 7.20	$ 7.20
Term (years)	0.13	0.52
Volatility	55.00 %	55.00 %
Risk-free rate	5.55 %	5.38 %
Fixed commitment purchase price (in thousands)	$ 10,000	$ 10,000
Number of Shares	1,387,949	1,387,949
Obligation probability	75%	100%

The volatility and obligation probability used to quantify the fair value of the Schuler Purchase Obligation are unobservable inputs, and because these are estimates, there are a range of values that could be considered appropriate, which could impact the fair value reported. In determining the obligation probability, the Company assessed the likelihood that the Schuler Purchase Obligation would be utilized to either sell common shares or backstop a public offering. Given the equity market environment as of December 31, 2023 and the significant number of unknowns that would lead to either a successful or unsuccessful conclusion of a public offering, the Company estimated the likelihood of such obligation probability at 75%. There are significant judgments, assumptions and estimates inherent in the determination of the fair value of the Schuler Purchase Obligation. These include determination of valuation method, selection of inputs, and assessment of possible outcomes. The valuation approach used and inputs described above may have a greater or lesser impact on the Company's estimate of fair value. See Note 4, Fair Value of Financial Instruments for additional information.

As discussed further in Note 18, Subsequent Events, the Company completed a public offering for $10.3 million of gross proceeds in January 2024. As a result, the Schuler Trust was not required to backstop the offering in accordance with the Schuler Purchase Obligation, but did purchase $2.0 million of common stock at a price above the public offering price in accordance with the amendment to the Schuler Purchase Obligation and also entered into a subscription agreement in conjunction with the offering to purchase $2.7 million of shares in May 2024. Upon completion of the public offering the fair value of the Schuler Purchase Obligation financial instrument was eliminated.

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 for the years ended December 31 (in thousands):

	2023	2022	2021
Shares issuable upon the release of RSUs	1,239	435	209
Shares issuable upon exercise of stock options	370	541	719
Shares issuable upon the exercise of the Warrant	247	247	—
	1,856	1,223	928

As discussed in Note 10, Convertible Notes, each holder of the 5.00% Notes has the right at their option to convert any portion of the 5.00% Notes at an initial conversion rate of 138.88889 shares of the common stock per $1,000 principal amount. Holders of the 5.00% Notes who convert their 5.00% Notes in connection with a Make-Whole Fundamental Change are, under certain circumstances, entitled to an increase in the conversion rate. The number of shares of common stock issuable upon conversion of the 5.00% Notes as of December 31, 2023, based on the final October 18, 2023 conversion rate is 9.4 million shares, convertible at the holders' option. These shares were not included in the computation of diluted net loss per share because they would have an anti-dilutive effect for the year ended December 31, 2023. The remaining outstanding 2.50% Notes are no longer convertible into common shares as of December 31, 2023 and were not included in diluted net loss per share for the years ended December 31, 2022 and 2021 as they would have had an anti-dilutive effect on loss per share for those periods.

As discussed in Note 11, Related Party Transactions, the Company entered into the Schuler Purchase Obligation, which was amended in December 2023, whereby the Schuler Trust was required, at the Company's option, to either purchase approximately 1.4 million shares of common stock from the Company at $7.20 per share for an aggregate purchase price of $10.0 million or to backstop a public offering (to be completed before February 15, 2024) by the Company of common stock for aggregate proceeds of $10.0 million at the public offering stock price with additional rights to purchase additional shares at the Schuler Trust's option. In the event the gross proceeds resulting from the public offering is more than $10.0 million, the Schuler trust agreed to purchase a $2.0 million of the Company's common stock at the public offering price. 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.

NOTE 13. EQUITY-BASED COMPENSATION

The Company has one equity-based compensation plan as of December 31, 2023. This plan, the 2022 Omnibus Incentive Compensation Plan ("2022 Incentive Plan"), was adopted by the Company's Board of Directors upon approval by the Company's stockholders in May 2022. Upon adoption, the Company's previous 2012 Omnibus Equity Incentive Plan (the "2012 Incentive Plan") was automatically replaced and superseded by the 2022 Incentive Plan. Outstanding awards granted under the 2012 Incentive Plan remain in effect pursuant to their terms with vesting periods ranging from immediate to five years with a maximum contractual term of ten years.

Upon adoption in May 2022, the total number of shares of the Company's common stock reserved and available for grant pursuant to the 2022 Incentive Plan was 0.6 million plus shares of common stock that remain available or that otherwise become available for grant under the 2012 Incentive Plan. At the Company's 2023 Annual Meeting of Stockholders, the Company's stockholders approved an additional 1.6 million shares of common stock reserved and available for grant under the 2022 Incentive Plan. As of December 31, 2023, the total shares reserved for the 2022 Incentive Plan is 3.4 million.

Stock options granted under the 2022 Incentive Plan vest in three years with a maximum contractual term of ten years while RSUs granted under this plan vest in a range from immediate to five years. The total number of shares of the Company's common stock reserved and available for grant pursuant to the 2022 Incentive Plan as of

December 31, 2023 is 1.3 million.

The following table summarizes option activity during the years ended December 31, 2023 and 2022 and shows the exercisable shares as of December 31, 2023:

	Number of Shares	Weighted Average Exercise Price per Share
Options Outstanding January 1, 2022	**719,066**	**$ 138.91**
Granted	14,000	30.47
Forfeited	(20,806)	125.54
Exercised	(610)	10.40
Expired	(170,918)	109.61
Options Outstanding December 31, 2022	**540,732**	**146.03**
Granted	10,000	5.10
Forfeited	(11,927)	81.01
Exercised	—	—
Expired	(168,966)	137.08
Options Outstanding December 31, 2023	**369,839**	**148.40**
Exercisable December 31, 2023	311,930	161.35

Cash received from the exercise of options was $0.0 million, $0.0 million and $1.6 million for the years ended December 31, 2023, 2022 and 2021, respectively. Upon exercise, shares are issued from shares authorized and held in reserve. The intrinsic value of options exercised was $0.0 million, $0.0 million and $3.3 million for the years ended December 31, 2023, 2022 and 2021, respectively.

The total fair value of options vesting during the period was $5.2 million, $7.2 million, and $11.1 million for the years ended December 31, 2023, 2022 and 2021, 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:

	2023	2022	2021
Expected term (in years)	6.30	6.30	5.79
Volatility	88 %	66 %	65 %
Expected dividends	—	—	—
Risk free interest rates	4.0 %	2.1 %	1.1 %
Estimated forfeitures	— %	— %	— %
Weighted average fair value	$ 3.89	$ 1.88	$ 4.09

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The following table shows summary information for outstanding options and options that are exercisable (vested) as of December 31, 2023:

	Options Outstanding	Options Exercisable
Number of options	369,839	311,930
Weighted average remaining contractual term (in years)	4.83	4.65
Weighted average exercise price	$ 148.40	$ 161.35
Weighted average fair value	$ 90.38	$ 97.42
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 $4.00 on the last trading day of 2023 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 activity during the years ended December 31, 2023 and 2022:

	Number of Shares	Weighted Average Grant Date Fair Value per Share
RSUs Outstanding January 1, 2022	**208,926**	**$ 107.77**
Granted	422,690	15.29
Forfeited	(66,175)	82.81
Vested/released	(129,953)	37.02
RSUs outstanding December 31, 2022	**435,488**	**42.91**
Granted	1,305,220	7.14
Forfeited	(128,588)	35.73
Vested/released	(372,684)	32.39
RSUs outstanding December 31, 2023	**1,239,436**	**9.15**

The total fair value of RSUs vested and released during the period was $12.1 million, $4.8 million, and $8.1 million for the years ended December 31, 2023, 2022 and 2021, 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 awarded for the years ended December 31:

	2023	2022	2021
Weighted average fair value	$ 7.14	$ 15.29	$ 112.38

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:

	2023	2022	2021
Cost of Sales	$ 300	$ 665	$ 325
Research and development	1,396	1,419	4,102
Sales, general and administrative	3,691	8,541	17,620
Total equity-based compensation expense	$ 5,387	$ 10,625	$ 22,047
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:

	2023	2022	2021
Cost capitalized to inventory	$ 138	$ 254	$ 401

As of December 31, 2023, unrecognized equity-based compensation cost related to unvested stock options, and unvested RSUs was $0.4 million and $6.6 million, respectively. This is expected to be recognized over the years 2024 through 2028 with a weighted-average period of 1.9 years.

Included in the above-noted stock options outstanding and share-based 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, and have contractual lives of 10 years. These options are valued in the same manner and with the same inputs as the time-based options. However, the Company only recognizes share-based compensation expense when the targets are determined to be probable of being achieved. Performance-based stock options outstanding as of December 31, 2021 totaling 9,000 expired during 2022 and no additional performance-based stock options were granted leaving no performance-based stock options outstanding at December 31, 2023. There was no share-based compensation expense recognized for performance-based stock options for years ended December 31, 2023 and 2022 with $0.2 million recognized for year ended December 31, 2021.

Included in the above-noted RSU outstanding and share-based compensation expense 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. These units are 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 share-based compensation expense to the extent the targets are determined to be probable of being achieved. There were 27,778 performance-based RSUs outstanding as of December 31, 2021, which were forfeited when the performance goal wasn't achieved with 17,448 and 10,330 forfeited in the years ended December 31, 2022 and 2023, respectively. No additional performance-based RSUs were granted leaving none outstanding at December 31, 2023. There was no share-based compensation expense recognized for performance-based RSUs for years ended December 31, 2023 and 2022 with $0.8 million recognized for year ended December 31, 2021.

NOTE 14. INCOME TAXES

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

	2023	2022	2021
U.S. Domestic	$ (54,784)	$ (54,099)	$ (68,131)
Foreign	(5,984)	(8,471)	(9,526)
Net loss before income taxes	$ (60,768)	$ (62,570)	$ (77,657)

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

	2023	2022	2021
Current:			
Federal	$ —	$ —	$ —
State	(54)	(19)	(18)
Foreign	(796)	96	(27)
Total benefit (provision)	(850)	77	(45)
Deferred:			
Federal	—	—	—
State	—	—	—
Foreign	—	—	—
Total deferred provision	—	—	—
Total benefit (provision)	$ (850)	$ 77	$ (45)

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):

	2023	2022
Deferred tax assets:		
Net operating loss carryforward	$ 102,687	$ 94,003
General business credit	18,466	17,293
Stock options	8,246	12,809
Intangible assets, definite-lived	6,775	7,239
Section 174 research & development	9,097	4,840
Inventory	1,943	2,145
Operating lease liability	379	568
Property & equipment	224	137
Other	608	310
Total deferred tax assets	148,425	139,344
Valuation allowance	(140,104)	(138,710)
Deferred tax assets	$ 8,321	$ 634
Deferred tax liabilities:		
Debt amortization	$ (7,785)	$ (24)
Right of use asset	(416)	(527)
Finance lease liability	$ (120)	$ (83)
Total deferred tax liabilities	$ (8,321)	$ (634)
Net deferred taxes	$ —	$ —

As of December 31, 2023, the Company generated regular tax federal net operating losses ("NOLs") of approximately $382.3 million net of Section 382 limitation. 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 NOLs of $382.3 million, $156.9 million will begin to expire in 2025 and $225.4 million will not expire but will only offset 80% of taxable income generated in tax years after 2017.

As of December 31, 2023, the Company has generated state NOLs of approximately $373.9 million. The Company's state NOLs will begin to expire in 2030.

As of December 31, 2023, the Company has generated $15.4 million of federal research and development (“R&D”) tax credits which begin to expire in 2032.

As of December 31, 2023, the Company has generated $13.3 million of state R&D tax credits which begin to expire in 2031.

Utilization of the Company’s NOL and R&D credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that have occurred previously or that could occur in the future in accordance with Section 382 of the Internal Revenue Code of 1986 (“Section 382”) as well as similar state provisions. These ownership changes may limit the amount of NOL and R&D credit carryforwards that can be utilized annually to offset future taxable income and taxes, respectively. In general, an ownership change as defined by Section 382 results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50% over a three-year period. The Company has not conducted a comprehensive study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to significant complexity with such a study. If the Company has experienced a change of control, as defined by Section 382, at any time since inception, utilization of the NOL or R&D credit carryforward would be subject to an annual limitation under Section 382. Since the Company has not completed its comprehensive analysis, it is reasonably possible that its federal and state NOLs, and R&D credits available to offset future taxable income could materially decrease. This reduction would be offset by an equal and offsetting adjustment to the existing valuation allowance. Any limitation may result in expiration of a portion of the NOL or R&D credit carryforward before utilization.

