

Accelerate Diagnostics, Inc
Form 10-K
February 26, 2015

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 10-K

☐ ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2014

○ TRANSITION REPORT UNDER 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 (I.R.S. Employer Identification No.)
of incorporation or organization)

3950 South Country Club, Suite 470
Tucson, Arizona 85714
(Address of principal executive offices)(Zip Code)

Registrant's telephone number, including area code:

(520) 365-3100

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

<u>Title of each class</u>	<u>Name of each exchange on which registered</u>
Common Stock, \$0.001 par value per share	The NASDAQ Stock Market LLC (NASDAQ Capital Market)

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

Edgar Filing: Accelerate Diagnostics, Inc - Form 10-K

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 and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer

Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company)

Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No

The aggregate market value of the shares of the registrant’s common stock held by non-affiliates on June 30, 2014, the last day of the registrant’s most recently completed second fiscal quarter, was approximately \$569.6 million based on the closing price quoted on the NASDAQ Stock Market.

There were 44,651,496 shares of common stock of the registrant outstanding as of February 17, 2015.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement relating to the registrant’s 2015 Annual Meeting of Stockholders are incorporated by reference in Part III of this Form 10-K.

TABLE OF CONTENTS

Introductory Note	4
Forward-Looking Statements	4
Industry and other data	4
PART I	5
Item 1. Business	5
Item 1A. Risk Factors	21
Item 1B. Unresolved Staff Comments	43
Item 2. Properties	43
Item 3. Legal Proceedings	43
Item 4. Mine Safety Disclosures	43
PART II	43
Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	43
Item 6. Selected Financial Data	44
Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations	45
Item 7A. Quantitative and Qualitative Disclosures About Market Risk	51
Item 8. Financial Statements and Supplementary Data	51
Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	79
Item 9A. Controls and Procedures	79
Item 9B. Other Information	80
PART III	80
Item 10. Directors, Executive Officers and Corporate Governance	80
Item 11. Executive Compensation	80
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	80
Item 13. Certain Relationships and Related Transactions, and Director Independence	80
Item 14. Principal Accounting Fees and Services	80
Item 15. Exhibits, Financial Statement Schedules	80
SIGNATURES	81
EXHIBIT INDEX	82

Introductory Note

Except as otherwise indicated by the context, references in this Annual Report on Form 10-K (this “Form 10-K”) to the “Company,” “Accelerate,” “we,” “us” or “our” are references to the combined business of Accelerate Diagnostics, Inc.

Forward-Looking Statements

This Annual Report on Form 10-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”) and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and the Company, intends that such forward-looking statements be subject to the safe harbors created thereby. These forward-looking statements, which can be identified by the use of words such as “may,” “will,” “expect,” “anticipate,” “estimate,” or “continue,” or variations thereon or comparable terminology, include the plans and objectives of management for future operations, including plans and objectives relating to the products and future economic performance of the Company. In addition, all statements other than statements of historical facts that address activities, events, or developments the Company expects, believes, or anticipates will or may occur in the future, and other such matters, are forward-looking statements.

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

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

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. (“we” or “us” or “our” or “Accelerate” or “the Company”) is an *in vitro* diagnostics company dedicated to providing solutions which improve patient outcomes and lower healthcare costs through the rapid diagnosis of serious infections. Microbiology laboratories are in need of new tools to address what the U.S. Centers for Disease Control and Prevention (“CDC”) calls one of the most serious healthcare threats of our time, antibiotic resistance. A significant contributor 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 these results is often due to the reliance of microbiology laboratories on traditional culture-based tests that often take two to three days to complete. Our technology platform is built to address these challenges by delivering significantly faster and accurate testing of infectious pathogens in various patient sample types.

Since 2004, we have focused our efforts on the development of an innovative rapid diagnostic platform, the Accelerate ID/AST System™ (the “ID/AST System” or “Accelerate ID/AST System”), intended for the rapid diagnosis of infectious pathogens. Our goal is to reduce the failure rate of initial antibiotic drug therapy by shortening lab turnaround time to approximately five hours, rather than the two to three days now required to deliver identification and susceptibility results. The ID/AST System utilizes genotypic technology to identify (“ID”) infectious pathogens and phenotypic technology to conduct antibiotic susceptibility testing (“AST”), which determines whether live bacterial or fungal cells are resistant or susceptible to a particular antibiotic. Development of this system and the first test kit for positive blood culture samples is substantially complete. Accordingly, we plan to initiate a U.S. clinical trial to support U.S. Food and Drug Administration (“FDA”) marketing approval in the first half of 2015, and following the successful completion of this trial, we plan to commercialize the FDA approved system. Achieving each of these milestones will depend on our ability to achieve the goals specified in our detailed project plan according to the deadlines included in such plan.

In addition to the ID/AST System, we have developed and licensed OptiChem® surface coatings for use in microarraying components. However, in 2012, we decided to discontinue our efforts to develop and actively market OptiChem® and our other surface chemistry products.

We plan to introduce additional test kits for use on the Accelerate ID/AST System enabling the system’s use with other sample types. In addition, we plan to invest in the development of additional instruments, tests, and other solutions to realize our mission of establishing global market leadership in clinical microbiology.

History and Strategy

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.

From 2001 to 2012, we focused primarily upon furthering the research and development of the OpTest portfolio of technologies (“OpTest”) that we acquired from DDx, Inc. in 2001 and the development of revenue producing products related to that technology. The purchase of OpTest provided us with a proprietary surface chemistry formulation, which led to our OptiChem® and other surface chemistry products, and quantitative bio-analytical measurement instruments. We have supplemented these assets to develop the ID/AST System.

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 ID/AST System and (2) to discontinue efforts to develop and actively market OptiChem and our other surface chemistry products. Our Board of Directors and management team decided to pursue this new strategic direction based on the belief that we could internally develop and commercialize the ID/AST System, formerly called the BacCel System.

Since the adoption of the new strategic direction in 2012, we have made significant investments in research and development personnel, facilities, equipment, and consumables to support the internal development of the ID/AST System. The Company has also invested in the hiring of regulatory, manufacturing, quality, sales, and marketing personnel experienced in the manufacture and commercialization of medical devices. In addition, the Company completed three successful prototypes of the ID/AST System. We anticipate initiating clinical trials for the ID/AST System in the first half of 2015.

The new strategic direction has also required the Company to raise additional capital. In March 2013, the Company obtained additional capital through the exercise of warrants issued to Abeja Ventures, LLC in the aggregate amount of \$20,068,000. In August 2013, the Company completed a rights offering that raised gross proceeds of \$20,000,000, and in April 2014, the Company completed a rights offering that raised additional gross proceeds of \$45,000,000.

Clinical Need

Sepsis is a leading cause of death in the United States and the most expensive hospital-treated condition. Sepsis is a severe inflammatory response to a bacterial or fungal infection, with a mortality rate of approximately 30%. According to data published by the U.S. Department of Health and Human Services for 2011, the cost of sepsis is over \$20 billion in the United States, or approximately 5% of the total aggregate costs associated with domestic hospital stays. Sepsis is typically caused by a relatively small number of bacterial or fungal pathogens, and effective treatment of sepsis requires the early detection, identification, and determination of antibiotic or anti-fungal treatment. Today, sepsis is typically diagnosed through traditional culture-based and culture-dependent testing methods with substantial limitations that require up to several days. Due to this timing, antibiotics are typically prescribed empirically and when the test results are available therapy is modified. Recent studies have shown that empiric antibiotic therapy is over-prescribed in 50% of cases and inadequate in 25-30% of cases leading to potentially avoidable patient mortality, morbidity, and hospital costs.

Sepsis is typically diagnosed based on the testing of blood samples. However, sepsis does not typically originate in the blood stream but instead is introduced to the blood stream through the progression of infections in other parts of the body. For example a progressive respiratory infection can infect the blood stream and if treated ineffectively further progress to sepsis. When a serious infection of any origin is suspected it is typical for both a blood and suspected origin sample (e.g., a respiratory sample) test to be ordered.

Respiratory infections are particularly difficult to accurately diagnose and treat and can result in serious pneumonias, acute respiratory distress syndrome, and sepsis. These infections are further complicated by the high occurrence of ventilator associated pneumonias which because they originate in a hospital setting have a much higher likelihood of being drug resistant and have a 33-50% attributable mortality rate. Patients suspected of a bacterial respiratory infection have sputum and/or bronchoalveolar lavage samples taken and provided to the hospital microbiology laboratory for identification and susceptibility testing. These samples are streaked onto petri dishes and incubated at least overnight. Then, the colonies are reviewed and picked for further incubation, and upon isolation are tested for identification and antibiotic susceptibility. This process is complex, laborious, and can take up to four days to complete.

In addition to blood and respiratory samples, the microbiology laboratory is responsible for delivering pathogen identification and susceptibility testing of additional sample types including skin and soft tissue, urine, spinal fluid, and stool samples. These varied sample types present unique analysis and workflow challenges in today's microbiology laboratories. Infections in all of these sample types can be serious and costly to manage. Skin and soft tissue infections often occur after trauma including hospital procedures and can necessitate costly follow-on procedures to revise infected tissue from surgical sites.

Microbiology labs are also experiencing a labor shortage exacerbating the need for laboratory automation.

Products

Accelerate ID/AST System & Positive Blood Culture Test Kit

The Accelerate ID/AST System is the Company's first *in vitro* diagnostic system and is intended for the identification and antibiotic susceptibility testing of pathogens most commonly associated with serious infections, including Gram-positive and Gram-negative organisms such as Staphylococcus organisms as well as yeasts. The Accelerate ID/AST System uses long-accepted bacteriological testing principles, but applies the Company's proprietary technology to adapt them to analyze live bacteria extracted directly from a patient specimen. The Accelerate ID/AST System uses automated digital microscopy to simultaneously detect and identify multiple pathogens directly from a single patient sample and then, following such identification, perform susceptibility tests based on the identification results. This technology eliminates the need for time-consuming traditional bacterial culturing, thus eliminating the major source of delay with current testing methods. The identification result is provided in approximately one hour of presenting the patient sample to the system, and the susceptibility result is provided approximately four hours after the presentation of the identification result. This combined turnaround time of five hours is a significant improvement over the 40-72 hours required to obtain these results using conventional culture-based and culture-dependent testing methods.

Diagnostic speed is highly impactful to patient outcomes and hospital costs. In a recent study, published in the journal *Antimicrobial Agents and Chemotherapy*, it was reported that starting patients on effective therapy within 48 hours of admission leads to a 50% reduction in mortality.

O

The ID/AST 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 ID/AST System the technician would pipette the patient sample into our system, insert the test kit, and initiate the run. In the case of our initial test a positive blood culture sample is introduced to the system through pipetting directly from the blood culture bottle into our test kit. Blood culture is a routine laboratory process which determines negative from positive samples through incubation and takes on average 8 hours to complete. After approximately one hour from sample introduction, an ID result would be available, and after an additional four hours the AST would also be complete.

The Accelerate ID/AST System is the result of over a decade of technology development and three years of instrument design/engineering. Initially prototype systems featured off-the-shelf pipetting robots, high-speed cameras, microscopes/illumination, and computers. The now final instrument is comprised entirely of custom-engineered functional components, including a pipette robot for fluidic manipulation, an optical system with both dark-field and fluorescent illumination, and an imaging system. These components, among others, are used in the four processes that follow, each of which is a crucial component in delivering approximately one hour ID, and five hour AST. These processes include:

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

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

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

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

The Accelerate ID/AST System in its various iterations has been the subject of 30 papers and scientific posters. Further, our internal laboratories have conducted thousands of tests on the various prototype systems and the final instrument. Published study abstracts and links to full papers are available on our website at <http://acceleratediagnostics.com/our-science/publications/>.

During the fiscal year ended July 31, 2008, the Company placed two identical development systems in collaborating research institutions: Denver Health, and Barnes-Jewish Hospital at Washington University in St. Louis, Missouri. The two institutions have replicated and extended the Company's own pre-clinical research using analytical methods developed by the Company. In 2008, both institutions have also begun a series of pilot clinical studies on

clinical isolates and then specimens from intensive care unit (“ICU”) patients using experimental protocols authorized by their respective Institutional Review Boards. We expect these pilot clinical studies to continue until we enter our clinical trials in 2015. In 2013, an additional instrument was placed at Geisinger Health System.

Our collaborations with each of Denver Health, Barnes-Jewish Hospital and Geisinger Health System are ongoing with various studies either in progress or planned with these institutions. Barnes-Jewish has been engaged to assist in pre-clinical studies utilizing ICU patient samples. Under the Company's agreement with Barnes-Jewish, Barnes-Jewish conducted an evaluation of our FISH identification assay using one of our prototype engineering units and leftover clinical positive blood culture specimens. Denver Health has similarly partnered with the Company as a part of the Defense Medical Research and Development Program ("DMRDP") to apply our rapid diagnostic system to wound infections and other serious infections secondary to trauma. This research began in September 2012 and will conclude in September 2015. Geisinger Health Systems is conducting a study to evaluate the antimicrobial susceptibility coagulase-negative staphylococci using an ID/AST System prototype and is expected to conclude in the first half of 2015.

The Company will be seeking a single FDA submission for the integrated Accelerate ID/AST System and positive blood culture test kit. This panel will cover over 80% of the routine and significant pathogens causing blood stream infections and over 90% of the antibiotics useful in treating those pathogens. While some molecular diagnostic companies have sought separate regulatory approval for each species of bacteria tested by an identification system, the Company is pursuing approval via a single, consolidated submission, similar to approaches taken since early 2013 by molecular diagnostic companies for their multiplexed identification tests. The difference in these approaches has been driven by the technology utilized. Consequently, as Accelerate's technology tests for multiple types of pathogens, simultaneously, we intend to file a single submission for our identification panel and susceptibility panel.

As of December 31, 2014 we have completed the following steps toward our goal of obtaining regulatory approvals for E.U. and U.S. launches of the ID/AST System and positive blood culture test kit:

- design of the final ID/AST System and positive blood culture test kit;
- meeting with the FDA to discuss the regulatory approval path for the ID/AST System and positive blood culture test kit;
- design of the U.S. clinical study;
- selection of clinical trial sites;
- obtain ISO13485 certification based on the establishment and audit of a product quality system; and
- building good manufacturing practice (GMP) manufacturing and test facilities.

Key remaining steps toward obtaining a CE-mark for commercialization in the E.U., anticipated for the first half of 2015, and upon obtaining FDA approval commercializing the product in the U.S., include:

- completing product technical files and providing a self-declaration of conformity to our E.U. authorized representative after which CE mark will be obtained;
- the execution of the U.S. clinical trials;
- preparation of the FDA submission following the clinical trials; and
- obtaining a positive review of this submission from the FDA.

Pilot studies with clinical partners and internal studies demonstrate sensitivity and specificity rates in the high nineties across all on-target species and specie drug combinations, which if replicated during the clinical trial should be more than sufficient to obtain market approval from the FDA. The Company anticipates entering clinical trials for the ID/AST System and positive blood culture test kit in the first half of 2015, and upon obtaining FDA market approval, the Company plans to commercialize the product. The ID/AST System and positive blood culture test kit is not yet cleared by the FDA and not commercially available. Therefore, we have not yet generated any sales revenues from the ID/AST System.

OptiChem

In addition to developing the Accelerate ID/AST System, we have developed and licensed OptiChem surface coatings for use in microarraying components. As a coating for analytical devices, management believes that OptiChem offers superior noise rejection (non-specific binding by interfering substances) and high capacity for target binding, compared with other bio-coatings. For example, in microarraying this results in higher sensitivity and simplified sample preparation.

We have licensed various OptiChem microarraying coatings to Schott Jenaer Glas GmbH (“SCHOTT”) (Germany), NanoString Technologies, Inc. (“NanoString”) (U.S., WA), and Nanosphere, Inc. (“Nanosphere”) (U.S., IL). See “Sales, Licensing, and Alliances” below. For the period ended December 31, 2014 licensing revenues from OptiChem were the Company’s only source of revenue.

As discussed above, we are discontinuing our efforts to develop and actively market OptiChem and our other surface chemistry products. Instead, we are focusing our efforts on the successful development, manufacture and commercialization of the ID/AST System.

Market Opportunity

Accelerate Diagnostics is focused on the clinical microbiology industry, which is currently valued at \$3.4 billion globally and is estimated to grow at a rate in excess of 15% through 2019. Initially, we plan on targeting our system across three regions; North America, Europe, and various countries in Asia Pacific. In these geographies, we estimate there are over 14 million high-acuity tests across various sample types including: blood, respiratory, skin and soft tissue, and urine. We believe the available market opportunity for our first *in vitro* diagnostic instrument, the Accelerate ID/AST System and first test kit for positive blood culture samples is 5 million annual tests across our targeted geographies.

Sales, Marketing, and Distribution

The target customer for our products is hospital microbiology laboratories that perform identification and antibiotic susceptibility testing. Globally, the vast majority of hospitals with an intensive care unit have such a laboratory. In general, we plan to build our own sales force to market the ID/AST System directly to our targeted customers. However, in select geographies, we plan to use third-party distributors to market the product.

Research and Development

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

With the development of the Accelerate ID/AST System and positive blood culture test kit substantially complete, the Company will immediately focus on the development of additional test kits to address opportunities in sample types including but not limited to respiratory, skin and soft tissue, and urine. Similar to the positive blood culture kit, the objective is to develop test kits which work seamlessly on the Accelerate ID/AST System and deliver substantial benefits to the microbiology laboratory and to physicians in the treatment of serious infections. Proof of concept research has already been completed on some of these sample types aided in part by DMRDP grant which aims to apply the Accelerate ID/AST System to respiratory and skin and soft tissue samples.

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

Our research activity is also focused on shortening the time required to distinguish between positive and negative whole blood and potentially urine samples prior to using the ID/AST System.

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 ID/AST System and is, thus, very important to the Company. Our patents are focused on several key technologies, including our automated process for sample preparation, automated immobilization process, and methods for imaging and analysis of individual pathogen cells. The Company's first patent on the ID/AST System technology, U.S. Patent No. 7,341,841 titled "Rapid Microbial Detection and Antimicrobial Susceptibility Testing" was issued on March 11, 2008. The patent specification covers methods used to derive identification and antibiotic susceptibility from tests on individual immobilized bacterial cells. As of December 31, 2014, we had 18 issued patents worldwide, including 12 patents issued in the United States and six issued outside the United States. One of our patents expires in 2017, and the remaining 17 will expire on various dates in 2022 through 2033. Additionally, as of December 31, 2014, we had 12 patent applications pending worldwide, including six U.S. applications and six applications outside the United States. The Company believes that its patent suite would make it difficult for any other company to conduct rapid antibiotic susceptibility testing of individual pathogens.

