Akers Biosciences Inc
Form 10-K
March 28, 2014

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the Fiscal Year Ended: **December 31, 2013**

or

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THESECURITIES EXCHANGE ACT OF 1934**

AKERS BIOSCIENCES, INC.
(Exact name of registrant as specified in its charter)

New Jersey	**22-2983783**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

(Commission File Number)

201 Grove Road

Thorofare, New Jersey USA 08086
(Address of principal executive offices, including zip code)

(856) 848-8698

(Registrant's telephone number, including area code)

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

Securities registered pursuant to Section 12(g) of the Act: **Common Stock, no par value**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 the Securities Act. Yes ¨ No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes¨ No x

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 last 90 days.

Yes x 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 (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) 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. Yes ¨ No ¨

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 definition of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer ¨ Accelerated Filer ¨

Non-Accelerated Filer ¨ Smaller reporting company x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

Issuer’s revenues for its most recent fiscal year were approximately $3,600,000.

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant on June 30, 2013, based on a closing price of $2.50 was approximately $4,479,420. As of March 25, 2014, the registrant had 4,894,837 shares of its common stock, no par value per share, outstanding.

Documents Incorporated By Reference: None.

AKERS BIOSCIENCES, INC.

FOR THE FISCAL YEAR ENDED

DECEMBER 31, 2013

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FORWARD LOOKING STATEMENTS

Included in this Form 10-K are “forward-looking” statements, as well as historical information. Although we believe that the expectations reflected in these forward-looking statements are reasonable, we cannot assure you that the expectations reflected in these forward-looking statements will prove to be correct. Our actual results could differ materially from those anticipated in forward-looking statements as a result of certain factors, including matters described in the section titled “Risk Factors.” Forward-looking statements include those that use forward-looking terminology, such as the words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “project,” “plan,” “will,” “shall,
similar expressions, including when used in the negative. Although we believe that the expectations reflected in these forward-looking statements are reasonable and achievable, these statements involve risks and uncertainties and we cannot assure you that actual results will be consistent with these forward-looking statements. We undertake no obligation to update or revise these forward-looking statements, whether to reflect events or circumstances after the date initially filed or published, to reflect the occurrence of unanticipated events or otherwise.

PART I

Item 1. Business.

Overview

Akers Biosciences, Inc. ("ABI," "we" or the "Company") develops, manufactures, and supplies rapid, point-of-care screening and testing products designed to bring health-related information directly to the patient or clinician in a time- and cost-efficient manner. ABI believes it has advanced the science of diagnostics through the development of several proprietary platform technologies that provide product development flexibility.

All of ABI's rapid, single-use tests are performed *in vitro* (outside the body) and are designed to enhance patient well-being and reduce total outcome costs of healthcare. The Company's current product offerings and pipeline products focus on delivering diagnostic assistance in a wide variety of healthcare fields/specialties, including cardiology/emergency medicine, metabolism/nutrition, neuropsychiatry, oncology and infectious diseases detection, as well as for on- and off-the-job alcohol safety initiatives.

ABI believes that low-cost, unit-use testing not only saves time and money, but allows for more frequent, near-patient testing which may save lives. We believe that ABI's FDA-cleared rapid diagnostic tests that help facilitate targeted diagnoses and real-time treatment. We also believe that ABI's rapid diagnostic tests surpass most other current diagnostic products with their flexibility, speed, ease-of-use, readability, low cost and accuracy. In minutes, detection of disease states and medical conditions can be performed on single-patient specimens, without sacrificing accuracy.

We believe the use of rapid tests, which can be performed at the point-of-care when and where the patient is being consulted, can result in immediate diagnostic decisions and subsequent treatment regimens and is an important development in the practice of medicine. Point-of-care testing addresses today's challenges in the healthcare industry, such as:

- cost pressures/efficiency of healthcare delivery;
- need for tools for pharmaceutical companies to monitor side effects of medicines/new agents in development;

- need for easy to use, accurate at-home tests for individuals to monitor their personal health and wellness;

- need for affordable mass screening tests for key infectious diseases, cardiac conditions, and metabolic markers; and

- public health needs in developing countries lacking basic health infrastructure.

Market Overview

Worldwide, healthcare professionals use laboratory tests to support their clinical diagnosis and treatment decisions. According to a MarketsandMarkets report, *In-Vitro Diagnostic (IVD) Market (Applications, End-users & Types) Trends & Global Forecasts (Major & Emerging Markets — G7, Japan & BRIC) (2011 – 2016)*, published in January 2012 (the "IVD Market Report"), the use of such tests continues to grow as a result of increased patient awareness, patient self-testing, and increasing baby booming population across the globe. Other major drivers for the growth of the *in vitro* diagnostic ("IVD") industry is a rise in the number of diseases like respiratory and hospital-acquired infections and a rise in the chronic diseases such as diabetes, hypertension, cardiovascular diseases, and cancer. Both an increasing understanding of the molecular processes underlying many disease states and the opportunity for clinicians to quickly incorporate that targeted information into treatment decisions (e.g. companion testing). According to an article published on in vitro diagnostics by Medical Device and Diagnostic Industry ("MDDI") online in March 2013, in the past, the *in vitro* diagnostics industry has focused on developing tests that require significant time, skill, and often costly, specialized equipment. Patient specimens often had to be collected remotely and processed in a central laboratory with test results sent to a physician at a later date. This general protocol is not particularly well-adapted to the practice of medicine in a cost-effective, timely manner. The pressures on public health budgets and falling profits among third party payors such as insurers, necessitates an alternative approach to disease management. Moreover, the implementation of "Obamacare" in the United States mandates that tens of millions of additional people receive cost-effective healthcare. This reality has changed the American healthcare landscape as evidenced by the steady growth of the retail health clinic and urgent care centers market.

According to the IVD Market Report, outside of the United States, socialized medicine and/or a general atmosphere of cost-containment and healthcare efficiency drive the need for diagnostic testing solutions that are fast, affordable, accurate, simple-to-perform and help enable early diagnosis and treatment of medical conditions or provide an assessment of a person's health status.

ABI designed its products based on single-use assay platforms with straightforward test procedures that can be completed in minutes. In the healthcare setting, the Company's clinical laboratory products can be utilized near or at the point-of-care and do not require the use of expensive equipment or a highly trained or specialized staff. As a result, an individual's current health status can immediately be incorporated into diagnostic and treatment decisions, improving the overall efficiency of the healthcare experience in the eyes of the patient, and ultimately the payor. In addition, in the developing world, the portability and ease-of-use of such point-of-care tests can serve to drastically improve the level of disease screening and subsequent patient care. We believe the benefits of our technology platforms are therefore well-suited to the diagnostic demands of third world countries that seek to deliver modern medical diagnosis in the midst of primitive infrastructures. In addition, some of our products have received FDA clearance for over-the-counter use and others that do not fall within the oversight of regulatory authorities have the added benefit of being self-tests that deliver personal health information on-demand. ABI believes that the products that emerge from ABI's technology platforms address the needs of the evolving healthcare delivery system that is moving patient care closer to or in the home.

In a June 6, 2013 article "*Global In Vitro Diagnostics Markets Outpace Pharma Industry Growth"* by Frost & Sullivan's estimated the global IVD market was $45 billion, with forecasted revenue expected to reach $64 billion in 2017. While the U.S. and Western Europe are the largest IVD markets, the Asian-Pacific region and Eastern Europe are projected to be the fastest growing by Frost & Sullivan's. The Company's main presence is in the United States, but recently executed distribution and licensing agreements have initiated ABI's strategic move to the China and European Union marketplaces.

Strategy

ABI's strategy is to target carefully chosen, high margin market segments within the diagnostics industry where existing tests do not effectively fulfill clinical requirements, or an emerging, unfulfilled need has been identified. The Company seeks to develop tests for applications based on their ability to compliment a particular treatment, lifestyle or testing regimen that requires a time- and cost-efficient diagnostic alternative or solution. ABI utilizes its existing platform technologies to internally develop its new products as the Company's proprietary methods.

ABI has established and will continue to pursue distribution relationships with high volume, medical and health & wellness product marketers to maximize its revenue potential, and to be a worldwide competitor in specialized markets within the diagnostics industry.

ABI has developed and continues to develop key strategic relationships with established companies with well-trained technical sales forces and strong distribution networks in the following key market segments:

- Clinical Laboratories;
- Physicians' Office/Retail and Urgent Care Clinics;
- Nutraceutical Suppliers; and
- Military/Government.

The Company plans to target other attractive markets such as aid organizations with purchasing power for rapid infectious disease tests and other biotechnology companies or pharmaceutical manufacturers that may require companion tests to promote patient compliance with a medication regimen or facilitate initial screenings to qualify patients for a particular therapy.

Technology Overview

ABI's proprietary platform technologies merge scientific innovation with user-friendly formats to deliver cost-effective and time-efficient testing and sample preparation solutions where and when they are needed.

Testing Platform Technologies

MPC Biosensor Technology

MicroParticle Catalyzed Biosensor ("MPC Biosensor") Technology permits the rapid identification of medical conditions through biomarkers in exhaled breath. These products contain microparticles that change color when a subject has a positive test result. The microparticles are coated with recently discovered agents that both decrease the time to result and provide a more defined color change when appropriate. MPC Biosensor-based products are packaged in small, disposable tubes through which test subjects can easily blow for several seconds. In the United States, the MPC Biosensor Technology is protected by two United States patents (7,285,246; 7,837,936), covering all MPC Biosensor products such as CHUBE, VIVO and the "Breath PulmoHealth "Check" suite of products. Breath Ketone "Check" has one US and three International patent applications pending. In addition, ABI also holds three US, three Australian and three European Community Design patents for Color Comparison Card technology that users can utilize to interpret detector results.

Particle ImmunoFiltration Assay (PIFA®) Technology

PIFA® technology is an accurate, rapid, immunoassay (*a procedure for detecting or measuring specific proteins or other substances through their properties as antigens or antibodies*) method based on the selective filtration of dyed microparticles coated with antigen or antibody. The microparticles are combined with a test sample (whole blood, serum, urine or saliva) within a self-contained device. If a patient tests positive for the antibody or antigen, a binding event will occur and the dyed microparticles will be trapped by a filter within the device. As a result, the test window will be void of any color. Conversely, if the patient tests negative, the dyed microparticles will flow freely into the test window. ABI's PIFA® Technology is currently protected by two United States patents (5,565,366; 5,827,749) covering all PIFA tests such as Heparin, Malaria and Chlamydia. Specific to the PIFA Heparin tests, the Company has one international Patent (JP 4,931,821) granted in force, and three patent applications pending (one US and two international).

SMC Technology

Synthetic Macrocycle Complex ("SMC") Technology is a colorimetric testing methodology that pairs a proprietary reagent (*a substance or mixture for use in chemical analysis or other reactions)* with a hand-held, photometric reader that determines the quantitative level of a therapeutic drug in a patient's blood sample. The technology also permits the

use of whole blood samples collected from a simple finger stick, making products that use this technology extremely flexible within the healthcare delivery system.

Rapid Enzymatic Assay

Rapid Enzymatic Assay ("REA") technology enables the rapid detection of metabolites in blood and urine in assay formats that are easy-to-use and deliver quantitative or semi-quantitative results. Products that employ REA technology are primarily intended for pharmaceutical, nutritional and over-the-counter (OTC) markets. ABI has two United States patents (8,003,061; 8,425,859) for this technology covering our Tri-Cholesterol "Check" test, along with one US patent application pending.

minDNA™ Technology

minDNA™ technology facilitates the analysis of DNA, in one minute, by a hand-held photometric reader. A mixture consisting of a patient's whole blood specimen and a disposable reagent is exposed to the minDNAnalyzer, a digital hand-held reflectance photometer. These assays can be utilized at the point of care setting by non-clinical laboratory personnel using finger stick blood samples, or in the laboratory using EDTA whole blood specimens obtained through venous blood draws. This technology can be applied to the development of rapid white blood cell count and absolute neutrophil count assays that can monitor side effects of certain psychiatric and oncology drugs.

Sample Preparation Technology

Rapid Blood Cell Separation Technology

ABI's Rapid Blood Cell Separation ("Separator") Technology, marketed under the brand name seraSTAT®, further accelerates the rate at which a test result is obtained as the often-required sample preparation step is abbreviated drastically. Conventional methods of blood cell separation are labor-intensive and time-consuming, typically involving blood collection and laboratory personnel, as well as electrically-powered centrifuges and other specialized equipment. The disposable Separator device requires only a small-volume blood sample obtained from a time- and cost-efficient finger stick procedure or through a venous blood draw. ABI has obtained the appropriate US FDA regulatory clearances for seraSTAT® as a stand-alone device and the technology is currently integrated into PIFA PLUSS PF4 devices, and will be utilized in the infectious disease products currently under development. The seraSTAT® Rapid Blood Cell Separation Technology is currently protected by two United States patents (7,896,167; 8,097,171) and one international patent (JP 4,885,134), with two additional international patent applications pending.

Product Portfolio

ABI is positioned as a provider of rapid diagnostic solutions that encompass the totality of the point-of-care testing process, from sample preparation to immediate test result. In addition, we believe we are a pioneer in disposable breath condensate technology, a testing format that has significant potential given the variety of wellness- and disease-predicting biomarkers present in an exhaled breath sample.

At present, ABI's commercialized and emerging product portfolio incorporate four of the Company's six proprietary platform testing technologies: PIFA®, MPC Biosensor, REA and Rapid Blood Cell Separation Technology. Directly below, is a discussion of the products within our current and emerging portfolio that will be segmented by platform.

ABI designed its products based on single-use assay platforms with straightforward test procedures that can be completed in minutes. In the U.S. some of the Company's clinical laboratory products and those with medical intended uses generally require "prescription use" Federal Drug Administration ("FDA") 510(k) clearance prior to product marketing given that they will be ordered or used by medical practitioners in the course of his or her professional practice. Despite this categorization, ABI's professional use products are still designed for ease of use, can be utilized near or at the point-of-care, and do not require the use of expensive equipment or a highly trained or specialized staff. As a result, an individual's current health status can rapidly be incorporated into diagnostic and treatment decisions, improving the overall efficiency of the healthcare experience in the eyes of the patient, and ultimately the payor. In addition, in the developing world, the portability and ease-of-use of such point-of-care tests can serve to drastically improve the level of disease screening and subsequent patient care. We believe the benefits of our technology platforms are therefore well-suited to the diagnostic demands of countries in the developing world that seek to deliver modern medical diagnosis in the midst of primitive infrastructures. In addition, some of our products have received

FDA 510(k) clearance for over-the-counter (“OTC”) use. Other self-tests deliver personal health information of a non-medical nature, on-demand, and are not FDA regulated; these products are still manufactured in compliance with a quality management system (“QMS-Compliant”). ABI believes that all its technology platforms and products address the needs of the evolving healthcare delivery system that is moving patient care closer to or in the home.

The following table sets forth our marketed and current pipeline products, indentifies the appropriate “prescription use” or “OTC” designation and whether the required clearance has been obtained or is still needed prior to product marketing.

Our marketed and emerging products include:

Product	Platform	Market/Pipeline	Not FDA-regulated; QMS-Compliant Only	FDA Clearance Required *Prescription Use/OTC*	FDA Clearance Status Obtained/Needed	Description
BreathScan®/CHUBE™	MPC	Marketed		OTC	Obtained	Disposable breath alcohol detector
BreathScan® PRO	MPC	Marketed		OTC	Obtained	Quantitative breath alcohol detection system
Breath Ketone “Check”®	MPC	Pipeline		Prescription Use	Needed	Disposable breath ketone device for diabetic monitoring and management of senile dementia and Alzheimers disease patients
METRON ®	MPC	Marketed	X			Disposable breath ketone device to monitor weight loss
Breath PulmoHealth “Check”®	MPC	Pipeline		Prescription Use	Needed	A suite of breath tests for biomarkers indicating asthma, chronic obstructive pulmonary disease (COPD), and lung cancer
VIVO	MPC	Marketed	X			Non-invasive, quantitative measurement

of biological markers for oxidative stress that relates to cellular damage

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Product	**Platform**	**Market/Pipeline**	**Not FDA-regulated; QMS-Compliant Only**	**FDA Clearance Required *Prescription Use/OTC***	**FDA Clearance Status Obtained/Needed**	**Description**
PIFA® Heparin/PF4 & PIFA PLUSS® PF4	PIFA	Marketed		Prescription Use	Obtained	Rapid tests for Heparin/PF4 antibodies to detect an allergy to the widely used blood thinner, Heparin
PIFA PLUSS® Infectious Diseases	PIFA	Pipeline		Prescription Use	Needed	Rapid tests for a variety of infectious diseases, especially those that are prevalent outside of the United States
seraSTAT®	seraStat	Marketed		Prescription Use	Obtained	Rapid Blood Cell Separator, marketed under the brand name seraSTAT®, further accelerates the rate at which a test result is obtained as the often-required sample preparation step is abbreviated drastically.
Tri-Cholesterol “Check”®	REA	Marketed		OTC	Obtained	Rapid test for Total and high density lipoprotein cholesterol and estimates low density lipo protein

MPC Biosensor Technology

The Company’s MPC Biosensor breath condensate testing platform forms the basis of a number of ABI’s marketed and pipeline products.

Breath Alcohol Franchise

BreathScan® originated the disposable breath alcohol detector category and was the first single-use breathalyzer to obtain the FDA 510(k) clearance in 2006 for Over-the-Counter use required to facilitate sales to US consumers; CE certification is not required to market the product in the EU given that BreathScan® results are not used to diagnose

any medical conditions. However, Chubeworkx and its indirect subsidiary (en)[10] Global Limited ("en10"), in partnership with the Company, received certification under the French Standard, NF X 20-702 which defines the specifications that chemical breath alcohol detectors must meet in order to be sold to consumers in France. In March 2013, a 2012 law mandating most motorists driving in France to equip their vehicles with two, "NF-Marked" breath alcohol detectors took effect. As a result, the Company's breathalyzers, under the Chubeworkx private label brand, CHUBE, can now be marketed to the approximately 34 million French nationals who own motorized vehicles and a portion of the estimated 81 million foreign visitors entering France annually by automobile. In fact it is estimated that at least 1.6 million cars, motorcycles and recreational vehicles are transported on the Eurotunnel train through the Channel Tunnel each year between England and France, while more vehicles make the same trip via ferry via the English Channel waterway. In addition, the Company's breath alcohol detector technology has been granted Australian Standard certification trademark, which cleared the commercial pathway for product sales in Australia, New Zealand, and South Africa that view certification as a requirement for market entrance through its distribution relations with Chubeworkx and en10. Chubeworkx sales and marketing initiatives also currently extend into the UK. On June 13, 2013, the Company announced that it was extending the Chubeworkx License and Supply Agreement to allow the marketing and distribution of the "BE CHUBE" program and its related product in North America to facilitate a worldwide sales and marketing initiative.