The net deferred tax asset valuation allowance is $140.1 million as of December 31, 2023, compared to $138.7 million as of December 31, 2022. 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. The change in the Company’s valuation allowance during 2023 of $1.4 million is comprised of an increase of $7.8 million in deferred tax expense and $0.4 million in Other Comprehensive Income offset by a decrease in valuation allowance of $6.8 million recorded to equity as discussed below.

As discussed in Note 11, Related Party Transactions, the Company entered into the August 2022 Exchange Agreement with the Schuler Trust on August 15, 2022 to exchange $49.9 million in 2.50% Notes for the Secured Notes of $34.9 million and the Warrant valued at $3.8 million to acquire the Company’s common stock. The gain from the partial extinguishment of the 2.50% 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.

As discussed in Note 10, Convertible Notes, in June 2023 the Company entered into a series of agreements with certain holders of the 2.50% Notes, the Schuler Trust, and the holders of the Company's Series A Preferred Stock to effect the restructuring of the Company's capital structure. The Company exchanged $55.9 million aggregate amount of principal 2.50% Notes for $56.9 million aggregate principal amount of newly issued 5.00% Notes including an additional 5.00% Notes for the accrued interest on the 2.50% Notes exchanged of approximately $1.0 million. In addition, the Company issued and sold an additional $10 million aggregate principal amount of 5.00% Notes, bringing the total debt of the 5.00% Notes to approximately $66.9 million. The Company accounted for the transaction as an extinguishment of debt and recognized a loss of $14.1 million which is not deductible for income tax purposes. The Company determined that the 5.00% Notes included an embedded derivative related to the conversion option which was accounted for as a derivative liability and related debt discount of $38.2 million. The Company recorded a deferred tax asset of $9.5 million and a deferred tax liability of $9.5 million for the embedded derivative liability and debt discount, respectively, upon issuance. The Company marked the derivative liability to market through October 17, 2023, the date at which the conversion price became fixed, at which time the derivative liability was reclassed to equity. The deferred tax asset related to the derivative liability of $6.8 million, which was fully offset by a valuation allowance, was reversed at that time and had no impact on the effective tax rate.

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

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:

	2023	2022	2021
U.S. federal statutory income tax rate	(21.00)%	(21.00)%	(21.00)%
State taxes, net of federal tax benefit	(2.06)%	(2.55)%	(4.26)%
Permanent and other differences	2.91 %	1.74 %	(9.01)%
Debt restructuring	3.48 %	— %	(1.31)%
Change in tax rates	(0.36)%	0.26 %	0.02 %
Return to provision adjustments	1.50 %	— %	— %
Tax rate differential	(0.65)%	(0.52)%	2.30 %
Unrecognized tax benefits	(0.17)%	1.01 %	2.64 %
Nondeductible equity and other compensation	7.75 %	5.44 %	1.72 %
Credit for increased research activities	(2.75)%	(2.80)%	(6.19)%
Change in valuation allowance	12.75 %	18.30 %	35.15 %
	1.40 %	(0.12)%	0.06 %

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

	2023	2022	2021
Balance at beginning of year	$ 13,596	$ 7,556	$ 4,866
Increases for prior positions	409	380	2,359
Decreases for prior positions	(5,859)	—	—
Increases for current year positions	698	5,660	1,746
Decreases due to settlements		—	(1,415)
Other increases	—	—	—
Balance at end of year	$ 8,844	$ 13,596	$ 7,556

These uncertain positions are not expected to change within the next twelve months. Of the $8.8 million of uncertain tax positions, $0.6 million would impact the effective tax rate, if reversed. The Company accounts for interest and penalties on uncertain tax positions within tax expense. During the years ended December 31, 2023, 2022 and 2021, the Company recognized $0.1 million, $0.0 million and $0.0 million in interest and penalties in the statements of operations. The Company had $0.1 million, $0.0 million and $0.0 million for the payment of interest and penalties accrued at December 31, 2023, 2022 and 2021, respectively. The Company incurred net operating losses since inception that are subject to adjustment under IRS and state examination. 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.

The Company incurred NOLs 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 adjustments reducing the Company's 2018 R&D tax credit and 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. No cash taxes, interest or penalties were paid in connection with this settlement. During the year ended December 31, 2022, the Company increased its reserve for uncertain tax positions in connection with the exchange of debt. 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.

Australia R&D Tax Incentive

The Australian government offers an R&D tax incentive to help companies conducting eligible R&D activities in Australia in the form of refundable tax credits if certain conditions are met. Management assesses the Company's R&D activities and expenditures to determine which activities and expenditures are likely to be eligible under the tax incentive regime. Annually, management estimates refundable tax credit available to the Company based on available information and submits an application to the Australian tax authority for R&D credit approval. The Company recognizes the refundable R&D tax credits when there is reasonable assurance that the terms have been met, income will be received, the relevant expenditure has been incurred and the consideration can be reliably measured. The refundable R&D tax credit is recorded as a reduction to research and development expense in the consolidated statements of operations when the aforementioned criteria are met. In July 2023, the Company received a $1.1 million refundable R&D tax credit for its 2022 R&D activities in Australia. The Company provided for a full reserve against the credit as sustainability of the credit upon potential examination by the Australian tax authority is uncertain. The Company does not currently believe it is probable that any penalties or interest will be assessed to the extent that the credit is not sustained.

NOTE 15. COMMITMENTS AND CONTINGENCIES

In April 2022, the Company entered into a non-cancellable purchase obligation with a supplier to acquire raw materials related to the development and commercialization of its next generation Accelerate Wave system 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, 2023, the commitment remains $11.9 million as the Company has not taken delivery of any of the related inventory.

NOTE 16. GEOGRAPHIC AND REVENUE DISAGGREGATION

The Company operates as one operating segment. Sales to customers outside the U.S. represented 12%, 14% and 14% of total revenue for the years ended December 31, 2023, 2022 and 2021, respectively. As of December 31, 2023 and 2022, accounts receivable balances due from these foreign customers, in U.S. dollars, were $0.9 million and $0.6 million, respectively.

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

	2023	2022
Domestic	$ 2,139	$ 3,120
Foreign	250	358
	$ 2,389	$ 3,478

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

	2023	2022	2021
Domestic	$ 10,611	$ 10,921	$ 10,121
Foreign	1,448	1,831	1,661
Net sales	$ 12,059	$ 12,752	$ 11,782

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

	2023	2022	2021
Accelerate instrument and consumable revenue	$ 11,928	$ 12,598	$ 11,628
Other revenue	131	154	154
Net sales	$ 12,059	$ 12,752	$ 11,782

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

	2023	2022	2021
Products	$ 10,609	$ 11,107	$ 10,430
Services	1,450	1,645	1,352
Net sales	$ 12,059	$ 12,752	$ 11,782

Lease income included in net sales in the consolidated statements of operations and comprehensive income was $1.5 million, $1.4 million and $1.9 million for the years ended December 31, 2023, 2022 and 2021, respectively, and was recorded in accordance with ASC 842. This income does not represent revenue recognized from contracts with customers in accordance with ASC 606.

NOTE 17. STOCKHOLDERS' DEFICIT

The Company has entered into a number of securities purchase and exchange agreements with affiliated and external parties throughout its history, and has provided equity-based compensation to its employees, directors and affiliated parties. See Note 10, Convertible Notes, Note 11, Related Party Transactions and Note 13, Equity-Based Compensation for further discussion of transactions impacting the Company's stockholders' deficit for the years ended December 31, 2023, 2022, and 2021.

At-The-Market Equity Sales Agreement

In 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 $50.0 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. William Blair is entitled to a commission of 3% of the aggregate gross proceeds from each sale of shares occurring pursuant to the ATM Sales Agreement. During the year ended December 31, 2021, the Company sold 0.2 million 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 years ended December 31, 2023 or 2022. As of December 31, 2023, the registration statement relating to the ATM Sales Agreement is expired.

August 2022 Public Offering

In August 2022, the Company completed a public offering of 1.8 million shares of its common stock at a public offering price of $20.00 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.

Treasury Stock

In 2018, in connection with the 2.50% 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 2.50% Notes to fund the Prepaid Forward. The aggregate number of shares of the Company's common stock underlying the Prepaid Forward was approximately 185,850. During March 2023, 185,850 shares of common stock were returned to the Company pursuant to its agreement with the Forward Counterparty. As of December 31, 2023 and 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).

NOTE 18. SUBSEQUENT EVENTS

January 2024 Unit Offering

On January 23, 2024, the Company completed an underwritten public offering (the "January Public 2024 Units Offering") consisting of 6.9 million Units, each consisting of one share of common stock and one warrant to purchase one share of common stock, and for certain investors in lieu thereof, pre-funded Units, each consisting of one pre-funded warrant to purchase one share of common stock and one warrant to purchase one share of common stock. The public offering price for each Unit was $1.50 and the public offering price for each pre-funded Unit was $1.49.

The Company granted the underwriters for the January 2024 Public Units Offering a 30-day option to purchase up to an additional 1.0 million shares of common stock and/or additional warrants to purchase up to 1.0 million shares of common stock, in any combination thereof, at the public offering price, less underwriting discounts and commissions. The underwriters elected to purchase an additional 36,003 warrants from the Company under this option.

The warrants issued to investors in January 2024 Public Units Offering have an exercise price of $1.65 per share, were immediately exercisable upon issuance and will remain exercisable until the date that is five years after their original issuance. The pre-funded warrants have an exercise price of $0.01 per share, are immediately exercisable and will remain exercisable until exercised in full. The gross proceeds from the January 2024 Public Units Offering, before deducting underwriting discounts and commissions and other public offering expenses payable by the Company were approximately $10.3 million (excluding any proceeds that may be received upon the exercise of the warrants or the pre-funded warrants).

Concurrently with the completion of the January 2024 Public Units Offering, the Company sold 1.2 million Units at a purchase price of $1.73 per Unit to the Schuler Trust which satisfied the Schuler Purchase Obligation, and an aggregate of 33,332 Units at a purchase price of $1.50 per Unit to the Company's Chief Executive Officer and Chief Financial Officer, in each case, in a private placement offering. In addition, the Schuler Trust agreed to purchase an additional 1.6 million Units at a purchase price of $1.73 per unit on or before May 20, 2024. The gross proceeds from the private placement offerings, before deducting private placement expenses payable by the Company, were approximately $4.7 million (excluding any proceeds that may be received upon the exercise of the warrants). Further information about the Schuler Purchase Obligation is described in Note 11, Related Party Transactions.

The current estimate of net proceeds, after consideration of estimated transaction expenses, is approximately $13.6 million.

Nasdaq Notice

On March 4, 2024, the Company received written notice from Nasdaq's Listing Qualifications Staff notifying the Company that for the last 31 consecutive business days, the Market Value of Listed Securities was below the minimum of $35 million required for continued listing on The Nasdaq Capital Market ("MVLS Requirement"). In accordance with Nasdaq rules, the Company has been provided with an initial period of 180 calendar days, or until September 3, 2024, to regain compliance with the MVLS Requirement. If, at any time before the this date, the market value of the Company's common stock closes at $35 million or more for a minimum of ten consecutive business days, Nasdaq will provide written confirmation to the Company and close the matter. If the Company does not regain compliance with the MVLS Requirement prior to this date, Nasdaq will provide written notification that the Company's common stock will be subject to delisting. At that time, the Company may appeal the Staff's delisting determination to a Nasdaq Hearing Panel. The Company is evaluating potential actions to regain compliance with the MVLS Requirement and intends to actively monitor the market value of common stock. The Company may also, if appropriate, consider other options to regain compliance with Nasdaq's continued listing standards.

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

None.

Item 9A. Controls and Procedures

107s

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 effective as of December 31, 2023, 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. 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 the Company's management, including our Principal Executive Officer and Principal Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control-Integrated Framework (2013), issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2023.

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.