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 implementing regulations.

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 classifies all medical devices into one of three classes. Devices deemed to pose the lowest risk are categorized as either Class I or II, which generally requires the manufacturer to submit to the FDA a 510(k) pre-market notification submission requesting clearance of the device for commercial distribution in the United States. Some low risk devices are exempted from this requirement. Devices deemed by the FDA to pose the greatest risk, such as life sustaining, life-supporting, or implantable devices, or devices deemed not substantially equivalent to a previously 510(k)-cleared device are categorized as Class III. These devices generally require submission and approval of a pre-market approval application, or 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 significant 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 Regulation ("QSR"), which imposes elaborate development, testing, control, documentation and other quality assurance requirements on the design and manufacturing process. The FDA has committed to review most PMAs within 180 days where an advisory panel is not required and within 320 days where an advisory panel is required, but the review clock may be stopped due to requests for additional information. A decision may take significantly longer, and approval is never assured. The FDA may approve a PMA with post-approval conditions intended to ensure the safety and effectiveness of the device including restrictions on labeling, promotion, sale, and distribution and collection of safety data. Failure to comply with the conditions of approval can result in enforcement action and sanctions, including those described below. New PMAs or PMA supplements are required for significant modifications to the manufacturing process, labeling of the product, or design of a device that is approved through the PMA process. PMA supplements often require submission of the same type of information as an original PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory panel.

De novo Classification Process

Medical device types that the FDA has not previously classified as Class I, II, or III are automatically classified into Class III regardless of the level of risk they pose. The Food and Drug Administration Modernization Act of 1997 established a new route to market for low-to-moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the de novo classification procedure. This procedure allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA. Prior to the enactment of the Food and Drug Administration Safety and Innovation Act ("FDASIA") in July 2012, a medical device could only be eligible for de novo classification if the manufacturer first submitted a 510(k) pre-market notification and received a determination from the FDA that the device was not substantially equivalent. 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. 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. We plan to utilize the de novo classification process to obtain marketing authorization for the ID/AST System, which we believe will be placed within Class II.

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 conducted in accordance with FDA regulations as well as other federal regulations and state laws concerning human subject protection and privacy. Moreover, the results of a clinical trial may not be sufficient to obtain clearance or approval of the product.

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

Pervasive and Continuing Regulation

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

- the QSR, which imposes elaborate development, testing, control, documentation, and other quality assurance requirements on the design and manufacturing process;
- establishment registration, which requires establishments involved in the production and distribution of medical devices, intended for commercial distribution in the United States, to register with the FDA;
- medical device listing, which requires manufacturers to list the devices they have in commercial distribution with the FDA;

labeling regulations and various statutory provisions, which prohibit false or misleading labeling, as well as the promotion of products for unapproved or "off-label" uses, and impose other restrictions on labeling; and post-market reporting requirements, which require that manufacturers report to the FDA deaths, serious injuries, and malfunctions that, if they were to recur, could lead to death or serious injury, recalls, and corrective field actions. In certain cases, advertising is also subject to scrutiny by the Federal Trade Commission. The FDA and other agencies actively enforce these and other applicable laws and regulations. Failure to comply with applicable requirements may result in enforcement action by the FDA and/or the U.S. Department of Justice, which may include one or more of the following administrative or judicial sanctions:

- untitled letters or warning letters;
- fines, injunctions, and civil penalties;
- mandatory recall or seizure of our products;
- administrative detention or banning of our products;
- operating restrictions, partial suspension, or total shutdown of production;
- import holds;
- refusing to approve pending 510(k) notifications or PMAs;
- revocation of 510(k) clearance or pre-market approvals previously granted; and
- criminal prosecution and penalties.

International Regulation

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

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

Other Healthcare Laws

Although we currently do not have any products on the market, we anticipate that the ID/AST System will receive FDA approval in calendar year 2015. Once commercialized, our business activities, including the activities of any third-party distributors that we retain, will likely be subject to additional healthcare laws and regulations and related enforcement by the federal government as well as the governments of states and foreign jurisdictions where we conduct our business. These laws and regulations include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security, and physician payment transparency laws and regulations. Violations of these laws or regulations can result in criminal or civil sanctions, including substantial fines and, in some cases, exclusion from participation in federal healthcare programs, such as Medicare and Medicaid. The following discussion describes certain federal and state healthcare laws and regulations that may impact our operations and the operations of our customers, but is not intended to be an exhaustive discussion of all potentially applicable federal and state health laws and regulations.

The 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 also have anti-kickback laws which establish similar prohibitions and, in some cases, may apply to items or services reimbursed by any third-party payor, including commercial insurers.

The federal False Claims Act imposes liability on any person or entity that knowingly presents or causes to be presented a false or fraudulent claim for payment to, or approval by, the U.S. government. Liability under the False Claims Act can give rise to treble damages and civil penalties of up to \$11,000 per claim. 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 payors 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 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 payor. Violations of any of these laws can lead to additional risk such as risk of plaintiff class actions, state attorney general actions, and investigation by agencies such as the Department of Justice (“DOJ”) or the Federal Trade Commission (“FTC”).

The Physician Payment Sunshine Act, implemented by Section 6002 of the Affordable Care Act, 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 Centers for Medicare & Medicaid Services (“CMS”) certain payments or "transfers of value" provided to U.S. licensed physicians and teaching hospitals during the preceding calendar year, as well as certain ownership and investment interests held by U.S. licensed physicians and their immediate family members. CMS releases the reported data on a public website on an annual basis. Failure to report as required under the Physician Payment Sunshine Act could subject applicable manufacturers to significant financial penalties, while tracking and reporting the required payments and transfers of value may result in considerable administrative expense. Several states currently have similar laws, and more states may enact similar legislation, some of which may be broader in scope. For example, certain states require the implementation of compliance programs, compliance with industry ethics codes, implementation of gift bans, and spending limits, and/or reporting of gifts, compensation, and other remuneration to healthcare professionals.

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

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

Healthcare Reform

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

In the United States, the Affordable Care Act (“ACA”), enacted in March 2010, made changes that are expected to have a continued and significant impact on the medical device industry and clinical laboratories, including the way healthcare is delivered and financed by governmental and private insurers. For example, the legislation provided for reductions in the Medicare clinical laboratory fee schedule and, since 2013, has required that certain medical device manufacturers pay an excise tax in an amount equal to 2.3% of the price for which such manufacturer sells its medical devices. We will be subject to this tax once we begin selling the ID/AST System.

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. Most recently, 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, and the President’s budget for fiscal year 2016 proposed reductions in Medicare spending.

Reimbursement

We do not believe that hospitals will specifically seek reimbursement from the government or private insurance companies for their purchase of the ID/AST System or the positive blood culture test kits. 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 payors to cover all or a portion of the costs and fees associated with diagnostic tests, including the cost of the purchase of our products. We currently expect that all of our diagnostic tests will be performed in a hospital inpatient setting, where governmental payors, 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.

Competition

Leading Competitors

To the best of our knowledge, no other company has a product with capabilities matching those of the ID/AST System. The leading companies with automated microbiological testing products include Becton, Dickinson and Company (“BD”), bioMérieux, Danaher Corporation, and Thermo Fisher Scientific’s subsidiary TREK Diagnostics Systems, Inc. (“TREK”). These companies provide products for the broad-based culturing and analysis of a wide variety of bacteria. However, none of our competitor’s products is able to provide results as quickly as the ID/AST System.

Our competitor's products require purified bacterial strains or "isolates" for analysis, which require at least overnight culturing of a sample to produce enough organisms to test. These standard culturing methods, including enrichment growth and colony isolation, cannot achieve the speed provided by the ID/AST System. The ID/AST System eliminates the need to produce an isolated culture and corresponding inoculums of a sample. Instead, once a sample is introduced into the ID/AST System by an operator, it automatically processes the sample using our proprietary sample preparation method. Once this sample preparation process is complete, our system uses a proprietary high speed imaging system to analyze the bacteria in real time. An identification result is available within approximately one hour of introducing the sample into the ID/AST System, and its susceptibility profile is generally available within four hours later. This greatly decreases the time of analysis and eliminates the need for a standardized, cultured inoculum, resulting in a process that takes approximately five hours in total instead of the much longer time period required under standard culturing methods.

Industry Developments

The clinical microbiology industry is subject to rapid technological changes, and new products are frequently introduced for rapid bacterial identification using genes or other molecular markers ("molecular diagnostics"). 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 offered by the ID/AST System. For example, gene detection can be highly sensitive and specific for the identification of pathogens, but very few antibiotic resistance mechanisms are simple enough to allow accurate guidance for drug selection. Even in those rare instances that have a direct relationship between a gene and effective resistance, such as particular *Methicillin-Resistant Staphylococcus Aureus* (MRSA) strains, leading literature has reported novel mutations that escape detection by recently commercialized tests.

Fundamental biological limitations arise from the complexity of the majority of drug resistance expression mechanisms. This complexity precludes direct interpretation of molecular marker presence or absence and extrapolating to prescription guidance. Many new diagnostic technologies also require prior isolation of cultured colonies in order to assure accuracy. The time required to obtain such isolates, with a minimum of overnight turnaround, prevents these technologies from serving as rapid diagnostics for treatment decision support.

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

MALDI-TOF systems have a major advantage over other molecular methods in identifying a very broad range of organisms. Cost of ownership is also substantially below that of older molecular methods. But the requirement for extensive organism enrichment and purification, as well as the inability to quantify live organisms or distinguish samples derived from viable organisms, substantially limits this technology from time-critical decision support. In this respect, the ID/AST System provides a substantial advantage for more rapid test results. Finally, as with the older molecular methods, MALDI-TOF systems cannot identify major drug resistance expression and faces the same fundamental biological barriers as gene detection.

Operations

In January 2013, we relocated our headquarters from Denver, Colorado to Tucson, Arizona, where we currently lease approximately 27,404 square feet of office and laboratory space and have plans to significantly expand our facilities in 2015. Further information regarding our Tucson facility is included in Part I, Item 2, "Properties," included elsewhere in this report, and details regarding our lease arrangement are included in Note 14, "Commitments," to the audited consolidated financial statements included elsewhere in this report.

We plan to assemble the ID/AST System instrument and consumable test kits in our facilities in Tucson, Arizona. The ID/AST System requires certain components that are custom-fabricated to our specifications. Such components include injection-molded plastic components, die-cut laminates, and machined mechanical components. We own the necessary production tooling and believe that we will be able to qualify secondary sources as needed to support future demand for the ID/AST System.

Raw Materials

We purchase many different types of raw materials, including plastics, glass, metals, electronic and mechanical sub-assemblies and various biological and chemical products. We seek to ensure continuity of raw material supply by securing multiple options for sourcing. However, our components are custom-made by only a few outside suppliers. In certain instances, we have a sole source supply for key product components of the ID/AST System. We have entered into supply agreements with most of our suppliers to help ensure component availability and flexible purchasing terms with respect to the purchase of such components.

Employees

We have 73 employees as of December 31, 2014. We have not entered into any collective bargaining agreements and consider our labor practices and employee relations to be good.

Available Information

We regularly file reports with the SEC, including Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any other filings required by the SEC. We make these reports available free of charge in the investor relations section of our corporate website (<http://ir.axdx.com/>) as soon as reasonably practicable after such material is electronically filed with or furnished to the SEC. 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.

The public may inspect and copy materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Room 1580, Washington, DC 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. You may also access these materials, and other information regarding issuers

like us that file information electronically with the SEC, from the SEC's internet website at <http://www.sec.gov/>.

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 Annual Report on Form 10-K, including our financial statements and the related notes. If any of the following risks materializes, our business, financial condition, results of operations or growth prospects could be materially adversely affected, and the value of an investment in our common stock may decline significantly.

Risks Related to Our Business and Strategy

Our future profitability and continued existence is dependent in large part upon the successful final development and the successful commercialization of the Accelerate ID/AST System™.

Our principle business strategy involves the successful development and commercialization of the Accelerate ID/AST System, associated test kits and complimentary products. Our development of the ID/AST System is substantially complete, although various clinical trials and regulatory authorizations are still in process. We have dedicated a significant amount of resources to finalize the development of and prepare to market and sell the ID/AST System, and we plan to continue our investment in finalizing the development and commercialization of the ID/AST 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 finalize the development of and commercialize the ID/AST System, associated test kits and complimentary products. We may be required to expend significantly more resources than planned in this process, and as a result we may have to cease investing in the ID/AST System or developing other products.

If we are not successful in the development of the ID/AST System, such failure could lead to impairment of certain of our intellectual property and may result in our ceasing operations.

Further, if we are not successful in conveying to hospitals that the ID/AST System provides equivalent or superior diagnostic information in a shorter period of time compared to existing technologies, or that the ID/AST System improves patient outcomes or decreases healthcare costs, we may experience reluctance from hospitals to order our product. If we fail to successfully commercialize the ID/AST System, we may never receive a return on the significant investments in product development, sales and marketing, regulatory compliance, manufacturing and quality assurance we have made and further investments we intend to make, and may fail to generate revenue and gain economies of scale from such investments.

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

Our success depends on our ability to obtain marketing authorization from the FDA or regulatory clearance of the ID/AST System and other product candidates in our pipeline. If our attempts to obtain marketing authorization 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 are 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 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 products will offer enhanced features or be sold for a more attractive price, they may delay purchases until such products are available.

We are developing additional uses for the ID/AST System. Any failure or delay in launching new applications may compromise our ability to achieve our growth objectives.

We are developing additional uses for the ID/AST System, including the ability to test on additional specimen types (e.g., respiratory samples, skin and soft tissue). We may have problems applying our technologies to additional specimen types, and our new applications may not be as effective in detection as our initial applications. We may also encounter difficulties obtaining regulatory approval for additional uses of the ID/AST System. Any failure or delay in launching new applications may compromise our ability to achieve our growth objectives.

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 development of our products, including the ID/AST System, we may be unable to attract additional customers for our products or license our products to other strategic partners.

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

Our success will depend on the market's confidence that our technologies can provide reliable, high-quality diagnostic results. We believe that our customers are likely to be particularly sensitive to any defects or errors in the ID/AST System. If we experience disruptions or other performance problems with the ID/AST System or any future diagnostic product, we could face warranty and liability claims against us or 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.

Limited revenues from our products and no assurance of future revenues.

We have received limited revenue from sales based on products using our OptiChem technology, and we are in the process of discontinuing our efforts to develop and actively market OptiChem and our other surface chemistry products. During the years ended December 31, 2014 and 2013 and the five-month transition period ended December 31, 2012 and the fiscal year ended July 31, 2012, we experienced losses from operations. Our future revenues are dependent on the successful development and commercialization of the ID/AST System, and there can be no assurance that we will be successful. If we are unsuccessful in completing the development of the ID/AST System and generating revenues from such product, we will likely continue to experience losses from operations and negative cash flow as we have in the past.

We are a development-stage company that has incurred significant losses in recent years, and we expect to incur losses in the future. We cannot be certain that we will achieve or sustain profitability.

We have incurred significant costs in connection with the development and commercialization of our technology, and there is no assurance that we will achieve sufficient revenues to offset anticipated operating costs. We have incurred significant losses in recent years and expect to incur losses in the future. We expect that our losses will continue for at least the next several years as we will be required to invest significant additional funds toward development and commercialization of our technology. We also expect that our selling, general and administrative expenses will continue to increase due to the additional costs associated with establishing a dedicated sales force and other marketing efforts for the ID/AST System. Our ability to achieve or sustain profitability depends on numerous factors, many of which are beyond our control, including our ability to achieve marketing authorization from the FDA or regulatory clearance for the Accelerate ID/AST System, the market acceptance of our product, future product development and our market penetration and margins. If we are unsuccessful in completing the development of the ID/AST System and generating revenues from ID/AST System sales, 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.

We have no experience in marketing and selling the ID/AST System.

We have no experience marketing and selling the ID/AST System. In anticipation of the receipt of marketing authorization from the FDA for the ID/AST System, we have begun to build our own sales force to market the ID/AST System directly to our target customers, and we plan to continue to build this sales force. In select geographies outside of the United States and Europe, we may also use third-party distributors to market our product.

Our future sales will depend in large part on our ability to successfully establish an effective sales force. Because we have no experience in marketing and selling the ID/AST System, our ability to forecast demand, the infrastructure required to support such demand and the sales cycle of our potential customers is unproven.

Moreover, we may use third-party distribution partners for certain geographic areas outside of the United States and Europe, and there is no guarantee that we will be able to enter into such arrangements on favorable terms. Distributors may not commit the necessary resources to market and sell the ID/AST System effectively or may choose to favor marketing the products of our competitors. If distributors do not perform adequately, or if we are unable to enter into effective arrangements with distributors in particular geographic areas, we may not realize our full potential for sales and growth in these areas.

If treatment guidelines for bacterial infection 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 for our product candidates. If treatment guidelines change so that different treatments become desirable, the ID/AST System may no longer provide the information sought by physicians, and we could be required to seek marketing authorization from the FDA for a revised product.

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

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

- the time and resources required to develop, and conduct clinical studies and obtain regulatory clearances for, the ID/AST System;
- the expenses we incur for research and development required to maintain and improve our technology, including developing the ID/AST System;
- the expenses we incur in connection with the development and regulatory approval of the use of the ID/AST System to test on additional specimen types;
- the costs of preparing, filing, prosecuting, defending and enforcing patent claims and other patent 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;
- 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 ID/AST 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 ID/AST System. We may be unable to reduce our expenditures in a timely manner to compensate for any unexpected events or a shortfall in revenue. Accordingly, a shortfall in demand for our products or other unexpected events could have an immediate and material impact on our cash levels.

Breaches of our information technology systems could have a material adverse effect on our operations.

We rely on information technology systems to process, transmit and store electronic information in our day-to-day operations. In addition, our research and development operations are highly dependent on our information technology and storage. Our information technology systems have been subjected to computer viruses or other malicious codes and phishing attacks, and we expect to be subject to similar viruses and codes in the future. These attacks could result in our intellectual property 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, 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.