The Company's disposable breath alcohol detectors are available in .02%, .04%, .05% and .08% blood alcohol concentrations ("BACs") and provide users with a test result in two minutes. If the crystals in the interior of the device change from yellow to aqua, the user has tested positive for the specific alcohol level. Should the crystals remain yellow, the result is negative.

The Company's proprietary breath alcohol detection technology is paired with the quantitative precision of an electronic analyzer in the BreathScan® PRO alcohol detection system. As with all BreathScan® products, the test subject exhales into a specially calibrated, BreathScan® PRO detector. The testing coordinator then inserts the used detector into the BreathScan® PRO Digital Analyzer. After two minutes, the Analyzer's sophisticated optics calculate the subject's BAC; the detectable range spans from 0.00% to 1.50% BAC. Unlike other electronic breathalyzers, BreathScan® PRO never requires recalibration so it is in "ready" mode at all times. In 2011, the Company received FDA over-the-counter clearance for the system, providing a commercialization path in the US for use by trained professionals, including those in civil and military law enforcement, and the general public; in addition, the CE-Mark was affixed to the alcohol detection system for professional use. Unlike the aforementioned BreathScan® disposable detectors, BreathScan® PRO is required to have a CE-Mark as the system includes an electronic component, namely the digital analyzer. ABI's distribution relationship with Chubeworkx also is expected to encompass a private-labeled version of BreathScan® PRO within its global distribution plan.

Since the appropriate regulatory clearances have been obtained in the United States and other major markets requiring specific certifications for specific devices (i.e. France and Australia for the Company's single-use detectors for these products), the Company does not anticipate needing to fund additional clinical trials to facilitate or initiate product marketing in other international regions thus far.

Other Emerging MPC Platform Products

The Company's MPC Biosensor technology is being applied to the development of products that serve the nutraceutical and weight loss marketplaces. As a category, these disposable screening tests are exempt from FDA 510(k) premarket clearances. Biomarkers related to various metabolic processes can be measured in breath condensate. As a result, ABI has used its proprietary, easy-to-use platform to design disposable breath tubes that measure ketone (acid) production associated with fat-burning (METRON®) and oxidative stress levels that relate to cellular damage and the development of many preventable diseases (VIVO™). Initial marketing activities have commenced for these products and they are heading toward full commercialization; the Company is currently assessing distribution opportunities with companies specializing in weight loss and/or mass distribution through health-related multilevel marketing organizations. Since devices with claims related to weight loss or nutrition are exempt from FDA oversight, a clinical program to support 510(k) submission is not required for either of these products. Given the non-medical intended use, the Company does not believe products will be required to hold a CE-mark prior to marketing in the EU.

ABI is continuing its clinical development of the Breath Ketone "Check" disposable breath tube for two clinical indications: (i) the diagnosis of ketoacidosis in diabetics, and (ii) the management of senile dementia and Alzheimer's

disease patients.

Breath Ketone “Check’ is being designed to provide real-time information that allows diabetics to determine if they have a more severe level of ketone (acid) build up in their body that can cause a life-threatening medical emergency called ketoacidosis. The estimated 28.5 million Type I (insulin-dependent) diabetics worldwide are at particular risk for ketoacidosis and require routine monitoring of their ketone levels. To date the medical industry relies on blood- and urine-based ketone testing methods, which are invasive and/or inconvenient. Since breath and blood ketone levels are closely correlated, the Breath Ketone “Check” is designed to offer healthcare professionals and their patients a convenient, accurate method, which can be completed anytime, anywhere, to quickly determine if an individual’s ketone level is approaching a dangerous threshold requiring medical attention. Since this product requires FDA 510(k) clearance, the Company continues to develop its technical file and complete required clinical studies to complete the regulatory submission.

An additional clinical indication for the Breath Ketone “Check” test is as an aid in the management of senile dementia and Alzheimer’s disease. There is no known cure for these neurological conditions, which slowly progress over years to decrease cognitive function. Moreover, the cost to the healthcare system to provide care for these patients is significant. However, recent advances in neuroscience indicate that these diseases can be greatly slowed, and in some cases the progression can stop, if the patient is maintained in a state of ketosis. Ketosis results from a diet low in carbohydrates that promotes the production of ketones in the bloodstream, and is a milder form of ketoacidosis. Because these patients are often confused or unreliable, it is important to ensure that they maintain a state of ketosis to keep the disease in check. This can be accomplished through routine monitoring with Breath Ketone “Check”.

ABI is also putting research and development resources to the development of Breath PulmoHealth “Check” suite of assays. These disposable detectors are being designed to signal the detection of various biomarkers related to pulmonary health, namely asthma, chronic obstructive pulmonary disease (“COPD”) and lung cancer, through convenient, rapid analysis of an individual’s breath sample. ABI has chosen to target this trio of conditions as their impact on global health is staggering:

- over 300 million people worldwide are living with asthma and up to 18% of a country’s population are undiagnosed asthmatics;
- 210 million individuals are being treated for COPD but each of the 1 billion smokers is at risk for the disease; and
- more than 1.6 million people worldwide receive the diagnosis of lung cancer annually with many more victims expected as 80% of all lung cancers can be attributed to smoking.

ABI believes these statistics suggest that pulmonary conditions are under-diagnosed and under-treated and will continue to pose a chronic strain on worldwide public health. Currently, diagnostic methods used for the detection of lung-related diseases and illnesses are often costly as specialized medical personnel must facilitate analysis and testing, and radiologic exams or invasive surgical procedures may be required. While ABI does not presume Breath PulmoHealth “Check” products to be replacements for such tests in all markets, it does however have ambitions for the devices to become effective, highly cost-efficient, primary screening tools. Their ease-of-use, portability and non-invasive nature provide healthcare professionals and public health officials with a testing platform that can be deployed in high volume, and even in regions of the developing world. At present, the Company’s primary development efforts are focused on configuring the clinical dossier for the asthma product.

The Breath Ketone “Check” and the Breath PulmoHealth “Check” suite of products will require the development of individual clinical trial programs to facilitate eventual FDA 510(k) submissions. The Company has self-certified an earlier version of the Breath Ketone “Check” as being in compliance with CE requirements in the EU, and intends to pursue the same designation for the emerging version, as well as for each product in the Breath PulmoHealth “Check” trio once the appropriate technical file is assembled.

MPC Biosensor technology is currently protected by two United States patents (7,285,246; 7,837,936).

PIFA® Technology

The core products marketed under the PIFA® platform are the PIFA® Heparin/PF4 Rapid Assay, PIFA PLUSS® PF4, and a variety of rapid Infectious Disease screening tests which target markets in the developing world.

PIFA® Heparin/PF4 Rapid Assay and PIFA PLUSS® PF4 remain the only FDA-cleared rapid manual assays that quickly determines if a patient, being treated with the blood thinner Heparin, may be developing a drug allergy. This clinical syndrome, referred to as Heparin-Induced Thrombocytopenia (HIT), reverses the Heparin's intended therapeutic effect and transforms it into a clotting agent. According to "*Current Concepts Review: Heparin-Induced Thrombocytopenia*", published by Foot and Ankle International in 2008 (the "HIT Report"), patients with HIT are at risk of developing limb- and life-threatening complications, so the timely test result provided by ABI's Heparin/PF4 devices, is paramount to effective, clinical decision making. In the US alone, approximately 12 million patients are exposed to Heparin annually and 1% to 5% of those patients receive a HIT diagnosis. The largest at-risk populations are patients undergoing major cardiac or orthopedic surgical procedures. It is estimated that up to 50% of cardiac surgery patients develop HIT-antibodies. Given the size of the aging baby boomer market segment and the prevalence of cardiac disease, surgeries within this category is expected to increase, as would the potential demand for the Company's convenient, rapid tests.

The PIFA® Heparin/PF4 Rapid Assay was fully commercialized in the U.S. in 2008, improving the standard of care in HIT-testing with its result delivered in less than ten minutes after the patient sample has been prepared. Traditional methods required the use of expensive equipment, specialized laboratory personnel and approximately 4 hours of technician time to complete the 20+ assay test procedure in-house, Clinicians were subjected to a 24-to-72 hour turnaround time if the HIT-antibody determination was outsourced to a reference laboratory. Especially in the latter scenario, the patient information obtained is retrospective in nature as the HIT-antibody result cannot be factored into time-sensitive diagnostic and treatment decisions. In November 2012, the Company introduced PIFA PLUSS PF4 to U.S. hospitals to further improve the rate at which healthcare professionals can obtain a HIT-antibody result.

This PIFA® line extension merges the ease-of-use of the PIFA testing platform with ABI's recently patented Rapid Blood Cell Separation Technology, marketed under the brand name seraSTAT®. The marriage of these two technologies condenses the sample preparation and analysis procedures as the precise micro-volume of a seraSTAT® -prepared patient specimen is delivered directly into the PIFA® cassette for immediate testing. This eliminates an additional one-hour of sample processing time and the need for healthcare personnel to have access to a centrifuge to separate the liquid fraction of blood from the cellular fraction. As a result, HIT-testing can be initiated and completed at or near the point-of-care, especially in emergency and critical care departments where time-efficient diagnostic results can drastically improve patient outcomes.

Since the appropriate regulatory clearances have been obtained in the United States for these products, the Company does not anticipate needing to fund additional clinical trials to facilitate product marketing domestically. In addition, the current technical file that has been assembled for seraSTAT® and PIFA PLUSS PF4® will also be used to support ABI's CE-marking self-certification process to initiate product sales in the EU; the PIFA Heparin/PF4 Rapid Assay is already CE-marked. The Company's strategy in foreign jurisdictions that may require additional clinical trials to support regulatory clearance, as is the case in China, is to partner with a distributor that will fund the required clinical program in exchange for some degree of marketing exclusivity.

Other PIFA® Platform Assays in development

According to the Center for Disease Control and Prevention, "*Emerging Infectious Diseases: a 10-Year Perspective from the National Institute of Allergy and Infectious Diseases, volume 11, Number 4 — April 2005,* infectious diseases account for more than 15 million deaths annually. That equates to one in every two deaths in developing countries. Given that greater than 80% of the world's population lives in the 100-plus developing countries, the need for infectious disease screening tests and effective treatment options has global implications. The expansive geographies combined with underdeveloped, underfunded healthcare infrastructures make rapid, single-use, portable devices that do not require special instrumentation, key to any infectious disease-containment solution.

ABI's PIFA® technology provides a testing format that meets the aforementioned criteria. The Company can quickly apply the PIFA PLUSS® methodology to its infectious disease testing products to further consolidate the test result

turn-around time and eliminate the need for any specialized sample preparation personnel or equipment which are usually not at the disposal of healthcare professionals in remote locations. To date, the Company's custom reagent work has focused on a variety of infectious diseases, especially those that are prevalent outside of the United States including the following:

- Chagas Disease
- Chlamydia
- Cytomegalovirus
- Dengue Fever
- Hepatitis B Surface Antigen
- Hepatitis C

- Human Immunodeficiency Virus (HIV 1+2)
- Infectious Mononucleosis
- Lyme Disease
- Malaria
- Syphilis

In addition, PIFA technology has been applied to a rapid blood typing card used to assess donor-patient blood grouping compatibility in minutes, to help facilitate fresh whole blood transfusions in triage situations. The "Battlefield Blood Transfusion Card" is designed to enhance combat casualty care or provide remote healthcare facilities in underdeveloped countries with critical patient-donor information, especially when blood requirements outpace blood supplies. As with the Company's Infectious Disease products, current business activities will focus on opportunities in international markets. As such, clinical trials to support FDA 510(k) clearances or CE self-certification will not be required. The Company intends to determine the clinical data needed to market products specifically within the developing world, once it completes the assessment of distribution options within the region. PIFA® technology is currently protected by two United States patents (5,565,366; 5,827,749) and one international patent (JP 4,931,821 – Heparin Tests).

REA Technology

ABI's Tri-Cholesterol "Check" test is initiated with an easy-to-obtain finger stick blood sample, and provides users with an estimate of both their Total and high density lipoprotein ("HDL") cholesterol levels, and by a simple calculation, approximates their low density lipoprotein ("LDL") level. We believe that there is global demand for this category of disposable tests given healthcare trends that identify cardiovascular disease, and related risk factors like high cholesterol, diabetes and high blood pressure. These complications are particularly on the rise in developing nations that have gained accessed to the dietary habits of the west. In fact, studies reported by Middle East Health Magazine recently conducted in various medical centers throughout Saudi Arabia and the United Arab Emirates ("UAE") categorized the cardiovascular health risk as being on the edge of a potentially serious epidemic. In addition, the research revealed that half the subjects were undiagnosed prior to participating in the study that may be indicative of insufficient healthcare resources. This regional case study has global application as cardiovascular disease is the leading cause of death worldwide and access to healthcare remains a challenge to much of the aggregate population. This drives home the need for rapid, straightforward screening tests that are easily accessible to individuals for routine monitoring.

Tri-Cholesterol “Check” has the appropriate U.S. FDA market clearances and is also CE-marked for sale in the European Union for professional use. At present, the Company’s Tri-Cholesterol “Check” business strategy is to focus on distribution activities in countries within the developing world. Once ABI completes an assessment of opportunities within the region, it intends to determine if additional clinical data outside of the robust technical file assembled to support FDA-clearance and CE-certification will be required for product marketing.

The REA Technology is currently protected by two United States patents (8,003,061; 8,425,859).

Sample Preparation Technology

Rapid Blood Cell Separation Technology

In addition to the Company’s testing platforms, ABI’s recently patented Rapid Blood Cell Separation (“Separator”) Technology, marketed under the brand name seraSTAT®, further accelerates the rate at which a test result is obtained as the often-required sample preparation step is abbreviated drastically. Conventional methods of blood cell separation are labor-intensive and time-consuming, typically involving blood collection and laboratory personnel, as well as electrically-powered centrifuges and other specialized equipment. The Separator device requires only a small-volume blood sample obtained from a time- and cost-efficient finger stick procedure.

The required micro-volume specimen of serum or plasma is immediately extracted and introduced into a rapid assay device for real-time analysis. The savings afforded by the Separator device can be measured in time and cost given its quick turn-around-time and straightforward, easy-to-master procedure.

Since the appropriate regulatory clearances have been obtained in the United States for seraSTAT® as a stand-alone device, the Company does not anticipate needing to fund additional clinical trials to expand product marketing domestically. seraSTAT® is currently integrated into PIFA PLUSS PF4 devices, and will be utilized in the infectious disease products currently under development. ABI may consider partnerships with other medical device companies, functioning as an Original Equipment Manufacturer ("OEM"), as the benefits of the seraSTAT® Rapid Blood Cell Separation Technology can be integrated into other assay platforms. Also, the current technical file that has been assembled for seraSTAT® will be used to support ABI's CE-marking self-certification process to initiate product sales in the EU. The Company's strategy in foreign jurisdictions that may require additional clinical trials to support regulatory clearance is to partner with a distributor that will fund the required clinical program in exchange for some degree of marketing exclusivity.

The seraSTAT® Rapid Blood Cell Separation Technologyis currently protected by two United States patents (7,896,167; 8,097,171) and one international patent (JP 4,885,134).

Competition

Competitors of ABI include other companies developing and marketing rapid, point-of-care diagnostic devices and companies with dedicated laboratory instruments and/or automated test systems. We face intense competition from companies with dominant market positions within the *in vitro* diagnostic testing market such as Abbott, ACON Laboratories, Inc., Alere, Diagnostica Stago, SA., Immucor, Inc., OraSure Technologies, Inc., and Quidel Corporation.

The Company believes the primary criteria for determining competitiveness within the rapid point-of-care sector are cost, ease-of-use, speed, readability, accuracy and flexibility. The time required by ABI to develop a working prototype test ready for clinical trials typically ranges from around eight to twelve weeks from inception. We believe that competitors' laboratory tests normally require at least a year to develop to a similar point.

However, our competitors have significantly greater financial, technical, marketing and other resources than we have and may be better able to:

- respond to new technologies or technical standards;

- react to changing customer requirements and expectations;

- acquire other companies to gain new technologies or products that may displace our product lines;

- manufacture, market and sell products;

- devote resources to the development, production, promotion, support and sale of products; and

- deliver a broad range of competitive products at lower prices.

Our principal competitors are able to leverage their broader product portfolios and dominant market positions in some segments by, for example, bundling their products into specially priced packages that create strong financial incentives for their customers to purchase their products. These practices may negate savings customers would gain from buying select products from ABI and may deter such customers from buying ABI's products. We expect competition in the markets in which we participate to continue to increase as existing competitors improve or expand their product offerings.

How We Generate Revenue

The majority of our revenue comes from selling rapid, screening and testing products, largely through our distribution networks. Some of our assays are used in the clinical laboratory to ultimately help healthcare professionals to diagnosis a medical condition or complication that may require treatment. Other products can be sold over-the-counter, to the general public, to help assess an individual's status as it relates to his/her blood alcohol or cholesterol level, to help monitor his/her progress on a specific wellness regimen, and/or to screen for a biomarker that may be indicative of an individual's general level of health. Some of our revenue is associated with licensing payments that often relate to exclusive access to specific markets.

Our Current Target Markets

Given that, according to the HIT Report, 50% of cardiac surgery patients develop antibodies that have been found to be the major determinant in the pathogenesis of HIT, the HIT-testing market largely resides within the clinical hospital laboratories of medical facilities that perform major cardiac surgeries such as coronary artery bypass graft (CABG) procedures. In the U.S., the Company accesses decision makers within these institutions through profiling by its highly trained technical sales team and collaborative prospecting with distributor sales representatives. ABI has also instituted an innovative teleconference program that trains laboratory professionals on the PIFA and PIFA PLUSS product profiles and with product in-hand, walks them through the straightforward test procedures. This training is intended to turn interest into immediate action and drives home the ease-of-use of the products. Individuals that participate in remote training usually start the verification process to bring one or both of the assays in-house, within a 4-week cycle. Internationally, ABI provides comprehensive training to its distributor partners to enable them to implement the same selling and technical training strategies.