Remediation of Previously Reported 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. As previously reported in the company's Annual Report on Form 10-K for the year ended December 31, 2022, Management identified a material weakness in its internal control over financial reporting as of December 31, 2022 that prevented it from identifying a misclassification of the 2.50% Notes in the consolidated balance sheet, was corrected in such Form 10-K. 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.

With oversight from the Audit Committee and input from management, the Company designed and implemented changes in processes and controls throughout 2023 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

Except for the changes in connection with our implementation of the remediation plan discussed above, 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, 2023, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Rule 10b5-1 Trading Plans

108s

During the three months ended December 31, 2023, none of our directors or officers (as defined in Exchange Act Rule 16a-1(f) adopted or terminated a “Rule 10b5-1 trading arrangement” or a “non-Rule 10b5-1 trading arrangement”, each as defined in Item 408 of Regulation S-K.

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 2024 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.

111s

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
3.1.7	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 24, 2023
3.1.8	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 July 13, 2023
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 as Exhibit A to 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	Indenture, dated June 9, 2023, between Registrant and U.S. Bank Trust Company, National Association, as trustee	Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on June 13, 2023
4.5	Form of 5.00% Senior Secured Convertible Notes due 2026 (included as Exhibit A to Exhibit 4.4)	Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed on June 13, 2023
4.6	Description of our Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934	Filed herewith
10.1	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
10.2*	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
10.2.1*	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
10.2.2*	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
10.2.3*	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
10.2.4*	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
10.2.5*	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 on March 22, 2013

10.2.6*	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 on March 22, 2013
10.2.7*	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
10.3	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
10.4	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
10.5*	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
10.6	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
10.7	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
10.8	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
10.9	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
10.9.1	Amendment No. 1 to Securities Purchase Agreement, dated June 9, 2023, between Registrant and the Jack W. Schuler Living Trust.	Incorporated by reference to Exhibit 10.7 to the Registrant's Current Report on Form 8-K filed on June 13, 2023
10.10*	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
10.10.1*	First Amendment to the 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 24, 2023
10.11	Exchange Agreement, dated as of August 15, 2022, by and between 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
10.12	Secured Promissory Note, dated as of August 15, 2022, by 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
10.12.1	Consent and Amendment No. 1 to Secured Promissory Note, dated June 9, 2023, between Registrant and the Jack W. Schuler Living Trust	Incorporated by reference to Exhibit 10.6 to the Registrant's Current Report on Form 8-K filed on June 13, 2023
10.13	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
10.14	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
10.15+	Sales and Marketing Agreement, dated as of August 15, 2022, by and between 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
10.16	Forbearance Agreement, dated as of March 9, 2023, by and among 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
10.17*	Reichling Consulting Services Agreement	Filed herewith
10.18+	Restructuring Support Agreement, dated as of April 21, 2023 between the Registrant and Consenting Stakeholders	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on April 24, 2023
10.19*	Agreement between Registrant and David Patience, dated as of March 9, 2023	Incorporated by reference to Exhibit 10.3 filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023
10.20	Note Exchange Agreement, dated June 9, 2023, between Registrant and certain investors named therein	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on June 13, 2023
10.20.1	First Amendment to Note Exchange Agreement, dated December 11, 2023, between Registrant and certain investors named therein	Incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed on December 13, 2023
10.21	Note Purchase Agreement, dated June 9, 2023, between Registrant and certain investors named therein	Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on June 13, 2023
10.21.1	First Amendment to Note Purchase Agreement, dated December 11, 2023, between Registrant and certain investors named therein	Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on December 13, 2023

10.22	Form of Security Agreement, dated June 9, 2023, between Registrant, as issuer, subsidiaries of Registrant, as guarantors, and U.S. Bank Trust Company, National Association, as Collateral Agent	Incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed on June 13, 2023
10.23	Form of Patent Security Agreement, dated June 9, 2023, by Registrant, as pledgor, in favor of U.S. Bank Trust Company, National Association, as collateral agent (included as Exhibit 3 to Exhibit 10.22).	Incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K filed on June 13, 2023
10.24	Form of Trademark Security Agreement, dated June 9, 2023, by Registrant, as pledgor, in favor of U.S. Bank Trust Company, National Association, as collateral agent (included as Exhibit 4 to Exhibit 10.22)	Incorporated by reference to Exhibit 10.5 to the Registrant's Current Report on Form 8-K filed on June 13, 2023
10.25	New Securities Purchase Agreement, dated June 9, 2023, between Registrant and the Jack W. Schuler Living Trust	Incorporated by reference to Exhibit 10.8 to the Registrant's Current Report on Form 8-K filed on June 13, 2023
10.25.1	First Amendment to Securities Purchase Agreement, dated December 12, 2023, between 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 December 13, 2023
10.26	Warrant Agency Agreement, dated January 23, 2024, between Registrant and Broadridge Corporate Issuer Solutions	Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on January 25, 2024
10.27	Form of Warrant	Incorporated by reference to Exhibit 4.6 to the Form S-1 Registration Statement (No. 333-276031) filed on January 18, 2024
10.28	Form of Pre-Funded Warrant	Incorporated by reference to Exhibit 4.7 to the Form S-1 Registration Statement (No. 333-276031) filed on January 18, 2024
10.29	Form of Subscription Agreement	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on January 25, 2024
10.30	Mertz Change in Employment Status Agreement	Filed herewith
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	Filed herewith
97	Clawback Policy	Filed 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 28, 2024

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.

115s

Signature	Title	Date
/s/ Jack Phillips Jack Phillips	President, Chief Executive Officer and Director (Principal Executive Officer)	March 28, 2024
/s/ David Patience David Patience	Chief Financial Officer (Principal Financial and Accounting Officer)	March 28, 2024
/s/ Hany Massarany Hany Massarany	Chairman of the Board of Directors	March 28, 2024
/s/ Mark Black Mark Black	Director	March 28, 2024
/s/ Wayne Burris Wayne Burris	Director	March 28, 2024
/s/ Louise Francesconi Louise Francesconi	Director	March 28, 2024
/s/ Marran H. Ogilvie Marran H. Ogilvie	Director	March 28, 2024
/s/ John Patience John Patience	Director	March 28, 2024
/s/ Jenny Regan Jenny Regan	Director	March 28, 2024
/s/ Jack Schuler Jack Schuler	Director	March 28, 2024
/s/ Matthew W. Strobeck, Ph.D. Matthew W. Strobeck, Ph.D.	Director	March 28, 2024

EXHIBIT 4.6

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

General

As of December 31, 2023, 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 455,000,000 shares with a par value of $0.001 per share, comprised of 450,000,000 authorized shares of common stock and 5,000,000 authorized shares of preferred stock. As of March 25, 2024, there were 21,664,387 shares of our common stock outstanding and no shares of preferred stock 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 4.6 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. Unless otherwise required by law, our certificate of incorporation or our bylaws: (i) the election of our directors will be decided by a plurality of the votes cast by the shares represented in person or by proxy at any meeting of stockholders held to elect directors and entitled to vote on such election of directors; and (ii) any other matter brought before any meeting of stockholders will be decided by the affirmative vote of the majority of the votes cast by the shares present in person or represented by proxy at the meeting and entitled to vote on the matter.

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.

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 10.17

ATTACHMENT B
CONSULTING SERVICES AGREEMENT

THIS Consulting Services Agreement ("Agreement") is entered into as of **March 9, 2023** with an effective date of April 3, 2023 ("Effective Date") by and between Accelerate Diagnostics, Inc., 3950 S. Country Club Road, Suite 470, Tucson, AZ 85714 ("Accelerate"), and Steve Reichling having an address at **12598 North Yellow Bird Road, Oro Valley Arizona 85755** ("Consultant"). Consultant and Accelerate are herein referred to collectively as "Parties" and individually as a "Party."

In consideration of the mutual covenants and conditions contained herein, Consultant and Accelerate agree as follows:

1. Services. Accelerate hereby engages Consultant, and Consultant hereby agrees, to provide the consulting services set forth in one or more Statements of Work mutually agreed upon by the Parties from time to time, the form of which is set forth Exhibit A hereto (the "Services"). Each such Statement of Work shall specify: (a) the specific scope of Services to be provided; (b) the compensation and payment terms associated with successful completion of such Services; and (c) the period of performance. Consultant will perform the Services to the best of its ability and in accordance with Accelerate's reasonable objectives and specifications under the guidance and instruction of Chief Executive Officer and/or Chief Finance Officer, or any successor Accelerate may in its sole discretion select, and, at Accelerate's request, at Accelerate's place of business, over the telephone or at other specific locations. Any Statement of Work, or any part thereof, may be revised, supplemented or amended by mutual agreement of the Parties. Consultant shall not subcontract the performance of any Services contemplated by this Agreement without Accelerate's prior written consent, and, notwithstanding any such consent, Consultant shall be liable for subcontractor's failure to perform in conformity with the terms and conditions of this Agreement.

2. Service Quality.

a. Consultant represents, warrants and covenants that all Services furnished under this Agreement shall be provided in accordance with all terms and conditions of this Agreement, including the applicable Statement of Work. Consultant shall promptly correct, at its own expense, any Services that are provided that, in Accelerate's sole determination, fail to conform to the applicable Statement of Work or any requirements of this Agreement.

b. Accelerate shall be solely responsible for all contacts and communications with any regulatory authorities with respect to matters relating to the Services. Consultant will notify Accelerate promptly, and in no event later than one (1) business day, after Consultant receives any contact or communication from any regulatory authority relating in any way to the Services and will provide Accelerate with copies of all any communication within one (1) business day after receipt. Unless required by applicable law, Consultant will have no contact or communication with any regulatory authority regarding the Services without the prior written consent of Accelerate, which consent will not be unreasonably withheld, and Consultant will comply with all reasonable requests and comments by Accelerate with respect to all such contacts and communications.

d. With reasonable notice from Accelerate to Consultant and during normal business hours, Consultant and/or any permitted subcontractor will allow Accelerate and its designees to review all records and facilities pertaining to Services.

1. Payment. As full and complete consideration for the Services to be performed by Consultant, Accelerate shall pay Consultant the undisputed amounts invoiced pursuant to each applicable Statement of Work in accordance with the payment schedule set forth in such Statement of Work. All fees due hereunder shall be contingent upon successful completion of the Services in accordance with this Agreement and the Statement of Work to the reasonable satisfaction of Accelerate. No payments shall be made by Accelerate to Consultant for any Services performed by Consultant unless such Services are specifically enumerated in the applicable Statement of Work. In addition, Consultant will be reimbursed for all reasonable and necessary out-of-pocket expenses (including travel, lodging, and the like), which are incurred at the request of and approved in writing in advance by Accelerate.

