

Accelerate Diagnostics, Inc  
Form 10-K  
March 07, 2014

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-K**

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

For the fiscal year ended December 31, 2013

**o 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**

(State or other jurisdiction  
of incorporation or organization)

**84-1072256**

(I.R.S. Employer Identification No.)

**3950 South Country Club, Suite 470**

**Tucson, Arizona**

**85714**

(Address of principal executive offices)(Zip Code)

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

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

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, 2013, the last day of the registrant's most recently completed second fiscal quarter, was approximately \$107.8 million based on the closing price quoted on the NASDAQ Stock Market.

There were 41,904,521 shares of common stock of the registrant outstanding as of February 25, 2014.

#### **DOCUMENTS INCORPORATED BY REFERENCE**

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

Portions of the definitive proxy statement relating to the registrant's 2014 Annual Meeting of Stockholders are incorporated by reference in Part III of this Form 10-K.

**TABLE OF CONTENTS**

PART I	5
Item 1.	5
Available Information	10
Item 1A. Risk Factors	10
Item 1B. Unresolved Staff Comments	14
Item 2. Properties	14
Item 3. Legal Proceedings	15
Item 4. Mine Safety DisclosuresI	15
PART II	15
Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	15
Item 6. Selected Financial Data	16
Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations	16
Item 7A. Quantitative and Qualitative Disclosures About Market Risk	23
Item 8. Financial Statements and Supplementary Data	23
Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	45
Item 9A. Controls and Procedures	46
Item 9B. Other Information	47
PART III	47
Item 10. Directors, Executive Officers and Corporate Governance	47
Item 11. Executive Compensation	47
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	48
Item 13. Certain Relationships and Related Transactions and Director IndependenceL	48
Item 14. Principal Accounting Fees and Services	48

Item 15. Exhibits, Financial Statement Schedules

48

3

## 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 BACcel™ system, the Company will obtain sufficient capital to complete the development and required clinical trials of the BACcel™ 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.





## **PART I**

### **Item 1. Business**

#### **Overview**

Accelerate Diagnostics, Inc. (“we” or “the Company”) is focused on developing and commercializing innovative instrumentation for the rapid identification and antibiotic susceptibility testing of infectious pathogens. The Company’s BACcel™ platform utilizes a proprietary culture-free process with both genomic and phenotypic detection technologies that decrease time to result while maintaining high sensitivity and specificity.

Every six minutes, another American dies from a hospital-acquired infection (HAI). The U.S. Centers for Disease Control and Prevention (“CDC”) estimates that almost 100,000 HAI fatalities occur annually that are attributable to bacterial infections acquired in a US healthcare facility. HAI occurs when a patient enters the hospital for some reason other than an infectious disease, then contracts infection more than two days after admission. Despite intensive efforts to improve prevention and care, mortality has remained the same for more than ten years.

Yet, in theory, none of these patients should die. An effective antibiotic exists for almost every HAI. Although bacterial strains exist that may resist any particular drug, strains that resist all antibiotics remain rare.

Lab delay is a major culprit leading to the high HAI mortality rate. Medical experts believe that inadequate initial therapy substantially elevates the risk of severe morbidity and mortality in critically ill patients. For critically ill patients, the physician must start adequate antibiotics within 2-4 hours of symptom onset. But lab cultures typically take 2-3 days to assess their antibiotic susceptibility. The physician has no choice but to start therapy without knowing the organism or its drug susceptibility. Most often, the physician must choose a combination of two or three broad-spectrum antibiotics, based on the patient’s history, clinical indicators, and the hospital’s recent history of antibiotic effectiveness in similar infections. Unfortunately, widespread and increasingly complex multiple antibiotic resistance typically causes such “empiric therapy” to prove inadequate in 20% to 40% of cases.

Further, switching to adequate therapy as soon as the next day fails to improve outcomes. Once an infection passes a critical point, antibiotics have little to no impact on its condition.

Popular news media have reported widely about methicillin-resistant *Staphylococcus aureus* (“MRSA”) as a multi-resistant "superbug." Organizations such as the CDC and the Infectious Diseases Society of America have also

identified other multi-drug resistant organisms as presenting even greater threats. They include Pseudomonas, Acinetobacter, and Klebsiella. In the hospital intensive care unit (“ICU”), “Staph” infections (including MRSA) typically cause approximately 30% of fatal HAIs. This increase in multi-drug resistant organisms creates an opportunity for the Company by driving demand for rapid susceptibility.

We believe that the development of new classes of antibiotics has significantly declined. Improved prevention and infection control have limited potential. In the meantime, bacteria continue to evolve and develop additional drug resistance. Bacteria have become so well adapted to the hospital that even the best preventive efforts do not eradicate them. Hospitals that lead in best preventive practices still suffer from endemic hospital-adapted strains that continue to cause high rates of attributable morbidity and mortality. Such examples suggest that each passing year sees a reduction in the number of cases that can be treated successfully with any particular drug.

We believe that dramatically speeding up laboratory diagnostics will help to improve the success rate for initial therapy for HAIs.

## **Products (BACcel™ System Development)**

Since 2004, we have focused our efforts on the development of an innovative rapid diagnostic platform, the BACcel™ system, intended for rapid diagnosis in life-threatening infectious pathogens. Our goal is to reduce the failure rate of initial therapy by shortening the lab turnaround time to less than eight hours, rather than the 2-3 days now required. Rapid testing would provide guidance in time to influence initial therapy.

The BACcel™ system applies our proprietary technology to eliminate time-consuming bacterial culturing, thus eliminating the major source of delay with current testing methods. Our system includes a fixed instrument and proprietary single-use (disposable) test cassettes. Each cassette tests a single patient specimen and is then discarded.

BACcel™ uses long-accepted bacteriological testing principles, but applies our proprietary technology to adapt them to analyze live bacteria extracted directly from a patient specimen. The instrumentation uses automated digital microscopy to measure the responses of extracted live bacterial cells to various test conditions. Our system analyzes thousands of these individual cells to arrive at organism identification and antibiotic resistance characteristics.

Based on internal lab data, we believe that the BACcel™ system will identify the organisms present in a patient's specimen and count the number of organisms of each type in less than one hour after receiving a specimen. We believe that the BACcel™ system will then additionally report antibiotic susceptibility for each type of organism in less than 7 hours after receiving a specimen. The clinical purpose of reporting antibiotic susceptibility is to determine the drug choices available for therapy.

We anticipate initiating US clinical trials for BACcel™ in the first half of 2015, obtaining a CE mark registration in early 2015, and United States FDA approval in early 2016.

## **Additional Products**

In addition to BACcel™ system development, 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. OptiChem also offers the ability to apply micro-patterns, enabling novel advanced analyzer designs. The coating is widely adaptable to virtually any base material, such as plastics, and even highly sophisticated designs can be economically scaled to high-volume production. We have licensed various OptiChem microarraying coatings to Schott Jenaer Glas GmbH (“SCHOTT”) (Germany), NanoString Technologies, Inc. (“NanoString”) (US, WA), and Nanosphere, Inc. (“Nanosphere”) (US, IL). See “Sales, Licensing, and Alliances” below.

## **Research and Development**

We have used a series of developmental instruments in our laboratory. In 2006, we began research using a modified microscope. In 2011, we upgraded one of the systems to test engineering improvements. Later in 2011, we installed a completely upgraded third system that substantially increased analytical sensitivity and scanning speed. This next-generation system included a separate fluidic robot and a custom high-speed scanning microscope. This prototype increased scan rate approximately 40-fold relative to the original prototypes and substantially improved detection sensitivity for working with specimens that have low microbial counts. It also improved our ability to analyze specimens requiring dilution. We used the latest prototype for formal proof of concept testing under independent outside observation.

In March 2013, after completing this proof of concept testing, the Company again improved on this design and built 10 instruments that were used for further assay development. In the latter half of 2013, we completed the design and build of our pre-clinical instrument. We have built 30 of these systems to use for continued development and pilot clinical studies.

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. Both institutions have also begun pilot clinical studies on specimens from ICU patients using experimental protocols authorized by their respective Institutional Review Boards. In 2013, an additional instrument was placed at Geisinger Health System. We anticipate that the number of collaborating research institutions will grow significantly in 2014.

In 2013, three studies conducted using the BACcel™ system were published by peer-reviewed journals, and an abstract was also accepted. We believe these joint studies will expand significantly and will be presented periodically to the relevant scientific and medical communities.

In 2014, we intend to continue technical validation of the BACcel™ system methods, continue field studies including pilot clinical studies at Denver Health and Barnes-Jewish Hospital among others, and continue to publish the results of internal and collaborative studies.

In May 2012, the Company and Denver Health were notified that the Defense Medical Research and Development Program ("DMRDP") approved \$2 million of funding for a 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 Company's BACcel™ rapid diagnostic system to wound infections and other serious infections secondary to trauma. Beginning October 2012, the Company began setting up experiments under this grant and billing Denver Health for these costs. Given these costs and their associated reimbursements consist of sponsored R&D and don't constitute operating revenues they have and will be recorded as a credit against research and development expenses. Through December 31, 2013, the Company has invoiced \$158,287 (\$142,591 for year ended December 31, 2013 and \$15,696 for the year ended December 31, 2012) in such billings.

Complementing BACcel™ system development, we have begun research on an instrument that will provide additional speed and workflow benefits for certain sample types such as blood.

During the fiscal year ended December 31, 2013, five-month periods ended December 31, 2012 and 2011, and fiscal years ended July 31, 2012 and 2011, we incurred expenses of \$10,673,016, \$1,777,244, \$163,340, \$431,906, and \$454,997, respectively, on research and development activities.

## **Sales, Licensing, and Alliance**

The Company signed a licensing agreement for microarraying slides using OptiChem coatings with SCHOTT on November 4, 2004. Since this time, SCHOTT and the Company have extended this license. On August 15, 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. Previous agreements excluded medical applications. This expansion makes SCHOTT the second company that intends to use OptiChem coatings on medical devices.

This agreement extends the non-exclusive license through November 24, 2014. SCHOTT paid the Company \$150,000 comprised of a one-time license fee of \$50,000 and non-refundable prepaid royalties of \$100,000. Royalties consist of 5% of SCHOTT's net product sales. For medical applications, SCHOTT agrees to refer individual customers directly to the Company for licensing if annual purchases by a customer exceed 20,000 units.

On October 5, 2007, the Company entered into an exclusive seven-year license with NanoString. The license grants NanoString the right to apply OptiChem coatings to NanoString's proprietary molecular detection products.

On July 9, 2010 the Company entered into a non-exclusive license to 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 calls 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. All of the amounts due from Nanosphere were recognized as OptiChem revenue during the fiscal year ended July 31, 2010. In July, 2013, we received the final installment of \$750,000.

