ACCELR8 TECHNOLOGY CORP
Form 10-K
October 26, 2012

U.S. SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the Fiscal Year Ended July 31, 2012

£ TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Transition Period from _____ to _____

Commission file number: 0-11485

ACCELR8 TECHNOLOGY CORPORATION

(Exact name of Registrant as Specified in Its Charter)

Colorado	84-1072256
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
7000 North Broadway, Bldg 3-307 Denver, Colorado	80221
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code:

(303) 863-8088

SECURITIES REGISTERED PURSUANT TO SECTION 12 (b) OF THE ACT:

Name of each exchange on which registered: The NYSE AMEX EQUITIES

COMMON STOCK, NO PAR VALUE PER SHARE

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

S 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 S 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 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. S Yes £ No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate web site, 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).

S 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. (Check one):

Large accelerated filer £	Accelerated filer £	Non-accelerated filer £ (Do not check if a smaller reporting company)	Smaller reporting company S

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

£ Yes S No

The aggregate market value of the shares of Common Stock, no par value per share, of the registrant held by non-affiliates on January 31, 2012 was $12,274,828, which was computed based upon the closing price of the Registrant's Common Stock on that date.

There were 25,231,939 shares of Common Stock of the registrant outstanding as of October 15, 2012.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement relating to its 2012 Annual Meeting of Shareholders are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. Such Proxy Statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

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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," "Accelr8," "we," "us" or "our" are references to the combined business of Accelr8 Technology Corporation.

Special Note Regarding Forward-Looking Statements

This report contains forward-looking statements and information relating to Accelr8 that are based on the beliefs of our management as well as assumptions made by and information currently available to us. When used in this Form 10-K, forward-looking statements include, but are not limited to, the words "anticipate," "believe," "estimate," "expect," "intend," "plan" and similar expressions, as well as statements regarding technologies and products we are developing or intend to develop in the future, the ability of such technologies and products to work as intended and bring to market, opportunities for the Company and its technologies, statements regarding competition, the market and industry in which we intend to compete, demand and acceptance of new products, any statements of the plans, strategies and objectives of management for future operations, any statements regarding future economic conditions or performance, any statements of belief or intention, and any statements or assumptions underlying any of the foregoing. These statements reflect our current view concerning future events and actions and are subject to risks, uncertainties and assumptions. There are important factors that could cause actual results to vary materially from those described in this Form 10-K as anticipated, estimated or expected, including, but not limited to the factors listed in Item 1A – Risk Factors in this Annual Report on Form 10-K. Except as required by law, we assume no obligation to update any forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in any forward- looking statements, even if new information becomes available in the future.

PART I

Item 1. Business

Overview

Accelr8 Technology Corporation 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.

Background

Every six minutes another American dies from a hospital-acquired infection (HAI). The US Centers for Disease Control and Prevention 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. The HAI mortality rate is more than double that from auto accidents, far more than any type of cancer except lung cancer, and more than seven and one-half times that from AIDS. 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 identify organisms and 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 US Centers for Disease Control and Prevention (“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 HAI’s. This increase in multi-drug resistant organisms creates an opportunity for the Company by driving demand for rapid identification.

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 bacterial infections. 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 resistance for each type of organism within a total of 4-6 hours after receiving a specimen. The clinical purpose of reporting antibiotic resistance is to narrow the drug choices available for therapy and rule out antibiotic classes that are most likely to fail. Quantitative identification in less than one hour enables first-dose therapy guidance that can improve the efficacy of antimicrobial treatment. In addition, de-escalation before the second dose helps to prolong the effectiveness of broad-spectrum antibiotics when lower-cost and older narrow-spectrum agents can provide at least equivalent activity (drug “stewardship”).

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 (Germany), NanoString (WA), and Nanosphere (IL). See “Sales, Licensing, and Alliances” below.

Research and Development

We have used two developmental instruments in our laboratory since 2006. In March 2011 we upgraded one of the systems to test engineering improvements. In April 2011, we installed a completely upgraded third system that substantially increases analytical sensitivity and scanning speed. This next-generation system includes a separate fluidic robot and a custom high-speed scanning microscope. The latest prototype increases scan rate approximately 40-fold relative to the original prototypes. This speed substantially improves detection sensitivity for working with specimens that have low microbial counts. It also improves our ability to analyze specimens that require dilution because of high levels of interfering materials, such as endotracheal aspirates used to monitor treatment effectiveness during therapy for pneumonia. We have used the latest prototype for formal proof of concept testing under independent outside observation of testing and outside performance assessment.