4. Term and Termination.

a. **This Agreement shall commence on the Effective Date and shall continue until December 29, 2023** ("Term"), unless earlier terminated in accordance with this Section. Notwithstanding the termination or expiration of this Agreement or any Statement of Work pursuant to this Section, the Term, unless otherwise elected by Accelerate in writing, shall continue for any period necessary for Consultant to complete all Services and deliver all Deliverables (as defined in the applicable Statement of Work) required by the applicable Statement of Work entered into by the Parties prior to such termination or expiration of this Agreement or the applicable Statement of Work, provided that no additional Statement of Work shall be entered into by the Parties following termination or expiration of this Agreement.

b. This Agreement or any Statement of Work may be terminated by Accelerate for any reason or no reason upon not less than ten (10) days' prior written notice. Consultant may also terminate this Agreement upon sixty (60) days' prior written notice. In addition, Consultant or Accelerate may terminate this Agreement and/or any Statement of Work immediately by written notice to the other Party, in the event of a material breach of this Agreement or such Statement of Work by the other Party, if the non-breaching Party gives written notice to the breaching Party specifying the nature of the breach and such breach shall not have been substantially cured within ten (10) days after such notice of breach. Any termination by any Party for breach by the other Party shall be without prejudice to any damages or remedies to which it may be entitled from the other Party. Consultant or Accelerate may terminate this Agreement or any Statement of Work immediately by written notice to the other Party, if the other Party (a) becomes insolvent, (b) makes or has made an assignment for the benefit of creditors, (c) is the subject of proceedings in voluntary or involuntary bankruptcy instituted on behalf of or against it (except for involuntary bankruptcies which are dismissed within ninety (90) days) or (d) has a receiver or trustee appointed for substantially all of its property.

c. Upon receipt of a termination notice under this Section, the Parties shall promptly meet to prepare a close-out and/or transition schedule, and Consultant shall cease performing all Services not necessary for the orderly close-out and transition of the applicable Services. Consultant shall use its best efforts to conclude or transfer such Services, as instructed by Accelerate, as expeditiously as possible. Consultant shall be entitled to all reasonable and necessary costs and expenses incurred for Services completed prior to the effective date of termination and all fees due and owing for Services satisfactorily completed at the time of termination notice unless this Agreement and/or any Statement of Work is terminated due to the willful malfeasance or neglect of, or breach of any term of this Agreement or any Statement of Work by Consultant.

d. Upon termination or expiration of this Agreement and/or any Statement of Work, Consultant shall immediately deliver to Accelerate, or if Accelerate so instructs, destroy all copies of and other embodiments of any of the Confidential Information (as defined in Section 5), Accelerate Materials (as defined in Section 6), Inventions (as defined in Section 8), and all other correspondence, documents, specifications, and any other property belonging to Accelerate which may be in Consultant's possession or control.

e. The termination or expiration of this Agreement or any Statement of Work, however arising, will be without prejudice to the rights and duties of the Parties accrued prior to termination. Sections 4, 5, 6-13 and 18 shall survive termination or expiration of this Agreement or of any Statement of Work between the Parties for whatever reason. Termination or expiration of this Agreement or any Statement of Work will not relieve either Party of any liability which accrued hereunder prior to the effective date of such termination or expiration, nor preclude either Party from pursuing all rights and remedies it may have hereunder at law or in equity with respect to any breach of this Agreement, nor prejudice either Party's right to obtain performance of any obligation.

5. Confidentiality.

a. The term *"*Confidential Information*"* shall mean any and all non-public scientific, technical, financial, or business information in whatever form (written, oral or visual) owned or controlled by Accelerate (including, but not limited to, confidential information of third-parties that is in the possession of Accelerate) and that is either furnished to Consultant, directly or indirectly, or otherwise becomes known to Consultant as a consequence of its relationship or access to Accelerate, including, by way of example and not limitation, and whether or not patentable, (i) trade secrets, know-how, show-how, designs, methods, diagnostics, biomarkers, drugs, compounds, formulations, ingredients, samples, information relating to pharmaceutical partners, vendors, customers and patients, processes, machines, processing and control information, manuals, draft or final regulatory filings, media and other biological materials (including without limitation organisms, cells, viruses, cell products, DNA, cDNA and RNA sequences), procedures and formulations for producing any such materials, research, preclinical, clinical, regulatory, commercial and intellectual property strategies, therapeutic indications, unmet medical needs, molecular targets and target product profiles, screening assays and screening flow charts, chemical compounds, chemical libraries, reaction protocols for chemical libraries, chemical structures, chemical design and model relationship data, chemical databases, assays, samples, products, processes, drawings, improvements, equations, methods, developmental or experimental work, structures, models, prototypes, data, test results, photographs, techniques, tapes, disks, or anything respecting management, finance or operations, including product development, marketing information, sales projects, profits, revenues, supplier, customer and employee lists and the contact information of same, purchase and sale records and cost and pricing information; (ii) any information designated by Accelerate as confidential; and (iii) the terms and conditions of this Agreement and each Statement of Work. Specific information disclosed to Consultant by Accelerate shall not be deemed to be available to the public or in prior possession of Consultant merely because such specific information is embraced by more general information available to the public or in prior possession of Consultant. "Confidential Information" shall not include information that (i) is or becomes generally known or available by publication, commercial use or otherwise through no fault of Consultant; (ii) is known and has been reduced to tangible form by Consultant prior to the time of the disclosure and is not subject to restriction, as reasonably established by Consultant; (iii) is independently developed by Consultant as evidence by written documents showing same; (iv) is lawfully obtained from a third party that has the right to make such disclosure, as reasonably established by Consultant; or (v) is made generally available to the public by the disclosing party without restriction on disclosure. Consultant agrees that the authorized use and confidentiality obligations set forth herein apply to any Confidential Information that Consultant may have received from Accelerate or to which Consultant has otherwise been given access prior to the effective date of this Agreement.

b. In view of Accelerate's proprietary rights and interests concerning its facilities and technology, during the term of this Agreement and thereafter, Consultant agrees: (a) to use Confidential Information solely in connection with the performance of the Services and for no other purpose, and to not cause or assist any person or entity to, directly or indirectly, use or access any Confidential Information for any other purpose whatsoever; (b) to not use, access, make available, or disclose, nor cause or assist any person or entity to, directly or indirectly, to disclose any Confidential Information to any thirty party except to the extent necessary for Consultant to perform the Services and as authorized by Accelerate; *provided*, that Consultant remains liable for the compliance of such authorized third party with the terms of this Agreement. Consultant will take all reasonable measures to protect the secrecy, and to prevent the unauthorized use or disclosure, of Confidential Information. Consultant will promptly notify Accelerate in writing of any misuse, misappropriation, or unauthorized disclosure of Confidential Information that may come to Consultant's attention.

c. Notwithstanding anything else herein, to the extent Consultant is required to disclose any Confidential Information in order to comply with applicable law or an order of a court of competent jurisdiction, such disclosure shall not constitute a violation of this Section, provided that Consultant: (i) immediately notifies Accelerate of such required disclosure, (ii) cooperates reasonably with Accelerate in any Accelerate effort to obtain a protective order or other confidential treatment with respect to such Confidential Information, and (iii) discloses only that portion of such Confidential Information that is required to be disclosed and shall be marked "Confidential and Proprietary."

d. Pursuant to the Defend Trade Secrets Act of 2016, if Consultant is an individual, Consultant acknowledges that she/he shall not have criminal or civil liability under any federal or State

trade secret law for the disclosure of a trade secret that (a) is made (i) in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (b) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. In addition, if Consultant files a lawsuit for retaliation by Accelerate for reporting a suspected violation of law, Consultant may disclose the trade secret to Consultant's attorney and may use the trade secret information in the court proceeding, if Consultant files any document containing the trade secret under seal and does not disclose the trade secret, except pursuant to court order.

6. Materials. Accelerate may provide to Consultant tangible materials necessary for Consultant's performance of particular Services. The material that is covered by this Agreement includes tangible materials, together with any related material or associated know-how and data which will be received by Consultant from Accelerate, and any substances or data that are replicated or derived therefrom by Consultant, including but not limited to any such material identified in a Statement of Work (collectively, "Material"). Consultant hereby acknowledges and agrees that Accelerate shall be the sole and exclusive owner of all right, title and interest in Materials. The Material is considered proprietary to Accelerate, and Accelerate grants to Consultant a non-exclusive, non-transferable right to use the Material solely for performing the Services and only during the term of this Agreement. Consultant shall store, handle and administer the Material in accordance with the Statement of Work and all applicable laws and shall not use the Material for any purpose other than that described in the applicable Statement of Work. Consultant shall not, without Accelerate's prior written consent, (a) distribute or transfer such Material to any third party other than employees of Consultant who require access to the Material, are under Consultant's direct supervision and control, and are informed of the proprietary nature of the Material or (b) perform compositional, structural, functional or other analysis of the Material, or undertake deconvolution, modification or reverse engineering with respect to the Material, except as is expressly provided herein. In the event Consultant conceives an Invention related to the Material in the course of activities that are in breach of Consultant's obligations under this Agreement, Accelerate shall be the sole and exclusive owner of such Invention and all intellectual property rights therein, and Consultant shall execute and deliver any documents of assignment or conveyance to effectuate the ownership rights of Accelerate in such Invention and related intellectual property rights. Unless the applicable Statement of Work states otherwise, upon completion of the Services, Consultant shall dispose of, return and/or keep such Materials for retention in compliance with regulatory requirements, in each case, according to Accelerate's directions.

7. Publications. The Parties agree that there will be no publication made of any of the Services resulting hereunder without the prior review and express written approval of Accelerate.

8. Intellectual Property.

a. Consultant agrees that any information, discovery, invention, innovation, suggestion, know-how, idea, improvement, technique, material and/or reports that Consultant conceives, reduces to practice or develops during the term of the Agreement, alone or in conjunction with others, during the performance of, or as a direct result of performing, the Services for Accelerate under this Agreement (each an "Invention"), including any and all intellectual property rights therein, shall be the sole and exclusive property of Accelerate without further compensation to Consultant. Consultant shall promptly disclose in writing to Accelerate each such Invention and provide to Accelerate all information known to Consultant reasonably relating to such Invention. The disclosure of proprietary information by Accelerate to Consultant shall not result in any obligation to grant Consultant any rights in and to said proprietary subject matter. If Consultant has any rights to any Inventions that cannot, under applicable law, be assigned to Accelerate, Consultant hereby unconditionally and irrevocably waives the enforcement of such rights and all claims and causes of action of any kind against Accelerate with respect to such rights. Consultant agrees, at Accelerate's request and expense, to consent to and join in any action to enforce such rights.

b. Consultant agrees that all works of authorship created by Consultant under this Agreement, including but not limited to reports, drawings, models, specifications, software code, notes, and memoranda (collectively, the "Work"), shall be deemed to be "work made for hire" and that

Accelerate, as the entity for which the Work is prepared, shall own all right, title and interest in and to the Work, including the entire copyright in the Work. Consultant further agrees that to the extent the Work or any part of the Work is not "work made for hire," Consultant agrees to assign, and hereby assigns, to Accelerate, ownership of all right, title and interest in and to the Work or such part thereof, including the entire copyright in the Work or such part thereof. No copyright license is granted to Consultant either expressly or by implication, estoppel or otherwise. To the extent any pre-existing materials are contained in the Work, Consultant agrees to grant, and hereby grants, to Accelerate an irrevocable, non-exclusive, perpetual, worldwide, royalty-free copyright license to such preexisting materials.

c. During and after the Term, Consultant shall, and shall cause its personnel to, (i) cooperate fully in obtaining patent and other proprietary protection for any patentable or protectable Inventions and Works, all in the name of Accelerate and at Accelerate's cost and expense; and (ii) execute and deliver all requested applications, assignments and other documents, and take such other measures as Accelerate reasonably requests, in order to perfect and enforce Accelerate's rights in the Inventions and Works.

d. Notwithstanding anything else herein, Consultant will retain full ownership rights in and to all know-how, templates, programs, methodologies, processes, technologies and other materials developed or licensed by Consultant prior to or apart from performing its obligations under this Agreement (collectively, with all associated intellectual property rights, the "Consultant Property"), regardless of whether such Consultant Property is used in connection with Consultant's performance of its obligations under this Agreement. Consultant agrees that if in the course of performing the Services, Consultant intends to incorporate into any Invention or Work any Consultant Property, (i) Consultant shall inform Accelerate, in writing, before incorporating such Consultant Property into any Invention or Work; and (ii) Accelerate is hereby granted and shall have a nonexclusive, royalty-free, perpetual, irrevocable, worldwide license to make, have made, modify, use and sell such item as part of or in connection with such Invention or Work. Notwithstanding anything to the contrary herein, Consultant shall not incorporate any invention, improvement, development, concept, discovery or other proprietary information owned by any third party into any Invention or Work without Accelerate's prior written permission.

9. Debarment / Other Sanctions. Consultant hereby certifies that neither it, nor any personnel involved in the performance of the Services, is or has been debarred under the Generic Drug Enforcement Act of 1992, 21 U.S.C. Sec. 335a(a) or (b), or sanctioned by a Federal Health Care Program (as defined in 42 U.S.C. § 1320 a-7b(f)), including, but not limited to, the federal Medicare or a state Medicaid program, or debarred, suspended, excluded, or otherwise declared ineligible from any Federal agency or program. In the event that during the Term of this Agreement Consultant or any personnel involved in the performance of the Services (a) becomes debarred, suspended, excluded, sanctioned, or otherwise declared ineligible; or (b) receives notice of an action or threat of an action with respect to any such debarment, suspension, exclusion, sanction, or ineligibility, Consultant agrees to immediately notify Accelerate. Consultant also agrees that in the event that it or any personnel involved in the performance of the Services becomes debarred, suspended, excluded, sanctioned, or otherwise declared ineligible, Consultant shall immediately cease all activities relating to this Agreement and all Statements of Work, and this Agreement and all Statements of Work shall automatically terminate, without any further action or notice by either Party.