## Competition

To the best of our knowledge, no other company now has a product with capabilities similar to those of the BACcel™ system. However, the industry in which we compete is subject to rapid technological changes, and we may face competition for the BACcel™ system.

Publicity frequently appears in the press concerning new products 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 appears applicable to treatment decision support for life-threatening infections. For example, gene detection can be highly sensitive and specific, 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 “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.

The leading companies with automated microbiological testing include Becton Dickinson, bioMerieux, MicroScan, and Trek Diagnostics. These companies provide products for the broad-based culturing and analysis of a wide variety of bacteria. Such products require purified bacterial strains or “isolates” for analysis, which requires at least overnight culturing to produce enough organisms to test. These products then require at least one additional growth cycle as part of the test. These products use standard culturing methods, including enrichment growth and colony isolation, and therefore cannot achieve the necessary speed for the applications addressed by the BACcel™ system.

Another new technology receiving wide attention is mass spectrometry, and particularly the MALDI-TOF (matrix-assisted laser desorption ionization time of flight) version, such as the Biotyper® system from Bruker which awaits FDA clearance. Bruker has agreements with a number of companies for distribution, including Becton Dickinson, 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 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. 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.

Many potential competitors have greater research and development, financial, manufacturing, marketing and sales resources than we do. In addition, some potential competitors may, individually, or together with companies affiliated with them, have greater human and scientific resources than we do. Potential competitors could develop technologies and methods for materials that render the BACcel™ system and our technologies and methodologies less competitive. However, management is not aware of any development programs that address the same applications as the BACcel™ system.



## Operations

As of January 3, 2013, we relocated our headquarters and leased approximately 15,315 square feet of office and laboratory space in Tucson, Arizona. In January 2014, we completed a 4,332 square foot expansion of our facility to accommodate growth. We anticipate adding an additional 7,553 square feet in 2014 for manufacturing and other operational needs.

BACcel™ system development requires certain components that are custom-fabricated to our specifications. Such components include injection-molded plastic components, die-cut laminates, and machined mechanical components. In all applicable cases, we own the production tooling and believe that we will be able to qualify secondary sources. We plan to maintain inventory levels sufficient to bridge second-source response times and include an adequate safety factor to support ongoing development.

## Intellectual Property

We rely upon 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 are committed to developing a continuing stream of intellectual property and aggressive protection of our position in key technologies. As of December 31, 2013, we have sixteen issued patents worldwide, including ten patents issued in the United States and six issued foreign patents. Additionally, we have ten patent applications pending worldwide, including five United States applications and five international and foreign applications. This includes five new United States and two new European filings in 2013.

The Company's first patent on the core BACcel™ 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.

There can be no assurance that third parties will not assert infringement or other claims against us with respect to any existing or future products. We cannot ensure that licenses would be available if any of our technology was successfully challenged for infringement by a third party, or if it became desirable to use any third-party technology to enhance the Company's products. Litigation to protect our proprietary information or to determine the validity of any third-party claims could result in a significant expense to us and divert the efforts of our technical and management personnel, whether or not such litigation is determined in our favor.

While we have no knowledge that we are infringing upon the proprietary rights of any third party, there can be no assurance that such claims will not be asserted in the future with respect to existing or future products. Any such assertion by a third party could require us to pay royalties, to participate in costly litigation and defend licensees in any such suit pursuant to indemnification agreements, or to refrain from selling an alleged infringing product or service. Similarly, we have no knowledge that third parties have infringed on our intellectual property rights. Should

we need to assert our intellectual property rights it may require us to incur costly litigation.

### **Employees**

We have 47 full-time employees as of December 31, 2013 compared to 15 as of December 31, 2012. We have not entered into any collective bargaining agreements and consider our labor practices and employee relations to be good.

### **Corporate History**

The Company's corporate predecessor was organized as a Colorado corporation under the name Sage Resources Corp. in May 1982. In June 1988, that entity (which had subsequently changed its name to Hydro-Seek, Inc.) merged with Accelr8 Technology Corporation, at which point the Company took the name Accelr8 Technology Corporation. In December 2012, we reincorporated in Delaware and changed our name to Accelerate Diagnostics, Inc.

## 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 risk. In evaluating the Company, careful consideration should be given to the following risk factors, in addition to the other information included or incorporated by reference in this Annual Report on Form 10-K. Each of these risk factors could materially adversely affect our business, operating results or financial condition, as well as adversely affect the value of an investment in our common stock. In addition, the "Forward-Looking Statements" located in this Form 10-K, and the forward-looking statements included or incorporated by reference herein describe additional uncertainties associated with our business that should be carefully evaluated prior to making a decision to invest in our securities.

### Risks Relating to Our Business

*Our future success, profitability and continued existence is dependent in large part upon the successful development of the BACcel™ system.* We have spent a significant amount of resources developing the BACcel™ system and intend to spend a significant amount more in the future and there can be no assurance that we will successfully develop the BACcel™ system. If we are not successful in the development of the BACcel™ system, or if we are unable to sell it into the marketplace or license it to a third party strategic partner for its development, manufacturing and marketing, it would have a material adverse effect upon the Company's revenues and results of operations, it could lead to impairment of certain of our intellectual property and would likely have a material adverse effect upon the price of the our Common Stock, our results of operations and may result in us having to cease operations.

*Our success depends partly on our ability to successfully introduce and the market acceptance of our current and new products.* In a market primarily driven by the need for innovative products, our revenue growth will depend on overcoming various technological challenges to successfully introduce our current and new products, including but not limited to the BACcel™ system or other technology based upon the intellectual property included in the BACcel™

system into the marketplace in a timely manner. In addition, we must continue to develop new applications for our existing technologies, including but not limited to, additional commercial applications for the BACcel™ system proprietary technology. Market acceptance of these products will depend on many factors, including, but not limited to, demonstrating that our technologies perform as intended and are superior to other technologies and products that are currently available or may become available in the future. If we are unable to successfully develop new products or if the market does not accept our products, or even if we experience difficulties or delays in the development of our products, including the BACcel™ system, we may be unable to attract additional customers for our products or license our products to other strategic partners, which would seriously harm our business and future growth prospects.

*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. There is no assurance that we will be successful in marketing our OptiChem products in the future or will receive any revenue from such products. Further, there can be no assurance that we will be successful in marketing the BACcel™ system or will receive any revenues from it. During the year ended December 31, 2013, five-month transition periods ended December 31, 2012 and 2011 and the fiscal years ended July 31, 2012 and 2011, we experienced losses from operations. If we are unsuccessful in completing the development of the BACcel™ 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, which may have a material adverse effect upon the Company, its results of operations and the price of our Common Stock may be adversely affected.

*Dependence on key employees.* The loss or failure to attract and retain key personnel could significantly impede our performance, including product development, strategic plans, marketing and other objectives. Our success depends to a substantial extent not only on the ability and experience of our senior management, but particularly upon Lawrence Mehren, our President and Chief Executive Officer. We do not have key man life insurance on Mr. Mehren. To the extent that the services of Mr. Mehren would be unavailable to us, we would be required to find another person to perform the duties Mr. Mehren otherwise would perform. We may be unable to employ another qualified person with the appropriate background and expertise to replace Mr. Mehren on terms suitable to us. Further, we believe that our future success will depend in large part upon our ability to attract and retain highly skilled technical, managerial, sales and marketing personnel. There can be no assurance that we will be successful in attracting and retaining the personnel we require to develop and market our products, develop new products and to conduct our operations successfully.

*If we are unable to effectively protect our intellectual property, we may be unable to prevent infringement.* Our success depends in part on our ability to obtain and maintain patent protection for the technology underlying our products, especially that used in the BACcel™ system, both in the United States and in other countries. We cannot assure you that any of the presently pending or future patent applications will result in issued patents, or that any patents issued to us or licensed by us will not be challenged, invalidated or held unenforceable. Further, we cannot guarantee that any patents issued to us will provide us with a significant competitive advantage. If we fail to successfully enforce our proprietary technology or otherwise maintain the proprietary nature of our intellectual property with respect to our significant current and proposed products, our competitive position, our ability to complete the development of the BACcel™ system and future sales or license of this product or technology could suffer, which would have a material adverse effect upon the Company and its results of operations. Notwithstanding our efforts to protect our intellectual property, our competitors may independently develop similar or alternative technologies or products that are equal to or superior to our technology and proposed products without infringing on any of our intellectual property rights or design around our proprietary technologies. If customers prefer these alternative technologies and products as compared to our technology and proposed products, it may have a material adverse effect upon the Company, our results of operations and the price of our Common Stock may be adversely affected.

*Our products could 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. 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, which could have a material adverse effect on our future revenues. 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.

*Third parties may seek to challenge, invalidate or circumvent issued patents owned by or licensed to us or claim that our products and operations infringe their patent or other intellectual property rights.* 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 measures that we employ to protect this technology and these rights may not be adequate. We may incur significant expense in any legal proceedings to protect our proprietary rights or to defend infringement claims by third parties. In addition, claims of third parties against us could result in awards of substantial damages or court orders that could effectively prevent us from manufacturing, using, importing or selling our products in the United States or abroad.

*Competition.* 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, including pharmaceutical companies that may offer alternatives to our products. Many of our competitors have greater research and development, financial, manufacturing, marketing and sales resources 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 render our technologies and methodologies less competitive. Accordingly, if competitors introduce products that are more effective than our current and proposed technologies, including but not limited to the BACcel™ system, it could have a material adverse effect upon the Company, our results of operations and the price of our Common Stock may be adversely affected.

*Ability to respond to technological change.* 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. 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. Our delay or failure to develop or acquire technological improvements or to adapt our products to technological change would have a material adverse effect on our business, results of operations and financial condition.

*We use hazardous materials in some of our research, development and manufacturing processes.* 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. We could be held liable for any damages that might result from any accident or release involving such materials. Any such liability could have a material adverse effect on our business, financial condition and results of operations.

*Changes in governmental regulations may reduce demand for our products or increase our expenses.* We compete in markets in which we or our customers must comply with federal, state, local and foreign regulations, such as environmental, health and safety and food and drug regulations. We develop, configure and market our products to meet customer needs created by these regulations. Any significant change in these regulations could reduce demand for our products.

*We have a single research and development facility and we may lose revenue and be unable to continue to conduct our research and development and product development activities if we lose this facility.* We currently conduct all of our research and development and product development activities in our existing facility in Tucson, Arizona. If we were unable to use these facilities to conduct our research and development and product development activities, 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. While we carry a nominal amount of

business interruption insurance to cover lost revenue and profits, this insurance does not cover all possible situations. 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. The loss of facility may have a material adverse effect upon the Company and its results of operations.