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

Because of the complex and technical nature of our products and the dynamic market in which we compete, our future success depends on our ability to recruit, train and retain key personnel, including our senior management, research and development, science and engineering, manufacturing and sales and marketing personnel. In particular, we are highly dependent on the management and business expertise of Lawrence Mehren, our President and Chief Executive Officer. We do not maintain key man life insurance for Mr. Mehren or any of our employees. Our industry is very competitive for qualified personnel. To the extent that the services of Mr. Mehren would be unavailable to us, we may be unable to employ another qualified person with the appropriate background and expertise to replace Mr. Mehren 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.

We face competition from industry participants who may have greater resources than we do.

The industry in which we compete is subject to rapid technological changes, and we face and expect to continue to face competition for our products. We may also face competition from non-medical device companies. The ID/AST System also faces competition from laboratory developed tests, or LDTs, developed by national and regional reference laboratories and hospitals. LDTs may not be subject to the same regulatory requirements, including those requiring clinical trials and FDA review and clearance or approval that apply to the ID/AST System.

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 technologies and methods that are more effective than our current and proposed technologies, including but not limited to the ID/AST System.

We cannot assure you that we will effectively compete or that we will be successful in the face of increasing competition from new products and technologies introduced by existing or new competitors. In addition, we cannot assure you that our future competitors do not have or will not develop products or technologies that enable them to produce competitive products with greater capabilities or at lower costs than our products. Any failure to compete effectively could materially and adversely affect our business, financial condition and operating results.

We expect to 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.

Assuming we receive the applicable regulatory approvals, we plan to market and sell the ID/AST System in Europe and other countries outside of the United States in the future. In order to market our products in the European Union and many other foreign jurisdictions, we, or our distributors or partners, must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements regarding safety and efficacy and governing, among other things, clinical studies and commercial sales and distribution of our products. The approval procedure varies among countries and can involve additional testing. In addition, in many countries outside the United States, a product must be approved for reimbursement before the product can be approved for sale in that country. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all, which could harm our ability to expand into markets outside the United States. In addition, engaging in international business involves a number of other difficulties and risks, including:

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

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

We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, principal investigators, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless or negligent failures to: (i) comply with the regulations of the FDA, the Centers for Medicare and Medicaid Services (“CMS”), the Department of Health and Human Services Office of Inspector General (“OIG”), 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 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 and other abusive practices. These laws may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and cause serious harm to our reputation. We currently have a code of conduct applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and our code of conduct and the other precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses, or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations. Any of these actions or investigations could result in substantial costs to us, including legal fees, and divert the attention of management from operating our business.

We may be unable to successfully manage our growth.

We expect to expand our operations following market authorization from the FDA and regulatory clearance and the commercial launch of the ID/AST System. We intend to develop a targeted sales force in connection with our commercialization efforts. Our growth has placed and will continue to place a significant strain on our management, operating and financial systems and our sales, marketing and administrative resources. As a result of our growth, operating costs may escalate faster than planned, and some of our internal systems and processes, including those relating to manufacturing our products, may need to be enhanced, updated or replaced. If we cannot effectively manage our expanding operations, manufacturing capacity and costs, including scaling to meet increased demand, we may not be able to continue to grow or we may grow at a slower pace than expected.

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

Global economic conditions may remain challenging and uncertain for the foreseeable future. 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. Additionally, challenging macroeconomic conditions and market turbulence may also impact our suppliers, causing them to be unable to supply in a timely manner sufficient quantities of customized components, thereby impairing our ability to manufacture on schedule and at commercially reasonable costs.

Compliance with public company corporate governance and reporting is complex and expensive.

We are subject to laws and regulations affecting our domestic and international operations in a number of areas. Many laws and regulations, notably those adopted in connection with the Sarbanes-Oxley Act of 2002 by the Securities and Exchange Commission (the "SEC"), the Dodd-Frank Wall Street Reform and Consumer Protection Act and The NASDAQ Stock Market, impose obligations on public companies, such as ours, which have increased the scope, complexity and cost of corporate governance, reporting and disclosure practices. Compliance with these laws, regulations and similar requirements may be onerous, requires substantial management time and oversight and requires us to incur significant additional accounting, legal and compliance costs. Any such costs, which may rise in the future as a result of changes in these laws and regulations or in their interpretation could individually or in the aggregate make our products and services more expensive, delay the introduction of new products in one or more regions, or cause us to change or limit our business practices. In addition, our larger competitors may be in a better position to absorb the costs of being a public company. We have implemented policies and procedures designed to ensure compliance with applicable laws and regulations, but there can be no assurance that our employees, contractors or agents will not violate such laws and regulations or our policies and procedures.

Additionally, changes to existing accounting rules and standards and the implementation of new accounting rules or standards, such as tax accounting or revenue recognition rules, may adversely impact our reported financial results and business, and may further require us to incur greater accounting fees.

Risks Related to Our Intellectual Property

If we are unable to effectively protect our non-patented 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 the intellectual property rights related to our proprietary technologies, both in the United States and in other countries. If we fail to protect our intellectual property, third parties may be able to compete more effectively against us and we may incur substantial litigation costs in our attempts to recover or restrict use of our intellectual property. We own or exclusively license 12 issued U.S. patents and 6 pending U.S. patent applications, including provisional and non-provisional filings. We also own or exclusively license 12 pending or granted counterpart applications worldwide. In addition to our patents, 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. Uncertainty created by these questions 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 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 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 found. Accordingly, there may be prior art that can invalidate our issued patents or prevent a patent from issuing from a pending patent application, at all or with 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 intellectual property, 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 we hold. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

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

We 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 infringement of these patents and other rights. Third parties may assert infringement or other intellectual property claims against us or our licensees.

In addition, patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after the earliest filing date for which a benefit is claimed. For this reason, and because publications in the scientific literature often lag behind actual discoveries, 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. Under the “first to invent” rules applicable to patents filed before March 2013, any such patent application may have priority over our patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the U.S. Patent and Trademark Office to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U.S. patent position with respect to such inventions.

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

Risks Related to Our Research and Development Activities

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

We currently conduct all of our research and development and product development activities in our existing facility in Tucson, Arizona. If this facility were to be damaged, destroyed or otherwise unable to operate, whether due to fire, floods, storms, tornadoes, other natural disasters, employee malfeasance, terrorist acts, power outages or otherwise, or if our business is disrupted for any other reason, we may not be able to develop the ID/AST System or any 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. Further, we may not be able to maintain our relationships with our licensees or customers.

The manufacture of components of the ID/AST System involves complex processes, sophisticated equipment and strict adherence to specifications and quality systems procedures. Any unforeseen manufacturing problems, such as contamination of our facility, equipment malfunction or failure to strictly follow procedures or meet specifications, could result in delays or shortfalls in production of our products. Identifying and resolving the cause of any manufacturing issues could require substantial time and resources. If we are unable to keep up with future demand for our products by successfully manufacturing and shipping our products in a timely manner, our revenue growth could be impaired and market acceptance of our product candidates could be adversely affected.

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

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

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

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

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

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 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 and our lack of experience marketing the ID/AST System, there could be significant differences between our estimates and the actual amounts of products we require. This can result in shortages if we fail to anticipate demand, or excess inventory and write-offs if we order more than we need.

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

- reliance on third parties for regulatory compliance and quality assurance;
- possible breaches of manufacturing agreements by the third parties because of factors beyond our control;
 - possible regulatory violations or manufacturing problems experienced by our suppliers;
- possible termination or non-renewal of agreements by third parties, based on their own business priorities, at times that are costly or inconvenient for us;
 - the potential obsolescence and/or inability of our suppliers to obtain required components;
- the potential delays and expenses of seeking alternate sources of supply or manufacturing services;
 - the inability to qualify alternate sources without impacting performance claims of our products;
- reduced control over pricing, quality and timely delivery due to the difficulties in switching to alternate suppliers or assemblers; and
 - increases in prices of raw materials and key components.

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

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

The ID/AST System integrates several of our component products, systems and processes. We have dedicated significant resources on research and development activities, and we intend to spend significantly more on research and development activities during the fiscal year ending December 31, 2015 and thereafter. Notwithstanding these investments, we anticipate that we will have to spend additional funds in the research and development of the ID/AST System, particularly with respect to its use for additional specimen types. There can be no assurance that we will be able to complete the development of the ID/AST System or that we will be able to expand its use for additional specimen types. Further, we might also encounter substantial delays in getting products to market.

Risks Related to Government Regulation

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) and employment laws. Violations of these laws can result in criminal or civil sanctions, including substantial fines and, in some cases, exclusion from participation in health care programs such as Medicare and Medicaid.

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

Once commercialized, we will likely be subject to various U.S. healthcare related laws regulating sales, contracting and marketing practices and the use and disclosure of individually identifiable health information. These include:

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

The Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which prohibits knowingly and willfully (i) executing a scheme to defraud any health care benefit program, including private payors, 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 health care benefits, items or services.

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

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

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

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

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

- administrative or judicially imposed sanctions;
 - injunctions or the imposition of civil penalties;
 - recall or seizure of our products;
 - total or partial suspension of production or distribution;
 - withdrawal or suspension of marketing clearances or approvals;
 - clinical holds;
 - warning letters;
 - refusal to permit the import or export of our products;
 - criminal prosecution; and
 - exclusion or debarment from participation in federal health care programs such as Medicare and Medicaid.
- Any of these actions, in combination or alone, could prevent us from marketing, distributing and selling our products.

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

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 and expose us to product liability or other claims, including contractual claims from parties to whom we sold products, and harm our reputation with customers.

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

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

Maintaining and growing sales of our product, if approved, may depend in part on the availability of adequate reimbursement to our customers from third-party payors, 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 payors to cover all or a portion of the costs and fees associated with diagnostic tests, including the cost of the purchase of our products. We currently expect that all of our diagnostic tests will be performed in a hospital inpatient setting, where governmental payors, such as Medicare, generally reimburse hospitals a single bundled payment that is based on the patient’s diagnosis under a classification system known as the Medicare severity diagnosis-related groups (MS-DRGs) classification for all items and services provided to the patient during a single hospitalization, regardless of whether our diagnostic tests are performed during such hospitalization. As a result, our customers’ access to adequate payment by government and private insurance plans is central to the acceptance of our products. We may be unable to sell our products, if approved, on a profitable basis if third-party payors reduce their current levels of payment or if our costs of production increase faster than increases in reimbursement levels.

Additionally, third-party payors 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. While we cannot predict whether third-party reimbursement to our customers will be adequate, cost-containment measures and similar efforts by third-party payors, 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.

35

The Affordable Care Act (the “ACA”), enacted in March 2010, made changes that are expected to have a continued and significant impact on the pharmaceutical and medical device industries and clinical laboratories. For example, the legislation provided for reductions in the Medicare clinical laboratory fee schedule, and since 2013, has required that certain medical device manufacturers pay an excise tax in an amount equal to 2.3% of the price for which such manufacturer sells its medical devices. We will be subject to this tax once we begin selling the ID/AST System. These 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 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. Reimbursement for the laboratory industry is under significant pressure. Most recently, 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, and, in February 2016, the President’s budget for fiscal year 2016 proposed reductions in Medicare spending. These measures can result in reduced prices, added costs, and decreased test utilization for our customers.

The full impact on our business of the ACA and the other laws, regulations, and policies described above is uncertain. It is also unclear whether other legislative changes will be adopted or how such changes would affect our industry generally or our ability to successfully commercialize the ID/AST System. Changes in healthcare policy, such as the creation of broad test utilization limits for diagnostic products in general or requirements that Medicare patients pay for portions of clinical laboratory tests or services received, could substantially impact the sales of our tests, increase costs and divert management’s attention from our business. Such co-payments by Medicare beneficiaries for laboratory services were discussed as possible cost savings for the Medicare program as part of the debt ceiling budget discussions in mid-2011 and may be enacted in the future. In addition, sales of our tests outside of the United States will subject us to foreign regulatory requirements, which may also change over time.

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 any future legislation or regulation will have on us. The expansion in the government’s regulation of the United States healthcare system may result in decreased profits to us, lower reimbursements to our customers for laboratory testing or reduced medical procedure volumes.

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

Our products, including the ID/AST System, are regulated as medical device products by the FDA and comparable agencies of other countries. In particular, FDA regulations govern activities such as product development, product testing, product labeling, product storage, premarket clearance or approval, manufacturing, advertising, promotion, product sales, reporting of certain product failures and distribution. Some of our products, depending on their intended use, will require premarket approval (“PMA”) or 510(k) clearance from the FDA prior to marketing. The 510(k) clearance process usually takes from three to four months from submission but can take longer. The PMA process is much more costly, lengthy and uncertain and generally takes from six months to one year or longer from submission. In the 510(k) clearance process, the FDA must determine that a proposed device is “substantially equivalent” to a device legally on the market, known as a “predicate” device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. The PMA pathway requires an applicant to demonstrate the safety and effectiveness of the device based, in part, on extensive data, including technical, preclinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. However, some devices are automatically subject to the PMA pathway regardless of the level of risk they pose, because they have not previously been classified into a lower risk class by the FDA. Manufacturers of these devices may request that the FDA review such devices in accordance with the *de novo* classification procedure, which allows a manufacturer whose novel device would otherwise require the submission and approval of a PMA prior to marketing to request down-classification of the device on the basis that the device presents low or moderate risk. If the FDA agrees with the down-classification, the applicant will then receive approval to market the device. This device type can then be used as a predicate device for future 510(k) submissions.

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

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

We intend to utilize the *de novo* classification procedures to seek marketing authorization for the ID/AST System. If the FDA requires us to go through a lengthier, more rigorous examination for our product candidates than we had expected, our product introductions or modifications could be delayed or canceled, which could cause our launch to be delayed or, in the future, our sales to decline. In addition, the FDA may determine that our product candidates require the more costly, lengthy and uncertain PMA process. For example, if the FDA disagrees with our determination that the *de novo* classification procedures are the appropriate path to obtain marketing authorizations for the ID/AST System product candidates, the FDA may require us to submit a PMA application, which is generally more costly and uncertain and can take from one to three years, or longer, from the time the application is submitted to the FDA until an approval is obtained.

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

Clinical trials are generally required to support both PMA and 510(k) submissions. We are planning clinical trials for the ID/AST System. Clinical trials are expensive and time-consuming. In addition, the commencement or completion of any clinical trials may be delayed or halted for any number of reasons, including product performance, changes in intended use, changes in medical practice and the opinion of evaluator Institutional Review Boards.

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

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

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

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

Sales of our diagnostic product candidates outside the United States are subject to foreign regulatory requirements governing clinical studies, vigilance reporting, marketing approval, manufacturing, product licensing, pricing and reimbursement. These regulatory requirements vary greatly from country to country. As a result, the time required to obtain approvals outside the United States may differ from that required to obtain FDA clearance, and we may not be able to obtain foreign regulatory approvals on a timely basis or at all. Clearance by 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 these regulatory requirements, or to obtain required clearances or approvals, could impair our ability to commercialize our diagnostic product candidates outside of the United States.

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

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

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

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

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

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

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Under the FDA's medical device reporting regulations, we are required to report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Repeated product malfunctions may result in a voluntary or involuntary product recall. Recalls of any of our products would divert managerial and financial resources, have an adverse effect on our reputation, and may impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide that we will need to obtain, new approvals or clearances for the device before we may market or distribute the corrected device. Seeking such approvals or clearances may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties, or civil or criminal fines. We may also be required to bear other costs or take other actions that may have a negative impact on our sales as well as face significant adverse publicity or regulatory consequences, which could harm our ability to market our products in the future.

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

Risks Related to Our Common Stock

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

The trading price of our common stock has been, and is likely to continue to be, highly volatile. One factor contributing to volatility in the price of our common stock is the low trading volume currently prevailing in the market for our shares. 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, 2014, the closing sale price for our common stock ranged from \$11.29 to \$30.56 per share. The market prices for securities of medical technology companies 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.

We do not anticipate paying any cash dividends on our capital stock in the foreseeable future.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. Any future debt agreements may also preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

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

We have historically relied upon our existing cash balance, revenues and capital from the sale of our securities to fund our operating losses, and we expect that we will continue to incur operating losses until we are able to complete the development of the ID/AST System and sell it into the marketplace or license it to a third party. If capital requirements vary materially from those currently forecast by management, we may require additional capital sooner than expected. We may also require additional capital in the future to expand our product offerings, expand our sales and marketing infrastructure, increase our manufacturing capacity, fund our operations, and continue our research and development activities. Our future funding requirements will depend on many factors, including:

- our ability to obtain marketing authorization from the FDA or clearance from the FDA to market our product candidates;

 - market acceptance of our product candidates, if cleared;

 - the cost and timing of establishing sales, marketing and distribution capabilities;

 - the cost of our research and development activities;

- the ability of healthcare providers to obtain coverage and adequate reimbursement by third-party payors 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 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, although we currently have no commitments or agreements to complete any such transactions.

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. We have the authority to issue up to 55,000,000 shares of common stock (of which 44,651,496 shares were outstanding as of February 17, 2015) and 5,000,000 shares of preferred stock (of which no shares were issued or outstanding as of the same date). 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 development or commercialization of the ID/AST System 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.

The ownership of our common stock is highly concentrated.

Our directors have beneficial ownership of approximately 49% of our outstanding common stock as of February 17, 2015, as determined based on a review of each director's filings under Section 16 of the Securities Exchange Act of 1934. 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.

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

Provisions contained in our certificate of incorporation and bylaws, as well as provisions of the Delaware General Corporation Law, could delay or make it more difficult to remove incumbent directors or for a third party to acquire us, even if a takeover would benefit our stockholders. For example, our board of directors may fill any vacancy on the board of directors, whether such vacancy occurs as a result of an increase in the number of directors or otherwise. Stockholders may not take action by written consent. 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 5,000,000 shares of preferred stock, par value \$0.001 per share, in one or more series, to designate the number of shares constituting any series, and to fix the rights, preferences, privileges and restrictions thereof, including dividend rights, voting rights, rights and terms of redemption, redemption price or prices and liquidation preferences 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 the provisions of Section 203 of the General Corporation Law of the State of Delaware, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

Until January 2013, we leased approximately 6,400 square feet of office and laboratory space in Denver, Colorado. The monthly rent and utilities averaged approximately \$6,000 per month. In January 2013, we relocated our headquarters and currently lease approximately 27,404 square feet of office and laboratory space in Tucson, Arizona. The lease provides for a term of three years, which may be extended by the Company for up to three additional one-year periods. The monthly rent and utilities average approximately \$24,000 per month. The Company exercised a lease option to lease additional space totaling approximately 18,481 square feet with an anticipated occupancy date during 2015. The monthly rent and utilities will increase to approximately \$60,000 per month upon occupancy of the new space. See Item 8, Note 13, Commitments for additional details regarding the lease.