10. Indemnification. Consultant shall protect, defend, indemnify, and hold Accelerate and its affiliates and each of their respective directors, officers, employees, and agents, and their respective successors and permitted assigns (each an "Accelerate Indemnitee") harmless from and against any and all losses, liabilities, damages and expenses (including reasonable attorneys' fees and costs) ("Losses") that an Accelerate Indemnitee may suffer or incur as a result of any claims, actions, causes of action, demands, suits or other proceedings ("Claim"), which directly or indirectly arise out of or relate to (a) the breach by Consultant of any of its representations, warranties, covenants, agreements, or obligations set forth in this Agreement, including the Statement of Work, (b) the violation of applicable law, negligence, recklessness, or willful misconduct of Consultant, its agents or subcontractors in connection with the performance of Consultant's obligations hereunder, or (c) third party Claim of infringement or misappropriation of such third party's intellectual property rights, including patents, copyrights, or trade secrets arising from the Services, Deliverables, Inventions and Works.

11. Insurance. Consultant will carry, with financially sound and reputable insurers, insurance coverage (including worker's compensation at or above the applicable statutory limits, comprehensive liability coverage with contractual liability, and professional liability/errors and omissions coverage) with respect to the conduct of its business against loss from such risks and in such amounts as is customary for well-insured companies engaged in similar businesses and sufficient to support its obligations under this Agreement. Upon the request of Accelerate, Consultant will provide Accelerate with a Certificate of Insurance evidencing such coverage, and providing that thirty (30) days' advance written notice will be given to Accelerate of any material change or cancellation in coverage or limits.

12. Representations, Warranties and Covenants: Consultant represents, warrants and covenants that:

a. Consultant is under no obligation or restriction, nor will Consultant assume any such obligations or restriction, which would in any way interfere or be inconsistent with, or present a conflict of interest concerning, the Services to be furnished hereunder.

b. Consultant is qualified to perform all Services hereunder and shall perform such Services hereunder in a professional and ethical manner and in compliance with all applicable laws, rules, regulations and ordinances applicable to Consultant's performance of the Services and Consultant's other obligations under this Agreement. Consultant further understands that Accelerate has internal policies and procedures relating to the sale and promotion of medical devices, including, but not limited to Accelerate's Code of Business Conduct, Good Promotional Practices Policies and Complaint Handling Procedures, which are available for Consultant's review upon request. Consultant agrees to abide by such policies and procedures.

c. During the Term of this Agreement and for a period of twelve (12) months thereafter, Consultant will not directly or indirectly solicit, induce, or attempt to induce any employee or independent contractor of Accelerate to terminate or breach any employment, contractual, or other relationship with Accelerate.

13. Limitations of Liability. Except for damages or liability arising from (a) breach of the confidentiality obligations set forth in Section 5, (b) third party claims that are subject to indemnification herein or (c) the grossly negligent acts or omissions or willful misconduct or violation of law of a Party in performing its obligations hereunder: (i) in no event will either Party be liable for any loss of profits, loss of use, business interruption or indirect, special, incidental or consequential damages of any kind in connection with or arising out of this Agreement; and (ii) the entire liability of either Party to the other for direct damages from any cause whatsoever shall not exceed the amount of fees paid under the specific Statement of Work resulting in such liability.

14. Force Majeure. No liability shall result from the delay in performance or nonperformance caused by force majeure or circumstances beyond the reasonable control of the Party affected and could not have been reasonably foreseen and provided against, including, but not limited to, Acts of God, fire, flood, war, terrorism, embargo, any United States or foreign government regulation, direction or request, accident, strike or other labor dispute or labor trouble, or any failure or delay of any transportation, power or communications system or any other or similar cause beyond that Party's reasonable control. The Party which is so prevented from performing shall give prompt notice to the other Party of the occurrence of such event of force majeure, the expected duration of such condition and the steps which it is taking to correct such condition. Performance hereunder shall be promptly resumed after the applicable force majeure event has been remedied, otherwise this Agreement and/or the impacted Statement(s) of Work may be terminated as provided in Section 4. Nothing herein shall limit either Party's rights to terminate this Agreement for convenience as permitted in Section 4.

15. Entire Agreement. This Agreement sets forth the entire understanding and agreement of the Parties relating to the subject matter hereof and merges all prior advertising, discussions, proposals, agreements, communications, and representations between them, whether written or oral.

16. Independent Contractor. For the purposes of this Agreement, Consultant shall be an Independent Contractor without the authority to bind or act as agent for Accelerate or its employees for any purpose. All taxes and social security payments for which Consultant is liable shall be the sole responsibility of Consultant.

17. Assignment. This Agreement and each Statements of Work is personal to Consultant and may not be assigned by Consultant without the prior written consent of Accelerate. Any purported assignment in violation of the foregoing shall be null and void. The Parties' rights and obligations under this Agreement and each Statement of Work will bind and inure to the benefit of their respective successors, heirs, executors, and administrators and permitted assigns.

18. Injunctive Relief; Governing Law; Venue; Dispute Resolution. Consultant hereby acknowledges and agrees that in the event of any breach of this Agreement by Consultant, including, without limitation, the actual or threatened disclosure or unauthorized use of Confidential Information without the prior express written consent of Accelerate, Accelerate would suffer an irreparable injury such that no remedy at law would adequately protect or appropriately compensate Accelerate for such injury. Accordingly, Consultant agrees that Accelerate shall have the right to enforce this Agreement and any of its provisions by injunction, specific performance or other equitable relief, without bond and without prejudice to any other rights and remedies that Accelerate may have for a breach of this Agreement. The Parties mutually acknowledge and agree that this Agreement shall be construed and enforced in accordance with the laws of the State of Arizona. Any and all disputes between the Parties shall be resolved in accordance with the provisions of this Section. Any Party having a dispute with the other Party shall notify the other Party in writing of the nature of such dispute. The Parties, on receipt of such written notification, shall work together in good faith for a period of fifteen (15) days in order to resolve such disputes. If any disputes remain unresolved after the conclusion of such fifteen (15) day period, either Party may file for resolution of such dispute with the American Arbitration Association ("AAA") in Tucson, Arizona. On filing for such arbitration, Consultant shall appoint one arbitrator, Accelerate shall appoint a second arbitrator, and AAA shall appoint a third arbitrator. The prevailing Party in any dispute relating to this Agreement will be entitled to recover such Party's reasonable attorneys' fees and court costs, in addition to any other relief that such Party may be awarded.

19. Amendments. No modification to this Agreement shall be effective unless made in writing and duly executed by or on behalf of each Party.

20. Waiver. Either Party's failure to require strict compliance by the other with respect to the terms and conditions of this Agreement shall not be construed as ongoing or as a waiver by that Party of its right to later enforce any term or condition hereof in the event of a subsequent default by the other.

21. Severability. In the event that one or more of the provisions of this Agreement should be held to be invalid or unenforceable, the same shall not affect any other provision in this Agreement, which shall be reformed as if such invalid or illegal or unenforceable provision had never been contained therein.

22. Headings. The Section headings appearing in this Agreement are inserted only as a matter of convenience and in no way define, limit, construe, or describe the scope or intent of such Section, or in any way affect this Agreement.

23. Notice. All notices required under this Agreement must be in writing and shall be effective on the date received (unless the notice specifies a later date). Notice to a Party shall be sent to such Party's address as set forth above.

24. Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. The exchange of copies of this Agreement and of signature pages by facsimile transmission or .pdf delivered via email will constitute effective execution and delivery of this Agreement as to the Parties and may be used in lieu of the original Agreement for all purposes.

IN WITNESS WHEREOF, the authorized representatives of the Parties hereto have executed this Agreement as of the Effective Date.

Accelerate Diagnostics, Inc.	**Steve Reichling**
By: /s/ Jack Phillp	By:
Print Name: John J. Phillip	Date Signed: _____
Title: Chief Executive Office	
Date Signed: 4/3/2023	

Statement of Work No. 1

THIS Statement of Work No. 1 (the "Statement of Work") ") is entered into on March 9, 2023 with an effective date of **April 3, 2023** ("Statement of Work Effective Date") by and between Accelerate Diagnostics, Inc., 3950 S. Country Club Road, Suite 470, Tucson, AZ 85714 ("Accelerate"), and Steve Reichling having an address at **12598 North Yellow Bird Road, Oro Valley Arizona 85755** ("Consultant"), pursuant to that certain Consulting Services Agreement ("Agreement") entered into by and between Accelerate and Consultant on April 3, 2023.

1. Services

Accelerate engages Consultant to conduct various consulting Services that include the following:

a. Transition of intelligence and relationships to new head of operations.
b. Transition of intelligence and relationships to new CFO.
c. Support resolution of debt refinancing and ongoing financing strategy.
d. Aide investor relations strategy and outreach.

2. Fees and Payment Schedule

In consideration of the Services to be provided by Consultant with respect thereto, Accelerate agrees to compensate Consultant with an equity grant of 275,248 shares. These shares will be awarded on/about April 3, 2023. This grant will be subject to a time-based vesting schedule over a 9 month period, with 50% vesting on/about the Effective Date, 25% vesting on/about August 13, 2023, and the final 25% vesting on/about December 13, 2023. This grant is subject to such other terms and conditions specified by the Compensation Committee, the Equity Plan, the award agreement that you must execute as a condition of the grant, and the Company's insider trading policy.

Accelerate shall reimburse Consultant for all reasonable and necessary pre-approved out-of-pocket expenses incurred by Consultant in connection with the performance of Services provided hereunder. Accelerate and Consultant will agree on the exact content of the Services to be conducted prior to the initiation of the respective Services. Consultant is to work from home or at sites designated by Accelerate.

Invoices submitted to Accelerate shall be sent to:
Accounts Payable / Accelerate Diagnostics, Inc.
3950 S. Country Club Road, Suite 470
Tucson, Arizona 85714

3. Term

This Statement of Work Agreement commences on the Statement of Work Effective Date and expires on the earlier of December 29, 2023.

IN WITNESS WHEREOF, the authorized representatives of the Parties hereto have executed this Statement of Work as of March 9, 2023.

Accelerate Diagnostics, Inc.

By: /s/ Jack Phillip

Print Name: John J. Phillip

Title: Chief Executive Office

Steve Reichling

By: /s/ Steve Reichling

Date Signed: _3/31/2023_____

ACCELERATE
DIAGNOSTICS

June 23, 2022

Lawrence Mertz
Delivered Electronically via Email

Re: Change in Employment Status

Dear Larry:

Congratulations! We are delighted to enter into this Letter Agreement (the "Agreement") to memorialize the terms under which you will serve first as an employee of Accelerate Diagnostics, Inc. (the "Company") as Chief Technological Officer of the Company.

The effective date of this change is June 23, 2022 (the "Effective Date").

Provision	**Agreement**
Title; Reporting; Duties; No Conflicts:	Beginning on the Effective Date, you will serve as the Chief Technology Officer of the Company, reporting directly to the President and Chief Executive Officer of the Company. In your capacity as Chief Technology Officer you will have control over, and responsibility for, the technological direction of the Company and shall have such other duties, authorities and responsibilities commensurate for such or a similar position at a similarly-situated company and such additional duties as may be assigned to you by the President and Chief Executive Officer from time to time. You understand that, while you are employed as the Chief Technology Officer of the Company: (i) your employment services will be full-time and exclusive to the Company and that you will be expected to devote substantially all of your full business time, attention, energy and skills to the Company; (ii) you agree to serve the Company faithfully, loyally, honestly and to the best of your ability; and (iii) you will not, without the express written consent of the Board, engage in any other outside employment. The preceding paragraph is not intended to prohibit you from engaging in charitable or nonprofessional activities such as personal investments or conducting private business affairs, as long as they do not conflict or interfere with the performance of your duties to the Company. You agree to observe and comply with the Company's rules and policies, as the same may be adopted and amended from time to time. By signing this Agreement, you represent and warrant that you are under no contractual or other obligations or commitments that are inconsistent with your obligations under this Agreement, including, without limitation, any restrictions that would preclude you from providing services to the Company (*e.g.*, a non-compete with a former employer).