Manufacturing and Suppliers

We are a vertically integrated manufacturer, producing substantially all of our devices in-house. The vast majority of our products start out as high quality, medical grade polymers and exit our facilities as fully manufactured and packaged medical devices. As a result, we have a short supply line between our raw materials and finished goods which gives us greater control over our product quality. The downside of our in-house manufacturing is the requirements for facilities, power, and equipment. This approach also requires mid-to-long-term planning and the ability to predict future needs. Many of our processes are unique to us, but the Company’s flexible manufacturing capabilities and unused current capacity generally translate into relatively short production timelines. As demand for our products increase, additional capacities may be required to advance our evolving needs.

We use a diverse and broad range of raw materials in the manufacturing of our products. We purchase all of our raw materials and select items, such as packaging, from external suppliers. In addition, we purchase some supplies from single sources for reasons of proprietary know-how, quality assurance, sole source availability, or due to regulatory qualification requirements. US medical device manufacturers must establish and follow quality systems to help ensure that their products consistently meet applicable requirements and specifications. The quality systems for FDA-regulated products are known as current good manufacturing practices (“cGMP’s”). CGMP requirements for devices in part 820 (21 CFR part 820) were first authorized by section 520(f) of the Federal Food, Drug, and Cosmetic Act. We work closely with our suppliers to ensure continuity of supply while maintaining high quality and reliability. To date, we have not experienced any significant difficulty locating and obtaining the materials necessary to fulfill our production requirements. During the year ended December 31, 2013 three suppliers accounted for 60% of the Company’s total purchases. This makes the Company vulnerable to a near-term severe impact should the relationships be terminated.

Distribution

We distribute our products through direct and indirect channels of distribution. We have well-developed indirect distribution channels in the U.S. with Cardinal Health 200, Inc. (“Cardinal Health”) and Fisher Healthcare for the Company’s PIFA Heparin/PF4 assays. Effective May 1, 2007 we entered into a distribution agreement (as subsequently amended the “Cardinal Health Agreement”) with Cardinal Health. The Cardinal Health Agreement grants Cardinal Health the non-exclusive right to distribute PIFA Heparin/PF4 Rapid Assays. Pricing terms for each product are included in the Cardinal Agreement and vary depending on product and volume of the order. The Cardinal Health Agreement automatically renews for successive twelve month unless either party (a) upon 30 days written notice if either party commits or suffers any act of bankruptcy or insolvency, or fails to cure any material breach of the provisions of the agreement within 30 days after written notice of such breach, or (b) upon 90 days written notice with or without cause. On June 15, 2010 we entered into a distribution agreement with Fisher Healthcare, a Division of Fisher Scientific Company L.L.C. (as subsequently amended, the “Fisher Agreement”). The Fisher Agreement grants non-exclusive rights for Fisher Healthcare to distribute PIFA Heparin/PF4 Rapid Assays, Heparin/PF4 serum panels, and BreathScan disposable breath alcohol detectors in the United States. Under the Fisher Agreement we are required to fill all orders placed by Fisher Healthcare and do not have the right to decline such orders. We must notify Fisher Healthcare of any proposed price increase at least 120 days prior to the effective date of such increase. Payment terms are net 45 days from the date of receipt of an accurate invoice, and Fisher Healthcare will not be in default if payments are made within five (5) days of the due date. The initial term of the agreement was June 15, 2010 through May 31, 2012 and included initial pricing terms for each product that varied depending on the product; however, ABI is able to submit pricing increases on an annual basis. The Fisher Agreement automatically renews for successive twelve month periods at Fisher Healthcare’s option in its sole discretion. All products sold to Cardinal Health and Fisher Healthcare must be purchased in ABI-designated case quantities, however, there are no minimum purchase requirements under the Cardinal Health Agreement or Fisher Agreement.

The relationships with Cardinal Health and Fisher Healthcare provide us with access to the majority of U.S. hospitals. During the year ended December 31, 2013 sales to Cardinal Health and Fisher Healthcare accounted for 23% and 6% of the Company's revenue, respectively. This concentration makes the Company vulnerable to a near-term severe impact should the relationships be terminated. Our dedicated technical sales force works in tandem with distributor sales representatives to uncover opportunities in the clinical laboratory marketplace. The Company facilitates direct sales for hospitals that prefer to purchase direct from the manufacturer. In select European countries and Australia we have distribution relationships with specialized sales and marketing organizations for some of our products. We do not have a strong presence in many emerging markets, but are seeking to enter into agreements to enable us to enter China in the current fiscal year.

With respect to the Company's breath alcohol franchise, historically ABI focused its commercial attention within the on-the-job safety/human resources sector. Access was and currently is largely achieved through designated BreathScan® distributors and limited arrangements in which the Company serves in an OEM capacity. On June 19, 2012, ABI entered into License and Supply Agreement (the "License and Supply Agreement") with Sono International Limited ("SIL"), BreathScan International (Guersney) Limited and BreathScan International Limited pursuant to which the Company granted SIL an exclusive license to market and distribute private-labeled versions of ABI's disposable breath alcohol detectors, to be supplied by the Company, outside the United States of America, Canada and Mexico. On June 12, 2013, the Company entered into an amended License and Supply Agreement (the "Amended License and Supply Agreement") with Chubeworkx Guernsey Limited (as successor to SIL), (EN)10 (Guernsey) Limited (formerly BreathScan International (Guernsey) Limited) and (EN)10 Limited (formerly BreathScan International Limited). Under the Amended License and Supply Agreement, among other obligations, Chubeworkx is required to provide product purchase forecasts and maintain minimum order volumes. Chubeworkx is required to pay invoices in full within 90 days of delivery. Chubeworkx shall pay the Company $0.30 per product unit sold to Chubeworkx for the duration of the agreement. The initial term of the agreement is three (3) years. The term will, unless mutually agreed by the Company and Chubeworkx in writing, automatically renew on a three year rolling basis. Chubeworkx may terminate the agreement at any time after the initial term in whole or in part by giving the Company not less than six months written notice.

We believe that the Amended License and Supply Agreement represents a significant shift in ABI's breath alcohol product strategy. Chubeworkx extensive "BE CHUBE" promotional program, which recently launched in the EU, is helping to transform the way people from among the most at-risk populations view alcohol consumption and emphasize the importance of proactive testing with their private-labeled CHUBE breath alcohol detectors. While the majority of this marketing has been aimed at the French market, with all drivers on French roads, including foreign passport holders and drivers of foreign vehicles legally required to carry at least one un-used NF Approved disposable breathalyzer kit, Chubeworkx, through en10, also has active sales and marketing initiatives in the UK, South Africa and Australia. The Amended License and Supply Agreement expanded the marketing and distribution of the "BE CHUBE" program worldwide using the ABI breathalyzer. We believe that our decision to expand Chubeworkx's reach into North America will facilitate a global presence and likely increase demand for ABI-manufactured private-label disposable breathalyzers. During the year ended December 31, 2013 sales to Chubeworkx accounted for 56% of the Company's revenue. Chubeworkx's partnerships within Asia and Africa may also serve to expand the demand for the Company's PIFA PLUSS® Infectious Disease assays. To date, the Company has not dedicated extensive production resources toward this product line as demand by the US Government within the GSA contracting system has been minimal. With the expected expansion into the international market with a focus on the developing world, it is anticipated that selling opportunities for infectious disease rapid assays will increase.

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We currently do not have a strong presence in many emerging markets. We have however, developed a distribution relationship with Novotek Therapeutics Inc. (“Novotek”), a Beijing-based pharmaceutical and *in vitro* diagnostic business development corporation. The multi-year agreement assigns exclusive sales and marketing rights to Novotek to make ABI’s Particle ImmunoFiltration Assay (“PIFA”) products available in Mainland China once market clearance is obtained (anticipated 2014). We are seeking to enter into additional agreements that will enable us to enter other international markets in the current fiscal year. Through our expanded distribution relationship with Chubeworkx, we anticipate pursuing business opportunities in Africa and other parts of Asia in the future. The Company is in the process of solidifying relationships with distributors in the UK for these assays, with selling expected to commence in the second quarter of 2014.

Intellectual Property

We rely on a combination of patent, trademark and trade secret laws in the U.S. and other jurisdictions to protect our proprietary platform technologies and our brands. We also rely on confidentiality procedures and agreements with key employees and distribution/business partners where appropriate, and contractual provisions to achieve the same. We do not pursue patent protection where the possibility for meaningful enforcement is limited.

The ABI logo is a registered trademark in the U.S. Other registered trademarks/service marks include: BreathScan®, PIFA®, PIFA PLUSS®, seraSTAT®, HealthTest®, and Be a Hero, Get Their Keys®, and METRON®.

The following table summarizes the US and international utility patents that currently protect ABI’s intellectual property; the core and emerging products to which they relate are also noted:

Description	Jurisdiction	Utility Patent No.	Type of Protection	Expiration Date	Product(s) To Which They Relate
blood separator and method of separating fluid fraction from whole blood	US	7,896,167	Manufacture	9/7/2026	seraSTAT®; PIFA PLUSS® PF4; PIFA PLUSS® Infectious Diseases Rapid Assays
blood separator and method of separating fluid fraction from whole blood	US	8,097,171	Manufacture	8/5/2025	seraSTAT®; rapid blood cell separator also integrated into PIFA PLUSS® PF4 and PIFA PLUSS® Infectious Diseases Rapid Assays
	Japan	4,885,134	Manufacture	8/5/2025	

blood separator and method of separating fluid fraction from whole blood					seraSTAT®; rapid blood cell separator also integrated into PIFA PLUSS® PF4 and PIFA PLUSS® Infectious Diseases Rapid Assays
hand-held fluid analyzer	US	7,285,246	Manufacture	11/19/2025	Breath Ketone “Check”®; Breath PulmoHealth “Check”® suite of products; BreathScan®; BreathScan® PRO; CHUBE™; METRON®; VIVO™
hand-held fluid analyzer	US	7,837,936	Manufacture	9/12/2024	Breath Ketone “Check”®; Breath PulmoHealth “Check”® suite of products; BreathScan®; BreathScan® PRO; CHUBE™; METRON®; VIVO™
kits and ligand assay plates using two-tiered separation for detection of immunoreagent particles	US	5,565,366	Manufacture	5/25/2014	PIFA® Heparin/PF4 Rapid Assay; PIFA PLUSS® PF4; PIFA PLUSS® Infectious Diseases Rapid Assays
ligand assay method	US	5,827,749	Manufacture	10/11/2016	PIFA® Heparin/PF4 Rapid Assay; PIFA PLUSS® PF4; PIFA PLUSS® Infectious Diseases Rapid Assays
methods and kits for detecting heparin/platelet factor 4 antibodies	Japan	4,931,821	Manufacture	10/4/2025	PIFA® Heparin/PF4 Rapid Assay; PIFA PLUSS® PF4
test strip card	US	8,003,061	Manufacture	5/6/2024	Tri-Cholesterol “Check”®
test strip card	US	8,425,859	Manufacture	5/6/2024	Tri-Cholesterol “Check”®

Circumstances outside our control could pose a threat to our intellectual property. For example, effective intellectual property protection may not be available in every country in which our products are distributed. Also, the efforts we have taken to protect our proprietary rights may not be sufficient or effective. Any significant impairment of our intellectual property rights is costly and time consuming. Any increase in unauthorized use of our intellectual property could make it more expensive to do business and harm our operating results.

ABI's Tri-Cholesterol "Check", PIFA Heparin/PF4 Rapid Assay, BreathScan PRO alcohol detection system, and an earlier version of the Breath Ketone "Check" are CE-marked for sale in the EU for professional use. The CE-mark must be affixed to a product that intended, by the manufacturer, to be used for a medical purpose and will be sold into EU member states as well as Iceland, Norway and Liechtenstein. For ABI's current and proposed "medical-purpose" products, the CE-marking process is facilitated by self-certification, as a manufacturer must carry out a conformity assessment, perform any appropriate electromagnetic testing, create a technical file with supporting documentation, and sign an EC declaration of conformity. The documentation is verified by the Company's authorized representative in the EU and must be made available to authorities upon request.

Government Regulations

FDA Approval/Clearance Requirements

Unless an exemption applies, each medical device that we wish to market in the U.S. must receive 510(k) clearance. It has been the Company's experience thus far, that the FDA's 510(k) clearance process usually takes from four to twelve months, but can last significantly longer. We cannot be sure that 510(k) clearance will ever be obtained for any product we propose to market. We have obtained any required FDA clearance for all of our current products that require clearance.

The FDA decides whether a device line must undergo either the 510(k) clearance or Premarket approval ("PMA"). PMA is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. PMA approval process based upon statutory criteria. These criteria include the level of risk that the agency perceives is associated with the device and a determination whether the product is a type of device that is similar to devices that are already legally marketed. Devices deemed to pose relatively less risk are placed in either Class I or II, which requires the manufacturer to submit a premarket notification ("PMN") requesting 510(k) clearance, unless an exemption applies. The PMN must demonstrate that the proposed device is "substantially equivalent" in intended use and in safety and effectiveness to a legally marketed predicate device, which is a pre-existing medical device to which equivalence can be drawn, that is either in Class I, Class II, or is a Class III device that was in commercial distribution before May 28, 1976, for which the FDA has not yet called for submission of a PMA application.

Class I devices are those for which safety and effectiveness can be assured by adherence to the FDA's general regulatory controls for medical devices, or the General Controls, which include compliance with the applicable portions of the FDA's quality system regulations, facility registration and product listing, reporting of adverse medical events, and appropriate, truthful and non-misleading labeling, advertising, and promotional materials. Some Class I devices also require premarket clearance by the FDA through the 510(k) PMN process described below. A small number of our products are Class I devices.

Class II devices are subject to the FDA's General Controls, and any other special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) PMN procedure. Pursuant to the Medical Device User Fee and Modernization Act of 2002, or MDUFMA, as of October 2002 unless a specific exemption applies, 510(k) PMN submissions are subject to user fees. Certain Class II devices are exempt from this premarket review process. A majority of our products, encompassing all of our significant product lines, are Class II devices. Class III devices are those devices which have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device. The safety and effectiveness of Class III devices cannot be assured solely by the General Controls and the other requirements described above. These devices almost always require formal clinical studies to demonstrate safety and effectiveness and must be approved through the premarket approval process described below. Premarket approval applications (and supplemental premarket approval applications) are subject to significantly higher user fees under MDUFMA than are 510(k) PMNs. None of our products are Class III devices.

A clinical trial may be required in support of a 510(k) submission. These trials generally require an Investigational Device Exemption, or IDE, application approved in advance by the FDA for a specified number of patients, unless the product is deemed a non-significant risk device eligible for more abbreviated IDE requirements. The IDE application must be supported by appropriate data, such as animal and laboratory testing results. Clinical trials may begin if the IDE application is approved by the FDA and the appropriate institutional review boards at the clinical trial sites.

Pervasive and Continuing FDA Regulation

A host of regulatory requirements apply to our marketed devices, including the quality system regulation (which requires manufacturers to follow elaborate design, testing, control, documentation and other quality assurance procedures), the Medical Reporting Regulations ("MDR") regulations (which require that manufacturers report to the FDA specified types of adverse events involving their products), labeling regulations, and the FDA's general prohibition against promoting products for unapproved or "off-label" uses. Class II devices also can have special controls such as performance standards, post-market surveillance, patient registries and FDA guidelines that do not apply to class I devices. Unanticipated changes in existing regulatory requirements or adoption of new cGMP requirements could hurt our business, financial condition and results of operations.

Health Care Fraud and Abuse

In the United States, there are federal and state anti-kickback laws that generally prohibit the payment or receipt of kickbacks, bribes or other remuneration in exchange for the referral of patients or other health-related business. For example, the Federal Health Care Programs' Anti-Kickback Law (42 U.S.C. §1320a-7b(b)) prohibits anyone from, among other things, knowingly and willfully offering, paying, soliciting or receiving any bribe, kickback or other remuneration intended to induce the referral of patients for, or the purchase, order or recommendation of, health care products and services reimbursed by a federal health care program (including Medicare and Medicaid). Recognizing that the federal anti-kickback law is broad and potentially applicable to many commonplace arrangements, the Office of Inspector General within the Department of Health and Human Services, or OIG, has issued regulations, known as the safe harbors, which identify permissible practices. If all of the requirements of an applicable safe harbor are met, an arrangement will not be prosecuted under this law. Safe harbors exist for a number of arrangements relevant to our business, including, among other things, payments to bona fide employees, certain discount arrangements, and certain payment arrangements involving GPOs. The failure of an arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal. However, conduct that does not fully satisfy each requirement of an applicable safe harbor may result in increased scrutiny by government enforcement authorities, such as the OIG or the Department of Justice. Violations of this federal law can result in significant penalties, including imprisonment, monetary fines and assessments, and exclusion from Medicare, Medicaid and other federal health care programs. Exclusion of a manufacturer would preclude any federal health care program from paying for its products. In addition to the federal anti-kickback law, many states have their own kickback laws. Often, these state laws closely follow the language of the federal law. Some state anti-kickback laws apply regardless of whether federal health care program payment is involved. Federal and state anti-kickback laws may affect our sales, marketing and promotional activities, and relationship with health care providers or laboratory professionals by limiting the kinds of arrangements we may

have with hospitals and others in a position to purchase or recommend our products.

Federal and state false claims laws prohibit anyone from presenting, or causing to be presented, claims for payment to third-party payors that are false or fraudulent. For example, the federal Civil False Claims Act (31 U.S.C. §3729 et seq.) imposes liability on any person or entity who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal health care program (including Medicaid and Medicare). Manufacturers, like us, can be held liable under false claims laws, even if they do not submit claims to the government, where they are found to have caused submission of false claims by, among other things, providing incorrect coding or billing advice about their products to customers that file claims, or by engaging in kickback arrangements with customers that file claims. A number of states also have false claims laws, and some of these laws may apply to claims for items or services reimbursed under Medicaid and/or commercial insurance. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer’s products from reimbursement under government programs, and imprisonment.

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, created two new federal crimes: health care fraud and false statements related to healthcare matters. The health care fraud statute prohibits knowingly and willingly executing a scheme to defraud any health care benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from government sponsored programs. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. A violation of this statute is a felony and may result in fines or imprisonment.