Item 3. Legal Proceedings

We are not currently a party to any material legal proceedings.

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

Since December 26, 2012, the Company’s Common Stock has been traded on the NASDAQ Capital Market under the trading symbol AXDX. Previously, our Common Stock was traded on the NYSE Amex Stock Market under the trading symbol AXK. The information in the following table sets forth the quarterly high and low sales price per share of our Common Stock, as reported by the NASDAQ Capital market, for the period from January 1, 2013 through December 31, 2014.

Common Stock Closing Price		
Quarter Ended	High	Low
March 31, 2013	\$8.52	\$4.06
June 30, 2013	9.22	4.87
September 30, 2013	13.41	7.17
December 31, 2013	15.69	12.10
March 31, 2014	21.81	11.29
June 30, 2014	30.56	16.87
September 30, 2014	26.48	15.94
December 31, 2014	29.22	17.25

Performance Graph

The following Performance Graph compares the cumulative 5-year total stockholder return on our common stock relative to the cumulative total returns of the NASDAQ Composite index (XCMP) and the NASDAQ Biotechnology index (XNBI). An investment of \$100 (with reinvestment of all dividends) is assumed to have been made in our common stock and in each of the indexes on December 31, 2009 and its relative performance is tracked through December 31, 2014. The Performance Graph and related information shall not be deemed to be “soliciting material” or to be “filed” with the Securities and Exchange Commission, nor shall such information be incorporated by reference into any filing under the Securities Act of 1933 or Securities Exchange Act of 1934, each as amended, except to the extent that we specifically incorporate it by reference into such filing.

* \$100 invested on 12/31/2009 in stock or index, including reinvestment of dividends.

Holdings

As of February 17, 2015, we had approximately 155 record owners of our Common Stock.

Dividends Paid and Dividend Policy

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

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

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Equity Compensation Plan Information

The table set forth below presents the securities authorized for issuance with respect to compensation plans under which equity securities are authorized for issuance as of December 31, 2014:

Equity Compensation Plan

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted average exercise price of available outstanding options, warrants and rights	Number of securities remaining for future issuance under equity compensation plans (excluding securities reflected in the 1st column)
Equity compensation plans approved by security holders	5,603,726	\$5.21	3,649,037
Equity compensation plans not approved by security holders	—	—	—
Total	5,603,726	\$5.21	3,649,037

Item 6. Selected Financial Data

The following selected consolidated financial data have been derived from our audited consolidated financial statements. The information below is not necessarily indicative of the results of future operations, and should be read in conjunction with Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations and the consolidated financial statements and related notes thereto included in Item 8, Financial Statements and Supplementary Data in order to fully understand factors that may affect the comparability of the information presented below.

Selected Consolidated Financial Data
(in thousands except per share data)

	12 months <u>12/31/2014</u>	12 months <u>12/31/2013</u>	12 months <u>12/31/2012</u> (unaudited)	5 months <u>12/31/2012</u>	12 months <u>7/31/2012</u>	12 months <u>7/31/2011</u>
Operating revenues	\$ 122	\$ 48	\$ 52	\$ 18	\$ 236	\$ 1,121
Net loss	(30,933)	(15,282)	(8,124)	(3,400)	(5,311)	(379)
Basic and diluted loss per share (1)	(0.71)	(0.41)	(0.44)	(0.13)	(0.43)	(0.04)
Cash dividends	—	—	—	—	—	—
	12/31/2014	12/31/2013	12/31/2012	12/31/2012	7/31/2012	7/31/2011
Total assets	\$69,801	\$43,431	\$13,316	\$13,616	\$17,214	\$6,264

Long-term obligations	13	—	—	—	986	1,380
-----------------------	----	---	---	---	-----	-------

(1) Loss per share has been adjusted for the effects of the rights offering (see Item 8, Note 9, Rights Offering).

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, recent developments, the significant factors affecting our results of operations, capital resources and liquidity, off-balance sheet arrangements, as well as 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 Annual Report on 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 "Risk Factors" in Item 1A of this Annual Report on 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.

Change in Fiscal Year

Effective December 31, 2012, we changed our fiscal year end from July 31 to December 31. This MD&A focuses on the fiscal year ended on December 31, 2014. Comparative financial information is also provided with respect to the fiscal years that ended on December 31, 2013 (audited) and December 31, 2012 (unaudited).

Recent Developments

On August 22, 2012, the Company entered into a Grant Agreement (the "Grant Agreement") with the Arizona Commerce Authority, an agency of the State of Arizona (the "Authority"), pursuant to which the Authority will provide certain state and county sponsored incentives for the Company to relocate its corporate headquarters to, and expand its business within, the State of Arizona (the "Project"). Details of this Grant Agreement are included in Item 8, Note 6, License Agreements and Grants.

On July 12, 2013, the Company publicly announced the final terms of a rights offering which resulted in gross proceeds of \$20.0 million before costs associated with the transactions, which totaled \$88,000. Further details regarding this rights offering are included in Item 8, Note 9, Rights Offering.

On April 7, 2014, the Company commenced a rights offering which resulted in gross proceeds of \$45.0 million before costs associated with the transactions, which totaled \$125,000. The proceeds will be used to fund continued operations, clinical trials, and product commercialization efforts. Further details regarding this rights offering are included in Item 8, Note 9, Rights Offering.

Changes in Results of Operations: Fiscal year ended December 31, 2014 compared to fiscal year ended December 31, 2013

During the year ended December 31, 2014, total revenues were \$122,000 as compared to \$48,000 during the year ended December 31, 2013, an increase of \$74,000 or 154%. The increase was due to deferred royalties recognized in 2014. Further information is included in Item 8, Note 7, Deferred Revenue and Income.

Research and development expenses for the year ended December 31, 2014 were \$20,053,000 as compared to \$10,673,000 during the year ended December 31, 2013, an increase of \$9,380,000 or 88%. The increase was primarily the result of increasing employee headcount, increased non-cash equity-based compensation expenses of \$2,679,000 and increased purchases of laboratory and instrument engineering supplies to support research and development as well as pre-launch efforts.

Edgar Filing: Accelerate Diagnostics, Inc - Form 10-K

During the year ended December 31, 2014, sales, general and administrative expenses were \$10,695,000 as compared to \$4,312,000 during the year ended December 31, 2013, an increase of \$6,383,000 or 148%. The increase is primarily driven by salaries and related expenses as we ramp up our operations and includes an increase in non-cash equity-based compensation expenses of \$3,117,000.

During the year ended December 31, 2014, amortization was \$71,000 as compared to \$77,000 during the year ended December 31, 2013, a decrease of \$6,000 or 8%. This decrease is the result of patents that became fully amortized during the year.

Depreciation for the year ended December 31, 2014 was \$817,000 as compared to \$286,000 during the year ended December 31, 2013, an increase of \$531,000 or 186%. The increased depreciation was the result of purchases of equipment to up-fit the Company's new Tucson facility laboratory, manufacturing and administrative space.

Impairment of intangibles for the year ended December 31, 2014 was \$3,000 compared to \$11,000 for the year ended December 31, 2013, a decrease of \$8,000 or 73%. Management routinely reviews intangible assets. As a result, certain capitalized intellectual property amounts carried on our balance sheet were determined to be no longer recoverable and we abandoned our plan to pursue marketability resulting in the impairment charge.

As a result of the above factors, loss from operations for the year ended December 31, 2014 was \$31,517,000 as compared to the loss of \$15,311,000 during the year ended December 31, 2013, an increase in loss from operations of \$16,206,000 or 106% which includes an increase of \$5,796,000 in non-cash equity-based compensation expenses. This loss and further losses are anticipated and was the result of our continued investments in research and development, expanded laboratory and operational space, increased employee headcount and other factors as we develop and prepare to commercialize the Company's products.

Other non-operating income during the year ended December 31, 2014 was \$57,000 as compared to \$29,000 during the year ended December 31, 2013, an increase of \$28,000 or 97%. This change was due to increased interest and dividend income on our cash balances and investments, which increased year-over-year.

Income tax benefit during the year ended December 31, 2014 was \$527,000 as compared to \$0 during the year ended December 31, 2013. This is due to becoming eligible for and electing a partial refund of research and development tax credits.

As a result of these factors, net loss for the year ended December 31, 2014 was \$30,933,000 as compared to a net loss of \$15,282,000 during the year ended December 31, 2013, an increase in net loss of \$15,651,000 or 102%.

Unrealized loss on available-for-sale investments for the year ended December 31, 2014 was \$15,000 as compared to a gain of \$22,000 during the year ended December 31, 2013. The resulting comprehensive losses were \$30,948,000 and \$15,260,000 for the years ended December 31, 2014 and December 31, 2013, respectively.

Changes in Results of Operations: Year ended December 31, 2013 (audited) compared to year ended December 31, 2012 (unaudited)

During the year ended December 31, 2013, total revenues were \$48,000 as compared to \$52,000 during the year ended December 31, 2012, a decrease of \$4,000 or 8%. The decrease was due to fluctuations in partner sales volumes on which royalties were due the Company.

Research and development expenses for the year ended December 31, 2013 were \$10,673,000 as compared to \$2,032,000 during the year ended December 31, 2012, an increase of \$8,641,000 or 425%. The increase is primarily the result of increasing employee headcount and increased purchases of laboratory and instrument engineering supplies to support research and development efforts.

During the year ended December 31, 2013, sales, general and administrative expenses were \$4,312,000 as compared to \$3,673,000 during the year ended December 31, 2012, an increase of \$639,000 or 17%. The increase is primarily driven by salaries and related expenses as we ramp up our operations.

During the year ended December 31, 2013, amortization was \$77,000 as compared to \$177,000 during the year ended December 31, 2012, a decrease of \$100,000 or 56%. This decrease is the result of impairment of patents and intellectual assets in the prior year as discussed below.

Depreciation for the year ended December 31, 2013 was \$286,000 as compared to \$6,000 during the year ended December 31, 2012, an increase of \$280,000 or 4467%. The increased depreciation was the result of purchases of equipment to up-fit the new Tucson facility laboratory and administrative space.

Impairment of intangibles for the year ended December 31, 2013 was \$11,000 compared to \$2,330,000 for the year ended December 31, 2012, a decrease of \$2,319,000 or 100%. Management determined certain capitalized intellectual property amounts carried on our balance sheet were no longer recoverable and abandoned its plan to pursue marketability resulting in the impairment charge.

As a result of the above factors, loss from operations for the year ended December 31, 2013 was \$15,311,000 as compared to the loss of \$8,166,000 during the year ended December 31, 2012, an increase in loss from operations of \$7,145,000 or 87%. This loss was anticipated and is the result of planned growth.

Other non-operating income during the year ended December 31, 2013 was \$29,000 as compared to \$42,000 during the year ended December 31, 2012, a decrease of \$13,000 or 31%. This change is due to investment activity.

As a result of these factors, net loss for the year ended December 31, 2013 was \$15,282,000 as compared to a net loss of \$8,124,000 during the year ended December 31, 2012, an increase in net loss of \$7,158,000 or 88%.

Unrealized gain on available-for-sale investments for the year ended December 31, 2013 was \$22,000 as compared to \$0 during the year ended December 31, 2012. The resulting comprehensive losses were \$15,260,000 and \$8,124,000 for the years ended December 31, 2013 and December 31, 2012, respectively.

Capital Resources and Liquidity

Our primary source of liquidity has been from sales of shares of common stock. As of December 31, 2014, the Company had \$66.7 million in cash and cash equivalents and available-for-sale securities, an increase of \$24.7 million from \$42.0 million at December 31, 2013. The primary reason for the change in these assets was the Company's successful completion of the rights offering described in Item 8, Note 9, Rights Offering.

As discussed in Item 8, Note 9, Rights Offering, on April 7, 2014, the Company commenced a rights offering to raise \$45.0 million which resulted in gross proceeds of \$45.0 million before expenses upon completion in May 2014. The purpose of the rights offering was to raise equity capital in a cost-effective manner that gives all of the Company's existing stockholders the opportunity to participate on a pro rata basis. The net proceeds of the offering will be used for working capital and specifically to fund continued operations, clinical trials, and product commercialization efforts.

The Company is subject to a Lease Agreement with Pima County of Arizona. The future minimum lease payments under the Lease Agreement are included in Item 8, Note 13, Commitments.

As of December 31, 2014, management believes that current cash balances will be more than sufficient to fund our capital and liquidity needs for the next twelve months.

The following summarizes selected items in the Company's condensed consolidated statements of cash flows for years ended December 31, 2014 and December 31, 2013 (in thousands):

Cash Flow Summary (in thousands)	12/31/2014	12/31/2013
Net cash used in operating activities	\$(18,785)	\$(9,749)
Net cash used in investing activities	(3,372)	(13,172)
Net cash provided by financing activities	45,691	40,881

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

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements as of December 31, 2014.

Recent Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-15, *Presentation of Financial Statements – Going Concern*. The new standard required management of public and private companies to evaluate whether there is substantial doubt about the entity's ability to continue as a going concern and, if so, disclose that fact. Management will also be required to evaluate and disclose whether its plans alleviate that doubt. The new standard is effective for annual periods ending after December 15, 2016, and interim periods within annual periods beginning after December 15, 2016. Early adoption is permitted. We do not expect the adoption of the ASU to have a significant impact on our consolidated financial statements.

In May 2014, the FASB issued ASU 2014-09 *Revenue from Contracts with Customers*, which will supersede nearly all existing revenue recognition guidance under U.S. GAAP. The standard's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. We are carefully evaluating our existing revenue recognition practices to determine whether any contracts in the scope of the guidance will be affected by the new requirements. The effects may include identifying performance obligations in existing arrangements, determining the transaction price and allocating the transaction price to each separate performance obligation. We will also establish practices to determine when a performance obligation has been satisfied, and

recognize revenue in accordance with the new requirements. The new standard is effective for us on January 1, 2017. Early adoption is not permitted. The standard allows for either “full retrospective” adoption, meaning the standard is applied to all of the periods presented, or “modified retrospective” adoption, meaning the standard is applied only to the most current period presented in the financial statements. We are currently evaluating the transition method that will be elected.

In December 2013, the FASB issued ASU No. 2013-12, *Definition of a Public Business Entity*. The purpose of this standard is to clarify which nonpublic entities potentially qualify for alternative financial accounting and reporting guidance by defining “public business entity” for future use in U.S. GAAP. Currently, FASB Accounting Standards Codification (“ASC”) includes multiple definitions of “public entity”. This standard provides a single definition of “public business entity” for use in future financial accounting and reporting guidance but does not affect existing requirements. There is no effective date for this standard but the definition will start to be used in ASU’s as FASB feels is appropriate. The standard defines “public business entity” as a business entity that meets any one of a number of criteria, one of which is the requirement to file financial statements with the SEC. We have reviewed the definition and have determined that we will be defined as a “public business entity” and there will be no impact on the Company’s financial position, results of operations or cash flows.

In July 2013, the FASB issued ASU 2013-11, *Presentation of an Unrecognized Tax Benefit (UTB) When a Net Operating Loss (NOL) Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists*, which requires a reporting entity to present an unrecognized tax benefit as a liability in the financial statements separate from deferred tax assets if a net operating loss carryforward, a similar tax loss, or a tax credit carryforward is not available as of the reporting date to settle taxes that would result from the disallowance of the tax position or if a reporting entity does not intend to use the deferred tax asset for such purpose. The amendments in ASU 2013-11 are effective for fiscal years, and interim periods within those years, beginning on or after December 15, 2013. The adoption of ASU 2013-11 did not have a material impact on our financial position, results of operations or cash flows.

In March 2013, the FASB issued ASU 2013-04, *Obligations Resulting from Joint and Several Liability Arrangements for Which the Total Amount of the Obligation is Fixed at the Reporting Date*, which provides guidance on the recognition, measurement, and disclosure of obligations resulting from joint and several liability arrangements for which the total amount of the obligation is fixed at the reporting date. The update requires an entity to measure obligations resulting from joint and several liability obligations for which the total amount of the obligation within the scope of the update is fixed at the reporting date, as the sum of the amount the reporting entity agreed to pay on the basis of its arrangements among its co-obligors and any additional amount the reporting entity expects to pay on behalf of its co-obligors. The update also requires an entity to disclose the nature and amount of the obligation as well as other information about those obligations. The amendments in ASU 2013-04 are effective for fiscal years, and interim periods within those years, beginning on or after December 15, 2013 and must be applied retrospectively. The adoption of ASU 2013-04 in the first quarter of 2014 did not have a material impact on our financial position, results of operations or cash flows.

Critical Accounting Policies and Estimates

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

Deferred Taxes

We recognize deferred tax assets and liabilities based on the differences between the financial statement carrying amounts and the tax bases of assets and liabilities. We regularly review our deferred tax assets for recoverability and establish a valuation allowance based on historical taxable income, projected future taxable income, and the expected timing of the reversals of existing temporary differences. As of December 31, 2014 and 2013, we have established a valuation allowance equal to our net deferred tax asset, as we have not been able to determine that we will generate sufficient future taxable income to allow us to realize the deferred tax asset prior to their limitations or expirations. See Item 8, Note 12, Income Taxes for additional information.

Equity-Based Compensation

We account for equity-based compensation in accordance with FASB ASC 718. Equity-based compensation is measured at the grant date based on the estimated fair value of the award and is recognized over the requisite service period.