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. 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.

Management believes that joint studies will expand and continue and will be presented periodically to the relevant scientific and medical communities. Since 2006, we have made 21 technical presentations at major peer-reviewed national scientific and clinical congresses. The 12 most recent were co-authored with principal investigators at Denver Health, and Barnes-Jewish Hospital. At the annual meeting of the American Thoracic Society in March 2011, our principal investigators at Denver Health presented preliminary results from a prospective clinical pilot study with ICU patients under informed consent. This was our first presentation of a clinical study solely to specialists in Critical Care Medicine. We intend to continue our presentation and publication program as a permanent part of our business development program. (See Note 13 to the footnotes to the consolidated financial statements included in this Annual Report on Form 10-K.)

In June 2010, the Company entered into an Evaluation Agreement and Letter of Intent with Novartis Vaccines and Diagnostics, Inc. ("Novartis"), a division of Novartis Corporation. Pursuant to the Evaluation Agreement, Novartis evaluated the results of the Company's BACcel™ system in identifying the type and quantity of bacterial pathogens in clinical specimens. Pursuant to the Letter of Intent, the Company and Novartis agreed to negotiate in good faith a formal business relationship and definitive agreement regarding the design, development, commercialization and support strength of each party. The Letter of Intent was non-binding and granted Novartis the exclusive right (the "Exclusive Right") to evaluate and negotiate a license or other comparable agreement for access to the Company's BACcel™ system intellectual property.

In connection with the Evaluation Agreement, the Company successfully performed a series of technical studies, including formal Proof of Concept studies, with Novartis that demonstrated performance of the advanced BACcel™ laboratory prototype. Further, Novartis independently tested Accelr8's key business assumptions and found general concurrence.

Pursuant to the Evaluation Agreement and the Letter of Intent, Novartis made up-front payments and funded the project on a monthly basis until September 30, 2011. Novartis also funded additional activities within its own organization, funded independent engineering firms to advance the product technology, and retained other outside providers to perform due diligence investigations on relevant business areas.

The Evaluation Agreement with Novartis expired on September 30, 2011 without Novartis exercising its option for licensing the Company's BACcel™ system intellectual property.

In ongoing technical development of the BACcel™ system, our internal technical team designs the analytical methods and validates them through well-controlled experiments. Studies include comparisons of results between standard methods and the BACcel™ system using well-characterized bacterial strains and clinical patient specimens. Examples of patient specimens tested to date include lower respiratory tract specimens (endotracheal aspirates, visually-guided bronchoalveolar lavage – BAL, and mini-BAL,) urine and cerebrospinal fluid. We have also tested positive blood cultures that originally contained extremely low numbers of infectious pathogens.

In addition to developing analytical methods, our internal team proactively guides engineering development and originates additional new technology. As one example, we internally conceived and proved feasibility of a rapid specimen preparation method that appears to enable complete and practical automation for all BACcel™ associated operations. We filed a patent application for this technology in March 2011. This subsystem can also stand alone as a product, and integrate into other medical devices that require specimen pre-processing by automated methods. We created specifications for an outside engineering firm to provide test fixtures and advance toward product development.

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 $750,000. 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.

In June 2012, the company began a reorganization, resulting in a significant planned increase in internal research and development staff. This team - including engineers, chemists, and microbiologists - has significant experience in the diagnostics field, having developed and commercialized numerous IVD instruments and tests.

During the fiscal years ended July 31, 2012 and 2011, we spent $431,906 and $454,997 respectively, on research and development activities.

Sales, Licensing, and Alliances

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. 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.

Effective June 14, 2010, the Company entered into the Evaluation Agreement and Letter of Intent with Novartis discussed above. During the fiscal years ended July 31, 2012 and 2011, total revenues from Novartis were $140,000 and $842,408, respectively or 59.3% and 75.1% of total revenues.

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. Pursuant to the Company's revenue recognition policies and generally accepted accounting principles, all of the amounts due from Nanosphere were recognized as OptiChem revenue during the fiscal year ended July 31, 2010.

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 active, 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 only by using the presence or absence of specific genes. Even in those rare instances that have a direct relationship between a gene and effective resistance, such as "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.