Lawrence Mertz
June 23, 2022

Base Salary:	As of the Effective Date, there will be no change to your current Base Salary. Your Base Salary will be reviewed at least annually and may be adjusted upward or downward by the Compensation Committee of the Board of Directors (the "Compensation Committee") in its sole discretion.
Opportunity:	Beginning with the Effective Date and for each full calendar year during the Term thereafter, you will be eligible to participate in an annual cash incentive program adopted in writing and approved by the Compensation Committee (the "AIP"). Your target incentive under the AIP will equal 60% of your Base Salary. Whether you are entitled to receive an AIP payment, and the amount of such payment, will depend on the attainment of written quantitative and qualitative performance goals, including financial performance goals, establish by the Compensation Committee in its sole discretion. The amount of the AIP, if any, will be certified by the Compensation Committee in January or February of the year following the year to which the AIP relates, and the earned AIP, if any, will be paid to you on or about March 15 of the year following the year to which the AIP relates (*e.g.*, the AIP for 2022, if any, will be paid on or about March 15, 2023). Except as set forth below, you must be employed by the Company through the date the AIP is paid in order to earn and be eligible to receive the AIP.
Long-Term Incentive Compensation:	As of the Effective Date, you will be eligible to receive grants of stock options, performance shares and other awards under the Equity Plan (the "Equity Awards"). The amount of Equity Awards, the mix of Equity Awards, the vesting schedule and the other terms and conditions of the Equity Awards will be established by the Compensation Committee in its sole discretion, provided, that your Equity Award grant will equal 150% of your then Base Salary. The Equity Awards will be subject to such other terms and conditions specified by the Compensation Committee, the Equity Plan, the award agreement that you must execute as a condition of the grant(s), and the Company's insider trading policy.
Benefits; Vacation:	During the Term, you will be eligible to participate in the Company's standard company benefit and vacation plans, as such plans may be amended, modified, or terminated by the Company from time to time, with or without notice, in accordance with the applicable benefit and vacation plan documents. For the avoidance of doubt, your participation in such plans will be subject to the terms and conditions set forth in the applicable benefit plan documents.
Term:	Your employment with the Company is at-will and either you or the Company may terminate your employment at any time and for any reason, with or without Cause in each case subject to the terms and provisions of this Agreement. Unless otherwise indicated in a writing to you from the Board of Directors (the "Board"), upon your termination of employment with Company for any reason, and without any further action on your part,

you will be deemed to immediately resign all other officerships, directorships, managerships, and other positions you hold with the Company and its affiliates. If for any reason this provision is determined to be insufficient to effectuate such resignations, you agree to sign any documents or instruments the Company determines necessary to effectuate such resignations.

Termination of Employment:

This Agreement, and your employment hereunder, may be terminated at any time, for any reason, by you or the Company upon at least 30 days prior written notice, provided, that, the Company may terminate your employment immediately for Cause. Upon your termination for any reason, the Company will pay you your accrued but unpaid Base Salary through your date of termination and any accrued but unpaid reasonable business expenses through your date of termination (the "Accrued Obligations"), with such amount paid in compliance in accordance with applicable law. In addition to the Accrued Obligations, you may be entitled to receive severance benefits and Equity Award acceleration as described below.

Death or Disability:

This Agreement, and your employment hereunder, will terminate immediately upon your death or Disability (as defined in Exhibit A). In such case, you (or your spouse or estate) will be entitled to the Accrued Obligations.

Termination and Severance Prior to a Change of Control:

In the event your full-time employment is terminated by the Company without Cause or by you with Good Reason (as defined in Exhibit A) prior to a Change of Control (as defined in Exhibit A then, in addition to the Accrued Obligations, and subject to your timely execution (and non-revocation) of the release described below, you will be entitled to receive a cash severance payment equal to the sum of: (i) 12 months of your then Base Salary; and (ii) your average earned AIP for over the Term (collectively, the "Base Severance Amount"). The Base Salary Severance Amount will be paid to you in installments over a 12-month period, in accordance with the Company's normal payroll cycle, with the first installment paid during the first payroll period following the expiration of the release revocation period described below. In addition to the Base Severance Amount, you will be entitled to receive a pro-rata AIP for the year in which your termination occurred, with such pro-rata AIP paid at the same time described above.

Full Vesting of Equity Awards on Change of Control:

Upon the closing of a transaction that results in a Change of Control, and notwithstanding anything in the Equity Plan to the contrary, your Option and other Equity Awards shall fully vest and become exercisable.

Termination and Severance Following a Change of Control:

In the event your full-time employment is terminated by the Company without Cause or by you with Good Reason (as defined in Exhibit A) during the 12 month period ***following*** a Change of Control, then, in

addition to the Accrued Obligations, and subject to your timely execution (and non-revocation) of the release described below, you will be entitled receive a cash severance payment equal to the sum of: (i) 18 months of your then Base Salary; and (ii) 18 times the monthly amount that is charged to COBRA qualified beneficiaries for the same medical coverage options elected by you immediately prior to your last day of employment (collectively, the "Enhanced Severance Amount"). The Enhanced Severance Amount will be paid to you in installments over an 18 month period, in accordance with the Company's normal payroll cycle, with the first installment paid during the first payroll period following the expiration of the release revocation period described below. In addition to the Enhanced Severance Amount, you will be entitled to receive a pro-rata AIP for the year in which your termination occurred, with such pro-rata AIP paid at the same time described above.

Release Required to Receive Severance:

In order to receive the severance pay and other benefits described above, you must, no later than 60 days following your last day of employment, execute (and not revoke) a general release and waiver of any claims that you may have in connection with your employment and termination of employment with the Company and its affiliates. Notwithstanding anything in this Agreement to the contrary, if the Company concludes that the severance pay and benefits are subject to Section 409A of the Internal Revenue Code, and if the consideration period described in the release, plus the revocation period described in the release spans two (2) calendar years, then, to the extent required by Section 409A of the Code, such severance payments and benefits shall not begin to be paid until the second calendar year (and such first installment shall include installment payments that would otherwise have been made prior to such date).

Restrictive Covenants:

This offer is contingent upon you signing the Restrictive Covenant Agreement attached hereto as Exhibit B.

Cooperation:

Following the termination of your service with the Company for any reason, you agree to cooperate fully with the Company and with the Company's counsel in connection with any present and future actual or threatened litigation, administrative proceeding or other investigation involving the Company or any affiliate that relates to events, occurrences or conduct occurring (or claimed to have occurred) during your employment. You are hereby instructed to tell the truth in any litigation, administrative proceeding, or other investigation involving the Company and nothing herein shall be deemed or construed to suggest otherwise. If your cooperation is required pursuant to this section, the Company will: (i) reimburse you for reasonable out-of-pocket expenses (excluding legal fees); and (ii) pay you hourly compensation at a rate equivalent to your hourly Base Salary at the time of your termination of employment.

Non-Disparagement; Social Media:

During the Term and following the termination of your service for any reason, you agree that you will not criticize, defame, be derogatory

toward or otherwise disparage the Company, its products, services, or the Company's past, present and future officers, directors, managers, stockholders, agents, representatives, employees, or affiliates, or its or their business plans or actions, to any third-party, either orally or in writing; provided that that this provision will not preclude you from giving truthful testimony in response to a lawful subpoena or preclude any conduct protected under any local, state or federal law, including those providing "whistleblower" protection to you or the right to engage in concerted activities. The Company also agrees that it will instruct its senior management and Board, as constituted as of your last day of employment, not to issue any official statements or press releases that disparage you; provided, that, you acknowledge and agree that senior management and the Board are permitted to discuss your employment and performance internally and confidentially as required to conduct business, or to make any legally required disclosures, or if otherwise required under law, in each such instance as reasonably determined by the Company or pursuant to the advice of the Company's legal counsel. Finally, on the date of your termination of service for any reason, you agree to update your profile on social media websites (such as LinkedIn) to reflect that you are no longer an employee of the Company.

Dispute Resolution:

You and the Company agree to meet to informally in a good faith effort to resolve any issues arising under this Agreement. If the parties are unable to resolve their differences, they agree to submit to binding arbitration in Tucson, Arizona, any and all claims and disputes arising hereunder. The parties agree that any dispute will be heard by a single arbitrator, applying Arizona and Federal substantive law, as applicable, in accordance with the American Arbitration Association's Employment Arbitration Rules. If necessary, an action may be brought in any court of competent jurisdiction solely to compel arbitration or enforce an arbitration award (or for injunctive relief to enforce the Restrictive Covenants of this Agreement). This agreement to arbitrate survives the termination of your employment.

You expressly agree and understand that, by agreeing to arbitration to resolve all claims described herein, **you, as well as the Company, are waiving your right to a jury or court trial for all such claims.** You further understand that arbitration is a private, claim resolution process which utilizes a neutral third-party, instead of a judge or jury, to resolve all claims and typically has more limited discovery than in a case filed in court. You understand that you may refuse to sign this Agreement, but that if the Agreement is not signed, you will not be entitled to the compensation and benefits outlined in this Agreement.

_____
Employee must initial above, indicating his agreement to submit all claims to arbitration.

Return of Property:

Upon the Company's request or your termination of employment for any reason, you shall promptly return to the Company all property of the Company, including but not limited to: originals and hard and electronic copies of records, documents, Confidential Information,

computer and office equipment, other equipment, plans, designs, electronic devices, keys, access cards, passwords, credit cards, and other tangible and intangible items, in whatever form, in your possession or control. You understand that all electronic mail, equipment, and all computer hardware and software are property of the Company.

Miscellaneous:

To the extent required by law, the Company shall withhold from any payments due to you under this Agreement any applicable federal, state or local taxes. You hereby acknowledge that neither the Company nor any of its affiliates, shareholders, members, directors, managers, officers, employees, agents or representatives have provided you with any tax-related advice with respect to the matters covered by this Agreement and that you are solely responsible for obtaining your own tax advice with respect to the matters covered by this Agreement.

This Agreement shall be governed by and construed in accordance with the laws of the State of Arizona without regard to conflicts of law principles. If any term or provision of this Agreement is declared by a court or tribunal of competent jurisdiction to be invalid or unenforceable for any reason, this Agreement shall remain in full force and effect, and either: (i) the invalid or unenforceable provision shall be modified to the minimum extent necessary to make it valid and enforceable; or (ii) if such a modification is not possible, this Agreement shall be interpreted as if such invalid or unenforceable provision were not a part hereof.

Each party acknowledges that such party had the opportunity to be represented by counsel in the negotiation and execution of this Agreement. Accordingly, the rule of construction of contract language against the drafting party is hereby waived by each party.

Section 409A of the Code:

This Agreement shall comply with Section 409A of the Internal Revenue Code or an exception thereto and each provision of the Agreement shall be interpreted, to the extent possible, to comply with Section 409A or an exception thereto. Nevertheless, the Company does not and cannot guarantee any particular tax effect or treatment of the amounts due under this Agreement. Except for the Company's responsibility to withhold applicable income and employment taxes from compensation paid or provided to you, the Company will not be responsible for the payment of any applicable taxes on compensation paid or provided pursuant to this Agreement. Neither the time nor schedule of any payment under this Agreement may be accelerated or subject to further deferral except as permitted by Section 409A of the Internal Revenue Code and the applicable regulations. You do not have any right to make any election regarding the time or form of any payment due under this Agreement. Notwithstanding anything in this Agreement to the contrary, if the Company concludes, that the Base Severance Amount or the Enhanced Severance Amount are subject to Section 409A of the Internal Revenue Code, then no such Severance Amount will be paid prior to your "separation from service" as defined in Treasury Regulation Section 1.409A-1(h) (applying the default rules of Treasury Regulation Section 1.409A-1(h)). Installment payments

made pursuant to this Agreement shall be treated as separate payments for purposes of Treasury Regulation Section 1.409A-2(b)(2)(iii).

If the Base Severance Amount or the Enhanced Severance Amount are subject to Section 409A of the Internal Revenue Code, and if you are a "specified employee" as defined in Treasury Regulation Section 1.409A-1(i)(1) on the date of your termination of employment, such payments shall not begin until the first day of the seventh month following your "separation from service" as defined in Treasury Regulation Section 1.409A-1(h) (applying the default rules of Treasury Regulation Section 1.409A-1(h)) (and such first payment shall include all prior payments that would otherwise have been made prior to such date).