In determining the fair value of the award, we use the Black-Scholes option pricing model. This model requires the input of subjective assumptions which are further discussed in Item 8, Note 2, Summary of Significant Accounting Policies and Item 8, Note 11, Employee and Consultant Equity-Based Compensation. Once estimated, the Black-Scholes assumptions remain fixed throughout the requisite service period for employee grants. For unvested consultant grants, the assumptions are updated at the end of each reporting period until the grant is vested. Changes in the inputs can materially affect the estimate of the fair value

Employees who terminate employment prior to the requisite service period forfeit their unvested options and we derecognize the fair value of these shares. In accordance with FASB ASC 718, we estimate the amount of such forfeitures. Our estimate is based on the forfeiture rate of unvested awards in the previous twelve-month period. The rate is calculated separately for awards to the board of directors/executives and all other awards. The rate is adjusted at the end of each period and any change is recognized through a cumulative catch-up adjustment. Rate changes will also impact the amount of equity-based compensation expense to be recognized in future periods. Due to our relatively small employee base this estimate is particularly sensitive to termination activity and any change in this assumption can materially affect the estimate of fair value of equity-based compensation.

Inventory

We currently purchase and produce inventory prior to U.S. Food and Drug Administration (“FDA”) or other regulatory agency approval. We do not believe probable future economic benefit can be asserted prior to the completion of 510(k) clearance or other non-U.S. regulatory body equivalent. Accordingly, we do not capitalize pre-launch inventory prior to the receipt of 510(k) clearance, unless regulatory approval has been achieved in other jurisdictions, or the regulatory review process has progressed to a point that we have objective and persuasive evidence that regulatory approval is probable. Inventory is reported as research and development costs on the Statements of Operations and Comprehensive Loss.

Contractual Obligations

The Company has certain contractual obligations and commercial commitments as disclosed in Item 8, Note 13, Commitments that do not meet the definition of long term debt obligations, capital leases, operating leases or purchase obligations. The Company has entered into a Lease Agreement as described in Item 2, Properties and Item 8, Note 13, Commitments. The operating and capital lease obligations associated with the Lease Agreement over the next five years are (in thousands):

Contractual Obligations

(in thousands)

	Total	2015	2016	2017	2018	2019
Operating Lease Obligations	\$693	\$633	\$60	\$—	\$—	\$—
Capital Lease Obligations	164	151	13	—	—	—
Total	\$857	\$784	\$73	\$—	\$—	\$—

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

The Company's interest income is sensitive to fluctuations in the general level of U.S. interest rates. As such, changes in U.S. interest rates affect the interest earned on the Company's cash and cash equivalents and investments.

Our exposure to market risk is limited to our cash and cash equivalents, all of which have original maturities of less than three months and available-for-sale investments some of which have maturities under a year and some of which have maturities of more than a year. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash and investments. We also seek to maximize income from our investments without assuming significant risk. To achieve our goals, we maintain a portfolio of cash equivalents and investments in a variety of securities that management believes to be of high credit quality. We currently do not hedge interest rate exposure. Further information regarding our investments is included in Item 8, Note 4, Investments.

Item 8. Financial Statements and Supplementary Data

Financial Statements of Accelerate Diagnostics, Inc.

Report of Independent Registered Public Accounting Firm

Report of Independent Registered Public Accounting Firm from Prior Audit Periods

Balance Sheets as of December 31, 2014 and 2013

Statements of Operations and Comprehensive Loss for the years ended December 31, 2014 and 2013, the five-month periods ended December 31, 2012 and 2011 and the fiscal year ended July 31, 2012

Statements of Stockholders' Equity for the years ended December 31, 2014 and 2013, transition period ended December 31, 2012 and the fiscal year ended July 31, 2012

Statements of Cash Flow for the years ended December 31, 2014 and 2013, the five-month periods ended December 31, 2012 and 2011 and the fiscal year ended July 31, 2012

Notes to Financial Statements

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Accelerate Diagnostics, Inc. and Subsidiaries

We have audited the accompanying consolidated balance sheets of Accelerate Diagnostics, Inc. and subsidiaries as of December 31, 2014 and 2013, and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for the years ended December 31, 2014 and 2013. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Accelerate Diagnostics, Inc. and subsidiaries at December 31, 2014 and 2013 and the results of its operations and its cash flows for the years ended December 31, 2014 and 2013, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Accelerate Diagnostics, Inc.'s internal control over financial reporting as of December 31, 2014, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 framework) and our report dated February 26, 2015, expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Phoenix, Arizona

February 26, 2015

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Accelerate Diagnostics, Inc. and Subsidiaries

We have audited Accelerate Diagnostics, Inc. and subsidiaries' internal control over financial reporting as of December 31, 2014, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 framework) (the COSO criteria). Accelerate Diagnostics, Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. 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.

In our opinion, Accelerate Diagnostics, Inc. and subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2014, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheet of Accelerate Diagnostics, Inc. and subsidiaries as of December 31, 2014 and 2013 and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2014 and our report dated February 26, 2015, expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Phoenix, Arizona

February 26, 2015

53

Report of Independent Registered Public Accounting Firm

Board of Directors

Accelerate Diagnostics, Inc.

Tucson, Arizona

We have audited the accompanying balance sheets of Accelerate Diagnostics, Inc. (a Delaware corporation) as of December 31, 2012, July 31, 2012 and July 31, 2011 and the related statements of operations and comprehensive loss, stockholders' equity and cash flows for the five month period ended December 31, 2012 and for each of the years ended July 31, 2012 and 2011. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Accelerate Diagnostics, Inc. as of December 31, 2012, July 31, 2012 and July 31, 2011 and the results of its operations and changes in its cash flows for the five month period ended December 31, 2012 and each of the years ended July 31, 2012 and 2011, in conformity with U.S. generally accepted accounting principles.

Denver, Colorado

March 19, 2013

/s/ COMISKEY & COMPANY

PROFESSIONAL CORPORATION

ACCELERATE DIAGNOSTICS, INC.
CONSOLIDATED
BALANCE SHEETS

(in thousands, except share data)

	<u>12/31/2014</u>	<u>12/31/2013</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$53,563	\$30,029
Investments	13,115	11,960
Trade accounts receivable	78	24
Prepaid expenses	342	130
Total current assets	67,098	42,143
Property and equipment, net	2,536	1,047
Intellectual property, net	167	241
Total assets	\$69,801	\$43,431
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$2,129	\$540
Accrued liabilities	494	515
Deferred revenue and income	13	82
Capital lease obligations	147	—
Total current liabilities	2,783	1,137
Long-term deferred income	1,014	777
Long-term capital lease obligation	13	—
Total liabilities	3,810	1,914
Stockholders' equity:		
Common stock, \$0.001 par value;		
55,000,000 common shares authorized		
44,639,829 (as of December 31, 2014) and 41,649,521 (as of December 31, 2013)	45	42
shares issued and outstanding		
5,000,000 preferred shares authorized and none outstanding as of December 31, 2014		
and December 31, 2013	—	—
Contributed capital	131,356	75,937
Accumulated deficit	(65,417)	(34,484)
Accumulated other comprehensive income	7	22
Total stockholders' equity	65,991	41,517
Total liabilities and stockholders' equity	\$69,801	\$43,431

See accompanying notes to financial statements.

55

ACCELERATED DIAGNOSTICS, INC.
CONSOLIDATED
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except per share data)

	12 months 12/31/2014	12 months 12/31/2013	5 months 12/31/2012	5 months 12/31/2011 (unaudited)	12 months 7/31/2012
Revenues:					
Licensing and royalty revenues	\$122	\$48	\$18	\$202	\$236
Total revenues	122	48	18	202	236
Costs and expenses:					
Research and development	20,053	10,673	1,777	163	432
Sales, general and administrative	10,695	4,312	1,267	562	2,954
Amortization	71	77	38	64	203
Depreciation	817	286	5	1	2
Impairment of intangibles	3	11	333	—	1,997
Total costs and expenses	31,639	15,359	3,420	790	5,588
Loss from operations	(31,517)	(15,311)	(3,402)	(588)	(5,352)
Interest expense and other	(7)	—	—	1	1
Interest and dividend income	64	29	2	4	16
Unrealized holding (loss) gain on investments	—	—	—	(4)	24
Total other income	57	29	2	1	41
Net loss before income taxes	(31,460)	(15,282)	(3,400)	(587)	(5,311)
Benefit from income taxes	527	—	—	—	—
Net loss	\$(30,933)	\$(15,282)	\$(3,400)	\$(587)	\$(5,311)
Basic and diluted net loss per share	\$(0.71)	\$(0.41)	\$(0.13)	\$(0.05)	\$(0.43)
Weighted average shares outstanding	43,626	37,599	25,354	11,132	12,462
Other comprehensive loss:					
Net loss	\$(30,933)	\$(15,282)	\$(3,400)	\$(587)	\$(5,311)
Net unrealized (loss) gain on available-for-sale investments	(15)	22	—	—	—
Comprehensive loss	\$(30,948)	\$(15,260)	\$(3,400)	\$(587)	\$(5,311)

See accompanying notes to financial statements.

ACCELERATE DIAGNOSTICS, INC.**CONSOLIDATED****STATEMENTS OF STOCKHOLDERS' EQUITY**

(in thousands)

	Shares	Common Stock Amount	Contributed Capital	Accumulated Deficit	For Employee Benefit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
Balances, August 1, 2011	11,103	\$ 14,333	\$ 1,247	\$(10,491)	(\$274)	\$—	\$4,815
Net loss	—	—	—	(5,311)	—	—	(5,311)
Issuance of common stock and warrants	14,000	8,524	5,896	—	—	—	14,420
Exercise of options and warrants	129	129	—	—	—	—	129
Equity-based compensation	—	—	782	—	—	—	782
Balances, July 31, 2012	25,232	22,986	7,925	(15,802)	(274)	—	14,835
Net loss	—	—	—	(3,400)	—	—	(3,400)
Issuance of common stock and warrants	—	—	—	—	—	—	—
Exercise of options and warrants	100	—	100	—	—	—	100
Transfer of Rabbi trust	—	—	(274)	—	274	—	—
Establish par value stock for DE corp	—	(22,961)	22,961	—	—	—	—
Equity-based compensation	—	—	533	—	—	—	533
Balances, December 31, 2012	25,332	25	31,245	(19,202)	—	—	12,068

Edgar Filing: Accelerate Diagnostics, Inc - Form 10-K

Net loss	—	—	—	(15,282)	—	—	(15,282
Issuance of common stock and warrants	2,488	3	19,909	—	—	—	—	19,912
Exercise of options and warrants	13,830	14	20,955	—	—	—	—	20,969
Unrealized gain on available-for-sale securities	—	—	—	—	—	—	22	22
Equity-based compensation	—	—	3,828	—	—	—	—	3,828
Balances, December 31, 2013	41,650	42	75,937	(34,484)	—	22	41,517
Net loss	—	—	—	(30,933)	—	—	(30,933
Issuance of common stock	2,678	3	44,872	—	—	—	—	44,875
Exercise of options	312	—	923	—	—	—	—	923
Unrealized loss on available-for-sale securities	—	—	—	—	—	—	(15) (15
Equity-based compensation	—	—	9,624	—	—	—	—	9,624
Balances, December 31, 2014	44,640	\$45	\$131,356	\$(65,417)	\$—	\$7	\$65,991

See accompanying notes to financial statements.

ACCELERATE DIAGNOSTICS, INC.**CONSOLIDATED****STATEMENT OF CASH FLOWS**

(in thousands)

	12 Months 12/31/2014	12 Months 12/31/2013	5 months 12/31/2012	5 months 12/31/2011 (unaudited)	12 months 7/31/2012
Cash flows from operating activities:					
Net loss	\$(30,933)	\$(15,282)	\$(3,400)	\$ (587)	\$(5,311)
Adjustments to reconcile net loss to net cash used in operating activities:					
Depreciation	817	286	5	1	2
Amortization of intangible assets	71	77	38	64	203
Amortization of investment discount	269	76	—	—	—
Equity-based compensation	9,624	3,828	533	273	782
Impairment loss	3	11	333	—	1,997
Unrealized gain on investments	—	—	—	—	(24)
Realized gain on sale of investments, interest and dividends reinvested	—	—	—	—	(8)
(Increase) decrease in assets:					
Accounts receivable	(54)	739	(13)	2	591
Inventory	—	—	10	—	20
Prepaid expense and other	(166)	(114)	2	(8)	3
Increase (decrease) in liabilities:					
Accounts payable	1,336	205	236	41	27
Accrued liabilities	80	(356)	127	7	719
Deferred revenue and income	168	781	(7)	95	76
Deferred compensation	—	—	—	(73)	107
Net cash used in operating activities	(18,785)	(9,749)	(2,136)	(185)	(816)
Cash flows from investing activities:					
Purchases of equipment and capitalized patents	(1,933)	(1,158)	(158)	(19)	(96)
Contribution to deferred compensation trust	—	—	—	16	(150)
Purchase of available-for-sale securities	(7,657)	(12,014)	—	—	—
Sales of available-for-sale securities	861	—	—	—	—
Maturity of available-for-sale securities	5,357	—	—	—	—
Net cash used in investing activities	(3,372)	(13,172)	(158)	(3)	(246)
Cash flows from financing activities:					
Exercise of warrants and options	923	20,969	100	—	129
Issuance of common stock and warrants	44,875	19,912	—	—	14,420
Payments on capital lease obligations	(107)	—	—	—	—

Edgar Filing: Accelerate Diagnostics, Inc - Form 10-K

Net cash provided by financing activities	45,691	40,881	100	—	14,549
Increase (decrease) in cash and cash equivalents	23,534	17,960	(2,194)	(188)	13,487
Cash and cash equivalents, beginning of period	30,029	12,069		776	776
Cash and cash equivalents, end of period	\$53,563	\$30,029	\$12,069	\$588	\$14,263

See accompanying notes to 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 which improve patient outcomes and lower healthcare costs through the rapid diagnosis of serious infections. Microbiology laboratories are in need of new tools to address what the U.S. Centers for Disease Control and Prevention (“CDC”) calls one of the most serious healthcare threats of our time, antibiotic resistance. A significant contributor 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 these results is often due to the reliance of microbiology laboratories on traditional culture-based tests that often take two to three days to complete. Our technology platform is built to address these challenges by delivering significantly faster and accurate testing of infectious pathogens in various patient sample types.

Basis of Presentation

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

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

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries after elimination of intercompany transactions and balances. There were no intercompany transactions for the years ending December 31, 2014 and 2013.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Concentration of Credit Risk

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

The Company periodically maintains cash balances at a commercial bank in excess of the Federal Deposit Insurance Corporation insurance limit of \$250,000. At December 31, 2014 and December 31, 2013, the Company’s uninsured cash balance was approximately \$53.6 million and \$30.1 million, respectively.

The Company grants credit to domestic and international clients in various industries. Exposure to losses on accounts receivable is principally dependent on each client's financial position. At December 31, 2014, 98% of the outstanding receivable balance was with Denver Health and the Department of Defense related to the Defense Medical Research and Development Program. See Note 6, License Agreements and Grants for more information.

Estimated Fair Value of Financial Instruments

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

- Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;
- Level 2: Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs that are observable, either directly or indirectly, for substantially the full term of the asset or liability;
- Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e. supported by little or no market activity).

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

See Note 3, 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. As part of our cash management process, excess operating cash is invested in overnight repurchase agreements with our bank. Repurchase agreements are not deposits and are not insured by the U.S. Government, the FDIC or any other government agency and involve investment risk including possible loss of principal. We believe however, that the market risk arising from holding these financial instruments is minimal.

Investments

The Company invests excess funds in various short-term and long-term investments which are primarily held in the custody of a major financial institution. Investments consist of debt securities in U.S. government-sponsored entities, corporate debt securities and commercial paper. Management classifies its investments as available-for-sale investments and records these investments in the Balance Sheets at fair value. Unrealized gains or losses for available-for-sale securities are included in accumulated other comprehensive income or loss, a component of stockholders' equity. The Company classifies its investments as current based on the nature of the investments and their availability for use in current operations.

The Company assesses whether an other-than-temporary impairment loss has occurred due to declines in fair value or other market conditions when an investment's fair value remains less than its cost for more than twelve months. This assessment includes a determination of whether the investment is expected to recover in value and whether the Company as the intent and ability to hold the investment until the anticipated recovery in value occurs. When an investment is identified as having an other-than-temporary impairment loss, we adjust the cost basis of the investment down to fair value resulting in a realized loss. The new cost basis is not changed for subsequent recoveries in fair value and future increases or decreases in fair value are included in other comprehensive income.

Property and Equipment

Property and equipment are recorded at cost. Maintenance and repairs are charged to expense as incurred and expenditures for major improvements are capitalized. Gains and losses from retirement or replacement are included in costs and expenses. Depreciation of property and equipment is computed using the straight-line method over the estimated useful life of the assets, ranging from one to seven years. Leasehold improvements are depreciated over the remaining life of the lease or the life of the asset, whichever is less. See Note 5, Property and Equipment below.

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.

Inventory

The Company produces inventory prior to U.S. Food and Drug Administration (“FDA”) or other regulatory agency approval. We do not believe probable future economic benefit can be asserted prior to the completion of 510(k) clearance or other non-U.S. regulatory body equivalent. Accordingly, the Company does not capitalize pre-launch inventory prior to the receipt of 510(k) clearance, unless regulatory approval has been achieved in other jurisdictions, or the regulatory review process has progressed to a point that the Company has objective and persuasive evidence that regulatory approval is probable. Inventory is reported as research and development costs on the Statement of Operations and Comprehensive Loss.

Revenue Recognition

The Company recognizes revenue in accordance with ASC 605, “Revenue Recognition,” when persuasive evidence of an arrangement exists, the price is fixed or determinable, collection is reasonably assured and delivery of products has occurred or services have been rendered.

Additional considerations include whether the applicable fee arrangement contains future delivery or performance obligations that should be divided into separate accounting units, whether the arrangement requires the Company to retain risks consistent with a collaborative arrangement, and/or whether any of the fees are contingent on the achievement of future milestones.

The Company recognizes income from royalty and licensing fee agreements based upon information and reports received from licensees and in accordance with the terms of the agreements underlying such arrangements.

Deferred revenue represents amounts received but not yet earned under existing agreements.

Accounts Receivable Allowances

Allowances on accounts receivable are recorded when circumstances indicate collection is doubtful for a particular accounts receivable. Receivables are written off if reasonable collection efforts prove unsuccessful. The Company provides for allowances on a specific account basis.

Leases

The Company accounts for leases in accordance with ASC 840, *Leases*, which requires leases to be classified as either operating or capital leases. In general, the Company classifies leases as capital leases when there is either a transfer of ownership at the end of the lease term, the lease contains a bargain purchase option, the lease term is seventy-five percent or more of the estimated economic life of the leased property or the minimum lease payments are ninety percent or more of the fair value at lease inception. Other leases are classified as operating leases.