*Our business strategy approach may be adversely affected by additional healthcare reform and changes in managed healthcare.* Our vision is to develop and commercialize the BACcel™ system, an innovative, integrated system for rapid identification of infectious pathogens and their antibiotic resistance in critically ill patients. 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 continue to and are expected in the future to place constraints on the levels of overall pricing and thus could have a material adverse effect on our future profit margins of our products or the amounts that we are able to receive from third parties for the licensing of such products. Such continuing 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 /or profit margin.

*We have 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 BACcel™ system integrates several of our component products, systems and processes. During the fiscal year ended December 31, 2013, five-month periods ended December 31, 2012 and 2011, and fiscal years ended July 31, 2012 and 2011, we spent \$10,673,016, \$1,777,244, \$163,340, \$431,906, and \$454,997, respectively, on research and development activities, and we intend to spend significantly more on research and development activities during the fiscal year ending December 31, 2014 and thereafter. Notwithstanding these investments, we anticipate that we will have to spend additional funds in the research and development of the BACcel™ system. There can be no assurance that the BACcel™ system will be successful, or even if it is successful will be accepted in the marketplace. Further, we might also encounter substantial delays in getting products to market in a timely fashion. There can be no assurance that we will complete the development of the BACcel System, will bring it to market or will generate revenues from licensing or sales.

*Acquisitions and joint ventures may have an adverse effect on our business.* In the future, we may make acquisitions or enter into joint ventures as part of our long-term business strategy. These transactions involve significant challenges and risks including that the transaction does not advance our business strategy, that we don't realize a satisfactory return on our investment, or that we experience difficulty in the integration of new employees, business systems, and technology, or there is a diversion of management's attention from our other business operations. These events could harm our operating results or financial condition.

*Changes in our business strategy or plans may adversely affect our operating results and financial condition.* If our business strategy or plans change, whether in response to changes in economic conditions or developments in the diagnostics industry, or otherwise, we may be required to expend significantly more resources than planned to develop the BACcel™ system, may have to cease developing the BACcel™ system or develop other products. The expense of such change could adversely affect our operating results and financial condition.

*The regulatory clearance or approval process is expensive, time consuming and uncertain, and the failure to obtain and maintain required clearances or approvals could prevent us from commercializing our future products.* We are investing in the research and development of new diagnostic tests, as well as to develop our novel BACcel™ system. Our products are subject to 510(k) clearance or pre-market approval by the FDA prior to their marketing for commercial use in the United States, and to any approvals required by foreign governmental entities prior to their marketing outside the United States. The 510(k) clearance and pre-market approval processes, as well as the process of obtaining foreign approvals, can be expensive, time consuming and uncertain. It generally takes from four to twelve months from submission to obtain 510(k) clearance, and from one to three years from submission to obtain pre-market approval; however, it may take longer, and 510(k) clearance or pre-market approval may never be obtained. Delays in receipt of, or failure to obtain, clearances or approvals for future products, including tests that are currently in design or development, would result in delayed, or no, realization of revenues from such products and in substantial additional costs which could decrease our profitability. We have limited experience in filing FDA applications for 510(k) clearance and pre-market approval. In addition, we are required to continue to comply with applicable FDA and other regulatory requirements once we have obtained clearance or approval for a product. There can be no assurance that we will obtain or maintain any required clearance or approval on a timely basis, or at all. Any failure to obtain or any material delay in obtaining FDA clearance or any failure to maintain compliance with FDA regulatory requirements could harm our business, financial condition and results of operations.

*Delaware law and our Certificate of Incorporation may protect our directors from certain types of lawsuits.* Delaware law provides that our directors will not be liable to us or our stockholders for monetary damages for all but certain types of conduct as directors. Our Certificate of Incorporation permits us to indemnify our directors and officers against all damages incurred in connection with our business to the fullest extent provided or allowed by law. The exculpation provisions may have the effect of preventing stockholders from recovering damages against our directors caused by their negligence, poor judgment or other circumstances. The indemnification provisions may require us to use our limited assets to defend our directors and officers against claims, including claims arising out of their negligence, poor judgment, or other circumstances.

## Risks Related to Our Common Stock

*Our stock price has been volatile and may continue to be volatile and traded on low volumes; Dividend Policy.* The trading price of our Common Stock has been, and is likely to continue to be, highly volatile, in large part attributable to developments and circumstances related to factors identified “Forward-looking Statements” and “Risk Factors” and the market’s response to our operations and financial condition. Another 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, 2013, the closing sale price for our Common Stock ranged from \$4.06 to \$15.69 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. Further, we do not intend to pay any cash dividends on our Common Stock in 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 BACcel™ 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. If we require additional capital, we may attempt to raise it through a variety of strategies, including but not limited to a rights offering and/or a follow-on offering of our Common Stock. There can be no assurance that such capital will be available in sufficient amounts or on terms acceptable to us, if at all. We have the authority to issue up to 55,000,000 shares of Common Stock (of which, as of 41,904,521 shares were outstanding as of February 25, 2014), to issue up to 5,000,000 shares of Preferred Stock (of which none were issued nor outstanding as of the same date) and to issue options and warrants to purchase shares of our Common Stock (of which 4,940,086 options and 571,160 warrants to acquire shares of our Common Stock were issued and outstanding as of the same date). Issuances of additional shares of our Common 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.

*The continued listing of our Common Stock on the NASDAQ Capital Market is subject to our compliance with various Listing Rules.* Currently, our Common Stock is listed for trading on the NASDAQ Capital Market. In order for our Common Stock to continue to be traded on such market, we must comply with various NASDAQ Listing Rules pertaining to, among other things, the bid price of our Common Stock (which must remain above \$1.00 per share), the composition of our board of directors and our various board committees, and other corporate governance matters. While we are currently in compliance with such NASDAQ Listing Rules (subject to any compliance grace periods that may be available thereunder), we can provide no assurance that we will remain in compliance with NASDAQ’s Listing Rules in the future, or that our Common Stock will continue to be traded on the NASDAQ Capital Market or any other market.

## **Item 1B. Unresolved Staff Comments**

Not applicable.

**Item 2. Properties**

Until January 3, 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. As of January 3, 2013, we relocated our headquarters and lease approximately 15,315 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 lease also provides that the Company has the option to lease either or both of two additional areas with an aggregate size of approximately 7,900 square feet. Pursuant to the lease, the Company agreed to pay rent equal to approximately \$139,600 per year during the initial term and approximately \$298,900 per year during any renewal term. We exercised part of our option for additional space in January 2014 when we completed a 4,332 square foot expansion.

### 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

As of December 26, 2012, the Company's Common Stock is 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 high and low sales price information for our Common Stock for the period from August 1, 2011 through December 31, 2013.

<u>Quarter Ended</u>	<u>High</u> <sup>(1)</sup>	<u>Low</u> <sup>(1)</sup>
October 31, 2011	\$3.80	\$2.42
January 31, 2012	\$2.98	\$1.12
April 30, 2012	\$2.86	\$0.77
July 31, 2012	\$3.80	\$2.25
October 31, 2012	\$4.08	\$2.80
December 31, 2012 <sup>(2)</sup>	\$4.15	\$2.97
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

(1) The above table sets forth the range of high and low closing prices per share of our Common Stock as reported by the finance page at [www.yahoo.com](http://www.yahoo.com) for the periods indicated.

(2) Two-month period as a result of the Company's transition to a fiscal year ending on December 31 of each year.

## **Holders**

As of February 25, 2014, we had approximately 172 record owners of our Common Stock.

## **Dividends Paid and Dividend Policy**

Holders of Common Stock are entitled to receive dividends as may be declared by the Board of Directors out of funds legally available therefore. 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, 2013:

<b><u>Plan category</u></b>	<b>Number of securities to be issued upon exercise of outstanding options, warrants and rights</b>	<b>Weighted average exercise price of available outstanding options, warrants and rights</b>	<b>Number of securities remaining for future issuance under equity compensation plans (excluding securities reflected in the 1st column)</b>
Equity compensation plans approved by security holders	5,160,086	\$ 3.45	504,414
Equity compensation plans not approved by security holders	—	—	—
<b>Total</b>	<b>5,160,086</b>	<b>\$ 3.45</b>	<b>504,414</b>

**Item 6. Selected Financial Data**

Not applicable to smaller reporting companies.

**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 the significant factors affecting our results of operations, liquidity, capital resources and contractual obligations, as well as discusses 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. Our MD&A is composed of four major sections: Recent Developments; Results of Operations; Capital Resources and Liquidity; and Application of Critical Accounting Policies.

### **Change in Fiscal Year**

Effective December 31, 2012, we changed our fiscal year end from July 31 to December 31. This MD&A is intended to cover the audited calendar year that began on January 1, 2013 and ended on December 31, 2013. Comparative financial information to 2013 is provided in this Form 10-K with respect to the calendar year that began on January 1, 2012 and ended on December 31, 2012, which is unaudited. Additional information is provided comparing the five-month periods ended December 31, 2012 (audited) and December 31, 2011 (unaudited), as well as the Company's former fiscal years ended July 31, 2012 and 2011 (both audited), respectively.



## 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”). 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.

## **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 \$48,285 as compared to \$52,215 during the year ended December 31, 2012, a decrease of \$3,930 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 \$10,673,016 as compared to \$2,031,593 during the year ended December 31, 2012, an increase of \$8,641,423 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 \$4,312,281 as compared to \$3,673,251 during the year ended December 31, 2012, an increase of \$639,030 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 \$76,903 as compared to \$177,396 during the year ended December 31, 2012, a decrease of \$100,493 or 57%. 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 \$285,592 as compared to \$6,225 during the year ended December 31, 2012, an increase of \$279,367 or 4488%. 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 \$11,352 compared to \$2,330,070 for the year ended December 31, 2012, a decrease of \$2,318,718 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 \$15,310,859 as compared to the loss of \$8,166,320 during the year ended December 31, 2012, an increase in loss from operations of \$7,144,539 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 \$29,038 as compared to \$42,565 during the year ended December 31, 2012, a decrease of \$13,527 or 32%. This change is due to investment activity.

As a result of these factors, net loss for the year ended December 31, 2013 was \$15,281,821 as compared to a net loss of \$8,123,755 during the year ended December 31, 2012, an increase in net loss of \$7,158,066 or 88%.

Unrealized gain on available-for-sale investments for the year ended December 31, 2013 was \$21,730 as compared to \$0 during the year ended December 31, 2012. The resulting comprehensive losses were \$15,260,091 and \$8,123,755 for the years ended December 31, 2013 and December 31, 2012, respectively.