Due to the breadth of some of these laws, it is possible that some of our current or future practices might be challenged under one or more of these laws. In addition, there can be no assurance that we would not be required to alter one or more of our practices to be in compliance with these laws. Evolving interpretations of current laws or the adoption of new federal or state laws or regulations could adversely affect many of the arrangements we have with customers and physicians. Our risk of being found in violation of these laws is increased by the fact that some of these laws are open to a variety of interpretations. If our past or present operations are found to be in violation of any of these laws, we could be subject to civil and criminal penalties, which could hurt our business, results of operations and financial condition.

Foreign Regulation

Many foreign countries in which we market or may market our products have regulatory bodies and restrictions similar to those of the FDA. International sales are subject to foreign government regulation, the requirements of which vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA approval and the requirements may differ. Companies are now required to obtain a CE Mark, which shows conformance with the requirements of applicable European Conformity directives, prior to sale of some medical devices within the European Union. Some of our current products that require CE Markings have them and it is anticipated that additional and future products may require them as well. As of the date of this filing, the Company has received CE marks for eight for of its commercialized products/product components: PIFA Heparin/PF4 Rapid Assay; Heparin/PF4 Serum Panels; Tri-Cholesterol “Check” and BreathScan PRO Detectors, Analyzer Field Kit, Starter Kit and Blow Bags. An earlier version of the Breath Ketone “Check” also bears a CE-Mark.

Third-Party Reimbursement

Health care providers, including hospitals, that purchase our products generally rely on third-party payors, including the Medicare and Medicaid programs, and private payors, such as indemnity insurers and managed care plans, to cover and reimburse all or part of the cost of the products and the procedures in which they are used. As a result, demand for our products is dependent in part on the coverage and reimbursement policies of these payors.

CMS, the federal agency responsible for administering the Medicare program, along with its contractors, establishes coverage and reimbursement policies for the Medicare program. In addition, private payors often follow the coverage and reimbursement policies of Medicare. We cannot assure you that government or private third-party payors will cover and reimburse the procedures using our products in whole or in part in the future or that payment rates will be adequate.

In general, Medicare will cover a medical product or procedure when the product or procedure is reasonable and necessary for the diagnosis or treatment of an illness or injury. Even if the medical product or procedure is considered medically necessary and coverage is available, Medicare may place restrictions on the circumstances where it provides coverage. For some of our products, our success in non-U.S. markets may depend upon the availability of coverage and reimbursement from the third-party payors through which health care providers are paid in those markets. Health care payment systems in non-U.S. markets vary significantly by country, and include single-payor, government managed systems as well as systems in which private payors and government-managed systems exist, side-by-side. For some of our products, our ability to achieve market acceptance or significant sales volume in international markets may be dependent on the availability of reimbursement for our products under health care payment systems in such markets. There can be no assurance that reimbursement for our products, will be obtained or that such reimbursement will be adequate.

Other U.S. Regulation

We must also comply with numerous federal, state and local laws relating to matters such as environmental protection, safe working conditions, manufacturing practices, fire hazard control and, among other things, the generation, handling, transportation and disposal of hazardous substances.

Employees

We currently employ 24 full-time equivalent employees, contractors or consultants, which include six in research and development, three in general and administrative, four in sales and marketing and eleven in direct and indirect manufacturing. We also engage a number of temporary employees and consultants. None of our employees are represented by a labor union or are a party to a collective bargaining agreement. We believe that we have good relations with our employees.

Available information

Our website address is *www.akersbiosciences.com*. We do not intend our website address to be an active link or to otherwise incorporate by reference the contents of the website into this Report. The public may read and copy any materials the Company files with the U.S. Securities and Exchange Commission (the "SEC") at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0030. The SEC maintains an Internet website (http://www.sec.gov) that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC.

Item 1A. Risk Factors.

You should carefully consider the risks described below, together with all of the other information included in this report, in considering our business and prospects. The risks and uncertainties described below are not the only ones facing the Company. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. The occurrence of any of the following risks could harm our business, financial condition or results of operations.

Risks Related to the Company and Our Business

We have a history of operating losses and we cannot guarantee that we can ever achieve sustained profitability.

We have recorded a net loss in most reporting periods since our inception. Our net loss for the years ended December 31, 2013 and December 31, 2012 were $1,526,773 and $2,557,820, respectively. Our accumulated deficit at December 31, 2013 was $81,721,126. Losses are expected to continue for the foreseeable future. The Company expects to continue to have development costs as it develops its next generation of products. We may never achieve profitable operations or positive cash flow.

Our operating expenses will increase as we make further expenditures to enhance and expand our operations in order to support additional growth in our business and public company reporting and compliance obligations.

Historically, we limited our investment in infrastructure; however, following this offering we expect our infrastructure investments to increase substantially to support our anticipated growth and as a result of our becoming a public reporting company in the United States. We intend to make additional investments in automated manufacturing systems and personnel in order to expand our operations to support anticipated growth in our business. In addition, to be competitive and take advantage of market opportunities, we may need to make changes to our sales model in the future. These changes may result in higher selling, general and administrative expenses as a percentage of our revenue. We also expect to incur additional operating costs as a public reporting company following the completion of this offering. As a result of these factors, we expect our operating expenses to increase.

Due to our dependence on a limited number of customers and the loss of any such customer would have a material adverse effect on our operating results and prospects.

As of December 31, 2013, our principal customers included two clinical laboratory distributors, Cardinal Health and Fisher Healthcare, that distribute our PIFA Heparin/PF4 Rapid Assays in the United States. Effective May 1, 2007 we entered into a distribution agreement (as subsequently amended, the "Cardinal Health Agreement") with Cardinal Health 200, Inc. ("Cardinal Health"). The Cardinal Health Agreement grants Cardinal Health the non-exclusive right to distribute PIFA Herapin/PF4 Rapid Assays. Pricing terms for each product are included in the Cardinal Agreement and vary depending on product and volume of the order. The Cardinal Health Agreement automatically renews for successive twelve month unless either party (a) upon 30 days written notice if either party commits or suffers any act of bankruptcy or insolvency, or fails to cure any material breach of the provisions of the agreement within 30 days after written notice of such breach, or (b) upon 90 days written notice with or without cause. On June 15, 2010 we entered into a distribution agreement with Fisher Healthcare, a Division of Fisher Scientific Company L.L.C. (as subsequently amended, the "Fisher Agreement"). The Fisher Agreement grants non-exclusive rights for Fisher Healthcare to distribute PIFA Heparin/PF4 Rapid Assays, Heparin/PF4 serum panels, and BreathScan disposable breath alcohol detectors in the United States. Under the Fisher Agreement we are required to fill all orders placed by Fisher Healthcare and do not have the right to decline such orders. The initial term of the agreement was June 15, 2010 through May 31, 2012 and included initial pricing terms for each product that varied depending on the product; however, ABI is able to submit pricing increases on an annual basis. The Fisher Agreement automatically renews for successive twelve month periods at Fisher Healthcare's option in its sole discretion. There are no minimum purchase requirements under the Cardinal Health Agreement or Fisher Agreement. All products sold to Cardinal Health and Fisher Healthcare must be purchased in ABI-designated case quantities, but there are no annual minimum purchase requirements under either of the agreements.

For the year ended December 31, 2013, these two entities and Chubeworkx accounted for approximately 85% of the Company's revenue. Chubeworkx, which distributes ABI'S breathalyzers for its "Be CHUBE" selling initiative that is being rolled out worldwide, became a significant purchaser of ABI's products in 2013. Because of our dependence on a limited number of key customers, the loss of a major customer (or loss of a key program with a major customer), or any significant reduction in orders by a major customer or termination of the Cardinal Health Agreement or Fisher Agreement would materially reduce our net sales and gross profit and adversely affect our business, our results of operations and our financial condition. We expect that sales to relatively few customers will continue to account for a significant percentage of our net sales for the foreseeable future, however there can be no assurance that any of these customers or any of our other customers will continue to utilize our products or our services at current levels.

Due to our dependence on a limited number of customers, we are subject to a concentration of credit risk.

As of December 31, 2013, Chubeworkx, Cardinal Health and Fisher Healthcare accounted for 97% of our accounts receivable. In the case of insolvency by one of our significant customers, an account receivable with respect to that customer might not be collectible, might not be fully collectible, or might be collectible over longer than normal terms, each of which could adversely affect our financial position.

The Company's business would suffer if the Company were unable to acquire adequate sources of supply.

We use a diverse and broad range of raw materials in the manufacturing of our products. We purchase all of our raw materials and select items, such as packaging, from external suppliers. In addition, we purchase some supplies from single sources for reasons of proprietary know-how, quality assurance, sole source availability, or due to regulatory qualification requirements and disruption of these sources could have, at a minimum, a temporary adverse effect on shipments and the financial results of the Company. US medical device manufacturers must establish and follow quality systems to help ensure that their products consistently meet applicable requirements and specifications. The quality systems for FDA-regulated products are known as current good manufacturing practices ("cGMP's"). CGMP requirements for devices in part 820 (21 CFR part 820) were first authorized by section 520(f) of the Federal Food, Drug, and Cosmetic Act. We work closely with our suppliers to ensure continuity of supply while maintaining high quality and reliability. To date, we have not experienced any significant difficulty locating and obtaining the materials necessary to fulfill our production requirements. During the year ended December 31, 2013, three suppliers accounted for 60% and during the year ended December 31, 2012, one supplier accounted for 42% of the Company's total purchases. Any prolonged inability to obtain certain materials or components could have an adverse effect on the Company's financial condition or results of operations and could result in damage to its relationships with its customers and, accordingly, adversely affect the Company's business.

We may require additional capital in the future to develop new products and otherwise support our operations. If we do not obtain any such additional financing, if required, our business prospects, financial condition and results of operations will be adversely affected.

We intend to invest significantly in our business before we expect cash flows from operations will be adequate to cover our anticipated expenses. We believe that the proceeds of this offering and revenue from operations will be sufficient to satisfy our needs for at least the next 18 months. We may need to obtain significant additional financing, both in the short- and long-term, to make planned capital expenditures to cover operating expenses, upgrades to our manufacturing operations, our ongoing product development and to fund to potential acquisitions, if any. We may not be able to secure adequate additional financing when needed on acceptable terms, or at all. To execute our business strategy, we may issue additional equity securities in public or private offerings, potentially at a price lower than our initial public offering price or the market price of our common stock at the time of such issuance. If we cannot secure sufficient additional funding we may be forced to forego strategic opportunities or delay, scale back and eliminate future product development which would harm our business and our ability to generate positive cash flow in the future.

Because we may not be able to obtain necessary regulatory clearances or approvals for some of our products, we may not generate revenue in the amounts we expect, or in the amounts necessary to continue our business.

All of our proposed and existing products are subject to regulation in the U.S. by the U.S. Food and Drug Administration and/or other domestic and international governmental, public health agencies, regulatory bodies or non-governmental organizations. In particular, we are subject to strict governmental controls on the development, manufacture, labeling, distribution and marketing of our products. The process of obtaining required approvals or clearances varies according to the nature of, and uses for, a specific product. These processes can involve lengthy and detailed laboratory testing, human clinical trials, sampling activities, and other costly, time-consuming procedures. The submission of an application to a regulatory authority does not guarantee that the authority will grant an approval or clearance for product. Each authority may impose its own requirements and can delay or refuse to grant approval or clearance, even though a product has been approved in another country.

The time taken to obtain approval or clearance varies depending on the nature of the application and may result in the passage of a significant period of time from the date of submission of the application. Delays in the approval or clearance processes increase the risk that we will not succeed in introducing or selling the subject products, and we may be required to abandon a proposed product after devoting substantial time and resources to its development.

Changes in domestic and foreign government regulations could increase our costs and could require us to undergo additional trials or procedures, or could make it impractical or impossible for us to market our products for certain uses, in certain markets, or at all.

Changes in government regulations may adversely affect our financial condition and results of operations because we may have to incur additional expenses if we are required to change or implement new testing, manufacturing and control procedures. If we are required to devote resources to develop such new procedures, we may not have sufficient resources to devote to research and development, marketing, or other activities that are critical to our business.

We are subject to regulations of various government agencies and if we are unable to comply with such regulations it would materially affect our business

We can manufacture and sell our products only if we comply with certain regulations of government agencies. As a U.S. manufacturer, we must operate our production facility in accordance with the requirements established by the FDA under the Federal Food, Drug, and Cosmetic Act (FD&C Act). As such, we have implemented a quality system that is intended to comply with applicable regulations. Our manufacturing plant is subject to periodic inspections by the FDA, and at last inspection, the facility was found to be in substantial compliance with current good manufacturing practice (cGMP) requirements. Although the Company is dedicated to remaining in compliance with such practices, the cGMP requirements could change and negatively impact our ability to manufacture our products without modifications to our operations procedures or changes to our equipment or human resource allocations which may materially affect our business.

The commercial success of our products will depend upon the degree of market acceptance by physicians, hospitals, third-party payors, and others in the medical community.

Ultimately, none of our current products or products in development, even if they receive approval, may ever gain market acceptance by physicians, hospitals, third-party payors or others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and we may not become profitable. The degree of market acceptance of our products, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages over alternative treatments;
- the ability to offer our products for sale at competitive prices;
- the willingness of the target population to accept and adopt our products;
- the strength of marketing and distribution support and the timing of market introduction of competitive products; and
- publicity concerning our products or competing products and treatments.

Even if a potential product displays a favorable profile, market acceptance of the product will not be known until after it is launched. Our efforts to educate the medical community and third-party payors on the benefits of our products may require significant resources and may never be successful. Such efforts to educate the marketplace may require more resources than are required by conventional technologies marketed by our competitors.

If we fail to obtain regulatory approval in foreign jurisdictions, then we cannot market our products in those jurisdictions.

We plan to market some of our products in foreign jurisdictions, initially in China, the European Union (“EU”) and South America, initially targeting Colombia and Brazil. Many foreign countries in which we market or may market our products have regulatory bodies and restrictions similar to those of the FDA. International sales are subject to foreign government regulation, the requirements of which vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA approval and the requirements may differ. Companies are now required to obtain a CE Mark, which shows conformance with the requirements of applicable European Conformity directives, prior to sale of some medical devices within the European Union. Some of our current products that require CE Markings have them and it is anticipated that

additional and future products may require them as well. We may be required to conduct additional testing or to provide additional information, resulting in additional expenses, to obtain necessary approvals. If we fail to obtain approval in such foreign jurisdictions, we would not be able to sell our products in such jurisdictions, thereby reducing the potential revenue from the sale of our products.

We may be unable to market our products outside the United States if our products cannot meet certain requirements of the Federal Food, Drug and Cosmetic Act requirements for exporting medical devices.

Any medical device that is legally marketed in the U. S. may be exported anywhere in the world without prior FDA notification or approval. Medical devices that are not FDA-cleared for marketing legally in the U.S. may be exported under section 801(e)(1) of the FD&C Act, provided that they are intended for export only, they are class I or class II devices, and they are:

- In accordance with the specifications of the foreign purchaser;
- Not in conflict with the laws of the country to which they are intended for export;
- Labeled on the outside of the shipping package that they are intended for export; and
- Not sold or distributed in the U.S.

We cannot guarantee that certain current and future products will meet all of the aforementioned specifications for export which could adversely impact our ability to market our products outside the U.S.

We may be unable to market our products outside the United States if our products cannot meet regulatory requirements of certain countries .

In the European Union, a product that meets the definition of an In Vitro Diagnostic Medical Device ("IVD") in accordance with the European Directive (98/79/EC) must receive regulatory approval known as a CE mark. The letters "CE" are the abbreviation of the French phrase "Conforme Européene," which means "European conformity." As such, export of these products to the European Union, and possibly other jurisdictions, without the CE mark is not possible. Although obtaining a CE Mark is often a self-certification process, preparation and submission of the technical file to an Authorized Representative in the EU, and their verification of a company's compliance with the Directive, can be a lengthy process. Some of the Company's current and future products may fall within the IVD categorization. As of the date of this filing, the Company has received CE marks for eight of its commercialized products/product components: PIFA Heparin/PF4 Rapid Assay; Heparin/PF4 Serum Panels; Tri-Cholesterol "Check" and BreathScan PRO Detectors, Analyzer Field Kit, Starter Kit and Blow Bags. An earlier version of the Breath Ketone "Check" also bears a CE-Mark.

Further, some foreign countries, such as Canada and India, require that a medical device company's manufacturing facility be certified for compliance with the ISO 13485, an international standard for quality systems management. The International Organization for Standardization ("ISO") is the world's largest developer of standards with 148 member countries. Given the expense and length of the ISO certification process, ABI is in the process of investigating the cost and time commitments necessary to pursued ISO certification for its manufacturing facility. If such certification is not possible to obtain with its current personnel resources, it may limit the Company's ability to launch selling initiatives, of certain products, within international markets such as India and Canada. ABI may not be able to obtain foreign regulatory approval on a timely basis, if at all and to do so may cause ABI to incur additional costs or prevent ABI from marketing its products in foreign countries, which may have a material adverse effect on its business and results of operations.

Our products may not be able to compete with new diagnostic products or existing products developed by well-established competitors, which would negatively affect our business.

According to "*In Vitro Diagnostic Tests Come out of the Lab and Into the Home"*, an article published by MDDI online in March 2013, the diagnostic industry is focused on the testing of biological specimens in a laboratory or at the point-of-care and is highly competitive and rapidly changing. Our principal competitors often have considerably greater financial, technical and marketing resources than we do. Several companies produce diagnostic tests that compete directly with our testing product line, including but not limited to, Abbott, ACON Laboratories, Inc., Alere, Diagnostica Stago, SA, Immucor, Inc., OraSure Technologies, Inc., and Quidel Corporation. Many of these

competitors have substantially greater financial, marketing and other resources than we do and enjoy other competitive advantages, including, greater name recognition; established relationships with health care professionals, companies and consumers; additional lines of products, the ability to offer rebates or higher discounts and incentives; and greater resources for product development, sales and intellectual property protection. As new products enter the market, our products may become obsolete or a competitor's products may be more effective or more effectively marketed and sold than ours. Although we have no specific knowledge of any competitor's product that will render our products obsolete, if we fail to maintain and enhance our competitive position or fail to introduce new products and product features, our customers may decide to use products developed by our competitors, which could result in a loss of revenue and cash flow.

