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

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

þ **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	**84-1072256**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
3950 South Country Club, Suite 470	
Tucson, Arizona	**85714**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code:

(520) 365-3100

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

Title of each class	Name of each exchange on which registered
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. o Yes þ 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. o Yes þ 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. þ Yes o 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). þ Yes o 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. þ

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 file	
Accelerated filer	þ
Non-accelerated filer	o(Do not check if a smaller reporting company)
Smaller reporting company	þ

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

o Yes þ 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

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.

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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.

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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.

Quarter Ended	High [1]	Low [1]
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 [2]	$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 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:

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