**Changes in Results of Operations: Five Months Ended December 31, 2012 (audited) Compared with Five Months Ended December 31, 2011 (unaudited)**

OptiChem fees and technical development revenues were \$17,712 for the five-month period ended December 31, 2012 as compared to \$202,008 for the five-month period ended December 31, 2011, a decrease of \$184,296 or 91%. The decrease was the result of the final payment under development agreement with Novartis of \$140,000, which had concluded prior to and therefore did not recur during the five-month period ended December 31, 2012.

During the five-month periods ended December 31, 2012 and 2011, there was no cost of sales due to the fact that no goods were manufactured and sold by the Company during these periods. License revenues recognized during these periods were earned through continuing license arrangements.

Research and development expenses for the five-month period ended December 31, 2012 were \$1,777,244, as compared to \$163,340 for the five-month period ended December 31, 2011, an increase of \$1,613,904 or 988%. This increase was primarily the result of instrument engineering hiring and related expenses.

Sales, general and administrative expenses for the five-month period ended December 31, 2012 were \$1,266,459, as compared to \$561,699 for the five-month period ended December 31, 2011, an increase of \$704,760 or 125% primarily associated with an increase in salaries and legal fees associated with corporate governance activities.

Amortization for the five-month period ended December 31, 2012 was \$38,023, as compared to \$64,087 for the five-month period ended December 31, 2011, a decrease of \$26,064 or 41%. The decrease was the result of intangible asset impairments taken in July and October 2012, which thereby decreased the amortization expenses for the five-month period ended December 31, 2012.

Depreciation for the five-month period ended December 31, 2012 was \$4,644, as compared to \$515 for the five-month period ended December 31, 2011, an increase of \$4,129 or 802%. The increased depreciation was the result of lab equipment and other infrastructure fixed asset additions during the five-month period ended December 31, 2012.

Impairment of intangibles for the five-month period ended December 31, 2012 was \$333,487 compared to \$0 for the five-month period ended December 31, 2011, an increase of \$333,487. 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 these factors, loss from operations for the five-month period ended December 31, 2012 was \$3,402,145 as compared to a loss of \$587,633 for the five-month period ended December 31, 2011, resulting in a greater loss of \$2,814,512.

Other income for the five-month period ended December 31, 2012 was \$1,921 as compared to other income during the five-month period ended December 31, 2011 of \$679 an increase in income of \$1,242 or 183%. This increase is mainly due to investment activity.

As a result of these factors, net loss for the five-month period ended December 31, 2012 was \$3,400,224, as compared to a net loss of \$586,954 for the five-month period ended December 31, 2011, resulting in a greater loss of \$2,813,270.

**Changes in Results of Operations: Fiscal Year Ended July 31, 2012 Compared with Fiscal Year Ended July 31, 2011**

Technical development fee revenues were \$140,000 for the year ended July 31, 2012, as compared to \$842,408 for the year ended July 31, 2011, a decrease of \$702,408 or 83%. The decrease in technical development fees was the result of the conclusion of work under the Novartis Technical Development Agreement during the 2012 fiscal year.

OptiChem slide revenues for the year ended July 31, 2012 were \$45,910, as compared to \$34,279 for the year ended July 31, 2011, an increase of \$11,631, or 34%. The increase in OptiChem revenues was primarily due to an increase in revenue recognized under our license arrangements with NanoString and SCHOTT.

License fees for the year ended July 31, 2012 were \$50,000, as compared to \$0 during the fiscal year ended July 31, 2011. The increase in license fees was the result of the licensing agreement executed with SCHOTT during the period which consisted of an upfront license fee of \$50,000 and \$100,000 in prepaid royalties. Pursuant to the Company's revenue recognition policy and generally accepted accounting policies, the upfront payment was recognized upon receipt and the prepaid royalties recognized in the period in which they are earned based on sales reported by SCHOTT.

During the fiscal year ended July 31, 2011, we received a Qualified Therapeutic Discovery Grant in the amount of \$244,479 that was not presented during the 2012 fiscal year.

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

During the fiscal year ended July 31, 2012 and 2011, there were no cost of sales due to the fact that the slides are manufactured by SCHOTT and NanoString pursuant to license agreements.

Research and development expenses for the year ended July 31, 2012, were \$431,906, as compared to \$454,997 during the year ended July 31, 2011, a decrease of \$23,091 or 5%. This decrease was primarily the result of reductions in clinical trial expenditures. Clinical trial expenditures decreased to \$27,342 for the year ended July 31, 2012 from \$35,871 for the year ended July 31, 2011, a decrease of \$8,529 or 24%.

Sales, general and administrative expenses for the year ended July 31, 2012 were \$2,953,624, as compared to \$819,699 during the year ended July 31, 2011, an increase of \$2,133,925 or 260% primarily due to a one-time severance charge to a former director.

The decrease in amortization for the year ended July 31, 2012 was negligible.

Depreciation for the year ended July 31, 2012 was \$2,097 as compared to \$2,396 during the year ended July 31, 2011 a decrease of \$299 or 12%. The decreased depreciation was primarily due to equipment becoming fully depreciated.

As a result of these factors, loss from operations for the year ended July 31, 2012 was \$5,351,760, as compared to a loss of \$409,425 for the year ended July 31, 2011, resulting in a greater loss of \$4,942,335.

Interest and dividend income for the year ended July 31, 2012 was \$16,297, consistent with \$16,092 for the year ended July 31, 2011.

During the fiscal years ended July 31, 2012 and 2011, the Company maintained a deferred compensation trust held for the benefit of a director and a former executive officer of the Company. Unrealized gains on marketable securities (which specifically excludes shares of the Company's Common Stock held in the deferred compensation trust) held in the deferred compensation trust for the year ended July 31, 2012 was \$23,987 as compared to an unrealized gain of \$14,572 during the year ended July 31, 2011. The increased unrealized gain was a result of market fluctuations on the securities that are held in the deferred compensation trust.

As a result of these factors, net loss for the year ended July 31, 2012 was \$5,310,476 as compared to a net loss of \$378,761 during the year ended July 31, 2011, a greater loss of \$4,931,715.

### **Capital Resources and Liquidity**

During the twelve months ended December 31, 2013, we did not generate positive cash flows from operating activities.

Our primary sources of liquidity have been from sales of shares of our Common Stock. As of December 31, 2013, the Company had \$41,988,345 in cash and cash equivalents and available-for-sale securities, an increase of \$29,919,598 from \$12,068,747 at December 31, 2012. The primary reason for the change in these assets was two equity transactions; first, the exercise of warrants previously issued to Abeja in June 2012, and second, a \$20,000,000 rights offering transaction completed in August 2013.

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 a Standby Purchase Agreement with Abeja (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 \$88,785.

The Company has now closed its Denver location and fully relocated to Tucson, Arizona, where it is subject to a Lease Agreement with Pima County of Arizona. The future minimum lease payments under the Lease Agreement are \$141,664, \$141,664, and \$1,164 for years ending 2014, 2015, and 2016, respectively.

As of December 31, 2013, management believes that current cash balances will be more than sufficient to fund our capital and liquidity needs for the next fiscal year.

The following summarizes the Company's capital resources at December 31, 2013 compared with December 31, 2012:

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

	December 31, 2013	December 31, 2012
	<u>(unaudited)</u>	<u>(unaudited)</u>
Cash and cash equivalents	\$ 30,028,961	\$ 12,068,747
Investments	11,959,384	—
Trade accounts receivable	24,400	763,899
Current assets	42,142,935	12,849,025
Total assets	43,430,377	13,316,116
Current liabilities	1,136,930	1,248,068
Working Capital	41,006,005	11,600,957
Net cash used in operating activities	9,748,951	2,136,153
Net cash used in investing activities	13,171,180	158,348
Net cash provided by financing activities	40,880,345	100,000



Our primary use of capital has been for the continued development and commercialization of the BACcel™ 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, 2013.

### **Recent Accounting Pronouncements**

In December 2013, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“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, 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. We do not expect the adoption of ASU 2013-11 in the first quarter of 2014 to have a material impact on our financial statements.

In March 2013, the FASB issued ASU 2013-04, 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. We do not expect the adoption of ASU

2013-04 in the first quarter of 2014 to 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, intangible assets, impairment of long-lived and intangible assets, and stock-based compensation to be critical accounting policies. A number of significant estimates, assumptions, and judgments are inherent in our determination of intangible asset amortization expense, how to evaluate our long-lived and intangible assets for impairment, and stock-based compensation expense. These estimates, assumptions and judgments include estimating the period an intangible asset is expected to contribute to future cash flows, estimating the fair value of an intangible asset, and estimating the useful life and volatility of stock awards. We base our estimates and judgments 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, 2013, December 31, 2012, July 31, 2012 and July 31, 2011, 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 (See Item 8, Note 12, Income Taxes, to the footnotes to the financial statements included in this Annual Report on Form 10-K for additional information).

### ***Intangible Assets***

We amortize our intangible assets over the period the asset is expected to contribute directly or indirectly to our future cash flows. We evaluate the remaining useful life of each intangible asset that is being amortized each reporting period to determine whether events and circumstances warrant a revision to the remaining period of amortization.

We review our intangible assets for impairment each reporting period as discussed below under “Impairment of Long-Lived and Intangible Assets.” An impairment loss will be recognized if the carrying amount of an intangible asset is not recoverable and its carrying amount exceeds its fair value (See Item 8, Note 6, Intellectual Property, to the footnotes to the financial statements included in this Annual Report on Form 10-K for additional information).

### ***Impairment of Long-Lived and Intangible Assets***

We assess the impairment of identifiable intangibles and long-lived assets whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Factors we consider important which could trigger an impairment review include the following:

- Significant under performance relative to expected historical or projected future operating results;
- Significant changes in the manner of our use of the acquired assets or the strategy for our overall business;
- Significant negative industry or economic trends;
- Significant decline in our stock price for a sustained period; and

Our market capitalization relative to net book value.

When we determine that the carrying value of intangibles and long-lived assets may not be recoverable based upon the existence of one or more of the above indicators of impairment, we measure any impairment based on a projected discounted cash flow method using a discount rate determined by our management to be commensurate with the risk inherent in our current business model. Our judgments regarding the existence of impairment indicators are also based on legal factors, market conditions and expected future operational performance of related product lines of the identifiable intangible. Future events could cause us to conclude that impairment indicators exist and that our identifiable assets are impaired. We also evaluate the remaining estimated useful lives of each asset each reporting period and determine whether events or circumstances require revised useful lives.