In addition, the point-of-care diagnostics industry is undergoing rapid technological changes, with frequent introductions of new technology-driven products and services, some of which focus on automated systems to provide rapid results. As new technologies become introduced into the point-of-care diagnostic testing market, we may be required to commit considerable additional efforts, time and resources to enhance our current product portfolio or develop new products. We may not have the available time and resources to accomplish this and many of our competitors have substantially greater financial and other resources to invest in technological improvements. We may not be able to effectively implement new technology-driven products and services or be successful in marketing these products and services to our customers, especially if rapid, manual testing products become secondary, in large markets, to automated point-of-care systems. If these potential developments come to fruition our operating results could be materially harmed.

Clinical trials that may be required to support regulatory submissions in the United States and in international markets are expensive. We cannot assure that we will be able to complete any required clinical trial programs successfully within any specific time period, and if such clinical trials take longer to complete than we project, our ability to execute our current business strategy will be adversely affected.

Conducting clinical trials is a lengthy, time-consuming and expensive process. Before obtaining regulatory approvals for the commercial sale of any products, we must demonstrate through clinical trials the safety and effectiveness of our products. We have incurred, and we will continue to incur, substantial expense for, and devote a significant amount of time to, product development, pilot trial testing, clinical trials and regulated, compliant manufacturing processes. During the year ended December 31, 2013 research and development expense totaled $1,006,800. The estimated research and development expense for the year ending December 31, 2014 is $1,400,000.

Even if completed, we do not know if these trials will produce statistically significant or clinically meaningful results sufficient to support an application for marketing approval. Whether or not and how quickly we complete clinical trials is dependent in part upon the rate at which we are able to advance the rate of patient enrollment, and the rate to collect, clean, lock and analyze the clinical trial database.

Patient enrollment in trials is a function of many factors, including the design of the protocol, the size of the patient population, the proximity of patients to and availability of clinical sites, the eligibility criteria for the study, the perceived risks and benefits of the product candidate under study and of the control, if any, the medical investigators' efforts to facilitate timely enrollment in clinical trials, the patient referral practices of local physicians, the existence of competitive clinical trials, and whether other investigational, existing or new products are available or approved for the indication. If we experience delays in patient enrollment and/or completion of our clinical trial programs, we may incur additional costs and delays in our development programs, and may not be able to complete our clinical trials on a cost-effective or timely basis. Accordingly, we may not be able to complete the clinical trials within an acceptable time frame, if at all. If we fail to enroll and maintain the number of patients for which the clinical trial was designed, the statistical power of that clinical trial may be reduced, which would make it harder to demonstrate that the product candidate being tested in such clinical trial is safe and effective. Further, if we or any third party have difficulty enrolling a sufficient number of patients in a timely or cost-effective manner to conduct clinical trials as planned, or if enrolled patients do not complete the trial as planned, we or a third party may need to delay or terminate ongoing clinical trials, which could negatively affect our business.

The results of our clinical trials may not support either further clinical development or the commercialization of our product candidates.

Even if our clinical trials are completed as planned, their results may not support either the further clinical development or the commercialization of our product-candidates. The FDA or government authorities may not agree with our conclusions regarding the results of our clinical trials. Success in preclinical testing and early clinical trials

does not ensure that later clinical trials will be successful, and the results from any later clinical trials may not replicate the results of prior clinical trials and pre-clinical testing. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for indicated uses. This failure would cause us to abandon a product candidate and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay the filing of our 510(k)’s and, ultimately, our ability to commercialize our product candidates and generate product revenue. Each medical device marketed in the U.S. must receive a 510(k) clearance from the FDA. A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent (“SE”), to a legally marketed device. Companies must compare their device to one or more similar legally marketed devices, commonly known as “predicates”, and make and support their substantial equivalency claims. The submitting company may not proceed with product marketing until it receives an order from the FDA declaring a device substantially equivalent. The substantially equivalent determination is usually made within 90 days, based on the information submitted by the submitter.

In addition, we or the FDA may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in the conduct of these trials. A number of companies in the biotechnology industry have suffered significant setbacks in advanced clinical trials despite promising results in earlier trials. In the end, we may be unable to develop marketable products.

Modifications to our devices may require additional FDA approval which could force us to cease marketing and/or recall the modified device until we obtain new approvals .

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require a Premarket approval ("PMA"). PMA is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. Currently the Company does not market devices within this Class III category nor does it intend to in the foreseeable future. However, the FDA requires each manufacturer to make this determination in the first instance, but the FDA can review any decision. If the FDA disagrees with a manufacturer's decision not to seek a new 510(k) clearance, the agency may retroactively require the manufacturer to seek 510(k) clearance or PMA approval. The FDA also can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or PMA approval is obtained. We have modified one of our prescription use, 510(k)-cleared devices, specifically the PIFA Heparin/PF4 Rapid Assay to include our seraSTAT Separator. However, we determined that, in our view, based on FDA guidance as to when to submit a 510(k) notification for changes to a cleared device, new 510(k) clearances or PMA approvals are not required. We cannot assure you that the FDA would agree with any of our decisions not to seek 510(k) clearance or PMA approval. If the FDA requires us to seek 510(k) clearance or PMA approval for any modification, we also may be required to cease marketing and/or recall the modified device until we obtain a new 510(k) clearance or PMA approval.

We are subject to inspection and market surveillance by the FDA to determine compliance with regulatory requirements. If the FDA finds that we have failed to comply, the agency can institute a wide variety of enforcement actions which may materially affect our business operations .

We are subject to inspection and market surveillance by the FDA to determine compliance with regulatory requirements. If the FDA finds that we have failed to comply, the agency can institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as:

- fines, injunctions and civil penalties;
- recall, detention or seizure of our products;
- the issuance of public notices or warnings;
- operating restrictions, partial suspension or total shutdown of production;

- refusing our requests for 510(k) clearance of new products;
- withdrawing 510(k) clearance already granted; and
- criminal prosecution.

The FDA also has the authority to request repair, replacement or refund of the cost of any medical device manufactured or distributed by us. Our failure to comply with applicable requirements could lead to an enforcement action that may have an adverse effect on our financial condition and results of operations.

We may not have sufficient resources to effectively introduce and market our products, which could materially harm our operating results.

Achieving market acceptance for our existing products such as our direct-to-consumer offerings (disposable breathalyzers) and clinical laboratory testing solutions (Particle Immuno Filtration Assay ("PIFA")-based heparin-induced thrombocytopenia and infectious disease rapid tests) and introducing new products (breath condensate detectors for the health & wellness categories) require substantial marketing efforts and will require our sales account executives, contract partners, outside sales agents and distributors to make significant expenditures of time and money. In some instances we will be significantly or totally reliant on the marketing efforts and expenditures of our contract partners, outside sales agents and distributors. In early 2012 the Company reduced its account executive staff by 40% to streamline operations and align ABI's sales resources with the regional sales segmentation of our clinical products distributors. Although this headcount reduction has positively impacted our budgets without negatively effecting sales in comparison to the first six months of the prior fiscal year, the large account executive territories may prove to be inefficient as we commercialize products and may hinder our revenue growth.

Because we currently have very limited marketing resources and sales capabilities, commercialization of our products, some of which require regulatory clearance prior to market entrance, we must either expand our own marketing and sales capabilities or consider collaborating with additional third parties to perform these functions. We may, in some instances, rely significantly on sales, marketing and distribution arrangements with collaborative partners and other third parties. In these instances, our future revenue will be materially dependent upon the success of the efforts of these third parties.

Should we determine that expanding our own marketing and sales capabilities is required, we may not be able to attract and retain qualified personnel to serve in our sales and marketing organization, to develop an effective distribution network or to otherwise effectively support our commercialization activities. The cost of establishing and maintaining a more comprehensive sales and marketing organization may exceed its cost effectiveness. If we fail to further develop our sales and marketing capabilities, if sales efforts are not effective or if costs of increasing sales and marketing capabilities exceed their cost effectiveness, our business, results of operations and financial condition would be materially adversely affected.

We may not have the resources to conduct clinical protocols sufficient to yield data suitable for publication in peer-reviewed journals and our inability to do so in the future could have an adverse effect on marketing our products effectively.

In order for our products targeted for use by hospital laboratory professionals and healthcare providers to be widely adopted, clinical protocols that are designed to yield data suitable for publication in peer-reviewed journals should be carried out. These studies are often time-consuming, labor-intensive and expensive to execute. The Company has not had the resources to effectively implement such clinical programs within its clinical development activities and may not be able to do so in the future. In addition, if a protocol is initiated, the results of which may ultimately not support the anticipated positioning and benefit proposition for the product. Either of these scenarios could hinder our ability to market our products and revenue may decline.

Our future performance will depend largely on the success of products we have not developed yet.

Technology is an important component of our business and growth strategy, and our success depends to a significant extent on the development, implementation and acceptance of new products. Commitments to develop new products must be made well in advance of any resulting sales, and technologies and standards may change during development, potentially rendering our products outdated or uncompetitive before their introduction. Our ability to develop products to meet evolving industry requirements and at prices acceptable to our customers will be dependent on a number of factors including, funding availability to complete development efforts, our ability to test and refine products, successfully conduct clinical trials and seek to obtain required FDA clearance or foreign approval/certification for products that require such regulatory authorizations. Physician patients and third party payors and the medical community may be slow to adopt any of our products. Moreover, there can be no assurance that the products that we

are developing will receive FDA clearance, work effectively in the marketplace or gain market acceptance. We may expend considerable funds and other resources on the development of next-generation products without any guarantee that these products will be successful.

If we are not successful in bringing new products to market, whether because we fail to address marketplace demand, fail to develop viable technologies or otherwise, our revenue may decline and our results of operations could be seriously harmed.

If we fail to establish, maintain and expand relationships with distributors, sales of our products would decline.

The Company does not control the efforts of its distributors and its distributors are not prohibited from selling competing products. Our ability to sell our products depends largely on the Company's relationships with such distributors. Accordingly, we are subject to the risk that they may not commit the financial and other resources to market and sell our products to our level of expectation, they may experience financial hardship or they may otherwise terminate our relationship on short notice. In the U.S. clinical laboratory marketplace, many of our existing and potential customers purchase our products through our two national distributors, Cardinal Health, Inc. and Fisher HealthCare. ABI's sales account executives work in tandem with distributor sales representatives to gain access to decision makers within the majority of U.S. medical facilities. In addition, the Company relies on its distribution network to negotiate pricing arrangements and contracts with Group Purchasing Organizations and their affiliated hospitals and other members. For the years ended December 31, 2013 and 2012, 81% and 79%, respectively of total revenue from the sale of the Company's Heparin/PF4 Assay products was generated through our U.S. distributors' purchases, with Cardinal Health accounting for 64% of total sales for each year ended December 31, 2013 and 2012. In the future, if we are unable to maintain existing relationships and/or grow to be recognized as a prominent medical device supplier within these organizations, and/or develop new relationships with additional U.S. and international distributors, our competitive position would likely suffer and our business would be harmed.

We have just begun to develop formal business relationships with foreign distributors for all of our in-line products. We will therefore be dependent upon the financial health of these organizations to further grow our business. If a distributor were to go out of business, it would take substantial time, cost and resources to find a suitable replacement and the product registrations and certifications held by such distributor may not be returned to us or to a subsequent distributor in a timely manner or at all. Any failure to produce foreign sales may negatively affect our profitability in the short- and long-term. Since some of our products have CE-Marks and/or are earmarked for sale in Europe where healthcare regulation and reimbursement for medical devices vary significantly from country to country, this changing environment could adversely affect our ability to sell our products in some European countries. In addition, the Company is working with an exclusive distributor in mainland China to register ABI's PIFA Heparin/PF4 Rapid Assay for eventual sale. Since additional clinical studies must be performed by our distributor partner within Chinese healthcare facilities as part of their regulatory submission, there is no guarantee that the results of their protocol will support the successful registration of the product and permit sales activity. Failure to gain product registration in China will hinder the Company's ability to increase its revenue.

Our business is vulnerable to the availability of raw materials, our ability to forecast customer demand and our ability to manage production capacity.

Our ability to meet customer demand depends, in part, on our production capacity and on obtaining supplies, a number of which can only be obtained from a single supplier or a limited number of suppliers. A reduction or disruption in our production capacity or our supplies could delay products and fulfillment of orders and otherwise negatively impact our business.

We must accurately predict both the demand for our products and the lead times required to obtain the necessary components and materials. If we overestimate demand, we may experience underutilized capacity and excess inventory levels. If we underestimate demand, we may miss delivery deadlines and sales opportunities and incur additional costs for labor overtime, equipment overuse and logistical complexities. Additionally, our production capacity could be affected by manufacturing problems. Difficulties in the production process could reduce yields or interrupt production, and, as a result, we may not be able to deliver products on time or in a cost-effective, competitive manner. Our failure to adequately manage our capacity could have a material adverse effect on our business, financial condition and results of operations.

Our ability to meet customer demand also depends on our ability to obtain timely and adequate delivery of materials, parts and components from our suppliers. We generally do not maintain contracts with any of our key suppliers. From time to time, suppliers may extend lead times, limit the amounts supplied to us or increase prices due to capacity constraints or other factors. Supply disruptions may also occur due to shortages in critical materials. In addition, a number of our raw materials are obtained from a single supplier. Many of our suppliers must undertake a time-consuming qualification process before we can incorporate their raw materials into our production process. If we are unable to obtain materials from a qualified supplier, it can take up to a year to qualify a new supplier, assuming an alternative source of supply is available. A reduction or interruption in supplies or a significant increase in the price of one or more supplies could have a material adverse effect on our business, financial condition and results of operations.

Our manufacturing facility is vulnerable to natural disasters and other unexpected losses, and we may not have adequate insurance to cover such losses.

We have one manufacturing facility, located in Thorofare, New Jersey, for production of all of our finished goods production. Our facility is susceptible to damage from fire, floods, loss of power or water supply, telecommunications failures and similar events. Since some of our raw materials and finished goods are temperature-sensitive and our facility currently does not have a back-up generator, a moderate-to-severe disruption in power may render various levels of our inventories unusable or unsalable, resulting in a sufficient write off of inventory and may immediately impact our ability to generate revenue.

Any natural disaster could significantly disrupt our operations. In the event that our facility was affected by a natural or man-made disaster, we would be forced to rely on third-party manufacturers. Our insurance for damage to our property and the disruption of our business from casualties may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all. If we are forced to seek alternative facilities, we may incur additional transition costs and we may experience a disruption in the supply of our products until the new facility is available and operating. In addition, much of the machinery we use in our production process is custom-made. If such machinery is damaged, we may experience a long lead-time before this unique machinery is replaced or rebuilt and we are able to resume production.

Our manufacturing and distribution operations are highly dependent on our information technology systems and we do not currently have a redundant data center. In the event of a failure of our primary data center, our manufacturing and distribution operations will be disrupted which will adversely affect our business.

In addition, any disruption, delay, transition or expansion of our manufacturing operations could impair our ability to meet the demand of our customers and our customers may cancel orders or purchase products from our competitors, which could adversely affect our business, financial condition and results of operations.

Some of our finished goods, including our PIFA products and control materials related to PIFA Heparin/PF4 assays, are temperature-sensitive.

Proper packaging and time in transit are critical to the stability of some of our clinical laboratory products when they are en route to our distributors or end users. If certain specialized packaging materials cannot be obtained, and/or if our contracted common carriers, or those of our distributors, cannot meet product-specific delivery requirements, our products may not perform as intended and may lead to requests for product replacement. If such issues become widespread it could hurt our reputation and we could potentially lose customers which would adversely affect our business.

Also, given the issue of temperature sensitivity, time in transit may limit our ability to service potential markets outside of the U.S. for those products, especially those with geographies that do not allow for shipment and customs clearance within four business days. This could adversely affect our potential to generate revenue for some products on an international level.

We are subject to environmental, health and safety laws, which could increase our costs and restrict our operations in the future.

Our operations are subject to environmental, health and safety laws and regulations in each of the jurisdictions in which we operate. These laws and regulations concern, among other things, the generation, handling, transportation and disposal of hazardous substances or wastes, the clean-up of hazardous substance releases, and the emission or discharge of materials into the air or water. Although we currently incur limited expenditures in connection with these environmental health and safety laws and regulations, if we fail to comply with the requirements of such laws and regulations or if such laws changes significantly in the future, we could incur substantial additional costs to alter our manufacturing processes and/or adjust our supply chain management. Such changes could also result in significant inventory obsolescence. Compliance with environmental, health and safety requirements could also restrict our ability to expand our facilities in the future.

Our business is vulnerable to inflation.

We are limited in our ability to raise prices for some products, particularly in the clinical laboratory marketplace where cost-containment pressures are significant. As a result, increases in our raw materials, production and transportation costs may have a material adverse impact on our results of operations.

Demands of third-party payors, cost reduction pressures among our customers and restrictive reimbursement practices may adversely affect our revenue.

Our ability to negotiate favorable contracts with non-governmental payors, including managed-care plans or Group Purchasing Organizations ("GPOs"), even if facilitated by our distributors, may significantly affect revenue and operating results. Our customers continue to face cost reduction pressures that may cause them to curtail their use of, or reimbursement for some of our products, to negotiate reduced fees or other concessions or to delay payment. Furthermore, the increasing leverage of organized buying groups among non-governmental payors may reduce market prices for our products and services, thereby reducing our profitability. Reductions in price increases or the amounts received from current customers or lower pricing for our products to new customers could have a material adverse effect on the financial position, cash flows and results of operations.

Failure to obtain medical reimbursement for our products under development, as well as a changing regulatory and reimbursement environment, may impact our business.

The U.S. healthcare regulatory environment may change in a way that restricts our ability to market our products due to medical coverage or reimbursement limits. Sales of our diagnostic tests will depend in part on the extent to which the costs of such tests are covered by health maintenance, managed care, and similar healthcare management organizations, or reimbursed by government health payor administration authorities, private health coverage insurers and other third-party payors. These healthcare payors are increasingly challenging the prices charged for medical products and services. The containment of healthcare costs has become a priority of federal and state governments. Accordingly, our potential products may not be considered to be cost effective, and reimbursement may not be available or sufficient to allow us to sell our products on a competitive basis. Legislation and regulations affecting reimbursement for our products may change at any time and in ways that are difficult to predict and these changes may be adverse to us.