Section 280G of the Code: In the event that any payments, distributions, benefits or entitlements of any type payable to you, whether or not payable upon a termination of employment ("Payments"): (i) constitute "parachute payments" within the meaning of Section 280G of the Code; and (ii) but for this Section would be subject to the excise tax imposed by Section 4999 of the Internal Revenue Code (the "Excise Tax"), then the Payments shall be reduced to such lesser amount (the "Reduced Amount") that would result in no portion of the Payments being subject to the Excise Tax; provided, however, that such Payments shall not be so reduced if a nationally recognized accounting firm or compensation consulting firm selected by the Company (the "Accountants") determines that without such reduction, you would be entitled to receive and retain, on a net after-tax basis (including, without limitation, any excise taxes payable under Section 4999 of the Internal Revenue Code, federal, state and local income taxes, social security and Medicare taxes and all other applicable taxes, determined by applying the highest marginal rates which applied (or is likely to apply) to you for the tax year in which the Payments are to be made, or such other rate(s) as the Accountants determine to be likely to apply to you in the relevant tax year(s) in which any of the Payments are expected to be made), an amount that is greater than the amount, on a net after-tax basis, that you would be entitled to retain upon receipt of the Reduced Amount. Unless otherwise agreed in writing, any determination made under this paragraph shall be made in good faith by the Accountants in a timely manner and shall be binding on the parties absent manifest error. In the event of a reduction of Payments pursuant to this paragraph, the Payments shall be reduced in the order determined by the Accountants that results in the greatest economic benefit to you in a manner that would not result in subjecting you to additional tax under Section 409A of the Internal Revenue Code. For purposes of making the calculations required by this paragraph, the Accountants may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of the Internal Revenue Code, and other applicable legal authority. The Accountants shall provide detailed supporting calculations to both you and the Company and the Company shall bear the cost of all fees charged by the Accountants in connection with any calculations contemplated by this paragraph. If the provisions of

Sections 280G and 4999 of the Internal Revenue Code are repealed without succession or if the Company determines that such provisions do not apply to it and/or you for whatever reason, this paragraph shall be of no further force or effect.

If you are in agreement with the terms and conditions of this Agreement, please execute and date the Agreement and return a copy to me.

Sincerely,

Accelerate Diagnostics, Inc.

By: _____ 7/8/2022
Jack Phillips, President and Chief Executive Officer

Accepted and agreed to:

_____ July 19, 2022
Lawrence Mertz Date

Lawrence Mertz
June 23, 2022

Exhibit A

Employment Letter Definitions

"Cause" to terminate your employment shall exist if the Company reasonably determines after due inquiry that any one or more of the following has occurred: (i) your commission or conviction of, or plea of guilty or nolo contendere to, a felony; (ii) your material breach of this Agreement, any other agreement you have entered into with the Company, or of any fiduciary duty you have to the Company; (iii) misconduct that is materially injurious to the Company or a significant violation of the Company's harassment or discrimination policies; (iv) your habitual drug or alcohol use which materially impairs your ability to perform your duties for the Company; (v) your engaging in fraud, embezzlement or any other illegal conduct that is materially injurious to the Company or any of its affiliates; (vi) deliberate or intentional refusal, or habitual failure to discharge your employment duties, responsibilities or obligations or to follow the Company's policies or procedures which is not cured, if curable, within 10 days following the Company's written notice to you of such behavior; or (vii) your engaging in any illegal, unethical, or immoral act (inside or outside of the scope of your employment) that results in material reputational or financial harm to the Company or any of its affiliates. In the case of a termination for Cause as a result of a material breach of this Agreement, you will be provided a written notice describing the breach at least 30 days prior to the proposed termination date and you will have 15 days to cure such breach (and whether such breach is capable of being cured or is adequately cured will be determined by the Company, in good faith). For the avoidance of doubt, the Company will have the right to suspend you with pay during the 30 day notice period and the 15 day cure period described in the preceding sentence.

"Change of Control" shall have the meaning ascribed to it in the Equity Plan.

"Disability" means you are unable to perform your duties under this Agreement for 90 consecutive days in any 12-month period.

"Good Reason" means: (i) a material diminution of your base compensation; (ii) a material diminution of your authorities, duties, or responsibilities; (iii) any action or inaction that constitutes a material breach of this Agreement by the Company; or (iv) material change in the geographic location at which you are required to provide services. For a termination to constitute "Good Reason" for purposes of this Agreement: (1) you must provide a notice of termination to the Company within 30 days of the initial existence of the facts or circumstances constituting such event; (2) the Company must fail to cure such facts or circumstances within 30 days after receipt of such notice; and (3) you must actually terminate your employment within 30 days after the expiration of the cure period described in clause (2).

Lawrence Mertz
June 23, 2022

Exhibit B

Employee Restrictive Covenant Agreement

In consideration for Accelerate Diagnostics, Inc. (the "Company") agreement to employ me and provide me with the compensation and benefits described in the attached Offer Letter and access to the Company's Confidential Information (as defined below) and trade secrets, I understand, acknowledge and agree, beginning as of the Part-Time Start Date (as defined in the attached Offer Letter), as follows:

Restrictive Covenants:

Non-Solicitation of Customers/Prospective Customers. You agree, for the duration of the Time Limit (as defined below), that you will not, either directly or indirectly, or in any individual or representative capacity, request or solicit any of the Company's current customers or clients with whom you have had contact in the past year to withdraw, curtail, cancel, or decrease the level of their business with the Company or request that they do business with any third party in competition with the Company. You further agree that, for the duration of the Time Limit, you will not, either directly or indirectly, or in any individual or representative capacity, request or solicit any of the Company's prospective customers (defined as any person or entity who has been directly solicited to become a customer or client by the Company and with whom you have had contact with within the past year or possesses Confidential Information about) or clients with whom you have had contact with in the past year or possesses Confidential Information about to forgo doing business with the Company or request that such prospective customer or client do business with any third party in competition with the Company.

Non-Solicitation of Employees/Applicants. You agree, for the duration of the Time Limit, that you will not, either directly or indirectly, or in any individual or representative capacity, solicit, induce or encourage or attempt to solicit, induce or encourage any Company employee and/or applicant to terminate his/her employment or prospective employment with the Company.

Non-Competition. You agree, for the duration of the Time Limit, (as defined below), that you will not, either directly or indirectly or in any individual or representative capacity, be employed by, engage, own, manage, operate, control, aid, or assist another in the operation, organization or promotion of, participate in, advise, contract with or otherwise engage in any manner with the ownership, management, operation, or control of any business, which has a place of business or regularly conducts business in the Geographical Limit (as defined below) and that promotes or sells products or services competitive with those of the Company. You acknowledge and agree that a business will be deemed "competitive" with the Company if it performs any of the services or produces, distributes or sells any of the products or services provided or offered by the Company during the term of your relationship with the Company.

Tolling. The non-competition and non-solicitation Time Limits set forth above shall be tolled during any period in which you are in breach of the restrictions set forth herein.

Reasonable Limitations. You hereby acknowledge and agree that the covenants and obligations made and undertaken in this Agreement are fair and reasonable with respect to duration, geographic area and scope of activity, and do not (and shall not) prevent you from earning a livelihood in complying with the covenants herein.

Injunctive Relief. You agree that a breach of the covenants described herein will result in substantial and irreparable damages to the Company, which would be difficult to fully ascertain and calculate, and, by reason of such fact, you agree that, in the event of any such breach or threatened or anticipated breach, the Company will have the right to a restraining order and injunction, both temporary and permanent, enjoining and restraining any such breach or threatened breach, without the necessity of proving actual damages or posting a bond. Such injunctive relief will be in addition to any other remedies available to the Company at law or in equity.

Survival of Restrictive Covenants. Your acknowledgements and agreements set forth in this Agreement shall survive the expiration or termination of this Agreement and the termination of your employment with the Company for any reason.

Notice to Future Employers: You agree that you will notify, and the Company shall have the right to notify, any future or prospective employers, or individuals or entities with whom you may be entering into a contractual relationship, of the Restrictive Covenant provisions of this Agreement for purposes of ensuring that the Company's interests are protected.

Company Proprietary Information: While you are providing services to the Company, the Company may disclose or make available to you, Confidential Information. By signing this Agreement, you agree to: (i) protect and safeguard the confidentiality of the Confidential Information with at least the same degree of care as you would protect your own confidential information, but in no event with less than a commercially reasonable degree of care; and (ii) not use or disclose the Confidential Information, or permit it to be accessed, used or disclosed, for any purpose other than to carry out the duties assigned to you by the Company or as may be required to be disclosed pursuant to applicable federal, state or local law, regulation or a valid order issued by a court or governmental agency of competent jurisdiction. Upon your termination of service for any reason, or upon the Company's written request, you shall promptly return to the Company all copies, whether in written, electronic or other form or media, of the Confidential Information, or destroy all such copies at the Company's written request and certify in writing to the Company that such Confidential Information has been destroyed. In addition to all other remedies available at law, the Company may seek equitable relief (including injunctive relief) against you to prevent the breach or threatened breach of this confidentiality covenant and to

secure its enforcement. Notwithstanding anything in this Agreement to the contrary, pursuant to the Defend Trade Secrets Act of 2016, you shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that: (a) is made in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney; and solely for the purpose of reporting or investigating a suspected violation of law; or (b) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. If you file a lawsuit for retaliation by the Company for reporting a suspected violation of law, you may disclose the Company's trade secrets to your attorney and use the trade secret in the court proceeding, if you file any document containing the trade secret under seal and do not disclose the trade secret, except pursuant to court order.

In addition to the obligations above, we may ask that you also sign the Company's standard Confidentiality and Intellectual Property Assignment Agreement.

Definitions:

For purposes of this Agreement, the following terms shall have the following meanings:

"Confidential Information" means non-public information about the Company's business affairs, products, services, confidential intellectual property, trade secrets, third-party confidential information and other sensitive or proprietary information, whether orally or in written, electronic or other form or media, and whether or not marked, designated or otherwise identified as "confidential." Confidential Information shall not include information that, at the time of disclosure and as established by documentary evidence: (i) is or becomes generally available to and known by the public other than as a result of, directly or indirectly, any breach of this Agreement by you; (ii) is or becomes available to you on a non-confidential basis from a third-party source, provided that such third-party is not and was not prohibited from disclosing such Confidential Information; (iii) was known by or in the possession of you prior to being disclosed by or on behalf of the Company; or (iv) was or is independently developed by you without reference to or use, in whole or in part, of any of the Confidential Information.

"Geographical Limit" means the United States of America; if a court determines that the United States of America is too broad, then the state of Arizona; if a court determines that Arizona is too broad, then Maricopa and Pima County; if a court determines that Maricopa and Pima County is too broad, then Pima County only; if a court determines that Pima County is too broad, then Tucson, Arizona.

"Time Limit" means the term of your employment with the Company and for a period of 18 months thereafter; if a court determines that 18 months is longer than necessary to protect the Company's legitimate interests, then 12 months; if a court determines 12 months is longer than necessary to protect the Company's legitimate interests, then 9 months.

Miscellaneous:

This Agreement shall be governed by and construed in accordance with the laws of the State of Arizona without regard to conflicts of law principles. If any term or provision of this Agreement is declared by a court or tribunal of competent jurisdiction to be invalid or unenforceable for any reason, this Agreement shall remain in full force and effect, and either: (i) the invalid or unenforceable provision shall be modified to the minimum extent necessary to make it valid and enforceable; or (ii) if such a modification is not possible, this Agreement shall be interpreted as if such invalid or unenforceable provision were not a part hereof.

Each party acknowledges that such party had the opportunity to be represented by counsel in the negotiation and execution of this Agreement. Accordingly, the rule of construction of contract language against the drafting party is hereby waived by each party.

The dispute resolution provisions of the Offer Letter attached hereto are incorporated by reference and by signing below you acknowledge and agree that any dispute arising under this Agreement will be resolved in accordance with the procedures set forth in the Offer Letter.