During the fiscal year ended July 31, 2012, management determined that acquired technology amounts carried on our balance sheet are no longer recoverable or abandoned its plan to pursue marketability and accordingly reduced the amortized book values by \$1,996,583 and recognized the loss in its reported net loss. Additionally, during the five-month period ended December 31, 2012 management determined that patent amounts carried on our balance sheet are no longer recoverable or abandoned its plan to pursue marketability and accordingly reduced the amortized book value by \$333,487 and recognized the loss in its reported net loss (See Item 8, Note 6, Intellectual Property, to the footnotes to the financial statements included in this Annual Report on Form 10-K for additional information).

### ***Stock-Based Compensation***

We account for stock-based compensation in accordance with FASB ASC 718. Stock-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 stock-based compensation, we use the Black-Scholes option pricing model. This model requires the input of subjective assumptions. These assumptions include: estimating the length of time employees will retain their vested stock options before exercising them (expected term), the estimated volatility of our common stock price over the expected term (expected volatility), risk-free interest rate (interest rate), expected dividends and the number of options that will ultimately not complete their vesting requirements (forfeitures). Changes in the assumptions can materially affect the estimate of fair value of stock-based compensation (See Item 8, Note 2, Equity Based Compensation and Item 8, Note 11, Employee Stock Based Compensation to the footnotes to the financial statements included in this Annual Report on Form 10-K for additional information).

### **Contractual Obligations**

The Company has certain contractual obligations and commercial commitments as disclosed in this Annual Report on Form 10-K and in the Company's 2012 Proxy Statement that is incorporated herein by reference that existed as of July 31, 2012 that do not meet the definition of long term debt obligations, capital leases, operating leases or purchase obligations. Subsequent to July 31, 2012, the Company has entered into a Lease Agreement as described in Item 2, Properties above (See Item 8, Note 13, Commitments, to the footnotes to the financial statements included in this Annual Report on Form 10-K for additional information).

Contractual Obligations	2014	2015	2016	2017	2018
Operating Lease Obligations	\$141,664	\$141,664	\$1,164	\$—	\$—

### **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, short-term investments, which have an average maturity of less than one year and available for sale investments which have a maturity of more than one 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, to the footnotes to the financial statements included in this Annual Report on Form 10-K.

## **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, 2013 and 2012

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

Statements of Stockholders' Equity for the year ended December, 2013, transition period ended December 31, 2012 and the fiscal years ended July 31, 2012 and 2011

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

Notes to Financial Statements

24

### **Report of Independent Registered Public Accounting Firm**

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

We have audited the accompanying balance sheet of Accelerate Diagnostics, Inc. as of December 31, 2013, and the related statements of operations and comprehensive loss, stockholders' equity, and cash flows for the year ended December 31, 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 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 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 audit provides 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. at December 31, 2013 and the results of its operations and its cash flows for the year ended December 31, 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, 2013, 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 March 7, 2014, expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Phoenix, Arizona

March 7, 2014



## **Report of Independent Registered Public Accounting Firm**

### **To Board of Directors and Stockholders of Accelerate Diagnostics, Inc.**

We have audited Accelerate Diagnostics, Inc.'s internal control over financial reporting as of December 31, 2013, 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. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2013, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheet of Accelerate Diagnostics, Inc. as of December 31, 2013 and the related statements of operations and comprehensive loss, stockholders' equity, and cash flows for the year ended December 31, 2013 and our report dated March 7, 2014, expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Phoenix, Arizona

March 7, 2014

26

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.**  
**BALANCE SHEETS**  
**DECEMBER 31, 2013 AND DECEMBER 31, 2012**

**ASSETS**

	<b>12/31/2013</b>	<b>12/31/2012</b>
Current assets:		
Cash and cash equivalents	\$30,028,961	\$12,068,747
Investments	11,959,384	—
Trade accounts receivable	24,400	763,899
Prepaid expenses and other	130,190	16,379
Total current assets	\$42,142,935	\$12,849,025
Property and equipment, net	1,046,774	147,811
Intellectual property, net	240,668	319,280
Total Assets	\$43,430,377	\$13,316,116

**LIABILITIES AND STOCKHOLDERS' EQUITY**

Current liabilities:		
Accounts payable	\$540,435	\$299,650
Accrued compensation and other liabilities	514,607	870,384
Deferred revenue and income	81,888	78,034
Total current liabilities	\$1,136,930	\$1,248,068
Long-term deferred income	776,667	—
Total liabilities	\$1,913,597	\$1,248,068
Stockholders' equity:		
Common stock, \$0.001 par value; 55,000,000 common shares authorized (as of December 31, 2013) and 45,000,000 (as of December 31, 2012) 41,649,521 (as of December 31, 2013) and 25,331,939 (as of December 31, 2012) shares issued and outstanding	\$41,648	\$25,332
5,000,000 preferred shares authorized and none outstanding as of December 31, 2013 and December 31, 2012		
Contributed capital	75,936,969	31,244,462
Accumulated deficit	(34,483,567)	(19,201,746)
Accumulated other comprehensive income	21,730	—
Total stockholders' equity	\$41,516,780	\$12,068,048
Total liabilities and stockholders' equity	\$43,430,377	\$13,316,116

See accompanying notes to financial statements.



**ACCELERATE DIAGNOSTICS, INC.**  
**STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**  
**FOR THE YEAR ENDED DECEMBER 31, 2013,**  
**THE FIVE-MONTH PERIODS ENDED DECEMBER 31, 2012 AND 2011 AND**  
**THE YEARS ENDED JULY 31, 2012 AND 2011**

	<b>12 months 12/31/2013</b>	<b>5 months 12/31/2012</b>	<b>5 months 12/31/2011 (unaudited)</b>	<b>12 months 7/31/2012</b>	<b>12 months 7/31/2011</b>
Revenues:					
Technical development fees	\$—	\$—	\$140,000	\$140,000	\$842,408
OptiChem revenue	48,285	17,712	62,008	45,910	34,279
License fees	—	—	—	50,000	—
Qualified discovery therapeutic grant	—	—	—	—	244,479
Total revenues	\$48,285	\$17,712	\$202,008	\$235,910	\$1,121,166
Costs and expenses:					
Research and development	\$10,673,016	\$1,777,244	\$163,340	\$431,906	\$454,997
Sales, general and administrative	4,312,281	1,266,459	561,699	2,953,624	819,699
Amortization	76,903	38,023	64,087	203,460	253,499
Depreciation	285,592	4,644	515	2,097	2,396
Impairment of intangibles	11,352	333,487	—	1,996,583	—
Total costs and expenses	\$15,359,144	\$3,419,857	\$789,641	\$5,587,670	\$1,530,591
Loss from operations	\$(15,310,859 )	\$(3,402,145 )	\$(587,633 )	\$(5,351,760 )	\$(409,425 )
Other expense	\$(4,448 )	\$—	\$—	\$—	\$—
Interest and dividend income	33,486	1,921	4,047	16,297	16,092
Unrealized holding gain (loss) on investments	—	—	(4,368 )	23,987	14,572
Unrealized holding gain on asset sale	—	—	1,000	1,000	—
Total other income	\$29,038	\$1,921	\$679	\$41,284	\$30,664
Net loss	\$(15,281,821 )	\$(3,400,224 )	\$(586,954 )	\$(5,310,476 )	\$(378,761 )
Net loss per share: Basic and diluted net loss per share	\$(0.41 )	\$(0.13 )	\$(0.05 )	\$(0.43 )	\$(0.04 )
Weighted average shares outstanding	37,503,391	25,289,834	11,103,367	12,430,060	10,791,597

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

Other comprehensive loss:

Net loss	\$(15,281,821 )	\$(3,400,224 )	\$(586,954 )	\$(5,310,476 )	\$(378,761 )
Net unrealized gain/(loss) on available-for-sale investments	21,730	—	—	—	—
Comprehensive loss	\$(15,260,091 )	\$(3,400,224 )	\$(586,954 )	\$(5,310,476 )	\$(378,761 )

See accompanying notes to financial statements.



**ACCELERATE DIAGNOSTICS, INC.**  
**STATEMENTS OF STOCKHOLDERS' EQUITY**  
**FOR YEAR ENDED DECEMBER 31, 2013,**  
**FIVE-MONTH PERIOD ENDED DECEMBER 31, 2012 AND**  
**YEARS ENDED JULY 31, 2012 AND 2011**

	Shares	Common Stock Amount	Contributed Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	For Employee Benefit	Total Stockhold Equity
Balances, July 31, 2010	10,757,317	\$14,138,820	\$1,156,843	\$0	\$(10,112,285 )	\$(273,600 )	\$4,909,778
Net Loss	—	—	—	—	(378,761 )	—	(378,761)
Exercise of Options and Warrants	346,050	194,438	—	—	—	—	194,438
Equity Based Compensation	—	—	90,021	—	—	—	90,021
Balances, July 31, 2011	11,103,367	\$14,333,258	\$1,246,864	\$0	\$(10,491,046 )	\$(273,600 )	\$4,815,476
Net Loss	—	—	—	—	(5,310,476 )	—	(5,310,476)
Issuance of Common Stock and Warrants	14,000,000	8,523,982	5,896,018	—	—	—	14,420,000
Exercise of Options and Warrants	128,572	128,569	—	—	—	—	128,569
Equity Based Compensation	—	—	781,998	—	—	—	781,998
Balances, July 31, 2012	25,231,939	\$22,985,809	\$7,924,880	\$0	\$(15,801,522 )	\$(273,600 )	\$14,835,567
Net Loss	—	—	—	—	(3,400,224 )	—	(3,400,224)
Issuance of Common Stock and Warrants	—	—	—	—	—	—	—
Exercise of Options and Warrants	100,000	100	99,900	—	—	—	100,000
Transfer of Rabbi Trust	—	—	(273,600 )	—	—	273,600	—
Establish par value stock for DE Corp	—	(22,960,577)	22,960,577	—	—	—	—
Equity Based Compensation	—	—	532,705	—	—	—	532,705
	25,331,939	\$25,332	\$31,244,462	\$0	\$(19,201,746 )	\$0	\$12,068,048

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

Balances, December 31, 2012							
Net Loss	—	—	—	—	(15,281,821 )	—	(15,281,821 )
Issuance of Common Stock and Warrants	2,487,562	2,488	19,908,727	—	—	—	19,911,215
Exercise of Options and Warrants	13,830,020	13,828	20,955,302	—	—	—	20,969,130
Unrealized gain on available for sale securities	—	—	—	21,730	—	—	21,730
Equity Based Compensation	—	—	3,828,478	—	—	—	3,828,478
Balances, December 31, 2013	41,649,521	\$41,648	\$75,936,969	\$21,730	\$(34,483,567 )	\$0	\$41,516,788

See accompanying notes to financial statements.