CMS, the federal agency responsible for administering the Medicare program, along with its contractors, establishes coverage and reimbursement policies for the Medicare program. In addition, private payors often follow the coverage and reimbursement policies of Medicare. We cannot assure you that government or private third-party payors will cover and reimburse the procedures using our products in whole or in part in the future or that payment rates will be adequate.

For some of our products, our success in non-U.S. markets may depend upon the availability of coverage and reimbursement from the third-party payors through which health care providers are paid in those markets. Health care payment systems in non-U.S. markets vary significantly by country, and include single-payor, government managed systems as well as systems in which private payors and government-managed systems exist, side-by-side. For some of our products, our ability to achieve market acceptance or significant sales volume in international markets may be dependent on the availability of reimbursement for our products under health care payment systems in such markets.

There can be no assurance that reimbursement for our products, will be obtained or that such reimbursement will be adequate.

Health care legislation, including the Patient Protection and Affordable Care Act and the Health Insurance Portability and Accountability Act of 1996, may have a material adverse effect on us.

The Patient Protection and Affordable Care Act ("PPACA") substantially changes the way healthcare is financed by government and private insurers, encourages improvements in healthcare quality, and impacts the medical device industry. The PPACA includes an excise tax on entities that manufacture or import medical devices offered for sale in the United States; a new Patient-Centered Outcomes Research Institute to conduct comparative effectiveness research; and payment system reforms.

The PPACA also imposes new reporting and disclosure requirements on device and drug manufacturers for any payment or transfer of value made or distributed to physicians or teaching hospitals. Under these provisions, known as the Physician Payment Sunshine Act, affected device and drug manufacturers need to begin data collection on August 1, 2013, with the first reports due in 2014. These provisions require, among other things, extensive tracking and maintenance of databases regarding the disclosure of relationships and payments to physicians and teaching hospitals. In addition, certain states have passed or are considering legislation restricting our interactions with health care providers and/or requiring disclosure of many payments to them. Failure to comply with these tracking and reporting laws could subject us to significant civil monetary penalties.

The Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) created new federal statutes to prevent healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from government sponsored programs such as the Medicare and Medicaid programs. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. A violation of this statute is a felony and may result in fines or imprisonment or exclusion from government sponsored programs. HIPAA also established uniform standards governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of individually identifiable health information maintained or transmitted by healthcare providers, health plans and healthcare clearinghouses.

Both federal and state government agencies are continuing heightened and coordinated civil and criminal enforcement efforts. As part of announced enforcement agency work plans, the federal government will continue to scrutinize, among other things, the billing practices of hospitals and other providers of healthcare services. The federal government also has increased funding to fight healthcare fraud, and it is coordinating its enforcement efforts among various agencies, such as the U.S. Department of Justice, the Office of Inspector General and state Medicaid fraud control units. We believe that the healthcare industry will continue to be subject to increased government scrutiny and investigations.

We may fail to recruit and retain qualified personnel.

We expect to rapidly expand our operations and grow our sales, development and administrative operations. This expansion is expected to place a significant strain on our management and will require hiring a significant number of qualified personnel. Accordingly, recruiting and retaining such personnel in the future will be critical to our success. There is intense competition from other companies for qualified personnel in the areas of our activities, particularly sales, marketing and research & development. If we fail to identify, attract, retain and motivate these highly skilled personnel, we may be unable to continue our marketing and development activities, and this could have a material adverse effect on the Company’s business, financial condition, results of operations and future prospects.

We may face risks in connection with potential acquisitions.

We may look to acquire businesses that complement or expand our operations as part of our business strategy going forward. We may not be able to successfully identify attractive acquisition candidates or negotiate favorable terms in the future. Furthermore, our ability to effectively integrate any future acquisitions will depend on, among other things, the adequacy of our implementation plans, the ability of our management to oversee and operate effectively the combined operations and our ability to achieve desired operational efficiencies. If we are unable to successfully integrate the operations of any businesses that we may acquire in the future, our business, financial position, results of

operations or cash flows could be adversely affected.

We rely on key executive officers, and their knowledge of our business and technical expertise would be difficult to replace.

We are highly dependent on our Executive Chairman, Raymond F. Akers, Jr., PhD because of his expertise and experience in biotechnology and diagnostics. We have a three year employment agreement with Dr. Akers containing customary non-disclosure, non-compete, confidentiality and assignment of inventions provisions. We do not have “key person” life insurance policies for any of our officers. The loss of the technical knowledge and management and industry expertise of any of our key personnel could result in delays in product development, loss of customers and sales and diversion of management resources, which could adversely affect our operating results.

We may need to obtain additional licenses to patents or other proprietary rights from other parties.

To facilitate development and commercialization of a proprietary technology base, we may need to obtain additional licenses to patents or other proprietary rights from other parties. Obtaining and maintaining these licenses, which may not be available, may require the payment of up-front fees and royalties. In addition, if we are unable to obtain these types of licenses, our product development and commercialization efforts may be delayed or precluded.

We may not be able to protect or enforce our intellectual property rights, which could impair our competitive position.

Our success depends significantly on our ability to protect our rights to the patents, trademarks, trade secrets, copyrights and all other intellectual property rights used in our products. Protecting our intellectual property rights is costly and time consuming. We rely primarily on patent protection and trade secrets, as well as a combination of copyright and trademark laws and nondisclosure and confidentiality agreements to protect our technology and intellectual property rights. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or maintain any competitive advantage. Despite our intellectual property rights practices, it may be possible for a third party to copy or otherwise obtain and use our technology without authorization, develop similar technology independently or design around our patents.

We cannot be assured that any of our pending patent applications will result in the issuance of a patent to us. The U.S. Patent and Trademark Office, or PTO, may deny or require significant narrowing of claims in our pending patent applications, and patents issued as a result of the pending patent applications, if any, may not provide us with significant commercial protection or be issued in a form that is advantageous to us. We could also incur substantial costs in proceedings before the PTO. Our issued and licensed patents and those that may be issued or licensed in the future may expire or may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related technologies. Upon expiration of our issued or licensed patents, we may lose some of our rights to exclude others from making, using, selling or importing products using the technology based on the expired patents. There is no assurance that competitors will not be able to design around our patents. We also rely on unpatented proprietary technology. We cannot assure you that we can meaningfully protect all our rights in our unpatented proprietary technology or that others will not independently develop substantially equivalent proprietary products or processes or otherwise gain access to our unpatented proprietary technology. Further, we may not be able to obtain patent protection or secure other intellectual property rights in all the countries in which we operate, and under the laws of such countries, patents and other intellectual property rights may be unavailable or limited in scope. If any of our patents fail to protect our technology, it would make it easier for our competitors to offer similar products. Our trade secrets may be vulnerable to disclosure or misappropriation by employees, contractors and other persons. Any inability on our part to adequately protect our intellectual property may have a material adverse effect on our business, financial condition and results of operations.

Expenses incurred with respect to monitoring, protecting, and defending our intellectual property rights could adversely affect our business.

Competitors and others may infringe on our intellectual property rights, or may allege that we have infringed on theirs. Monitoring infringement and misappropriation of intellectual property can be difficult and expensive, and we may not be able to detect infringement or misappropriation of our proprietary rights.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights and we may be unable to protect our rights to, or use of, our technology.

Some or all of our patent applications may not issue as patents, or the claims of any issued patents may not afford meaningful protection for our technologies or products. In addition, patents issued to us or our licensors, if any, may be challenged and subsequently narrowed, invalidated, found unenforceable or circumvented. Patent litigation is widespread in the biotechnology industry and could harm our business. Litigation might be necessary to protect our patent position. Patentability, invalidity, freedom-to-operate or other opinions may be required to determine the scope and validity of third-party proprietary rights. If we choose to go to court to stop a third party from using the inventions protected by our patent, that third party would have the right to ask the court to rule that such patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and we may not have the required resources to pursue such litigation or to protect our patent rights. In addition, there is a risk that the court will decide that our patents are not valid or that we cannot stop the other party from using their inventions. There is also the risk that, even if the validity of these patents is upheld, the court will find that the third party's activities do not infringe our rights in these patents. On January 9, 2012, the Company was notified of an action to recover unpaid royalties for the exclusive use of a patent used in the production of our MPC Biosensor products (MicroParticle Catalyzed Biosensor). The dispute related to the method used to calculate royalty payments and the scope of the products involved for the period dated March 17, 2007 through March 19, 2012. On April 23, 2012, the Company agreed to an arbitration settlement of $137,791. On January 11, 2012, the Company was notified of a demand for arbitration from Trinity Biotech Manufacturing Limited related to the distributor agreement between the parties dated June 19, 2008. On October 15, 2012, the Company agreed to an arbitration settlement of $118,000. The settlement is being paid over 13 months, with an initial payment of $18,000 and 12 equal payments of $8,333.

Furthermore, a third party may claim that we are infringing the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our product candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we are infringing the third party's patents and would order us to stop the activities covered by the patents. In addition, there is a risk that a court will order us to pay the other party's treble damages or attorneys' fees for having violated the other party's patents. The biotechnology industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods of use either do not infringe the claims of the relevant patent and/or that the third party patent claims are invalid, and we may not be able to do this. Proving invalidity in the United Sates, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

In addition, changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection. In September 2011, the U.S. Congress passed the Leahy-Smith America Invents Act ("AIA") which became effective in March 2013. The AIA reforms United States patent law in part by changing the standard for patent approval for certain patents from a "first to invent" standard to a "first to file" standard and developing a post-grant review system. It is too early to determine what the effect or impact the AIA will have on the operation of our business and the protection and enforcement of our intellectual property. However, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition. Because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, and publications in the scientific literature often lag behind actual discoveries. We cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications or that we were the first to invent the technology (pre-AIA) or first to file (post-AIA). Our competitors may have filed, and may in the future file, patent applications covering technology similar or the same as ours. Any such patent application may have priority over our patent application and could further require us to obtain rights to such technologies in order to carry on our business. If another party has filed a U.S. patent application on inventions similar or the same as ours, we may have to participate in an interference or other proceeding in the U.S. Patent and Trademark Office, or the USPTO, or a court to determine priority of invention in the United States, for pre-AIA applications and patents. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our U.S. patent position with respect to such inventions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. To date, neither the Company, its founders, directors nor officers have been involved in any material litigation relating to Company matters. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

Our failure to secure trademark registrations could adversely affect our ability to market our product candidates and our business.

Our trademark applications in the United States and any other jurisdictions where we may file may not be allowed registration, and we may not be able to maintain or enforce our registered trademarks. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in corresponding foreign agencies, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our applications and/or registrations, and our applications and/or registrations may not survive such proceedings. Failure to secure such trademark registrations in the United States and in foreign jurisdictions could adversely affect our ability to market our product candidates and our business.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although the Company has no knowledge of any claims against us, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. To date, none of our employees have been subject to such claims.

We may not be able to adequately protect our intellectual property outside of the United States.

The laws in some foreign jurisdictions may not provide protection for our trade secrets and other intellectual property. If our trade secrets or other intellectual property are misappropriated in foreign jurisdictions, we may be without adequate remedies to address these issues. Additionally, we also rely on confidentiality and assignment of invention agreements to protect our intellectual property. These agreements may provide for contractual remedies in the event of misappropriation. We do not know to what extent, if any, these agreements and any remedies for their breach, will be enforced by a foreign or domestic court. In the event our intellectual property is misappropriated or infringed upon and an adequate remedy is not available, our future prospects will likely diminish.

Additionally, prosecuting and maintaining intellectual property (particularly patent) rights are very costly endeavors. We do not know whether legal and government fees will increase substantially and therefore are unable to predict whether cost may factor into our intellectual property strategy.

If we deliver products with defects, we may be subject to product recalls or negative publicity, our credibility may be harmed, market acceptance of our products may decrease and we may be exposed to liability.

The manufacturing and marketing of professional and consumer diagnostics involve an inherent risk of product liability claims. For example, a defect in one of our diagnostic products could lead to a false positive or false negative result, affecting the eventual diagnosis. Our product development and production are extremely complex and could expose our products to defects. Manufacturing and design defects could lead to recalls (either voluntary or required by the FDA or other government authorities) and could result in the removal of a product from the market. Defects in our products could also harm our reputation, lead to product liability claims, claims that inaccurate test results lead to death or injury, negative publicity and decrease sales of our products. We have obtained $10,000,000 of product liability insurance and we have never received a product liability claim, and have generally not seen product liability

claims for screening tests that are accompanied by appropriate disclaimers. However, in the event there is a claim, this insurance may not fully cover our potential liabilities. In addition, as we attempt to bring new products to market, we may need to increase our product liability coverage which would be a significant additional expense that we may not be able to afford. If we are unable to obtain sufficient insurance coverage at an acceptable cost to protect us, we may be forced to abandon efforts to commercialize our products or those of our strategic partners, which would reduce our revenue.

If our estimates relating to our critical accounting policies are based on assumptions or judgments that change or prove to be incorrect, our operating results could fall below expectations of financial analysts and investors, resulting in a decline in our stock price.

The preparation of financial statements in conformity with U.S. GAAP requires our management to make estimates, assumptions and judgments that affect the amounts reported in the financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity, revenue and expenses that are not readily apparent from other sources. Our operating results may be adversely affected if our assumptions change or if actual circumstances differ from those in our assumptions, which could cause our operating results to fall below the expectations of financial analysts and investors, resulting in a decline in our stock price. Significant assumptions and estimates used in preparing our financial statements include those related to revenue recognition, inventory, product warranties, allowance for doubtful accounts, stock-based compensation expense and income taxes.

As an emerging growth company within the meaning of the Securities Act, we will utilize certain modified disclosure requirements, and we cannot be certain if these reduced requirements will make our common stock less attractive to investors.

We are an emerging growth company within the meaning of the rules under the Securities Act. We have utilized, and we plan in future filings with the SEC to continue to utilize, the modified disclosure requirements available to emerging growth companies, including reduced disclosure about our executive compensation and omission of compensation discussion and analysis, and an exemption from the requirement of holding a nonbinding advisory vote on executive compensation. In addition, we will not be subject to certain requirements of Section 404 of the Sarbanes-Oxley Act, including the additional testing of our internal control over financial reporting as may occur when outside auditors attest as to our internal control over financial reporting, and we have elected to delay adoption of new or revised accounting standards applicable to public companies. As a result, our stockholders may not have access to certain information they may deem important.

In addition, Section 107 of the JOBS Act also provides that an emerging growth company can utilize the extended transition period provided in Section 7(a)(2)(B) of the Securities Act which allows us to delay the adoption of compliance with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to utilize this extended transition period. Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards as they become applicable to public companies. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

We could remain an “emerging growth company” for up to five years, or until the earliest of (i) the last day of the first fiscal year in which our annual gross revenue exceeds $1 billion, (ii) the date that we become a “large accelerated filer” as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock that is held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter or (iii) the date on which we have issued more than $1 billion in non-convertible debt during the preceding three-year period.

We have not performed an evaluation of our internal control over financial reporting, such as required by Section 404 of the Sarbanes-Oxley Act, nor have we engaged our independent registered public accounting firm to perform an audit of our internal control over financial reporting as of any balance sheet date or for any period reported in our financial statements. Had we performed such an evaluation or had our independent registered public accounting firm performed an audit of our internal control over financial reporting, material weaknesses may have been identified. For so long as we qualify as an “emerging growth company” under the JOBS Act, which may be up to five years following this offering, we will not have to provide an auditor’s attestation report on our internal controls in future annual reports on Form 10-K as otherwise required by Section 404(b) of the Sarbanes-Oxley Act. During the course of the evaluation, documentation or attestation, we or our independent registered public accounting firm may identify

weaknesses and deficiencies that we may not otherwise identify in a timely manner or at all as a result of the deferred implementation of this additional level of review.

Our legal counsel has advised us that we may have violated Section 402 of the Sarbanes-Oxley Act of 2002, which prohibits an issuer from extending or maintaining personal loans to its directors or executive officers. As a result, we could become subject to criminal, civil or administrative sanctions or penalties and we may also face potential private securities litigation.

On September 14, 2012, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with Mr. Thomas J. Knox. Pursuant to the Purchase Agreement, Mr. Knox purchased, amongst other things, 10,000,000 shares of the Series A Preferred Stock. The Series A Preferred Stock were convertible at any time into 320,512 shares of common stock. The Company requested that Mr. Knox convert the Series A Preferred Stock, and though under no obligation to do so, on November 15, 2013, Mr. Knox converted all 10,000,000 shares of Series A Preferred Stock into 320,512 shares of common stock pursuant to the terms of the Series A Preferred Stock. In order to satisfy the required onetime payment of $500,000 (the "Purchase Price") due upon conversion as set forth in the Purchase Agreement, Mr. Knox issued a promissory note in favor of the Company for the principal aggregate amount of $500,000 (the "2013 Knox Note"). The 2013 Knox Note required payment of the principal in full prior to maturity date of November 15, 2014 (the "Maturity Date") with interest on the unpaid principal balance at the rate of the thirty day average LIBOR per annum commencing on November 15, 2013. The 320,512 shares of common stock were to be held by the Company as collateral until all amounts owing under the 2013 Knox Note were paid in full.

We have taken immediate steps to address the above situation by cancelling the 2013 Knox Note and seeking immediate repayment from Mr. Knox. On December 3, 2013 the Company issued Mr. Knox 261,997 shares of common stock and cancelled the remaining shares issuable to him under the terms of the Series A Preferred Stock in full satisfaction of the Purchase Price. Section 402 of the Sarbanes-Oxley Act of 2002 prohibits public U.S. companies, including us, from extending or maintaining personal loans to its directors or executive officers. The arrangements with Mr. Knox may have violated this prohibition. The potential violation of the Section 402 may cause governmental authorities, such as the SEC or other U.S. authorities, to impose certain criminal, civil, and administrative sanctions or penalties upon us. Similarly, private parties may also bring civil litigations against us for such violations.

Risks Related to the Market

Recent global economic trends could adversely affect our business, liquidity and financial results.

Recent global economic conditions, including a disruption of financial markets, could adversely affect us, primarily through limiting our access to capital. In addition, the continuation or worsening of general market conditions in economies important to our businesses may adversely affect our clients' level of spending and ability to obtain financing, leading to us being unable to generate the levels of sales that we require. Current and continued disruption of financial markets could have a material adverse effect on the Company's business, financial condition, results of operations and future prospects.