Operating lease rent is recorded as an operating expense monthly. For capital leases, both an asset and liability are recorded at the inception of the lease based on the present value of lease payments. The asset is included with property and equipment on the Balance Sheet and amortization is recorded on a straight-line basis over the term of the lease with the amortization expense included with depreciation on the Statements of Operations and Comprehensive Loss. For the liability, the amount due within the next year is recorded as capital lease obligations and the amount due in more than a year is recorded as long-term capital lease obligation on the Balance Sheet. Interest expense is recorded based on the implicit or explicit interest rate used in the lease and is included as non-operating interest expense on the Statements of Operations and Comprehensive Loss.

Income Taxes

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 of sustaining the position, and the measurement of the benefit is calculated as the largest amount that is more than 50% likely to be realized upon resolution of the benefit. Interest and penalties, if any, would be recorded as tax expense in general and administrative expenses.

Earnings Per Share

The Company follows ASC 260, *Earnings Per Share*, which requires companies to present basic earnings per share and diluted earnings per share. Basic earnings (loss) per share includes no dilution and is computed by dividing income (loss) available to common stockholders by the weighted average number of common shares outstanding for the period. Diluted earnings per share are computed similarly to basic earnings (loss) per share except the denominator includes additional common shares that would have been outstanding if warrants and share-based payments had been issued. Diluted earnings are not presented when the effect of adding such additional common shares is antidilutive.

Earnings per share are restated when certain transactions or events, including rights offerings determined to have bonus elements have occurred.

See Note 10, Earnings per Share for more information.

Equity-Based Compensation

The Company awards stock options and other equity-based instruments to its employees, directors and consultants. Compensation cost related to equity-based awards 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). For unvested consultant grants, the assumptions are updated at the end of each reporting period until the grant is vested. The Company estimates the fair value of 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.

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

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 future.

The Company estimates the forfeiture rate of unvested awards based on the forfeitures in the previous twelve-month period. The rate is calculated separately for awards to the board of directors/executives and all other awards.

See Note 11, Employee and Consultant Equity-Based Compensation for further information.

Comprehensive Income (loss)

The Company follows *ASC 220, Reporting Comprehensive Income*, which establishes standards for reporting and displaying comprehensive income (loss) and its components (revenues, expenses, gains and losses) in a full set of general-purpose financial statements. The Company holds investments classified as available-for-sale securities and records the change in fair market value as a component of comprehensive income (loss).

Recently Issued Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2014-15, *Presentation of Financial Statements – Going Concern*. The new standard required management of public and private companies to evaluate whether there is substantial doubt about the entity’s ability to continue as a going concern and, if so, disclose that fact. Management will also be required to evaluate and disclose whether its plans alleviate that doubt. The new standard is effective for annual periods ending after December 15, 2016, and interim periods within annual periods beginning after December 15, 2016. Early adoption is permitted. We do not expect the adoption of the ASU to have a significant impact on our consolidated financial statements.

In May 2014, the FASB issued ASU 2014-09 *Revenue from Contracts with Customers*, which will supersede nearly all existing revenue recognition guidance under U.S. GAAP. The standard’s core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. We are carefully evaluating our existing revenue recognition practices to determine whether any contracts in the scope of the guidance will be affected by the new requirements. The effects may include identifying performance obligations in existing arrangements, determining the transaction price and allocating the transaction price to each separate performance obligation. We will also establish practices to determine when a performance obligation has been satisfied, and recognize revenue in accordance with the new requirements. The new standard is effective for us on January 1, 2017. Early adoption is not permitted. The standard allows for either “full retrospective” adoption, meaning the standard is applied to all of the periods presented, or “modified retrospective” adoption, meaning the standard is applied only to the most current period presented in the financial statements. We are currently evaluating the transition method that will be elected.

In December 2013, the FASB issued ASU No. 2013-12, *Definition of a Public Business Entity*. The purpose of this standard is to clarify which nonpublic entities potentially qualify for alternative financial accounting and reporting guidance by defining “public business entity” for future use in U.S. GAAP. Currently, FASB Accounting Standards Codification (“ASC”) includes multiple definitions of “public entity”. This standard provides a single definition of “public business entity” for use in future financial accounting and reporting guidance but does not affect existing requirements. There is no effective date for this standard but the definition will start to be used in ASU’s as FASB feels is appropriate. The standard defines “public business entity” as a business entity that meets any one of a number of criteria, one of which is the requirement to file financial statements with the SEC. We have reviewed the definition and have determined that we will be defined as a “public business entity” and there will be no impact on the Company’s financial position, results of operations or cash flows.

In July 2013, the FASB issued ASU 2013-11, *Presentation of an Unrecognized Tax Benefit (UTB) When a Net Operating Loss (NOL) Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists*, which requires a reporting entity to present an unrecognized tax benefit as a liability in the financial statements separate from deferred tax assets if a net operating loss carryforward, a similar tax loss, or a tax credit carryforward is not available as of the reporting date to settle taxes that would result from the disallowance of the tax position or if a reporting entity does not intend to use the deferred tax asset for such purpose. The amendments in ASU 2013-11 are effective for fiscal years, and interim periods within those years, beginning on or after December 15, 2013. The adoption of ASU 2013-11 did not have a material impact on our financial position, results of operations or cash flows.

In March 2013, the FASB issued ASU 2013-04, *Obligations Resulting from Joint and Several Liability Arrangements for Which the Total Amount of the Obligation is Fixed at the Reporting Date*, which provides guidance on the recognition, measurement, and disclosure of obligations resulting from joint and several liability arrangements for which the total amount of the obligation is fixed at the reporting date. The update requires an entity to measure obligations resulting from joint and several liability obligations for which the total amount of the obligation within the scope of the update is fixed at the reporting date, as the sum of the amount the reporting entity agreed to pay on the basis of its arrangements among its co-obligors and any additional amount the reporting entity expects to pay on behalf of its co-obligors. The update also requires an entity to disclose the nature and amount of the obligation as well as other information about those obligations. The amendments in ASU 2013-04 are effective for fiscal years, and interim periods within those years, beginning on or after December 15, 2013 and must be applied retrospectively. The adoption of ASU 2013-04 in the first quarter of 2014 did not have a material impact on our financial position, results of operations or cash flows.

NOTE 3. FAIR VALUE OF FINANCIAL INSTRUMENTS

The following tables represent the financial instruments measured at fair value on a recurring basis on the financial statements of the Company and the valuation approach applied to each class of financial instruments at December 31, 2014 and 2013 (see Note 2, Summary of Significant Accounting Policies for further information):

December 31, 2014

(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:				
Money market funds (cash equivalents)	\$13,127	\$ —	\$ —	\$13,127
Corporate notes and bonds	—	12,974	—	12,974
Asset-backed securities	—	141	—	141
Total assets measured at fair value	\$13,127	13,115	\$ —	\$26,242

December 31, 2013

(in thousands)

	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Quoted Prices in Active			

Markets for
Identical
Assets
(Level 1)

Assets:

Money market funds (cash equivalents)	\$27,096	\$—	\$—	\$27,096
Corporate notes and bonds	—	11,460	—	11,460
Asset-backed securities	—	500	—	500
Total assets measured at fair value	\$27,096	\$11,960	\$—	\$39,056

Level 1 assets are priced using quoted prices in active markets for identical assets which include cash accounts and money market 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 year ended December 31, 2014.

NOTE 4. INVESTMENTS

The following tables summarize the Company's available-for-sale investments at December 31, 2014 and 2013 (in thousands):

AVAILABLE-FOR-SALE INVESTMENTS

December 31, 2014

(in thousands)

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Asset-backed securities	\$ 141	\$—	\$—	\$ 141
Corporate notes and bonds	12,967	10	(3)	12,974
Total	\$ 13,108	\$ 10	\$(3)	\$ 13,115

AVAILABLE-FOR-SALE INVESTMENTS

December 31, 2013

(in thousands)

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Asset-backed securities	\$ 500	\$ —	\$ —	\$ 500
Corporate notes and bonds	11,438	23	(1)	11,460
Total	\$ 11,938	\$ 23	\$(1)	\$ 11,960

The following table summarizes the maturities of the Company's available-for-sale securities at December 31, 2014 and 2013 (in thousands):

AVAILABLE-FOR-SALE INVESTMENT MATURITIES

(in thousands)

	At December 31, 2014		At December 31, 2013	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
Due in less than 1 year	\$10,586	\$10,585	\$4,999	\$5,002
Due in 1-3 years	2,522	2,530	6,939	6,958
Total	\$13,108	\$13,115	\$11,938	\$11,960

For the year ended December 31, 2014, \$861,000 in proceeds from sales of marketable securities (including principle paydowns) were collected while no proceeds were received for the year ended December 31, 2013. The Company determines gains and losses of marketable securities based on specific identification of the securities sold. There were no gross realized gains and losses from sales of marketable securities for the years ended December 31, 2013 and 2014.

No other-than-temporary impairments are recorded as no investments had a fair value that remained less than its cost for more than twelve months as of December 31, 2014 and 2013. The Company does not intend to sell investments and it is more likely than not that we will not be required to sell investments before recovering the amortized cost.

NOTE 5. PROPERTY AND EQUIPMENT

Property and equipment are recorded at cost and consisted of the following at December 31, 2014 and 2013 (in thousands).

PROPERTY AND EQUIPMENT (in thousands)	12/31/2014	12/31/2013
Computer equipment	\$1,020	\$567
Laboratory and scientific equipment	1,435	791
Furniture and fixtures	212	37
Leasehold improvements	630	279
Manufacturing equipment	190	—
Capital lease – leasehold improvements	266	—
Capital projects in progress	227	—
Total property and equipment	\$3,980	\$1,674
Accumulated amortization – capital lease	(133)	—
Accumulated depreciation - other	(1,311)	(627)
Net property and equipment	\$2,536	\$1,047

Depreciation expense (which includes amortization of capital lease assets) for the for the years ended December 31, 2014 and 2013, five months ended December 31, 2012 and 2011, and twelve months ended July 31, 2012 was \$817,000, \$286,000, \$5,000, \$1,000, and \$2,000, respectively.

NOTE 6. LICENSE AGREEMENTS AND GRANTS

Schott Jenaer Glas GmbH

The Company signed a licensing agreement for microarraying slides using OptiChem coatings with Schott Jenaer Glas GmbH (“SCHOTT”) in November 2004. Since this time, SCHOTT and the Company have extended this license. In August 2011, SCHOTT renewed and expanded its licenses for OptiChem microarray slide products, designated as Schott Nexterion Slide H and Slide HS. The terms remain substantially the same as in previous agreements, with the expansion to include microarray slide products intended for use in medical diagnostic devices.

The August 2011, agreement extended the non-exclusive license through November 2014. SCHOTT paid the Company \$150,000 comprised of a one-time license fee (\$50,000) and non-refundable prepaid royalties (\$100,000). Royalties consist of 5% of SCHOTT’s net product sales. The prepaid royalty was recognized as deferred revenue, and was recognized as SCHOTT’s net product sales were reported to the Company. Upon expiration of the amendment in 2014, the remaining royalty fees totaling \$60,000 were recognized as revenue.

In November 2014 the agreement was amended and extended with an expiration date that coincides with the expiration of the underlying patents. The terms remain substantially the same with royalties continuing to be 5% of SCHOTT's net product sales. SCHOTT is not required to pay a one-time license fee or non-refundable prepaid royalty as part of the new agreement. Revenue will be recognized as SCHOTT's net product sales are reported to the Company.

NanoString Technologies

In October 2007, the Company entered into an exclusive seven-year license with NanoString Technologies, Inc. ("NanoString"). The license grants NanoString the right to apply OptiChem coatings to NanoString's proprietary molecular detection products.

Nanosphere, Inc.

In July 2010, the Company entered into a non-exclusive license to Nanosphere, Inc. (“Nanosphere”). The license grants to Nanosphere the right to apply OptiChem coatings to Nanosphere’s proprietary analytical products. The products may also include FDA-regulated diagnostics devices. Pursuant to the license agreement, Nanosphere paid the Company a non-refundable first-year fee of \$150,000 plus a \$15,000 technology transfer fee. On each anniversary of the agreement date, the license called for Nanosphere to pay to the Company the amounts of \$350,000 in 2011; \$600,000 in 2012, and \$750,000 in 2013 in order to complete the payments for rights under the remaining patent life. The final installment of this arrangement for \$750,000 was received in full in July 2013. All of the amounts due from Nanosphere were recognized as revenue during the fiscal year ended July 31, 2010.

Defense Medical Research and Development Program

In May 2012, the Company and Denver Health were notified that the Defense Medical Research and Development Program (“DMRDP”) recommended \$2.0 million of funding for a proposed 35-month project of which the Company estimates it will receive direct monies for internal research and development of \$650,000. The joint proposal became the sole recipient under the Military Infectious Diseases Applied Research Award program for rapid detection of serious antibiotic-resistant infections. The project will apply the Accelerate ID/AST system to wound infections and other serious infections secondary to trauma. The Company has invoiced a cumulative total of \$379,000 under this grant which is recorded as an offset to research and development expenses. The amount invoiced for the years ended December 31, 2014 and 2013, five months ended December 31, 2012 and 2011, and twelve months ended July 31, 2012 amounting to \$221,000, \$143,000, \$15,000, \$0, and \$0, respectively.

Arizona Commerce Authority

In August 2012, the Company entered into a Grant Agreement (the “Grant Agreement”) with the Arizona Commerce Authority, an agency of the State of Arizona (the “Authority”), pursuant to which the Authority provided certain state and county sponsored incentives for the Company to relocate its corporate headquarters to, and expand its business within, the State of Arizona (the “Project”). Pursuant to the Grant Agreement, the Authority agreed to provide a total grant in the amount of \$1,000,000 (the “Grant”) for the use by the Company in the advancement of the Project. The Grant is payable out of an escrow account in four installments, upon the achievement of the following milestones:

- Milestone 1 – Relocation of Company’s operations and corporate headquarters to Arizona and creation of 15 Qualified Jobs (as defined below).
- Milestone 2 – Creation of 30 Qualified Jobs (including Qualified Jobs under Milestone 1).
- Milestone 3 – Creation of 40 Qualified Jobs (including Qualified Jobs under Milestones 1 and 2).
- Milestone 4 – Creation of 65 Qualified Jobs (including Qualified Jobs under Milestones 1, 2 and 3) and capital investment of at least \$4,520,000.

For purposes of the Grant Agreement, a “Qualified Job” is a job that is permanent, full-time, new to Arizona, and for which the Company pays average (across all Qualified Jobs identified by the Company in its discretion) annual wages of at least \$63,000 and offers health insurance benefits and pays at least 65% of the premiums associated with such benefits. The amount of each installment payment will be determined in accordance with a formula specified in the Grant Agreement. The Grant Agreement also contains other customary provisions, including representations, warranties and covenants of both parties. As of December 31, 2014, the Company has collected all of the \$1,000,000 in milestones. The full amount is recorded in long-term deferred income until the economic development provisions of the grant have been satisfied in full, as there are “claw-back” provisions which would require repayment of certain

amounts received if employment levels are not sustained during the term of the arrangement. Once the “claw-back” provisions expire in January 2018, we will recognize the grant as other non-operating income. Further details are included in Note 7, Deferred Revenue and Income.

NOTE 7. DEFERRED REVENUE AND INCOME

Deferred revenue consists of amounts received for products or services not yet delivered or earned. Deferred income consists of amounts received for commitments not yet fulfilled. If we anticipate that the revenue or income will not be earned within the following twelve months, the amount is reported as long-term deferred income. A summary of the balances as of December 31, 2014 and 2013 follows (in thousands):

Deferred Revenue and Income

(in thousands)

	12/31/2014	12/31/2013
Prepaid royalties	\$0	\$69
Fisher agreement	13	13
Total current deferred revenue and income	\$13	\$82
Arizona Commerce Authority grant	\$1,000	\$750
Fisher agreement	14	27
Total long-term deferred income	\$1,014	\$777

Deferred revenue recognized was approximately \$69,000, \$10,000, \$7,000, \$5,000, and \$24,000 during the years ended December 31, 2014 and 2013, five-month periods ended December 31, 2012 and 2011, and the fiscal year ended July 31, 2012, respectively. Deferred revenue consists of prepaid royalty fees from Nanostring and SCHOTT. During the year ended July 31, 2012 an additional \$100,000 was received from SCHOTT as prepaid royalties of which \$69,000, \$4,000, \$7,000, \$0, and \$20,000 was recognized during the years ended December 31, 2014 and 2013, five-month period ended December 31, 2012 and 2011, and the fiscal year ended July 31, 2012, respectively and are reflected as licensing and royalty revenues. Further information regarding the SCHOTT agreement is included in Note 6, License Agreements and Grants.

Deferred income includes a \$40,000 payment received from Fisher Scientific in July 2013, of which \$13,000 has been recognized as an offset against research and development expenses in the year ended December 31, 2014. We anticipate earning \$13,000 of the remaining amount in the next twelve months and the final \$14,000 in future years.

Through December 31, 2014, \$1,000,000 in milestone payments from the Arizona Commerce Authority were received of which none has been recognized in income and we do not anticipate earning any of it in the next fiscal year. Further details regarding the Arizona Commerce Authority agreement are included in Note 6, License Agreements and Grants.

NOTE 8. STOCK PURCHASE

In April 2012, we entered into a Securities Purchase Agreement with Abeja Ventures, LLC (“Abeja”), pursuant to which the Company agreed to sell and issue to Abeja at a purchase price of \$1.03 per share for an aggregate purchase price of \$14,420,000; (i) 14,000,000 shares of the Company’s common stock (“Common Stock”); (ii) a warrant to purchase 7,000,000 shares of Common Stock at an exercise price of \$1.03 per share (the “\$1.03 Warrant”); and (iii) another warrant to purchase 7,000,000 shares of Common Stock at an exercise price of \$2.00 per share (the “\$2.00 Warrant”), with each warrant exercisable prior to the fifth anniversary of the closing of the transactions contemplated by the Securities Purchase Agreement (collectively, the “Investment”). The purchase of Common Stock and warrants

pursuant to the Investment, which was consummated in June, 2012, qualified for equity treatment under U.S. GAAP. The respective values of the warrants and Common Stock were calculated using their relative fair values and both are classified under Contributed Capital. The value therefore recorded for the warrants was \$5,896,000 and for the Common Stock was \$8,524,000.