**ACCELERATE DIAGNOSTICS, INC.**  
**STATEMENT OF CASH FLOWS**  
**FOR THE YEAR ENDED DECEMBER 31, 2013,**  
**FIVE MONTHS ENDED DECEMBER 2012 AND 2011**  
**AND YEARS ENDED JULY 31, 2012 AND 2011**

	<b>12 Months</b>	<b>5 months</b>	<b>5 months</b>	<b>12 months</b>	<b>12 months</b>
	<b><u>12/31/2013</u></b>	<b><u>12/31/2012</u></b>	<b><u>12/31/2011</u></b>	<b><u>7/31/2012</u></b>	<b><u>7/31/2011</u></b>
			<b>(unaudited)</b>		
<b>Cash flows from operating activities:</b>					
Net loss	\$(15,281,821)	\$(3,400,224)	\$(586,954)	\$(5,310,476)	\$(378,761)
Adjustments to reconcile net loss to net cash used in operating activities:					
Depreciation	285,592	4,644	515	2,097	2,396
Amortization of intangible assets	76,903	38,023	64,087	203,460	253,499
Amortization of investment discount	75,962	—	—	—	—
Stock-based compensation	3,828,478	532,705	272,529	781,998	90,021
Other expense, impairment loss	11,352	333,487	—	1,996,583	—
Unrealized gain on investments	—	—	—	(23,987)	(14,572)
Realized gain on sale of investments, interest and dividends reinvested	—	—	—	(7,944)	(6,413)
(Increase) decrease in assets:					
Accounts receivable	739,499	(12,952)	2,273	590,621	411,477
Inventory	—	10,263	—	20,015	2,342
Prepaid expense and other	(113,811)	1,549	(8,208)	2,649	(1,182)
Increase (decrease) in liabilities:					
Accounts payable	204,151	236,621	39,895	28,068	2,826
Accrued liabilities	(355,777)	127,042	7,391	718,760	1,291
Deferred revenue and income	780,521	(7,311)	95,479	75,548	(10,428)
Deferred compensation	—	—	(72,569)	106,936	95,985
Net cash (used in)/provided by operating activities	\$(9,748,951)	\$(2,136,153)	\$(185,562)	\$(815,672)	\$448,481
<b>Cash flows from investing activities:</b>					
Purchases of equipment and capitalized patents	\$(1,157,564)	\$(158,348)	\$(19,057)	\$(95,505)	\$(75,336)
Contribution to deferred compensation trust	—	—	16,319	(150,000)	(75,000)
Purchase of available-for-sale securities	(12,013,616)	—	—	—	—
Net cash used in investing activities	\$(13,171,180)	\$(158,348)	\$(2,738)	\$(245,505)	\$(150,336)
<b>Cash flows from financing activities:</b>					
Exercise of warrants and options	\$20,969,130	\$100,000	\$—	\$128,569	\$194,438
Issuance of common stock and warrants	19,911,215	—	—	14,420,000	—
Net cash provided by financing activities	\$40,880,345	\$100,000	\$—	\$14,548,569	\$194,438
Increase (decrease) in cash and cash equivalents	\$17,960,214	\$(2,194,501)	\$(188,300)	\$13,487,392	\$492,583
Cash and cash equivalents, beginning of period	12,068,747	14,263,248	775,856	775,856	283,273
Cash and cash equivalents, end of period	\$30,028,961	\$12,068,747	\$587,556	\$14,263,248	\$775,856

See accompanying notes to financial statements.

31

**ACCELERATE DIAGNOSTICS, INC.**

**NOTES TO THE FINANCIAL STATEMENTS**

**NOTE 1. ORGANIZATION AND NATURE OF BUSINESS; BASIS OF PRESENTATION**

Accelerate Diagnostics, Inc. (“Accelerate” or the “Company”) is a Delaware corporation focused on developing and commercializing innovative instrumentation for the rapid identification and antibiotic susceptibility testing of infectious pathogens. The Company’s BACce™ platform utilizes a proprietary culture-free process with both genomic and phenotypic detection technologies that decrease time to result while maintaining high sensitivity and specificity.

**NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Recently Issued Accounting Pronouncements**

There have been no new accounting pronouncements issued but not yet adopted that are expected to materially affect the Company’s financial condition or results of operations.

**Use of Estimates**

The preparation of financial statements in conformity with U.S. Generally Accepted Accounting Principles (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, 2013 and December 31, 2012, the Company’s uninsured cash balance was approximately \$30,105,171 and \$12,004,575, 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, 2013 100% 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 7, License Agreements and Grants for more information.

#### **Estimated Fair Value of Financial Instruments**

The carrying amount of cash and cash equivalents, and other long-term liabilities approximates fair value at that respective period's balance sheet date.

The carrying value of all other financial instruments potentially subject to valuation risk, principally consisting of accounts receivable and accounts payable, also approximates fair value.

The following methods and assumptions were used to estimate the fair value of financial instruments:

**Cash and Cash Equivalents** – Generally, cash and cash equivalents consist of cash on deposit with banks, money market instruments, U.S. Treasury securities, and overnight repurchase agreements. The carrying amount approximates fair value.

**Investments** – investments held are classified as available for sale securities and are included at amounts approximating the fair value of the underlying instruments.

### **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. 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. These available-for-sale investments are primarily held in the custody of a major financial institution. The Company classifies its investments as current based on the nature of the investments and their availability for use in current operations.

### **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 three to seven years. See Note 5, Property and Equipment below.

### **Intellectual Property**

Intellectual property is amortized over the period the asset is expected to contribute directly or indirectly to the Company's future cash flows. The Company evaluates the remaining useful life of each intellectual property that is being amortized each reporting period to determine whether events and circumstances warrant a revision to the remaining period of amortization. Included in intellectual property are patents and technology. Intellectual properties are currently being amortized over their estimated useful lives of generally 20 years. See Note 6, Intellectual Property 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. See Note 6, Intellectual Property below.



### **Inventory**

The Company produces inventory prior to US 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-US regulatory body equivalent. Accordingly, the Company does not capitalize pre-launch inventory prior to the receipt of 510(k) clearance, unless there are alternative uses of the inventory, 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.

### **Revenue Recognition**

We recognize 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.

Technical development fee revenue was recorded in the period in which it was earned.

OptiChem revenue is recognized when the Company ships the product to customers or upon the receipt of royalty payments from our licenses.

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.

### **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. We provide a valuation allowance for deferred tax assets when it is more likely than not that the related benefits will not be realized.

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 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. The Company determined that no uncertain tax positions have been taken or are expected to be taken that could have a material effect on the Company's income tax liabilities. Interest and penalties, if any, would be recorded to 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.

The Company's net loss for the periods presented caused the inclusion of certain outstanding warrants and options to purchase our Common Stock to be antidilutive. For the period ended December 31, 2013 and the fiscal year ended December 31, 2012, there were Common Stock options and warrants exercisable for 5,731,246 (571,160 warrants and 5,160,086 options) and 18,431,930 (14,071,430 warrants and 4,360,500 options) shares of Common Stock, respectively, which were not included in diluted loss per share as the effect was antidilutive.

## **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. 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. The Company's 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. The estimated expected option life is based on the calculation published by the SEC in SAB110 for use when there is not a sufficient history of employee exercise patterns. The Company has not paid dividends in the past and does not have any plans to pay any dividends in the future. See Note 11, Employee Stock 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).

## **NOTE 3. FAIR VALUE OF FINANCIAL INSTRUMENTS**

The carrying amounts of financial instruments such as cash equivalents, restricted cash, accounts receivable, prepaid expenses, other current assets, accounts payable, accrued expenses, and other current liabilities approximate the related fair values due to the short-term maturities of these instruments. The Company may invest its excess cash into financial instruments that are readily convertible into cash, such as marketable securities, money market funds and

certificates of deposit with original maturities of three months or less at the date of purchase. The Company considers all highly liquid investments with maturities of three months or less from the date of purchase to be cash equivalents. The Company has established guidelines to maintain safety and liquidity for our financial instruments, and the cost of securities sold is based on the specific identification method.

*ASC Topic 820, Fair Value Measurements and Disclosures* has redefined fair value and required the Company to establish a framework for measuring fair value and expand disclosures about 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 following tables represent the financial instruments measured at fair value on a recurring basis on the financial statements of the Company subject to *ASC Topic 820, Fair Value Measurements and Disclosure*, and the valuation approach applied to each class of financial instruments at December 31, 2013 and December 31, 2012:

**December 31, 2013**

	<b>Quoted Prices in Active Markets for Identical Assets (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>	<b>Total</b>
<b>Assets:</b>				
Money Market funds (cash equivalents)	\$27,095,852	\$—	\$—	\$27,095,852
Corporate notes and bonds	—	11,459,375	—	11,459,357
Asset-backed securities	—	500,027	—	500,027
Total assets measured at fair value	\$27,095,852	\$11,959,384	\$—	\$39,055,236

**December 31, 2012**

	<b>Quoted Prices in Active Markets for Identical Assets (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>	<b>Total</b>
<b>Assets:</b>				
Repurchase agreement (cash equivalents)	\$12,004,575	\$—	\$—	\$12,004,575
Total assets measured at fair value	\$12,004,575	\$—	\$—	\$12,004,575

value

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 significant transfers between levels during the year ended December 31, 2013.

#### NOTE 4. INVESTMENTS

The following tables summarize the Company's available-for-sale investments at December 31, 2013:

	<b>Amortized Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Fair Value</b>
Asset-backed securities	\$500,113	\$—	\$(86	) \$500,027
Corporate notes and bonds	11,437,541	22,825	(1,009	) 11,459,357
<b>Total</b>	<b>\$11,937,654</b>	<b>\$22,825</b>	<b>\$(1,095</b>	<b>) \$11,959,384</b>

The following table summarizes the maturities of the Company's available-for-sale securities at December 31, 2013:

	Amortized Cost	Fair Value
Due in less than 1 year	\$4,999,251	\$5,001,969
Due in 1-2 years	6,938,403	6,957,415
Total	\$11,937,654	\$11,959,384

#### NOTE 5. PROPERTY AND EQUIPMENT

Property and equipment are recorded at cost and consisted of the following as of years ending December 31, 2013 and 2012.

#### PROPERTY AND EQUIPMENT

	12/31/2013	12/31/2012
Computer equipment	\$566,471	\$89,109
Laboratory and scientific equipment	791,295	323,151
Furniture and fixtures	36,988	36,988
Leasehold improvements	278,791	39,741
Total property and equipment	\$1,673,545	\$488,989
Accumulated depreciation	(626,771 )	(341,178 )
Net property and equipment	\$1,046,774	\$147,811

Depreciation expense for the for the twelve months ended December 31, 2013, five months ended December 31, 2012 and 2011, and twelve months ended July 31, 2012 and 2011 was \$285,592, \$4,644, \$515, \$2,097 and \$2,396, respectively.