Risks Relating to our Common Stock

We currently have a limited trading volume, which results in higher price volatility for, and reduced liquidity of, our common stock.

There has been limited trading of our common stock in the U.S since we began trading on the NASDAQ Capital Market in January 2014. Since 2002, our shares of common stock have been listed for trading on AIM. However, historically there has been limited volume of trading in our common stock on AIM, which has limited the liquidity of our common stock on that market. We cannot predict whether or how investor interest in our common stock on the AIM market might translate to the market price of our common stock or the development of an active trading market in the U.S. or how liquid that market might become.

Furthermore, if we cease to be listed on AIM or NASDAQ, holders would find it more difficult to dispose of, or to obtain accurate quotations as to the market value of, our common stock, and the market value of our common stock would likely decline.

If and when a larger trading market for our common stock develops, the market price of our common stock is still likely to be highly volatile and subject to wide fluctuations, and you may be unable to resell your shares at or above the price at which you acquired them.

The market price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to a number of factors that are beyond our control, including, but not limited to:

- variations in our revenue and operating expenses;
- actual or anticipated changes in the estimates of our operating results or changes in stock market analyst recommendations regarding our ordinary shares, other comparable companies or our industry generally;

- market conditions in our industry and the economy as a whole;
- developments in the financial markets and worldwide or regional economies;
- announcements of innovations or new products or services by us or our competitors;
- announcements by the government relating to regulations that govern our industry;
- sales of our common stock or other securities by us or in the open market; and
- changes in the market valuations of other comparable companies.

In addition, if the market for biotech stocks or the stock market in general experiences loss of investor confidence, the trading price of our common stock could decline for reasons unrelated to our business, financial condition or operating results. The trading price of our shares might also decline in reaction to events that affect other companies in our industry, even if these events do not directly affect us. Each of these factors, among others, could harm the value of your investment in our common stock. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business, operating results and financial condition.

Our common stock is listed on two separate stock markets and investors seeking to take advantage of price differences between such markets may create unexpected volatility in our share price; in addition, investors may not be able to easily move shares for trading between such markets.

Our common stock is already admitted to trading on AIM and the NASDAQ Capital Market. Price levels for our ordinary shares could fluctuate significantly on either market, independent of our share price on the other market. Investors could seek to sell or buy our shares to take advantage of any price differences between the two markets through a practice referred to as arbitrage. Any arbitrage activity could create unexpected volatility on either exchange with respect to both our share price and the volume of shares available for trading. In addition, holders of shares in either jurisdiction will not be immediately able to transfer such shares for trading on the other market without effecting necessary procedures with our transfer agent. This could result in time delays and additional cost for our shareholders. Further, if we are unable to continue to meet the regulatory requirements for listing on AIM or NASDAQ, we may lose our listing on AIM or NASDAQ, which could impair the liquidity of our shares.

Our stock price could fall and we could be delisted from the NASDAQ in which case U.S. broker-dealers may be discouraged from effecting transactions in shares of our common stock because they may be considered penny stocks and thus be subject to the penny stock rules.

The SEC has adopted a number of rules to regulate "penny stock" that restricts transactions involving stock which is deemed to be penny stock. Such rules include Rules 3a51-1, 15g-1, 15g-2, 15g-3, 15g-4, 15g-5, 15g-6, 15g-7, and 15g-9 under the Securities and Exchange Act of 1934, as amended. These rules may have the effect of reducing the liquidity of penny stocks. "Penny stocks" generally are equity securities with a price of less than $5.00 per share (other than securities registered on certain national securities exchanges or quoted on the NASDAQ Stock Market if current price and volume information with respect to transactions in such securities is provided by the exchange or system). Our securities have in the past constituted, and may again in the future constitute, "penny stock" within the meaning of the rules. The additional sales practice and disclosure requirements imposed upon U.S. broker-dealers may discourage such broker-dealers from effecting transactions in shares of our common stock, which could severely limit the market liquidity of such shares and impede their sale in the secondary market.

A U.S. broker-dealer selling penny stock to anyone other than an established customer or "accredited investor" (generally, an individual with net worth in excess of $1,000,000 or an annual income exceeding $200,000, or $300,000 together with his or her spouse) must make a special suitability determination for the purchaser and must receive the purchaser's written consent to the transaction prior to sale, unless the broker-dealer or the transaction is otherwise exempt. In addition, the "penny stock" regulations require the U.S. broker-dealer to deliver, prior to any transaction involving a "penny stock", a disclosure schedule prepared in accordance with SEC standards relating to the "penny stock" market, unless the broker-dealer or the transaction is otherwise exempt. A U.S. broker-dealer is also required to disclose commissions payable to the U.S. broker-dealer and the registered representative and current quotations for the securities. Finally, a U.S. broker-dealer is required to submit monthly statements disclosing recent price information with respect to the "penny stock" held in a customer's account and information with respect to the limited market in "penny stocks".

Stockholders should be aware that, according to SEC, the market for “penny stocks” has suffered in recent years from patterns of fraud and abuse. Such patterns include (i) control of the market for the security by one or a few broker-dealers that are often related to the promoter or issuer; (ii) manipulation of prices through prearranged matching of purchases and sales and false and misleading press releases; (iii) “boiler room” practices involving high-pressure sales tactics and unrealistic price projections by inexperienced sales persons; (iv) excessive and undisclosed bid-ask differentials and markups by selling broker-dealers; and (v) the wholesale dumping of the same securities by promoters and broker-dealers after prices have been manipulated to a desired level, resulting in investor losses. Our management is aware of the abuses that have occurred historically in the penny stock market. Although we do not expect to be in a position to dictate the behavior of the market or of broker-dealers who participate in the market, management will strive within the confines of practical limitations to prevent the described patterns from being established with respect to our securities.

We have not paid dividends in the past and do not expect to pay dividends for the foreseeable future, and any return on investment may be limited to potential future appreciation on the value of our common stock.

We currently intend to retain any future earnings to support the development and expansion of our business and do not anticipate paying cash dividends in the foreseeable future. Our payment of any future dividends will be at the discretion of our board of directors after taking into account various factors, including without limitation, our financial condition, operating results, cash needs, growth plans and the terms of any credit agreements that we may be a party to at the time. To the extent we do not pay dividends, our stock may be less valuable because a return on investment will only occur if and to the extent our stock price appreciates, which may never occur. In addition, investors must rely on sales of their common stock after price appreciation as the only way to realize their investment, and if the price of our stock does not appreciate, then there will be no return on investment. Investors seeking cash dividends should not purchase our common stock.

Non-U.S. investors may have difficulty effecting service of process against us or enforcing judgments against us in courts of non-U.S. jurisdictions.

We are a company incorporated under the laws of the State of New Jersey. All of our directors and officers reside in the United States. It may not be possible for non-U.S. investors to effect service of process within their own jurisdictions upon our company and our directors and officers. In addition, it may not be possible for non-U.S. investors to collect from our company, its directors and officers, judgments obtained in courts in such non-U.S. jurisdictions predicated on non-U.S. legislation.

If securities or industry analysts do not publish or cease publishing research or reports about us, our business or our market, or if they change their recommendations regarding our stock adversely, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts may publish about us, our business, our market or our competitors. If any of the analysts who may cover us change their recommendation regarding our stock adversely, or provide more favorable relative recommendations about our competitors, our stock price would likely decline. If any analyst who may cover us were to cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

The requirements of being a U.S. public company may strain our resources and divert management's attention.

As a U.S. public company, we will be or become subject to the reporting requirements of the Securities Exchange Act of 1934, as amended ("Exchange Act"), the Sarbanes-Oxley Act, the Dodd-Frank Act, the listing requirements of NASDAQ, and other applicable securities rules and regulations. Compliance with these rules and regulations will increase our legal and financial compliance costs, make some activities more difficult, time-consuming, or costly, and increase demand on our systems and resources. The Exchange Act requires, among other things, that we file annual and current reports with respect to our business and operating results.

As a result of disclosure in filings required of a public company, our business and financial condition will become more visible, which we believe may result in threatened or actual litigation, including by competitors and other third parties. If such claims are successful, our business and operating results could be harmed, and even if the claims do not result in litigation or are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert resources of our management and harm our business and operating results.

We will incur significant costs as a result of being a publicly traded company and such costs may increase when we cease to be an emerging growth company.

As a publicly traded company, we will incur legal, accounting and other expenses estimated to range from $150,000 to $250,000 per year, including costs associated with the periodic reporting requirements applicable to a company whose securities are registered under the Exchange, as well as additional corporate governance requirements, including applicable requirements under the Sarbanes-Oxley Act and other rules implemented by the SEC. The expenses incurred by public companies generally for reporting and corporate governance purposes have been increasing. We expect compliance with these public reporting requirements and associated rules and regulations to increase our legal and financial costs, particularly after we are no longer an emerging growth company, and to make some activities more time-consuming and costly, although we are currently unable to estimate these costs with any degree of certainty. These laws and regulations could also make it more difficult or costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. These laws and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as our executive officers. Further, if we are unable to satisfy our obligations as a public company, we could be subject to delisting of our common stock, fines, sanctions and other regulatory action and, potentially, civil litigation.

The recently enacted JOBS Act reduces certain disclosure requirements for emerging growth companies, thereby decreasing related regulatory compliance costs. We qualify as an emerging growth company as of the date of this offering. However, when we cease to be an emerging growth company, we will be unable to take advantage of the reduced regulatory requirements and any associated cost savings.

Efforts to comply with the applicable provisions of Section 404 of the Sarbanes-Oxley Act will involve significant expenditures, and non-compliance with Section 404 of the Sarbanes-Oxley Act may adversely affect us and the market price of our common stock.

Under current SEC rules, beginning with our fiscal year ending December 31, 2014, we will be required to report on our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act, and related rules and regulations of the SEC; although, as an emerging growth company, we are exempt from the requirement to provide an auditor attestation to management’s assessment of its internal controls as required by Section 404(b) of the

Sarbanes-Oxley Act. We will be required to review on an annual basis our internal control over financial reporting, and on a quarterly and annual basis to evaluate and disclose changes in our internal control over financial reporting. As a result, we expect to incur additional expenses in the near term that may negatively impact our financial performance and our ability to make distributions. This process also will result in a diversion of management's time and attention. We cannot be certain as to the timing of completion of our evaluation, testing and remediation actions or the impact of the same on our operations, and we may not be able to ensure that the process is effective or that our internal control over financial reporting is or will be effective in a timely manner. In the event that we are unable to maintain or achieve compliance with the applicable provisions of Section 404 of the Sarbanes-Oxley Act and related rules, we and the market price of our common stock may be adversely affected.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Property.

Our corporate headquarters which houses our research and development, engineering, manufacturing, operations and support personnel, is located in Thorofare, New Jersey, in an office consisting of a total of 17,000 square feet. For the past ten years, the Company has leased this facility at this location. The current lease term is effective from January 1, 2013 through December 31, 2019 with an annual rent of $132,000.

We believe our current facilities are sufficient for our current needs and will be adequate, or that suitable additional or substitute space will be available on commercially reasonable terms, for the foreseeable future.

Item 3. Legal Proceedings.

From time to time, we are a party to litigation and subject to claims incident to the ordinary course of business. Future litigation may be necessary to defend ourselves and our customers by determining the scope, enforceability and validity of third party proprietary rights or to establish our proprietary rights.

On November 7, 2013, the Company received a letter from counsel to Rapid Breath Diagnostics, LLC, among others (collectively, “RBD”) alleging, among other things, the violation of certain rights purported to have been granted with respect to a purported Distributor and License Agreement. Additionally, RBD claims that the Company has violated certain rights of RBD with respect to the Company’s Ketone Check and Metron products. RBD is alleging that it has suffered $250,000 in damages and that it has development and ownership of the market use of Ketone Check for the management of neurological diseases as well as rights to the name “Metron”. Notwithstanding the allegations set forth by RBD, the purported Distributor and License Agreement was never fully executed by the parties and thus is not in effect. The Company is vigorously defending itself against RBD’s allegations.

With the exception of the foregoing dispute, the Company is not involved in any disputes and does not have any litigation matters pending.

Item 4. Mine Safety Disclosures.

Not applicable.

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PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

(a) Market Information

We began trading on The NASDAQ Capital Market on January 23, 2014 and have not been previously listed on any other U.S. market. However, our shares are currently listed on AIM under the symbol "AKR.L". Our shares began trading on AIM in May 2002.

The following table shows the high and low market prices, for our shares since we began trading on the NASDAQ Capital Market.

Quarter ended	Low Price	High Price
January 23, 2014 - March 25, 2014	$4.47	$5.52

The following table shows the high and low market prices, for our shares for each fiscal quarter for the two most recent fiscal years. Market prices for our shares have fluctuated significantly since they were listed on AIM and trading volume on AIM have been very small in relation to the number of our total outstanding shares. As a result, the market prices shown in the following table may not be indicative of the market prices at which our shares will trade after this offering.

Period	High GBP	USD	Low GBP	USD	Exchange Rate
Fourth Quarter 2013	£6.9108	$11.1015	£3.6348	$5.8389	$ 1.6064
Third Quarter 2013	3.9468	6.3686	1.6380	2.6431	1.6136
Second Quarter 2013	2.6988	4.1265	1.6380	2.5045	1.5290
First Quarter 2013	2.3088	3.6059	1.7160	2.6800	1.5618
Fourth Quarter 2012	2.2152	3.5669	1.2480	2.0095	1.6102
Third Quarter 2012	1.5600	2.4236	0.9672	1.5026	1.5536
Second Quarter 2012	1.5600	2.4344	1.0608	1.6554	1.5605
First Quarter 2012	3.9000	6.2264	1.2792	2.0422	1.5965

Fourth Quarter 2011	5.0700	7.9432	2.9328	4.5948	1.5667
Third Quarter 2011	6.2400	9.7338	3.5100	5.4752	1.5599
Second Quarter 2011	6.8328	10.9906	4.4928	7.2267	1.6085
First Quarter 2011	10.5300	16.9575	4.6800	7.5367	1.6104

* The Company's stock is listed on the AIM where stock prices are in pounds. All shares prices in the table above are reflected in dollars after having been converted according to the periods average exchange rates.

(b) Holders

As of March 25, 2014, there were approximately 620 holders of record of our common stock. This figure does not take into account those shareholders whose certificates are held in the name of broker-dealers or other nominees.

(c) Dividends

We have never paid any cash dividends on our common shares, and we do not anticipate that we will pay any dividends with respect to those securities in the foreseeable future. Our current business plan is to retain any future earnings to finance the expansion development of our business.

(d) Securities Authorized for Issuance under Equity Compensation Plan

The following table shows information with respect this plan as of the fiscal year ended December 31, 2013.

Equity Compensation Plan Information

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average Exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	—	—	—
Equity compensation plans not approved by security holders	—	—	—
Total	—	—	—

Transfer Agent

Our transfer agent is American Stock Transfer & Trust Company, LLC, 6201 15th Avenue, Brooklyn, NY 11219.

Recent Sales of Unregistered Securities

On December 23, 2013, the Company completed a private placing of depository interests representing 114,072 of its common stock, no par value per share to institutional and other investors at a price of 430 pence per share (approximately $7.02 per share)

On December 3, 2013, the Company issued Mr. Thomas Knox 261,997 shares of its common stock pursuant to the cashless conversion of the Series A Preferred Stock

On June 13, 2013, the Company sold 512,820 shares of its common stock for a purchase price of $1,600,000 to Chubeworkx.

Rule 10B-18 Transactions

During the years ended December 31, 2013, there were no repurchases of the Company’s common stock by the Company.

Item 6. Selected Financial Data.

Not applicable.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

THE FOLLOWING DISCUSSION OF OUR PLAN OF OPERATION AND RESULTS OF OPERATIONS SHOULD BE READ IN CONJUNCTION WITH THE FINANCIAL STATEMENTS AND RELATED NOTES TO THE FINANCIAL STATEMENTS INCLUDED ELSEWHERE IN THIS REPORT. THIS DISCUSSION CONTAINS FORWARD-LOOKING STATEMENTS THAT RELATE TO FUTURE EVENTS OR OUR FUTURE FINANCIAL PERFORMANCE. THESE STATEMENTS INVOLVE KNOWN AND UNKNOWN RISKS, UNCERTAINTIES AND OTHER FACTORS THAT MAY CAUSE OUR ACTUAL RESULTS, LEVELS OF ACTIVITY, PERFORMANCE OR ACHIEVEMENTS TO BE MATERIALLY DIFFERENT FROM ANY FUTURE RESULTS, LEVELS OF ACTIVITY, PERFORMANCE OR ACHIEVEMENTS EXPRESSED OR IMPLIED BY THESE FORWARD-LOOKING STATEMENTS. THESE RISKS AND OTHER FACTORS INCLUDE, AMONG OTHERS, THOSE LISTED UNDER "FORWARD-LOOKING STATEMENTS" AND "RISK FACTORS" AND THOSE INCLUDED ELSEWHERE IN THIS REPORT.

Results of Operations

Management's Plans and Basis of Presentation

To date, the Company has in large part relied on equity financing to fund its operations, raising $676,068 in private placements in 2012, $2,345,024 in private placements in 2013 and $13,115,126, net of expenses, in an initial public offering on the NASDAQ Stock Exchange in 2014. The Company has experienced recurring losses and negative cash flows from operations, however, the Company's performance for the year ended December 31, 2013 had improved. Management's strategic plans include the following:

- continuing to advance the development and commercialization of the Company's products, especially those that utilize MPC Biosensor, PIFA and seraSTAT technologies;
- continuing to strengthen and forge domestic and international relationships with well-established sales organizations with strong distribution channels in specific target markets for both our currently marketed and emerging products;
- establishing clinical protocols that support regulatory submissions and publication of data within peer-reviewed journals; and
- continuing to monitor and implement cost control initiatives to conserve cash.

Despite our plans, the Company expects to continue to incur losses from operations for the near-term and these losses could be significant for the following reasons:

- some of ABI's distribution partnerships have been recently established or are in the process of being initiated and, therefore, consistent and historical ordering patterns have not been instituted;

- the Company continues to incur expenses related to the initial commercialization and marketing activities for METRON and VIVO, and product development (research, clinical trials, regulatory tasks) costs for its emerging products, Breath PulmoHealth "Check" rapid assays and PIFA PLUSS® Infectious Disease point-of-care tests); and

- to expand the use of its clinical laboratory products, the Company may need to invest in additional marketing support programs to increase brand awareness.