Both warrants were exercisable until June 26, 2017, which was the fifth anniversary of the date on which the warrants were issued. Other significant terms and conditions of the warrants are as follows:

- the warrants provide for partial exercises, but they do not provide for a “cashless” exercise feature (i.e., they may only be exercised for cash);
- the warrants do not contain anti-dilution provisions that would trigger exercise price or other adjustments as a result of subsequent issuances of the Company’s equity securities, but they do contain customary provisions for equitable adjustments in connection with stock dividends, stock splits or reclassifications of Common Stock;
- following certain types of fundamental transactions involving the Company (e.g., a transaction resulting in a change in control of the Company), the holder of the warrants would continue to be entitled to exercise the warrants in exchange for the equity securities or alternate consideration receivable by a holder of Common Stock as a result of the fundamental transaction; and
- the holder of the warrants is entitled to certain demand and piggy-back registration rights, including for shelf registrations, with respect to the shares of Common Stock issuable upon its exercise of the warrants.

In March 2013, Abeja exercised in full its warrant to purchase 7,000,000 shares of Common Stock at an exercise price of \$1.03 per share. On the same date, Abeja also exercised the 92% of its warrant to purchase an additional 7,000,000 shares of Common Stock at an exercise price of \$2.00 per share (Abeja exercised such warrant for 6,428,840 shares, leaving 571,160 shares unexercised). The Company received aggregate funds of \$20,068,000 in connection with such exercises. Shares issued by the Company in connection with the warrant exercises were issued directly to the members of Abeja on a pro rata basis in accordance with their membership interests and written exercise instructions provided to the Company by Abeja. Immediately after giving effect to the warrant exercises, Abeja also distributed in kind to its members (on a pro rata basis in accordance with their membership interests) the remaining shares of Common Stock held by that entity.

NOTE 9. RIGHTS OFFERING

April 2014 Offering

On April 7, 2014, the Company commenced a rights offering to raise \$45.0 million to fund continued operations, clinical trials, and product commercialization efforts. Under the terms of the rights offering, the Company distributed, at no charge to the holders of its Common Stock as of 5:00 p.m., New York City time, on March 14, 2014, which was established as the record date for the rights offering, 0.063921 non-transferable subscription rights for each share of Common Stock owned on the record date. Each whole subscription right allowed the holder to subscribe to purchase one share of Common Stock at a subscription price of \$16.80 per share which was lower than the market price of \$17.64 per share on the date of the rights offering commencement and the \$17.54 per share on the date the rights offering period expired. In the aggregate, the Company intended to issue 2,678,571 shares of Common Stock in connection with the rights offering. The purpose of the rights offering was to raise equity capital in a cost-effective manner that gives all of the Company’s existing stockholders the opportunity to participate on a pro rata basis.

In connection with the rights offering, the Company received standby commitments from the Jack W. Schuler Living Trust and the Schuler Family Foundation. The standby purchasers agreed to purchase any and all shares of Common Stock that were not subscribed for by stockholders in connection with the rights offering. On May 1, 2014, the Company entered into an Assignment and Assumption Agreement with the standby purchasers, Oracle Institutional Partners, L.P. and Oracle Partners, L.P., pursuant to which each standby purchaser assigned and transferred its respective rights, responsibilities, liabilities and obligations under the Standby Purchase Agreement to purchase 297,619 shares of Common Stock not subscribed for by the Company’s stockholders in connection with the rights offering to (i) Oracle Institutional Partners, L.P., with respect to 119,047 shares of such Common Stock, and (ii)

Oracle Partners, L.P., with respect to the remaining 178,572 shares of such Common Stock.

The rights offering period expired at 5:00 p.m., New York City time, on April 28, 2014, and the transactions contemplated by the rights offering and the Standby Purchase Agreement described above (including the Company's issuance of an aggregate of 2,678,571 shares of its Common Stock to the rights offering participants and standby purchasers) were completed on May 19, 2014. The Company received gross proceeds of \$45,000,000 before costs associated with the transactions which totaled \$125,000 and are treated as a reduction of contributed capital in the Stockholders' Equity section of the Balance Sheets.

Because the exercise price of the rights offering of \$16.80 was less than the fair value of the Company's shares of Common Stock at the expiration of the offering, there is a bonus element that is treated similar to a stock dividend. The weighted average shares outstanding, as well as the basic and diluted loss per share for the year ended December 2013, five-month periods ended December 31, 2012 and 2011, and fiscal year ended July 31, 2012 have been revised for those effects.

July 2013 Offering

On July 12, 2013, the Company publicly announced the final terms of a rights offering. Rights offering materials were subsequently distributed to the Company's stockholders on July 18, 2013, at which time the rights offering period commenced. Pursuant to the terms of the rights offering, the Company distributed, at no charge to the holders of its Common Stock as of 5:00 p.m., New York City time, on July 8, 2013, which was established as the record date for the rights offering, 0.064038 non-transferable subscription rights for each share of Common Stock owned on the record date. Each whole subscription right allowed the holder to subscribe to purchase one share of Common Stock at a subscription price of \$8.04 per share. In addition, any holder of subscription rights exercising his, her or its basic subscription privilege in full was eligible to subscribe to purchase additional shares of Common Stock at the same subscription price per share, subject to the conditions and limitations described further in the prospectus.

In connection with the rights offering, the Company received a standby commitment from Abeja to purchase, at \$8.04 per share, any and all shares of Common Stock that were not subscribed for by stockholders in connection with the rights offering.

The rights offering period expired at 5:00 p.m., New York City time, on August 7, 2013, and the transactions contemplated by the rights offering and the Standby Purchase Agreement described above (including the Company's issuance of an aggregate of 2,487,562 shares of its Common Stock to the rights offering participants and standby purchaser) were completed on August 8, 2013. The Company received gross proceeds of \$20,000,000 before costs associated with the transactions, which totaled \$88,000 and are treated as a reduction of contributed capital in the Stockholders' Equity section of the Balance Sheets.

NOTE 10. EARNINGS PER SHARE

The financial statements show basic earnings (loss) per share.

The Company's net loss for the periods presented caused the inclusion of all outstanding warrants and options to purchase our Common Stock to be antidilutive. As of December 31, 2014 and December 31, 2013, there were Common Stock options and warrants exercisable for 6,174,886 (571,160 warrants and 5,603,726 options) and 5,731,246 (571,160 warrants and 5,160,086 options) shares of Common Stock, respectively, which were not included in diluted loss per share as the effect was antidilutive.

Weighted average shares outstanding for the year ended December 2013, five-month periods ended December 31, 2012 and 2011, and fiscal year ended July 31, 2012 have been revised for the effects of the rights offering (See Note

9, Rights Offering).

70

NOTE 11. EMPLOYEE and CONSULTANT EQUITY-BASED COMPENSATION

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

Qualified Stock Option Plan

The Qualified Stock Option Plan (the “Qualified Plan”) was a stockholder-approved plan that provided for stock option grants to employees, including executive officers. The exercise price of each option, which has a maximum ten-year life, was established by the Company's Compensation Committee on the date of grant.

As of December 31, 2014, there were 527,500 options exercised under the Qualified Plan and none that remain outstanding. The Qualified Plan has been replaced by the 2012 Omnibus Equity Incentive Plan, so no further options are available for grant.

Non-Qualified Stock Option Plan

The Non-Qualified Stock Option Plan (the “Non-Qualified Plan”) was a stockholder-approved plan that provided for stock option grants to independent contractors, technical advisors and directors of the Company. The exercise price of each option, which has a maximum ten-year life, was established by the Company's Compensation Committee on the date of grant.

As of December 31, 2014, there were 245,000 options exercised under the Non-Qualified Plan and 10,000 that remain outstanding. The Non-Qualified Plan has been replaced by the 2012 Omnibus Equity Incentive Plan, so no further options are available for grant.

2004 Omnibus Stock Option Plan

In December 2004, the Company's stockholders approved the Omnibus Stock Option Plan and reserved 500,000 shares of its authorized but unissued Common Stock for stock options to be granted to employees, independent contractors, technical advisors and directors of the Company. The authorized shares in this plan were increased by 5,000,000 shares to an aggregate amount of 5,500,000 upon stockholder approval during the fiscal year ended July 31, 2012.

As of December 31, 2014, there were 371,737 options exercised under the 2004 Omnibus Stock Option Plan and 3,568,263 that remain outstanding. The 2004 Omnibus Stock Option Plan has been replaced by the 2012 Omnibus Equity Incentive Plan, so no further options are available for grant.

2012 Omnibus Equity Incentive Plan

In December 2012, the Company's stockholders approved the Company's 2012 Omnibus Equity Incentive Plan to replace the Qualified Stock Option Plan, Non-Qualified Stock Option Plan and 2004 Omnibus Stock Option Plan (“Prior Plans”). The Prior Plans remain in effect until all awards granted under those plans have been exercised, forfeited, canceled, expired or otherwise terminated.

In connection with the approval of such plan, all stock options, totaling 1,677,500 formerly available for new awards under the Prior Plans were transferred to the 2012 Omnibus Equity Incentive Plan.

At the Company's 2014 Annual Meeting of Stockholders held in May 2014, stockholders approved an amendment to the Company's 2012 Omnibus Equity Incentive Plan increasing the number of stock options of Common Stock reserved and available for grant by 4,000,000 to 5,677,500 shares.

Stock options granted under this plan typically vest either (i) one year after grant date, (ii) monthly over a one year period, or (iii) 40% two years after grant date and the remaining 60% monthly over the next three years. The maximum term is ten years.

As of December 31, 2014, there were 3,000 options exercised under the 2012 Omnibus Equity Incentive Plan and 2,025,463 that remain outstanding, leaving 3,649,037 available for grant.

Combined Plans

The following table summarizes option activity under all plans during the years ending December 31, 2014 and December 31, 2013 and shows the exercisable shares as of December 31, 2014:

Stock Option Activity	Number of Shares	Weighted Average Exercise Price per Share
Options outstanding January 1, 2013	4,360,500	\$2.14
Granted	1,308,086	7.56
Forfeited	(58,000)	6.47
Exercised	(328,000)	2.54
Expired	(122,500)	1.78
Options Outstanding December 31, 2013	5,160,086	3.45
Granted	769,055	16.22
Forfeited	(13,678)	13.06
Exercised	(311,737)	2.96
Expired	(0)	—
Options Outstanding December 31, 2014	5,603,726	5.21
Exercisable December 31, 2014	2,354,678	2.75

The cash received from the exercise of options during the year ending December 31, 2014 was \$923,000 and the tax benefit realized was \$0 for the same period. Upon exercise, shares are issued from shares authorized and held in reserve. The intrinsic value of options exercised was \$3,846,000 and \$2,583,000 for the years ending December 31, 2014 and 2013, respectively. No options were exercised for the five-months ending December 31, 2012 and 2011 and fiscal year ending July 31, 2012.

The total fair value of shares vesting during the period was \$3,786,000, \$600,000, and \$89,000 for the years ending December 31, 2014 and 2013, and five-months ending December 31, 2012, respectively.

As discussed in Note 2, Summary of Significant Accounting Policies, the Company accounts for all option grants using the Black-Scholes option pricing model in accordance with ASC 718 for options granted or extended. Note 2 also describes the significant assumptions utilized for estimating the various inputs required this pricing model. The table below summarizes the resulting weighted average inputs used to calculate the estimated fair value of options awarded for during the periods shown below:

Black-Scholes Assumptions for Option Granted

	12 months 12/31/2014	12 months 12/31/2013	5 months 12/31/2012	12 months 7/31/2012
Expected term (in years)	6.25	6.28	6.53	2.86
Volatility	96 %	97 %	98 %	109 %
Expected dividends	—	—	—	—

Edgar Filing: Accelerate Diagnostics, Inc - Form 10-K

Risk free interest rates	1.9	%	1.5	%	1.0	%	0.5	%
Estimated forfeitures	0.4	%	14	%	22	%	23	%
Weighted average fair value	\$ 12.63		\$ 6.05		\$ 2.92		\$ 0.65	

In general, option awards have a requisite service period and unvested options are forfeited upon employee or consultant termination. The Company estimates a forfeiture rate which is applied to outstanding options to determine options expected to be forfeited with the remaining outstanding options being those expected to vest. Further information regarding the forfeiture rate calculation is included in Note 2, Summary of Significant Accounting Policies. The following table shows summary information for outstanding options, options that are exercisable (vested) and outstanding options that are either vested or expected to vest as of December 31, 2014:

Stock Option Supplemental Information

	Options Outstanding	Options Exercisable	Options Vested and Expected to Vest
Number of options	5,603,726	2,354,678	5,595,747
Weighted average remaining contractual term (in years)	7.92	7.55	7.92
Weighted average exercise price	\$5.21	\$2.75	\$5.20
Weighted average fair value	\$4.01	\$1.97	\$4.00
Aggregate intrinsic value (in thousands)	\$76,494	\$38,056	\$76,423

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 \$19.19 on the last trading day of 2014 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 market value of the Company's stock.

The expense and tax benefits recognized on Company's Statements of Operations and Comprehensive Loss related to options is summarized below (in thousands):

Equity-Based Compensation Expense and Tax Benefit

(in thousands)

	12 months 12/31/2014	12 months 12/31/2013	5 months 12/31/2012	5 months 12/31/2011 (unaudited)	12 months 7/31/2012
Equity-based compensation expense	\$ 9,624	\$ 3,828	\$ 533	\$ 273	\$ 782
Recognized tax benefit	\$ —	\$ —	\$ —	\$ —	\$ —

As of December 31, 2014, unrecognized equity-based compensation cost related to unvested stock options was \$8,176,000. This is expected to be recognized over the years 2015 through 2019.

NOTE 12. INCOME TAXES

At December 31, 2014, the provision for income taxes was (\$527,000), which resulted in an overall effective tax rate of (1.7%). The tax rate was favorably affected by refundable state income tax credits which were realized in January of 2014. This compares with a tax provision of \$0 for the tax year ended December 31, 2013, with an effective tax rate of 0.0% for that year.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's net deferred income taxes for the years ending December 31, 2014 and 2013, are as follows (in thousands):

Deferred Income Tax Components

(in thousands)

	12/31/2014	12/31/2013
Deferred tax assets:		
Property & equipment	\$77	\$21
Intangible assets, definite-lived	421	478
Deferred revenue	380	313
Stock options	3,644	1,319

Edgar Filing: Accelerate Diagnostics, Inc - Form 10-K

Inventory	620	—
Charitable contribution	13	11
General business credit	885	637
Net operating loss carryforward	15,492	8,313
Valuation allowance	(21,532)	(11,092)
Deferred tax assets	\$—	\$—

As of December 31, 2014, the Company has generated regular tax net operating losses of approximately \$49,200,000. The Company's ability to realize tax benefit from the net operating loss is subject to annual limitation under Internal Revenue Code Section 382. Due to the change in control which occurred as a result of Abeja Ventures, LLC's investment in the Company on June 26, 2012, the Company estimates that the annual Section 382 limitation on utilization of net operating losses will be \$420,000. As such, the Company will never get the benefit of approximately \$4,200,000 of the net operating losses generated prior to June 26, 2012. The deferred tax asset has been adjusted to reflect the Section 382 limitation. Section 382 also applies to built-in losses at the time of the transaction. The amounts of any unrealized built-in losses or gains were not calculated at the date of the transaction. The gross net operating losses available for future use are approximately \$45,000,000. For federal purposes, net operating losses can be carried forward for up to 20 years. The Company's net operating losses will begin to expire in 2023.

Additionally, the Company has relocated its headquarters to Arizona. They began filing in Arizona starting with the year ending December 31, 2013. To date, the Company has generated Arizona-source net operating losses of approximately \$33,700,000. The Company's Arizona net operating losses will begin to expire in 2033.

The net deferred tax asset valuation allowance is \$21,532,000 as of December 31, 2014 compared to \$11,092,000 as of December 31, 2013. The prior year deferred taxes and effective tax rate reconciliation have been adjusted to correct for temporary items that were not originally reflected. Offsetting changes in the valuation allowance to reflect the additional deferred tax assets at the value that is more-likely-than-not to be realized resulted in no effect on the Company's balance sheet as of December 31, 2013 or results of operations for the year then ended. 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.

The difference between the U.S. federal statutory income tax rate and the Company's effective tax rate for years ending December 31, 2013 and 2014 is as follows:

Effective Tax Rate	12/31/2014		12/31/2013	
U.S. Federal statutory income tax rate	(34.00)%	(34.00)%
State taxes, net of federal tax benefit	(3.20)	(3.80)
Non-deductible equity and other compensation	3.70		1.20	
State income tax credits, net of Federal effects	(1.00)	—	
Limitation on net operating losses due to §382	0.50		1.00	
Credit for increased research activities	(0.80)	(3.20)
Change in valuation allowance	33.10		38.80	
	(1.70)%	0.00	%

At December 31, 2014, the Company had uncertain tax positions of \$161,000, determined as follows:

Uncertain Tax Positions

(in thousands)

Balance December 31, 2013	\$—
Increases for prior positions	78
Increases for current year positions	83
Balance December 31, 2014	\$161

These uncertain positions are not expected to change within the next twelve months. At December 31, 2014, the Company has not recorded any expenses related to these uncertain tax positions. Rather, the item is a reduction of the Company's deferred tax assets.

The Company has incurred federal net operating losses (NOLs) dating to the tax year ended July 31, 2004. As such, all loss carryovers are subject to adjustment under IRS and state examination, depending on the jurisdiction in which

they were incurred.

NOTE 13. COMMITMENTS

Leases

As of December 31, 2012, the Company was a party to a lease for office and laboratory space located in Denver, Colorado that subsequently expired on February 1, 2013. Total rent expense including common area charges was approximately \$0, \$11,000, \$40,000, \$35,000, and \$74,000 during the years ended December 31, 2014 and 2013, five-month periods ended December 31, 2012 and 2011, and the fiscal year ended July 31, 2012, respectively.

In August 2012, the Company entered into a Lease Agreement (“Lease”) with Pima County, a political subdivision of the State of Arizona (“Landlord”), pursuant to which the Company leased approximately 15,096 square feet of office space located in Tucson, Arizona for a period of three years (the “Initial Term”), which may be extended by the Company for up to three additional one-year periods (each a “Renewal Term”). The Lease also provides that the Company has the option, with six months prior notice to Landlord, to lease either or both of two additional areas with an aggregate size of approximately 7,920 square feet.