Nevertheless, commercial suppliers of gene marker tests, such as Cepheid, have gained approval for direct analysis of positive blood cultures. Blood cultures also typically require a minimum of overnight growth to produce enough organisms to detect. Existing marker-based tests identify a very small number of organism genera or species, and none identify enough of the high-threat organisms to provide an alternative to standard culturing. Furthermore, the inability to identify multiple drug resistance mechanisms precludes them from effective treatment decision support for critically ill patients.

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

We own all of our laboratory equipment. We lease approximately 6,400 square feet of laboratory and administrative space in Denver, Colorado. Within our laboratory facility, we constructed a cleanroom for research and development and pilot production. We are also under contract to Denver Health for approximately $3,000 per month for use of its facilities and oversight by an ICU Physician.

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 July 31, 2012, we have eight issued patents plus four United States and eight international patent filings pending.

Accelr8's first patent on the OptiChem technology, U.S. Patent No. 6,844,028 titled "Functional Surface Coating" was issued on January 18, 2005. The patent specification covers the core OptiChem technology. On June 27, 2006, the United States Patent Office issued Patent No. 7,067,194 which awarded the Company a patent for devices that use OptiChem coatings.

Accelr8'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 assure you 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.

Employees

We have six full-time employees. We have not entered into any collective bargaining agreements and consider our labor practices and employee relations to be good.

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. 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 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 Chief Executive Officer and President. 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 significant 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 Denver, Colorado. The lease expires in February 2013, at which time we intend to move into a single 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 bacterial and its 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. For the year ended July 31, 2012, we spent $431,906 and during the fiscal year ended July 31, 2011 we spent $454,997 on research and development expenses and we intend to spend significantly more on research and development activities during the fiscal year ending July 31, 2013 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.

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.

Colorado law and our Articles of Incorporation may protect our directors from certain types of lawsuits. Colorado 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 Articles of Incorporation permit 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; 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 in "Forward-looking Statements" and "Risk Factors" and the markets

response to our operations and financial condition. 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 stock. During the fiscal year ended July 31, 2012, the closing sale price for our Common Stock ranged from $0.77 to $3.80 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 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. Further, any sale of a substantial number of additional shares will cause dilution to an investment in our Common Stock and could also cause the market price of our Common Stock to decline. We have the authority to issue up to 45,000,000 shares of Common Stock, of which, as of October 15, 2012, 25,231,939 shares were outstanding) and to issue options and warrants to purchase shares of our Common Stock (of which 4,140,000 options and 14,171,430 warrants to acquire shares of our Common Stock were issued and outstanding). Issuances of additional shares of our stock in the future could dilute existing shareholders and may adversely affect the market price of our Common Stock.

Item 1B. Unresolved Staff Comments

Not Applicable.

Item 2. Properties

We lease approximately 6,400 square feet of office and laboratory space in Denver, Colorado. The monthly rent and utilities average approximately $6,000 per month. The lease was due to expire on September 30, 2012. On August 3, 2012, the Company entered into an extension of this lease on similar terms whereby it will now expire on February 1, 2013.

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 15,100 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 7,900 square feet.

Pursuant to the Lease, the Company agreed to: (i) pay rent equal to $9.25 per usuable square foot per year (approximately $139,600 per year or approximately $11,600 per month) during the Initial Term and $19.80 per usuable 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 usuable 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. When completed, the Company believes this facility will be adequate for its needs for the foreseeable future.

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 Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

The Company's Common Stock is traded on the NYSE Amex Equities Exchange 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, 2010 through July 31, 2012.

Quarter Ended	High[1]	Low[1]
October 31, 2010	$1.16	$0.67
January 31, 2011	$1.37	$0.89
April 30, 2011	$4.90	$1.30
July 31, 2011	$7.17	$3.54
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

(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.

Holders

As of October 15, 2012, we had approximately 226 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.

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 July 31, 2012:

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	3,180,000	$1.56	2,812,500
Equity compensation plans not approved by security holders	-	-	-
Total	3,180,000	$1.56	2,812,500

Item 6. Selected Financial Data.

Not applicable to smaller reporting companies.

Item 7. Management's Discussion and Analysis and Results of Operation

Overview

On June 26, 2012, we closed upon the sale to Abeja at a purchase price of $1.03 per share for an aggregate purchase price of $14,420,000 of 14,000,000 shares of the Company’s Common Stock, a warrant to purchase 7,000,000 shares of the Company’s Common Stock at an exercise price of $1.03 per share and another warrant to purchase 7,000,000 shares of the Company’s Common Stock at an exercise price of $2.00 per share (collectively the “Investment”).