Accepted and agreed to:

Lawrence Mertz

July 19, 2022
Date

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-1 No. 333-276031) 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. 333-225585) pertaining to the 2012 Omnibus Equity Incentive Plan of Accelerate Diagnostics, Inc.,

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

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

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

(9) Registration Statement (Form S-8 No. 333-272792) pertaining to the 2022 Omnibus Equity Incentive Plan of Accelerate Diagnostics, Inc.

of our report dated March 28, 2024, 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, 2023.

/s/ Ernst & Young LLP

Phoenix, Arizona
March 28, 2024

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 28, 2024

/s/ Jack Phillips

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

EXHIBIT 31.2

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

I, David Patience, 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 28, 2024

/s/ David Patience

David Patience
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, 2023 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 28, 2024

/s/ Jack Phillips

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

March 28, 2024

/s/ David Patience

David Patience
Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT 97

ACCELERATE DIAGNOSTICS, INC.
Clawback Policy for the Recovery of Erroneously Awarded Compensation

In accordance with the applicable rules of The Nasdaq Stock Market (the "NASDAQ Rules"), Section 10D and Rule 10D-1 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") ("Rule 10D-1"), the Board of Directors (the "Board") of Accelerate Diagnostics, Inc. ("Accelerate") has adopted this Policy (this "Policy") effective as of December 1, 2023 to provide for the recovery of erroneously awarded Incentive-Based Compensation from Section 16 Officers.

All capitalized terms used and not otherwise defined herein shall have the meanings set forth in Section 2, below.

1. **Applicability.** This Policy applies to all Incentive-Based Compensation Received by a Section 16 Officer (each as defined below).
2. **Definitions.** For purposes of this Policy, the following capitalized terms shall have the meanings set forth below.

"Accounting Restatement" means an accounting restatement due to the material noncompliance of Accelerate with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements (a "Big R" restatement), or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period (a "little r" restatement). An out-of-period of adjustment – when the error is immaterial to the previously issued financial statements, and the correction of the error is also immaterial to the current period – does not trigger a compensation recovery under this Policy because it is not an "accounting restatement".

"Clawback Eligible Incentive Compensation" means all Incentive-Based Compensation Received by a Section 16 Officer (i) on or after October 2, 2023; (ii) after beginning service as a Section 16 Officer; (iii) who served as a Section 16 Officer at any time during the applicable performance period relating to any Incentive-Based Compensation (whether or not such Section 16 Officer is serving at the time the Erroneously Awarded Compensation is required to be repaid to Accelerate); (iv) while Accelerate has a class of securities listed on a national securities exchange or a national securities association; and (v) during the applicable Clawback Period (as defined below).

"Clawback Period" means, with respect to any Accounting Restatement, the three completed fiscal years of Accelerate immediately preceding the Restatement Date (as defined below), and if Accelerate changes its fiscal year, any transition period of less than nine months within or immediately following those three completed fiscal years.

"Erroneously Awarded Compensation" means, with respect to each Section 16 Officer in connection with an Accounting Restatement, the amount of Clawback Eligible Incentive Compensation that exceeds the amount of Incentive-Based Compensation that otherwise would have been Received had it been determined based on the restated amounts, computed without regard to any taxes paid.

"Financial Reporting Measures" means measures that are determined and presented in accordance with the accounting principles used in preparing Accelerate's financial statements, and all other measures that are derived wholly or in part from such measures. Stock price and total shareholder return (and any measures that are derived wholly or in part from stock price or total shareholder return) shall, for purposes of this Policy, be considered Financial Reporting Measures. For the avoidance of doubt, a Financial Reporting Measure need not be presented in Accelerate's financial statements or included in a filing with the SEC.

"Incentive-Based Compensation" means any compensation that is granted, earned or vested based wholly or in part upon the attainment of a Financial Reporting Measure.

"NASDAQ" means The Nasdaq Stock Market.

"Received" means, with respect to any Incentive-Based Compensation, actual or deemed receipt. Incentive-Based Compensation shall be deemed received in Accelerate's fiscal period during which the Financial Reporting Measure specified in the Incentive-Based Compensation award is attained, even if the payment or grant of the Incentive-Based Compensation to the Section 16 Officer occurs after the end of that period.

For purposes of illustration only, a performance-based stock unit award is made to an executive (i) with the number of units determined at the end of a three-year performance period ending on December 31, 2022 and (ii) subject to continued employment until December 31, 2024. While the executive would not have a non-forfeitable interest in the award until the end of 2024, if an Accounting Restatement was made in 2023 for any of the fiscal years within the three-year Clawback Period (fiscal years 2020, 2021 or

2022), this Policy would require a recalculation of the number of units that will ultimately vest at the end of 2024.

"Restatement Date" means the earlier to occur of (i) the date the Board, a committee of the Board or the officers of Accelerate authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that Accelerate is required to prepare an Accounting Restatement, or (ii) the date a court, regulator or other legally authorized body directs Accelerate to prepare an Accounting Restatement.

"Section 16 Officer" means each individual who is currently or was previously designated as an "officer" of Accelerate as defined in Rule 16a-1(f) under the Exchange Act, including the president, principal financial officer, principal accounting officer, any vice-president of the issuer in charge of a principal business unit, division or function (such as sales, administration or finance), any other officer who performs a policy-making function, or any other person who performs similar policy-making functions for Accelerate. For the avoidance of doubt, the identification of Section 16 Officer for purposes of this Policy shall include each executive officer who is or was identified pursuant to Item 401(b) of Regulation S-K or Item 6.A of Form 20-F, as applicable, as well as the principal financial officer and principal accounting officer (or, if there is no principal accounting officer, the controller).

1. **Recovery of Erroneously Awarded Compensation.**

a. In the event of an Accounting Restatement, Accelerate will reasonably promptly recover the Erroneously Awarded Compensation Received in accordance with NASDAQ rules and Rule 10D-1 as follows:

a. After an Accounting Restatement, the Compensation and Nominating Committee (if composed entirely of independent directors, or in the absence of such a committee, a majority of independent directors serving on the Board) (the "Committee") shall determine the amount of any Erroneously Awarded Compensation Received by each Section 16 Officer and shall promptly notify each Section 16 Officer with a written notice containing the amount of any Erroneously Awarded Compensation and a demand for repayment or return of such compensation, as applicable.

For Incentive-Based Compensation based on (or derived from) Accelerate's stock price or total shareholder return, where the amount of Erroneously Awarded Compensation is not subject to mathematical recalculation directly from the information in the applicable Accounting Restatement:

a. The amount to be repaid or returned shall be determined by the Committee based on a reasonable estimate of the effect of the Accounting Restatement on Accelerate's stock price or total shareholder return upon which the Incentive-Based Compensation was Received; and

b. Accelerate shall maintain documentation of the determination of such reasonable estimate and provide the relevant documentation as required to NASDAQ.

a. The Committee shall have discretion to determine the appropriate means of recovering Erroneously Awarded Compensation based on the particular facts and circumstances.

Accelerate shall pursue the recovery of the compensation subject to this Policy reasonably promptly, using an appropriate balance of cost and speed in determining the appropriate means to seek recovery. Accelerate may establish a deferred payment plan that allows repayment by a Section 16 Officer as soon as possible without unreasonable economic hardship to the Section 16 Officer, depending on the particular facts and circumstances. A deferred repayment plan would generally not be a prohibited personal loan, but unpaid amounts would be subject to disclosure under Item 402 of Regulation S-K.

Notwithstanding the foregoing, except as set forth in Section 3(b) below, in no event may Accelerate accept an amount that is less than the amount of Erroneously Awarded Compensation in satisfaction of a Section 16 Officer's obligations hereunder.

a. To the extent that the Section 16 Officer has already reimbursed Accelerate for any Erroneously Awarded Compensation Received under any duplicative recovery obligations established by Accelerate or applicable law, such reimbursed amount will to be credited to the amount of Erroneously Awarded Compensation that is subject to recovery under this Policy.

b. To the extent that a Section 16 Officer fails to repay all Erroneously Awarded Compensation to Accelerate when due, Accelerate shall take all actions reasonable and appropriate to recover such Erroneously Awarded Compensation from the applicable Section 16 Officer. The applicable Section 16 Officer shall be required to reimburse Accelerate for any and all expenses reasonably incurred (including legal fees) by Accelerate in recovering such Erroneously Awarded Compensation in accordance with the immediately preceding sentence.

a. Notwithstanding anything herein to the contrary, Accelerate shall not be required to take the actions contemplated by Section 3(a) above if the Committee determines that recovery would be impracticable and any of the following two conditions are met:
a. The Committee has determined that the direct expenses paid to a third party to assist in enforcing the Policy would exceed the amount to be recovered. Before making this determination, Accelerate must make a reasonable attempt to recover the Erroneously Awarded Compensation, document such attempt(s), and provide such documentation to NASDAQ; or
b. Recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of Accelerate, to fail to meet the requirements of Section 401(a)(13) or Section 411(a) of the Internal Revenue Code of 1986, as amended, and regulations thereunder.

1. **Disclosure Requirements.** Accelerate shall file all disclosures with respect to this Policy required by applicable U.S. Securities and Exchange Commission ("SEC") filings and rules.
2. **Prohibition of Indemnification.** Accelerate shall not insure or indemnify any Section 16 Officer against (i) the loss of any Erroneously Awarded Compensation that is repaid, returned or recovered pursuant to the terms of this Policy; or (ii) any claims relating to Accelerate's enforcement of its rights under this Policy.
3. **No Exemption.** Accelerate shall not enter into any agreement that exempts any Incentive-Based Compensation that is granted, paid or awarded to a Section 16 Officer from the application of this Policy or that waives Accelerate's right to recovery of any Erroneously Awarded Compensation, and this Policy shall supersede any such agreement (whether entered into before, on or after the Effective Date of this Policy).

Each Section 16 Officer shall sign a return a copy of the Attestation and Acknowledgement attached to this Policy as Exhibit A before any Incentive-Based Compensation is Received by such Section 16 Officer.

1. **Administration and Interpretation.** This Policy shall be administered by the Committee, and any determinations made by the Committee shall be final and binding on all affected individuals. The Committee is authorized to interpret and construe this Policy and to make all determinations necessary, appropriate or advisable for the administration of this Policy and for Accelerate's compliance with NASDAQ Rules, Section 10D, Rule 10D-1 and any other applicable law, regulation, rule or interpretation of the SEC or NASDAQ promulgated or issued in connection therewith.
2. **Amendment; Termination.** The Committee may amend this Policy from time to time in its discretion and shall amend this Policy as it deems necessary. Notwithstanding anything in this Section 7 to the contrary, no amendment or termination of this Policy shall be effective if such amendment or termination would (after taking into account any actions taken by Accelerate contemporaneously with such amendment or termination) cause Accelerate to violate any federal securities laws, SEC rule or NASDAQ rule.
3. **Other Recovery Rights.** This Policy shall be binding and enforceable against all Section 16 Officers and, to the extent required by applicable law or guidance from the SEC or NASDAQ, their beneficiaries, heirs, executors, administrators or other legal representatives. The Board intends that this Policy will be applied to the fullest extent required by applicable law. Any employment agreement, equity award agreement, compensation plan or any other agreement or arrangement with a Section 16 Officer shall be deemed to include, as a condition to the grant of any benefit thereunder, an agreement by the Section 16 Officer to abide by the terms of this Policy.

Any right of recovery under this Policy is in addition to, and not in lieu of, any other remedies or rights of recovery that may be available to Accelerate under applicable law, regulation or rule or pursuant to the terms of any policy of Accelerate or any provision in any employment agreement, equity award agreement, compensatory plan, agreement or other arrangement.

Secretary's Certificate

This Accelerate Diagnostics, Inc. Clawback Policy for the Recovery of Erroneously Awarded Compensation was unanimously approved by the Board at its meeting on November 8, 2023.

/s/ Davide Patience
David Patience, Secretary

Exhibit A

ACCELERATE DIAGNOSTICS, INC.
Clawback Policy for the Recovery of Erroneously Awarded Compensation
Attestation and Acknowledgement

By my signature below, I acknowledge and agree that:
I have received and read the attached Clawback Policy for the Recovery of Erroneously Awarded Compensation (the "Policy").
I hereby agree to abide by all of the terms of this Policy both during and after my employment with Accelerate, including, without limitation, by promptly repaying or returning any Erroneously Awarded Compensation to Accelerate as determined in accordance with the Policy.

Signature Date

Name