Pursuant to the Lease, the Company agreed to: (i) pay rent equal to \$9.25 per usable square foot per year (approximately \$140,000 per year) during the Initial Term and \$19.80 per usable square foot per year (approximately \$299,000 per year) during any Renewal Term; (ii) relocate its corporate offices to the Tucson area and begin operations within 30 days of the date that the tenant improvements are substantially completed (the “Commencement Date”); and (iii) within 18 months of the Commencement Date, employ at least 30 individuals with a median salary of at least \$70,000, which median salary must be maintained throughout the term of the Lease. For any month that the Company fails to satisfy the condition described in clause (iii) of the preceding sentence, the rental rate under the Lease will be increased for that month by a percentage that is twice the percentage by which the Company’s annual payroll has fallen short of the specified goal (subject to a cap equal to \$19.80 per usable square foot per year). The Lease also provides that Landlord will pay for tenant improvements (up to a cap of \$1,400,000) as well as certain repairs, utilities and insurance. In January 2013, we relocated our headquarters into the above described leased space in Tucson, Arizona and are otherwise in compliance with the lease terms as of December 31, 2014 and 2013, thus no increased rental rates were paid.

In October 2013, the Company executed the First Amendment to the Lease with Pima County to exercise its option and to expand its lease premises by 4,551 square feet whereby Pima County provided tenant improvements. After the completion of tenant improvements, the Company occupied this additional space in January 2014. Pursuant to the First Amendment, the Company agreed to (i) pay rent equal to \$9.25 per square foot per year (approximately \$42,000 per year) and (ii) repay tenant improvements over the remaining lease term. These tenant improvements are treated as a capital lease whereby both an asset and a liability have been recorded and periodic interest based on an annual rate of 4% and depreciation are recorded to amortize the value of this asset and the liability over the remaining lease term. The Company incurred interest cost of \$7,000 in the year ended December 31, 2014 and no interest costs in prior years as a result of this capital lease. Further details regarding this capital lease are included in Note 5, Property and Equipment.

The future minimum lease payments under the capital lease together with the present value of the net minimum lease payments as of December 31, 2014 are as follows:

Capital Lease Obligations
(in thousands)

Year ending December 31:	
2015	\$ 151
2016	13
2017	—
2018	—
2019	—
Total minimum lease payments	\$ 164
Less amount representing interest	(4)
Present value minimum lease payments	\$ 160

In April 2014 and June 2014, the Company entered into a Second Amendment and Third Amendment, respectively, to the Lease with Pima County pursuant to which the Company exercised its option to build-out and occupy 3,594 square feet and an additional 4,163 square feet not contemplated in the Lease for manufacturing and other operational requirements. Pursuant to these Amendments, the Company also agreed to: (i) pay rent equal to \$9.25 per usable square foot per year for the 3,594 option space and \$17.63 per usable square foot per year for the additional 4,163 square feet during the Initial Term; (ii) pay rent of \$19.80 per usable square foot per year for the 3,594 option space and \$17.63 per usable square foot per year for the additional 4,163 square feet during any Renewal Term; (iii) restore the 3,594 option space and the 4,163 additional space to a reasonable office typical tenant space at the end of the Lease; and (iv) adhere to all other terms of the Lease. The Company estimates that the costs for restoration at the end of the Lease as described in (ii) of these Amendments are immaterial and, therefore, no accrual has been recorded. As part of these Amendments, the Company was granted first refusal rights to possible future space that might become available.

In November 2014, the Company entered into a Fourth Amendment to the Lease with Pima County exercising the first refusal rights for an additional 18,481 square feet of space that became available. Pursuant to this Amendment, the Company agreed to: (i) pay rent equal to \$17.63 per usable square foot per year during the Initial Term; (ii) pay rent of \$19.80 per square foot per year for any Renewal Term, (iii) restore the 18,481 square foot space to a reasonable office typical tenant space at the end of the Lease (iv) pay utilities of \$8,000 per month (v) adhere to all other terms of the Lease. The Company estimates that the costs for restoration at the end of the Lease as described in (iii) of this Amendment is immaterial and, therefore, no accrual has been recorded.

Total rent expense for the Tucson facility, including common area charges was \$293,000 and \$168,000 for the years ended December 31, 2014 and 2013, respectively with no amounts in previous periods. Future minimum lease payments under this agreement are as follows (in thousands):

Operating Lease Obligations
(in thousands)

Year ending December 31:	
2015	\$633
2016	60
2017	—
2018	—
2019	—
Thereafter	—
Total operating lease obligations	\$693

Purchase and License Agreements

The Company periodically enters into agreements to license patents whereby royalty payments and/or payments are made based on sales. In years ending December 31, 2014 and 2013 there were \$50,000 and \$0 royalty payments made which are included in research and development expenses. No amounts have been incurred or recorded for payments based on sales.

Clinical Trial Agreements

The Company has entered into master agreements with clinical trial sites in which we typically pay a set amount for start-up costs and then pay for work performed. No amounts have been incurred for these arrangements through December 31, 2014.

Employment Agreement and Consulting Agreement

In December, 2007, we entered into an Employment Agreement with Mr. Geimer. The agreement provided for an annual base salary of \$165,000 with annual deferred compensation of \$75,000 and was to have expired on December 31, 2012. In June, 2012, Thomas V. Geimer resigned as the Company's Chief Executive Officer, Chief Financial Officer and Secretary. In connection with his resignation, Mr. Geimer entered into an Amendment to Employment Agreement with the Company, as well as a new Consulting Agreement. Pursuant to the Amendment to Employment Agreement, Mr. Geimer and the Company agreed to stagger certain payments due to him such that \$650,000 was paid to Mr. Geimer upon the closing of the Investment and \$700,000 payable to him on July 1, 2013. Any payments due to Mr. Geimer under his Employment Agreement (as amended) but not timely paid by the Company bear interest at a rate of 18% per annum. In addition, the \$75,000 deferred compensation payment for the Company's fiscal year ending

July 31, 2012 was contributed prior to the closing of the Investment. Pursuant to the Consulting Agreement, Mr. Geimer agreed to provide certain transition and other services to the Company. In exchange, during the remainder of 2012, the Company paid Mr. Geimer an amount equal to \$24,000 per month. From January 1, 2013 through December 31, 2013, Mr. Geimer's aggregate consulting fee was \$96,000 (\$8,000 per month). As of December 31, 2013, no additional amounts are due under the Consulting Agreement and no further amounts were incurred during the year ending December 31, 2014.

NOTE 14. SEGMENTS

The Company operates as one operating segment. Operating segments are defined as components of an enterprise for which separate financial information is evaluated regularly by the chief operating decision maker, who is the chief executive officer, in deciding how to allocate resources and assessing performance. The Company's business operates in one operating segment because the Company's chief operating decision maker evaluates the Company's financial information and resources and assesses the performance of these resources on a consolidated basis. Since the Company operates in one operating segment, all required financial segment information can be found in the consolidated financial statements.

NOTE 15. SUBSEQUENT EVENTS

Arizona Department of Revenue

In January 2015, we were notified by the Arizona Commerce Authority ("Authority") that we meet the program requirements to receive a "Certificate of Qualification" and, therefore, are eligible for a partial refund of research and development investments amounting to a maximum of \$647,000. The "Certificate of Qualification" does not obligate the Arizona Department of Revenue to issue the refund. Furthermore, the calculation of the actual refund due will be based on actual qualifying expenses and income tax liability for the 2014 tax year and if qualifying expenses decrease or income tax liability increases, the refund amount may be less than the \$647,000. If the amount received for this tax credit is later determined to be incorrect or invalid, the excess may be treated as a tax deficiency.

National Institute of Health

In February 2015, we were notified that the National Institute of Health awarded a five year, \$5 million grant to Denver Health Medical Center and ourselves to develop a fast and reliable identification and categorical susceptibility test carbapenem-resistant Enterobacteriaceae directly from whole blood. We are still working out the final contractual agreement with Denver Health Medical Center and anticipate that our portion of the award will be approximately \$1.8 million over the next five years.

NOTE 16. SUPPLEMENTAL DATA QUARTERLY FINANCIAL INFORMATION (UNAUDITED)**QUARTERLY FINANCIAL INFORMATION**

(in thousands, except per share data)

Unaudited

For the quarters ending:

	12/31/2014	9/30/2014	6/30/2014	3/31/2014	12/31/2013	9/30/2013	6/30/2013	3/31/2013
Revenue	\$79	\$16	\$13	\$14	\$12	\$13	\$7	\$16
Net loss	(8,765)	(8,814)	(8,152)	(5,202)	(5,159)	(3,797)	(3,777)	(2,549)
Basic and diluted net loss per share (1)	(0.20)	(0.20)	(0.19)	(0.12)	(0.12)	(0.10)	(0.10)	(0.09)

(1) Loss per share has been adjusted for the effects of the rights offering (see Item 8, Note 9, Rights Offering).

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Based on an evaluation under the supervision and with the participation of the Company's management, the Company's Principal Executive Officer and Principal Financial Officer have concluded that the Company's disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act were effective as of December 31, 2014 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 Securities and Exchange Commission'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

Management is responsible for establishing and maintaining adequate internal control over financial reporting. The Company's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP. The Company's internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and our directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Management, including the Company's Chief Executive Officer and Chief Financial Officer, does not expect that the Company's internal controls will prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of internal controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Also, any evaluation of the effectiveness of controls in future periods are subject to the risk that those internal controls may become inadequate because of changes in business conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2014. In making this assessment, we used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control - Integrated Framework* (1992 Framework). Based on that assessment, management concluded that, during the period covered by this report, such internal controls and procedures were effective as of December 31, 2014.

Attestation Report of Independent Registered Public Accounting Firm

Edgar Filing: Accelerate Diagnostics, Inc - Form 10-K

The attestation report required under this Item 9A is contained in Item 8 of Part II of this Annual Report on Form 10-K under the heading “Report of Independent Registered Public Accounting Firm”.

Changes in Internal Control Over Financial Reporting

There was no change in the Company's internal control over financial reporting during the period ended December 31, 2014 that materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

Item 9B. Other Information

Not Applicable.

PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K because the required information will be incorporated by reference to our definitive proxy statement for our 2015 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 Annual Report on Form 10-K.

Item 10. Directors, Executive Officers and Corporate Governance

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

Item 11. Executive Compensation

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

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

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

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

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

Item 14. Principal Accounting Fees and Services

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

Item 15. Exhibits, Financial Statement Schedules

a) Documents filed as part of this report

1) All financial statements

	<u>Page</u>
Report of Independent Registered Public Accounting Firm	52
Report of Independent Registered Public Accounting Firm for Prior Audit Periods	54
Balance Sheets as of December 31, 2014 and 2013	55
Statements of Operations and Comprehensive Loss for the years ended December 31, 2014 and 2013, five months ended December 31, 2012 and 2011, and fiscal year ended July 31, 2012	56
Statements of Stockholders' Equity for the years ended December 31, 2014 and 2013, five months ended December 31, 2012 and fiscal year ended July 31, 2012	57
Statements of Cash Flow for the years ended December 31, 2014 and 2013, five months ended December 31, 2012 and 2011, and fiscal year ended July 31, 2012	58
Notes to Financial Statements	59

2) Financial Statement of 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 that follows the signature page of this report.

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.

February 26, 2015 By: /s/ Lawrence Mehren
Lawrence Mehren

President and Chief Executive Officer

Power of Attorney

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

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

Signature	Title	Date
/s/ Lawrence Mehren Lawrence Mehren	President, Chief Executive Officer and Director	February 26, 2015
/s/ Steve Reichling Steve Reichling	Corporate Secretary, Chief Financial Officer and Chief Accounting Officer	February 26, 2015
/s/ John Patience John Patience	Chairman of the Board of Directors	February 26, 2015
/s/ Jack Schuler Jack Schuler	Director	February 26, 2015
/s/ Matthew W. Strobeck Ph.D. Matthew W. Strobeck, Ph.D.	Director	February 26, 2015
/s/ Frank ten Brink	Director	

Frank ten Brink

February 26,
2015

/s/ Mark Miller

Mark Miller

Director

February 26,
2015

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>	<u>Filing Information</u>
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
3.2	Bylaws of Registrant	Incorporated by reference to Exhibit 3.2 filed with the Registrant's Annual Report on Form 10-K for the fiscal year ended July 31, 2012.
4.1	Warrant No. 2 issued by Registrant to Abeja Ventures, LLC on June 26, 2012	Incorporated by reference to Exhibit 4.2 filed with the Registrant's Annual Report on Form 10-K for the fiscal year ended July 31, 2012
4.2	Subscription and Information Agent Agreement, dated March 10, 2014, by and between the Registrant and Broadridge Corporate Issuer Solutions, Inc.	Incorporated by reference to Exhibit 4.2 to the Form S-3 Registration Statement (No. 333-194474) filed by the Registrant on March 10, 2014
4.3	Form of Non-Transferable Subscription Rights Certificate	Incorporated by reference to Exhibit 4.1 to the Registration Statement on Form S-3/A (Amendment No. 1) (File No. 333-194474) filed by the Registrant on April 7, 2014
4.4	Form of Senior Indenture	Incorporated by reference to Exhibit 4.2 of the Registrant's Form S-3 Registration Statement (No. 333-192321), Amendment No. 1, filed on December 2, 2013
4.5	Form of Subordinated Indenture	Incorporated by reference to Exhibit 4.2 of the Registrant's Form S-3 Registration Statement (No. 333-192321), Amendment No. 1, filed on December 2, 2013
10.1	Registrant's 2004 Omnibus Stock Option Plan*	Incorporated by reference to Appendix A of the Registrant's Definitive Proxy Statement on Schedule 14A filed on November 15, 2004
10.2	Amendment to Registrant's 2004 Omnibus Stock Option Plan*	Incorporated by reference to Annex C of the Registrant's Definitive Proxy Statement on Schedule 14A filed on May 17, 2012
10.3	Form of Stock Option Award Agreement under Registrant's 2004 Omnibus Stock Option Plan*	Incorporated by reference to Exhibit 4.4 filed with the Registrant's Form S-8 Registration Statement (No. 333-182930) on July 30, 2012
10.4	Securities Purchase Agreement between Registrant and Abeja Ventures, LLC, dated as of April 20, 2012	Incorporated by reference to Exhibit 10.1 filed with the Registrant's Form 10-Q/A for the quarterly period ended April 30, 2012
10.5	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
10.6		

Edgar Filing: Accelerate Diagnostics, Inc - Form 10-K

Offer Letter between Registrant and Lawrence
Mehren, dated as of June 24, 2012*

Incorporated by reference to Exhibit 10.9 filed with the
Registrant's Annual Report on Form 10-K for the fiscal
year ended July 31, 2012

10.7	CFO Offer Letter between Registrant and Steve Reichling, dated as of August 8, 2012*	Incorporated by reference to Exhibit 10.10 filed with the Registrant's Annual Report on Form 10-K for the fiscal year ended July 31, 2012
10.8	Lease Agreement between Registrant and Pima County, dated as of August 20, 2012	Incorporated by reference to Exhibit 10.11 filed with the Registrant's Annual Report on Form 10-K for the fiscal year ended July 31, 2012
10.9	Grant Agreement between Registrant and the Arizona Commerce Authority, dated as of August 22, 2012	Incorporated by reference to Exhibit 10.12 filed with the Registrant's Annual Report on Form 10-K for the fiscal year ended July 31, 2012
10.10	Registrant's 2012 Omnibus Equity Incentive Plan*	Incorporated by reference to Appendix C of the Registrant's Definitive Proxy Statement on Schedule 14A filed on November 13, 2012
10.10.1	First Amendment to Registrant's 2012 Omnibus Equity Incentive Plan*	Incorporated by reference to Exhibit 99.2 to the Form S-8 Registration Statement (No. 333-187439) filed by the Registrant on March 22, 2013
10.10.2	Form of Nonqualified Stock Option Award Agreement under Registrant's 2012 Omnibus Equity Incentive Plan*	Incorporated by reference to Exhibit 99.3 to the Form S-8 Registration Statement (No. 333-187439) filed by the Registrant on March 22, 2013
10.10.3	Form of Incentive Stock Option Award Agreement under Registrant's 2012 Omnibus Equity Incentive Plan*	Incorporated by reference to Exhibit 99.4 to the Form S-8 Registration Statement (No. 333-187439) filed by the Registrant on March 22, 2013
10.10.4	Second Amendment to Registrant's 2012 Omnibus Equity Incentive Plan*	Incorporated by reference to Appendix A of the Registrant's Definitive Proxy Statement on Schedule 14A filed on April 15, 2014
10.11	Standby Purchase Agreement, dated March 10, 2014, among the Registrant and the Jack W. Schuler Living Trust and the Schuler Family Foundation	Incorporated by reference to Exhibit 10.1 to the Form S-3 Registration Statement (No. 333-194474) filed by the Registrant on March 10, 2014
10.12	Assignment and Assumption Agreement, dated as of May 1, 2014, by and among Schuler Family Foundation, Jack Schuler, Trustee of the Jack W. Schuler Living Trust, Oracle Institutional Partners, L.P., Oracle Partners, L.P. and the Registrant	Incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by the Registrant on May 2, 2014
21	List of Subsidiaries	Filed herewith
23.1	Consent of Independent Registered Public Accounting Firm (Ernst & Young LLP)	Filed herewith
23.2	Consent of Independent Registered Public Accounting Firm (Comiskey & Company, P.C.)	Filed herewith
31.1		Filed herewith

Edgar Filing: Accelerate Diagnostics, Inc - Form 10-K

- Certification of Principal Executive Officer pursuant to Section
302 of the Sarbanes-Oxley Act of 2002
- 31.2 Certification of Principal Financial Officer pursuant to Section 302
of the Sarbanes-Oxley Act of 2002 Filed herewith
- Certificate of Principal Executive Officer and Principal Financial
Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 32 Filed herewith
- 101** XBRL Instance Document
- 101** XBRL Taxonomy Extension Schema Document
- 101** XBRL Taxonomy Calculation Linkbase Document
- 101** XBRL Taxonomy Extension Definition Linkbase Document
- 101** XBRL Taxonomy Label Linkbase Document
- 101** XBRL Taxonomy Presentation Linkbase Document

83