#### NOTE 6. INTELLECTUAL PROPERTY

Intellectual property consisted of the following at the dates indicated:

#### INTELLECTUAL PROPERTY

	12/31/2013	12/31/2012
OptiChem Technologies	\$192,954	\$192,954

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

Patents	210,125	211,833
Subtotal	\$403,079	\$404,787
Accumulated amortization	(162,411 )	(85,507 )
Net intellectual property	\$240,668	\$319,280

Future amortization expense for the intangible assets is estimated as follows:

Years Ending December	
31,	
2014	\$63,313
2015	8,082
2016	8,082
2017	8,082
Thereafter	153,109
Total future amortization	\$240,668



Intellectual properties are recorded at cost and are being amortized on a straight-line basis over their estimated useful lives of 20 years or the patent application life specific to each capitalized patent. Amortization expense for the twelve months ended December 31, 2013, five months ended December 31, 2012 and 2011, and twelve months ended July 31, 2012 and 2011 was \$76,903, \$38,023, \$64,087, \$203,460 and \$253,499, respectively. The Company routinely evaluates the recoverability of its long-lived assets based upon estimated future cash flows from and estimated fair value of such long-lived assets. If in management's judgment, the anticipated undiscounted cash flows or estimated fair value are insufficient to recover the carrying amount of the long-lived asset, the Company will determine the amount of the impairment and the value of the asset will be written down. Management determined that certain capitalized intellectual property amounts carried on our balance sheet are no longer recoverable or abandoned its plan to pursue marketability and accordingly reduced the amortized book values and recognized the loss in its reported loss from operations for the twelve months ended December 31, 2013, five months ended December 31, 2012 and 2011, and twelve months ended July 31, 2012 and 2011 amounting to \$11,352, \$333,487, \$0, \$1,996,583 and \$0, respectively.

#### **NOTE 7. LICENSE AGREEMENTS AND GRANTS**

The Company signed a licensing agreement for microarraying slides using OptiChem coatings with Schott Jenaer Glas GmbH ("SCHOTT") on November 4, 2004. Since this time, SCHOTT and the Company have extended this license. On August 15, 2011, Schott Technical Glass Solutions GmbH 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. Previous agreements excluded medical applications. This expansion makes SCHOTT the second company that intends to use OptiChem coatings on medical devices.

The new agreement extends the non-exclusive license through November 24, 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 has been recognized as deferred revenue, and is recognized as SCHOTT's net product sales are reported to the Company. For medical applications, SCHOTT agrees to refer individual customers directly to the Company for licensing if annual purchases by a customer exceed 20,000 units.

On October 5, 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.

On July 9, 2010 the Company entered into a non-exclusive license to Nanosphere, Inc. 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 calls 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 on July 8, 2013. All of the amounts due from Nanosphere were recognized as OptiChem revenue during the fiscal year ended July 31, 2010.

In May 2012, the Company and Denver Health were notified that the Defense Medical Research and Development Program (“DMRDP”) recommended \$2 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 Company’s BACcel rapid diagnostic system to wound infections and other serious infections secondary to trauma. As of December 31, 2013 the Company has invoiced \$158,287 (\$142,591 for year ended December 31, 2013, and \$15,696 for the year ended December 31, 2012) under this grant recorded as an offset to research and development expenses.

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”). 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, 2013 the Company has collected \$750,000 of the \$1,000,000 in milestones. The full amount is recorded in deferred revenue (long term liabilities) 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, we will recognize the grant as other non-operating income.

#### **NOTE 8. 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 fiscal year, the amount is reported as long-term deferred income. A summary of the balances as of December 31, 2013 and 2012 follow:

Deferred Revenue and Income	12/31/2013	12/31/2012
Schott Royalties (see Note 7)	\$68,555	\$72,757
NanoString (see Note 7)	—	5,276
Fisher Agreement	13,333	—
Total deferred revenue and income	\$81,888	\$78,034
Arizona Commerce Authority Grant (see Note 7)	\$750,000	—
Fisher Agreement	26,667	—
Total Long-term deferred income	\$776,667	\$0

Deferred revenue recognized was approximately \$9,478, \$7,311, \$4,521, \$24,452 and \$10,428 during the year ended December 31, 2013, five-month period ended December 31, 2012 and 2011, and the fiscal years ended July 31, 2012 and 2011, 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 \$4,202, \$7,311, \$0, \$19,931 and \$0 was recognized during the year ended December 31, 2013, five-month period ended December 31, 2012 and 2011, and the fiscal years ended July 31, 2012 and 2011, respectively and are reflected as OptiChem revenues.

In the year ended December 31, 2013, \$40,000 was received from Fisher Laboratory of which none has been recognized as income. We anticipate earning \$13,333 of this amount in the next fiscal year and the remaining \$26,667 in future years.

Also in the year ended December 31, 2013, \$750,000 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 of the Arizona Commerce Authority agreement are in Note 7, License Agreements and Grants.

#### **NOTE 9. STOCK PURCHASE**

On April 20, 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; (ii) a warrant to purchase 7,000,000 shares of the Company’s 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 the Company’s 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 on June 26, 2012, qualified for equity treatment under Generally Accepted Accounting Principles. 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 is \$5,896,018 and for the Common Stock is \$8,523,982.

As noted above, the warrants sold by the Company include (i) a warrant to purchase 7,000,000 shares of the Company’s common stock at an exercise price of \$1.03 per share, and (ii) a warrant to purchase an additional 7,000,000 shares of the Company’s common stock at an exercise price of \$2.00 per share. 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 the Company’s 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 the Company's 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.

On March 6, 2013, Abeja exercised in full its warrant to purchase 7,000,000 shares of the Company's 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 the Company's 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 \$20,067,680 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 10. RIGHTS 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 \$88,785.

## **NOTE 11. EMPLOYEE STOCK BASED COMPENSATION**

The Company has three stock-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, 2013, there were 322,500 options exercised under the Qualified Plan and 235,000 that remain outstanding. The Qualified Plan has been dissolved, 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, 2013, there were 245,000 options exercised under the Non-Qualified Plan and 10,000 that remain outstanding. The Non-Qualified Plan has been dissolved, so no further options are available for grant.



### **2004 Omnibus Stock Option Plan and 2012 Omnibus Equity Incentive Plan**

On December 14, 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.

On December 12, 2012 the Company's stockholders approved the Company's 2012 Omnibus Equity Incentive Plan to replace the 2004 Omnibus Stock Option Plan. In connection with the approval of such plan, all shares formerly available for new awards under the 2004 Omnibus Stock Option Plan were transferred to the 2012 Omnibus Equity Incentive Plan.

As of December 31, 2013, 268,000 options had been exercised pursuant to the 2012 Omnibus Equity Incentive Plan, 4,915,086 that remain outstanding, leaving 316,914 available for grant.

### **Accounting for Employee Based Option Plans**

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.

On December 31, 2013, there were Common Stock options outstanding at exercise prices ranging from \$1.04 to \$13.30 per share with expiration dates between March 15, 2015 and November 5, 2023. At December 31, 2013 and December 31, 2012, stock options and warrants exercisable into 5,731,246 and 18,431,930 shares of Common Stock, respectively, were not included in the computation of diluted earnings per share because their effect was antidilutive.

For the years ending ended December 31, 2013 and 2012, the Company accounted for the compensation cost related to awards of stock options and other equity-based instruments to its employees, directors and consultants based on the fair value of the instrument on the grant date, and recognized this cost using the accelerated attribution method over the requisite service period. During the year ended December 31, 2013, the Company issued options to purchase a total of 1,308,086 common shares at an average exercise price of \$7.56 per share.

The fair value of options granted under the stock option agreements and stock-based compensation plans discussed above is estimated on the date of grant using the Black-Scholes option pricing model with the following

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

weighted-average assumptions used for grants in the year ended December 31, 2013: no expected dividend yield; risk free interest rate of 0.793% to 2.193%; expected life of 5.27 to 6.50 years; and expected volatility of 91% to 100%. The weighted average remaining contractual life of options outstanding at December 31, 2013 was 8.53 years. Weighted average expected forfeiture rate used was 14%.

As of December 31, 2013 and 2012, unrecognized share-based compensation cost related to unvested stock options was \$6,339,510 and \$3,421,901, respectively. For the year ended December 31, 2013, the five-month periods ended December 31, 2012 and 2011, and the fiscal years ended July 31, 2012 and 2011, the Company recognized \$3,828,478, \$532,705, \$272,529, \$781,998 and \$90,021, respectively in stock-based compensation costs related to the issuance of stock options to employees.

The following table summarizes information on stock option activity for the Omnibus Plan, the Qualified Plan and the Non-Qualified Plan.

	<b>Number of Shares</b>	<b>Exercise Price per Share</b>	<b>Weighted Average Exercise Price per Share</b>
Options outstanding July 31, 2012	3,180,000	\$0.73-4.50	\$1.56
Granted	1,433,000	\$2.98-3.95	\$3.65
Cancelled	250,000	\$2.25-4.50	\$3.34
Exercised	—	—	—
Expired	2,500	\$2.36-3.20	\$3.02
Options Outstanding December 31, 2012	4,360,500	\$0.73-3.95	\$2.14
Granted	1,308,086	\$3.45-13.30	\$7.56
Cancelled	58,000	\$2.69-9.83	\$6.47
Exercised	328,000	\$1.04-3.69	\$2.54
Expired	122,500	\$0.73-3.20	\$1.78
Options Outstanding December 31, 2013	5,160,086	\$1.04-13.30	\$3.45

As of December 31, 2013 and December 31, 2012, 1,021,056 and 1,360,500 options outstanding were currently exercisable and carried weighted average exercise prices of \$2.29 and \$1.92 respectively. The following table summarizes information about stock options outstanding and exercisable at December 31, 2013:

Range of Exercise Price	Outstanding			Exercisable		
	Number of Shares	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number of Shares	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price
\$0 to \$3.50	2,605,000	8.17	\$1.31	775,000	7.73	\$1.40
\$3.51 to \$7.00	2,053,691	8.69	4.45	244,120	7.05	5.01
\$7.01 to \$10.50	394,500	9.66	9.71	—	—	—
\$10.51 to \$13.50	106,895	9.85	13.30	1,936	9.85	13.30
Total	5,160,086	8.53	\$3.45	1,021,056	7.57	\$2.29

#### NOTE 12. INCOME TAXES

The components of the income tax provision (benefit) are as follows:

	12/31/2013	12/31/2012	7/31/2012	7/31/2011
Current	\$—	\$—	\$—	\$—
Deferred	—	—	—	—
Total	\$—	\$—	\$—	\$—

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 are as follows:

	12/31/2013	12/31/2012
<b>Deferred tax assets:</b>		
Intangible assets, definite-lived	\$478,000	\$452,000
Property & equipment	21,000	—
Deferred revenue	26,000	30,000
Charitable contribution	11,000	6,000
Stock options	516,000	172,000
Officer's compensation	—	270,000
General business credit	637,000	144,000
Net operating loss carryforward	8,595,000	4,083,000

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

Valuation allowance	(10,284,000)	(5,156,000 )
Deferred tax assets	\$—	\$1,000
<b>Deferred tax liabilities:</b>		
Property & equipment	\$—	\$(1,000 )
Total deferred tax liabilities	\$—	\$(1,000 )
Total net deferred taxes	\$—	\$—

As of December 31, 2013, the Company has generated regular tax net operating losses of approximately \$28,000,000. Our ability to utilize our U.S. federal and state NOLs may be limited if we experience an ownership change as defined by U.S. Internal Revenue Code Section 382. When a company undergoes an ownership change, Section 382 limits the future use of NOLs generated before the change in ownership and certain subsequently recognized “built-in” losses and deductions, if any, existing as of the date of the ownership change. A company’s ability to utilize new NOLs arising after the ownership change is not affected. At this time, we have not performed an analysis under Section 382 to determine if an ownership change has occurred. The Company has estimated that due to Abeja Ventures, LLC’s investment in the company on June 26, 2012, the annual Section 382 limitation on utilization of net operating losses will be \$420,000. The gross net operating losses available for future use are approximately \$24,000,000. 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 and will begin filing tax returns in Arizona starting with the year ending December 31, 2013. The Colorado net operating loss carryovers may not be utilized and as a result are fully reserved. The deferred attributes have been adjusted to reflect the change to the Arizona state income tax rates.

The valuation allowance is \$10,284,000 as of December 31, 2013 compared to \$5,156,000 as of December 31, 2012. 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 is as follows:

<b>Fiscal year ended,</b>	<b>12/31/2013</b>	<b>12/31/2012</b>	<b>7/31/2012</b>	<b>7/31/2011</b>
U.S. Federal statutory income tax rate	(34.00 )%	(34.00 )%	(34.00 )%	(34.00 )%
State taxes, net of federal tax benefit	(3.80 )	(2.70 )	(3.00 )	(3.00 )
Change in state rate	0.00	(0.90 )	—	—
Non-deductible equity and other compensation	6.50	4.20	5.19	0.10
Limitation on net operating losses due to S382	1.00	32.50	—	—
Removal of Colorado net operating losses	0.00	10.80	—	—
Prior period net operating loss correction	—	—	(1.70 )	—
Credit for increased research activities	(3.20 )	—	—	—
Change in valuation allowance	33.50	(9.90 )	33.51	36.90
	0.00 %	0.00 %	0.00 %	0.00 %

### NOTE 13. COMMITMENTS

### **Employment Agreement and Consulting Agreement**

Effective December 1, 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. On June 26, 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 this consulting agreement.

## Operating Lease

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 (pursuant to an extension effective as of August 3, 2012). Total rent expense including common area charges was approximately \$10,844, \$39,867, \$35,470, \$73,965 and \$68,330 during the year ended December 31, 2013, five-month period ended December 31, 2012 and 2011, and the fiscal years ended July 31, 2012 and 2011, respectively.

On August 20, 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 will lease 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 \$139,600 per year or approximately \$11,600 per month) during the Initial Term and \$19.80 per usable square foot per year (approximately \$298,900 per year or approximately \$24,900 per month) 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. If the Company fails to satisfy the condition described in clause (iii) of the preceding sentence, the rental rate under the Lease will be increased 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.

As of February 1, 2013, we relocated our headquarters into the above described leased space in Tucson, Arizona. Total rent expense including common area charges was approximately \$167,864 during the year ended December 31, 2013 with no amounts in previous periods. Future minimum lease payments under this agreement are as follows:

	2014	2015	2016	2017	2018
Operating Lease Obligations	\$141,664	\$141,664	\$1,164	\$—	\$—

## NOTE 14. SUBSEQUENT EVENTS

In January 2014, we completed a 4,332 square foot expansion of our facility in Tucson, Arizona to accommodate growth. We anticipate adding an additional 7,553 square feet in 2014 for manufacturing and other operational needs.

On January 8, 2014, 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. Our research and development tax credit for 2013 is \$703,377 which makes us eligible to claim a partial refund of 75% or \$527,495. By claiming this partial refund, we irrevocably forfeit the remaining 25% tax credit amount along with any additional tax credits that might become available if our qualifying expenses increase or income tax liability decreases. The “Certificate of Qualification” does not guarantee the receipt of tax incentives; nor does it obligate the Arizona Department of Revenue to issue the refund. Furthermore, if qualifying expenses decrease or income tax liability increases, the refund amount may be less than the \$527,495. 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.

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

As previously disclosed, on July 1, 2013, the Audit Committee of the Board of Directors of Accelerate Diagnostics, Inc. (the “Company”) dismissed Comiskey & Company, P.C. (“Comiskey”) as its independent registered public accounting firm and approved the engagement of Ernst & Young LLP (“E&Y”) to replace Comiskey as its independent registered public accounting firm for the fiscal year ending December 31, 2013.



The reports issued by Comiskey with respect to the Company's financial statements for (i) the past two fiscal years, which ended on July 31, 2011 and July 31, 2012, respectively, and (ii) the transition period that began on August 1, 2012 and ended on December 31, 2012, did not contain an adverse opinion or a disclaimer of opinion, nor were they qualified or modified as to uncertainty, audit scope or accounting principles.

During the Company's two most recent fiscal years and the transition period that ended on December 31, 2012 (and the subsequent interim period preceding Comiskey's dismissal), there were no disagreements between the Company and Comiskey on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which if not resolved to the satisfaction of Comiskey, would have caused Comiskey to make reference to the matter.

During the Company's two most recent fiscal years and the transition period that ended on December 31, 2012 (and the subsequent interim period preceding the Company's engagement of E&Y), neither the Company nor anyone on its behalf consulted E&Y regarding any of the matters or events set forth in Item 304(a)(2) of Regulation S-K.

## **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, 2013 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 US 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, 2013. 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, 2013.

### **Attestation Report of Independent Registered Public Accounting Firm**

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 quarter ended December 31, 2013 that materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

An evaluation was conducted under the supervision and with the participation of the Company's Management, including the Company's Chief Executive Officer (“CEO”) and Chief Financial Officer (“CFO”), of the effectiveness of the design and operation of the Company's disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Based on that evaluation, the CEO and the CFO concluded that as of December 31, 2013, the Company's disclosure controls and procedures were effective as of such date to ensure that information required to be disclosed in the reports that it files or submits under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms. The CEO and the CFO also confirmed that there was no change in the Company's internal control over financial reporting during year ended December 31, 2013.

### **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 2014 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.

**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***

	<b><u>Page</u></b>
Report of Independent Registered Public Accounting Firm	25-26
Report of Independent Registered Public Accounting Firm for Prior Audit Periods	27
Balance Sheets as of December 31, 2013 and 2012	28
Statements of Operations and Comprehensive Loss for the year ended December 31, 2013, five months ended December 31, 2012 and 2011, fiscal years ended July 31, 2012 and 2011	29
Statements of Stockholders' Equity for the year ended December 31, 2013, five months ended December 31, 2012 and fiscal years ended July 31, 2012 and 2011	30
Statements of Cash Flow for the year ended December 31, 2013, five months ended December 31, 2012 and 2011, fiscal years ended July 31, 2012 and 2011	31
Notes to Financial Statements	32

#### **2) Financial Statement Schedules**

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

**b) Exhibits required by Item 601 of Regulation 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.

March 7, 2014 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
<u>/s/ Lawrence Mehren</u> Lawrence Mehren	President, Chief Executive Officer and Director	March 7, 2014
<u>/s/ Steve Reichling</u> Steve Reichling	Corporate Secretary, Chief Financial Officer and Chief Accounting Officer	March 7, 2014
<u>/s/ John Patience</u> John Patience	Chairman of the Board of Directors	March 7, 2014
<u>/s/ Jack Schuler</u>	Director	

Jack Schuler		March 7, 2014
<u>/s/ Matthew W. Strobeck</u> <u>Ph.D.</u>	Director	March 7, 2014
Matthew W. Strobeck, Ph.D.		
<u>/s/ Frank ten Brink</u>	Director	March 7, 2014
Frank ten Brink		
<u>/s/ Mark Miller</u>		
Mark Miller	Director	March 7, 2014



**EXHIBIT INDEX**

<b><u>Exhibit No.</u></b>	<b><u>Description</u></b>	<b><u>Filing Information</u></b>
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. 1 issued by Registrant to Abeja Ventures, LLC on June 26, 2012	Incorporated by reference to Exhibit 4.1 filed with the Registrant's Annual Report on Form 10-K for the fiscal year ended July 31, 2012
4.2	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
4.3	Subscription and Information Agent Agreement, dated May 31, 2013, between the Registrant and Broadridge Corporate Issuer Solutions, Inc.	Incorporated by reference to Exhibit 4.2 to the Registrant's Form S-3 Registration Statement (No. 333-189065) filed on June 4, 2013
4.4	Form of Non-Transferable Subscription Rights Certificate	Incorporated by reference to Exhibit 4.1 to the Registrant's Form S-3 Registration Statement (No. 333-189065), Amendment No. 2, filed on July 10, 2013
4.5	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
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

50

<u>Exhibit No.</u>	<u>Description</u>	<u>Filing Information</u>
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	Employment Agreement between Registrant and Thomas V. Geimer*	Incorporated by reference to Exhibit 10.6 filed with the Registrant's Annual Report on Form 10-K for the fiscal year ended July 31, 2012
10.7	Amendment to Employment Agreement between Registrant and Thomas V. Geimer*	Incorporated by reference to Exhibit 10.7 filed with the Registrant's Annual Report on Form 10-K for the fiscal year ended July 31, 2012
10.8	Consulting Agreement between Registrant and Thomas V. Geimer*	Incorporated by reference to Exhibit 10.8 filed with the Registrant's Annual Report on Form 10-K for the fiscal year ended July 31, 2012
10.9	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
10.10	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
10.11	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
10.12	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
10.13	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
10.13.1	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

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

10.13.2	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
10.13.2	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
10.14	Standby Purchase Agreement, dated May 31, 2013, between the Registrant and Abeja Ventures, LLC	Incorporated by reference to Exhibit 10.1 to the Form S-3 Registration Statement (No. 333-189065) filed by the Registrant on June 4, 2013
23.1	Consent of Independent Registered Public Accounting Firm	Filed herewith
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith
32.1	Certificate of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	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	