At December 31, 2013, ABI had cash and cash equivalents of $103,634 working capital of $1,415,994, stockholders' equity of $4,122,234 and an accumulated deficit of $81,721,126. The Company believes that its current working capital position will be sufficient to meet its estimated cash needs for at least 12 months following the consummation of this offering. If the Company does not obtain additional capital as needed, the Company would potentially be required to reduce the scope of its research and development activities. The Company is closely monitoring its cash balances, cash needs and expense levels.

Revenue

ABI's total revenue for the year ended December 31, 2013, totaled $3,577,851, a 129% increase over the same period in 2012. Revenues improved in both of the major product lines, MPC products increased by 375%, PIFA Heparin/PF4 Rapid Assay increased by 1%. Licensing revenues increased by 1,820%.

The significant increase in MPC product and licensing revenues are attributable to our world-wide distribution agreement with ChubeWorkx Gurnsey Limited. During the year ended December 31, 2013, ChubeWorkx accounted for $1,719,340 of our MPC product revenue and an additional $333,333 in licensing fees.

Domestic sales growth of the Company's PIFA Heparin/PF4 Rapid Assay was relatively flat given the restructuring of the Company's selling resources initiated at the start of Q1 2013. The Company's dedicated technical sales account executives have moved away from a direct selling model to one that works in tandem with over 300 sales representatives of ABI's US distribution partners, Cardinal Health ("Cardinal") and Fisher HealthCare ("Fisher"). This reorganization and need to dedicate time and resources to building relationships with distributor representatives hampered 2013 domestic sales growth but has set the stage for an enhanced selling effort in 2014. In addition, the Company began shipping its PIFA PLUSS PF4 product line extension to Cardinal in late 2012, but the assay was just added to Fisher's distribution agreement in January of 2014; this expansion and relationship-building initiative have already delivered a measureable increase in product trials and adoptions in the current fiscal year. For the year ended December 31, 2013, the aforementioned domestic distributors, Cardinal and Fisher, accounted for close to $900,000 of the total PIFA Heparin/PF4 Rapid Assay as compared to $868,000 for the same period of 2012 and individually represented 64% and 17%, and of such sales. The remaining $216,000 in sales was generated from ABI's direct customers during 2013 as compared to $235,000 in 2012.

Cost of sales for the year ended December 31, 2013 increased by 90% compared to the same period in 2012 to $1,913,844 from $1,007,951 in 2012. The rise in cost of sales is attributed to the increased consumption of raw materials and other manufacturing components, the use of temporary labor and sub-contractors due to the significant increase in Breathalyzer production to meet enhanced sales demand.

Although the total cost of sales increased, ABI's gross profit margin improved to 47% for the year ended 2013 as compared to 36% in 2012. The improvement in gross profit margin was derived from a significant increase in licensing fees ($533,333 in 2013 as compared to $27,778 in 2012) and an increase in production volume which allowed us to improve efficiency by producing materials in larger lots, reducing setup, quality assurance testing and other production costs associated with the manufacturing process.

General and Administrative Expenses

General and administrative expenses in the year ended December 31, 2013, totaled $1,524,626, which was a 2% increase as compared to $1,493,707 for the year ended 2012.

Sales and Marketing Expenses

Sales and marketing expenses in the year ended December 31, 2013, totaled $684,722, which was a 7% increase as compared to $638,732 for the year ended 2012. The increase was the result of royalties and sales commissions related to the improved Breathalyzer sales and the restructuring of the commission program for our internal sales staff to reflect their increasing technical involvement with our distributors for the PIFA Heparin/PF4 Rapid Assay products.

Research and Development

Research and development expenses in the year ended December 31, 2013 totaled $1,006,800, which was an 11% increase as compared to $900,380 for the year ended 2012. This increase was due to expanded development of the PIFA Heparin/PF4 Rapid Assay products and the METRON single-use ketone test for the health & wellness industries.

The following table illustrates research and development costs by project for the years ended December 31, 2013 and 2012, respectively.

	2013	2012
Ascorbic Acid	$-	$2,049
Asthma/pH	-	18,393
BreathScan	2,432	20,393
BreathScan Pro	4,751	-
CHUBE	4,751	157,165
COPD	-	93,062
H/PF4	376,838	99,782
HIV	13,193	-
Ketone/Metron	268,960	55,615
Lyophilization	71,916	94,500
Malondialdehyde	56,965	-
PF4 PLUSS	107,493	83,670
Tri Cholesterol	-	2,475
VIVO/FreD	99,501	273,276
Total R&D Expenses:	$1,006,800	$900,380

Other Income and Expense

Other income increased for the year ended December 31, 2013 over the same period in 2012, primarily as a result of income from two notable events. On June 13, 2013, ABI sold its interest in (en)10, the Company's exclusive CHUBE distributor based in the UK, to Chubeworkx for $100,000; a realized gain of $99,710, representing the difference between the sale price and carried value of the interest. We have determined that the sale of our interest was an independent transaction, unrelated to the extension of the licensing agreement to include North America.

In addition, the Company recognized $91,286 in other income from the net proceeds gained from ABI's insurer demutualizing upon receiving a payment of such amount representing our share of the demutualization as determined by the insurer.

Other items, including interest and other miscellaneous income amounted to $92,942 for the year ended December 31, 2013 as compared to $10,013 for the year ended December 31, 2012. During 2013, approximately $92,000 in old trade payables were reversed and the income recognized as miscellaneous income.

Income Taxes

During 2012, the Company was approved by the State of New Jersey to sell a portion of its state tax benefits that existed as of December 31, 2011, pursuant to the Technology Tax Certificate Transfer Program. The Company

received net proceeds of $167,408 in 2012 as a result of the sale of the tax benefits. The Company did not participate in the program during 2013.

As of December 31, 2013 and 2012, the Company had Federal net operating loss carry forwards of approximately $47,600,000 and $46,500,000, respectively, expiring through the year ending December 31, 2033. As of December 31, 2013 and 2012, the Company had New Jersey state net operating loss carry forwards of approximately $8,100,000 and $5,600,000, respectively, expiring the year ending December 31, 2020.

The principal components of unrecognized deferred tax assets consisted of the following as of December 31, 2013 and December 31, 2012:

Deferred Tax Assets

	Year Ended December 31,	
	2013	2012
Reserves and other	$844,729	$921,068
Net operating loss carry-forwards	$17,165,809	$16,149,472
Valuation Allowance	$(18,010,538)	$(17,070,540)
Net	$-	$-

The valuation allowance for deferred tax assets as of December 31, 2013 and 2012 was 18,010,538 and $17,070,540. The change in the total valuation for the years ended December 31, 2013 and 2012 were increases of $939,998 and $1,108,127. In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which the net operating losses and temporary differences become deductible. Management considered projected future taxable income and tax planning strategies in making this assessment. The value of the deferred tax assets was fully offset by a valuation allowance, due to the current uncertainty of the future realization of the deferred tax assets.

The reconciliation of income taxes using the statutory U.S. income tax rate and the benefit from income taxes for the years ended December 31, 2013 and December 31, 2012 are as follows.

Tax Rates & Benefits

	Year Ended December 31			
	2013		2012	
Statutory U.S. Federal Income Tax Rate	(35.00	)%	(35.00	)%
New Jersey State income taxes, net of U.S. Federal tax effect	(5.9	)%	(6.0	)%
Change in Valuation Allowance	40.9	%	35.0	%
Net	0.00	%	(6.0	)%

Liquidity and Capital Resources

For the years ended December 31, 2013 and 2012, the Company generated a net loss of $1,526,773 and $2,557,820, respectively. As of December 31, 2013 and 2012, the Company has an accumulated deficit of $81,721,126 and $80,194,353 and had cash and cash equivalents totaling $103,634 and $633,022, respectively.

Currently, our primary focus is to expand the domestic and international distribution of our PIFA Heparin/PF4 rapid assays and support Chubeworkx international distribution of its CHUBE private-labeled breath alcohol detectors. The Company continues initial commercialization tasks for METRON and VIVO, as well as development activities for its PIFA PLUSS® Infectious Disease single-use assays, Breath Ketone “Check”, and Breath PulmoHealth “Check” products, including advancement of the steps required for FDA clearance or CE marking in the EU where necessary.

We expect to continue to incur losses from operations for the near-term and these losses could be significant as we incur product development, clinical and regulatory activities, contract consulting and other product development and commercialization related expenses. We believe that our current working capital position will be sufficient to meet our estimated cash needs for at least 12 months following the consummation of this offering. The Company is pursuing additional financing opportunities; however, there can be no assurance that the Company will be able to obtain sufficient additional financing on terms acceptable to the Company, if at all. We are closely monitoring our cash balances, cash needs and expense levels. The accompanying financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that might result in the possible inability of the Company to continue as a going concern.

We expect that our primary expenditures will be to continue development of PIFA PLUSS® Infectious Disease single-use assays, Breath Ketone “Check” and Breath PulmoHealth “Check” products and enroll patients in clinical trials to support performance claims, generate studies in peer-reviewed journals to support product marketing, and provide data for the FDA 510(k) clearance/CE certifications processes when required. We will also continue to support commercialization and marketing activities of in-line products (PIFA Heparin/PF4 rapid assays, PIFA PLUSS® PF4, breath alcohol detectors, METRON and VIVO)) in the US and internationally. Based upon our experience, clinical trial and related regulatory expenses can be significant costs. Steps to achieve commercialization of emerging products will be an ongoing and evolving process with expected improvements and possible subsequent generations being evaluated for commercialized and emerging tests. Should we be unable to achieve FDA clearance for products that require such regulatory “approval”, develop performance characteristics for rapid tests that satisfy market needs, or generate sufficient revenue from commercialized products, we would need to rely on other business or product opportunities to generate revenue and costs that we have incurred for the patents may be deemed impaired.

We may consider entering into agreements with ISO-certified contract manufacturers which would allow the Company to meet the regulatory requirements for product sales in large, international markets (e.g. India). We may also consider acquisitions of development technologies or products, if opportunities arise that we believe fit our business strategy and would be appropriate from a capital standpoint.

Capital expenditures, primarily for production, laboratory and facility improvement costs for the year ending December 31, 2014 are anticipated to total approximately $250,000. As per the Company’s lease agreement, the owner of the facility will be handling the majority of facility upgrades, and we anticipate financing any production and laboratory capital expenditures through working capital.

The Company may enter into generally short-term consulting and development agreements primarily for testing services and in connection with clinical trials conducted as part of the Company’s development process which may include activities related to the development of technical files for FDA 510(k) clearance submissions. Such commitments at any point in time may be significant but the agreements typically contain cancellation provisions.

We lease our manufacturing facility which also contains our administrative offices. Our current lease was executed January 1, 2013 and is effective through December 31, 2019. The Company has leased this property from the current owner since 1997. Due to recent market events that have adversely affected all industries and the economy as a whole, management has placed increased emphasis on monitoring the risks associated with the current environment, particularly the recoverability of current assets, the fair value of assets, and the Company's liquidity. At this point in time, there has not been a material impact on the Company's assets and liquidity. Management will continue to monitor the risks associated with the current environment and their impact on the Company's results.

Operating Activities

ABI's net cash consumed by operating activities totaled $2,730,002 during the year ended December 31, 2013. Cash was consumed by the loss of $1,526,773 less non-operating gains of $282,901 plus a non-cash adjustment of $354,397 for depreciation and amortization of non-current assets. For the year ended December 31, 2013, decreases in other receivables and license fees receivables of $450,559 and an increase in trade and other payables of $116,739 provided cash, primarily related to routine changes in operating activities. A net increase in trade receivables, trade receivables – related parties, inventories and other assets of $1,349,809, a decrease in trade and other payables – related parties of $51,957 and a net decrease in legal settlements payable and deferred revenue of $440,257 consumed cash from operating activities.

ABI's net cash consumed by operating activities was $999,166 during the year ended December 31, 2012. Cash was consumed by the loss of $2,557,820, less non-cash expenses of $561,623 for provisions for bad debt, write-off of notes receivable, establishment of an inventory reserve for obsolescence and depreciation and amortization of non-current assets. For the year ended December 31, 2012, decreases in trade and other receivables, and other assets generated cash of $382,724. There was a $334,178 increase in inventories in the year ended December 31, 2012, primarily due to increases in the production of CHUBE breath alcohol tubes. At year-end 2012, there was also an increase of $948,485 in trade and other payables, legal settlement liabilities, and deferred revenue.

Critical Accounting Policies

We intend to utilize the extended transition period provided in Securities Act Section 7(a)(2)(B) as allowed by Section 107(b)(1) of the JOBS Act for the adoption of new or revised accounting standards as applicable to emerging growth companies. Under the JOBS Act, emerging growth companies may delay adopting new or revised accounting standards that have different effective dates for public and private companies until such time as those standards apply to private companies. We have elected to use the extended transition period for complying with these new or revised accounting standards. Since we will not be required to comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies, our financial statements may not be comparable to the financial statements of companies that comply with public company effective dates. If we were to elect to comply with these public company effective dates, such election would be irrevocable pursuant to Section 107 of the JOBS Act.

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America (US GAAP) requires management to make estimates and assumptions about future events that affect the amounts reported in the financial statements and accompanying notes. Future events and their effects cannot be determined with absolute certainty. Therefore, the determination of estimates requires the exercise of judgment. Actual results inevitably will differ from those estimates, and such differences may be material to the financial statements. The most significant accounting estimates inherent in the preparation of our financial statements include estimates associated with revenue recognition, impairment analysis of intangibles and stock-based compensation.

The Company's financial position, results of operations and cash flows are impacted by the accounting policies the Company has adopted. In order to get a full understanding of the Company's financial statements, one must have a clear understanding of the accounting policies employed. A summary of the Company's critical accounting policies follows:

Trade Receivables, Trade Receivables – Related Party and Allowance for Doubtful Accounts:

The carrying amounts of current trade receivables is stated at cost, net of allowance for doubtful accounts and approximate their fair value given their short term nature.

The normal credit terms extended to customers ranges between 30 and 90 days. The Company reviews all receivables that exceed terms and establishes an allowance for doubtful accounts based on management's assessment of the collectability of trade and other receivables. A considerable amount of judgment is required in assessing the amount of allowance. The Company considers the historical level of credit losses, makes judgments about the credit worthiness of each customer based on ongoing credit evaluations and monitors current economic trends that might impact the level of credit losses in the future.

Intangible Assets:

Intangible assets primarily represent legal and filing costs associated with obtaining patents on the Company's new discoveries or acquiring patents for diagnostic technologies or tests that will enhance the Company's product portfolio. The Company has developed or acquired several diagnostic tests that can detect the presence of various substances in a person's breath, blood, urine and saliva. Propriety protection for the Company's products, technology and process is important to its competitive position. To date, the Company has eleven patents from the United States Patent Office in effect (7,896,167, 8,097,171, 7,285,246, 7,837,936, 8,003,061, 8,425,859, 5,565,366, 5,827,749, D691,056, D691,057 and D691,058). Other patents are in effect in Australia through the Design Registry (348,310, 348,311 and 348,312), the Community Trade Mark in the European Union ((OHIM) 002216895-0001, 002216895-0002 and 002216895-0003) and in Japan (4,885,134 and 4,931,821). Patents are in the national phase of prosecution in many PCT participating countries. Additional proprietary technology consists of numerous different inventions. The Company intends to file additional patent applications, where appropriate, relating to new products, technologies and their use in the U.S., European and Asian markets. Management intends to protect all other intellectual property (e.g. copyrights, trademarks and trade secrets) using all legal remedies available to the Company.

Costs associated with applying for patents are capitalized as patent costs. Once the patents are approved, the respective costs are amortized over a period of twelve to seventeen years on a straight-line basis. Patent pending costs for patents that are not approved are charged to operations the year the patent is rejected.

In addition, patents may be purchased from third parties. The costs of acquiring the patent are capitalized as patent costs if it represents a future economic benefit to the Company. Once a patent is acquired it is amortized over its remaining life. The Company amortizes these costs over the shorter of the legal life of the patent or its estimated economic life using the straight-line method. The Company tests intangible assets with finite lives upon significant changes in the Company's business environment.

The testing resulted in no patent impairment charges during the years ended December 31, 2013 and 2012 respectively.

Long-Lived Assets:

Recognition and measurement

Items of property, plant and equipment are measured at cost less accumulated depreciation and accumulated impairment losses. Cost includes expenditure that is directly attributable to the acquisition of the asset. When parts of an item of property, plant and equipment have different useful lives, they are accounted for as separate items (major components) of property, plant and equipment. Gains and losses on disposal of an item of property, plant and equipment are determined by comparing the proceeds from disposal with the carrying amount of property, plant and equipment and are recognized net within "other income" in profit or loss.

Revenue Recognition

In accordance with FASB ASC 605, the Company recognizes revenue when (i) persuasive evidence of a customer or distributor arrangement exists, (ii) a retailer, distributor or wholesaler receives the goods and acceptance occurs, (iii) the price is fixed or determinable, and (iv) the collectability of the revenue is reasonably assured. Subject to these criteria, the Company recognizes revenue from product sales when title passes to the customer based on shipping terms. The Company typically does not accept returns nor offer charge backs or rebates except for certain distributors. Revenue recorded is net of any discount, rebate or sales return.

License fee revenue is recognized on a straight-line basis over the term of the license agreement.

When the Company enters into arrangements that contain more than one deliverable, the Company allocates revenue to the separate elements under the arrangement based on their relative selling prices in accordance with FASB ASC 605-25.

Stock-based Compensation

FASB ASC 718, *Share-Based Payment*, defines the fair-value-based method of accounting for stock-based employee compensation plans and transactions used by the Company to account for its issuances of equity instruments to record compensation cost for stock-based employee compensation plans at fair value as well as to acquire goods or services from non-employees. Transactions in which the Company issues stock-based compensation to employees, directors and consultants and for goods or services received from non-employees are accounted for based on the fair value of the equity instruments issued. The Company utilizes pricing models in determining the fair values of options and warrants issued as stock-based compensation. The Black-Scholes model is utilized to calculate the fair value of equity instruments.

Recently Issued and Adopted Accounting Pronouncements

The Company has evaluated all recently issued and adopted accounting pronouncements and believes such pronouncements do not have a material effect on the Company's financial statements.

Reclassifications

Certain prior period amounts in the accompanying financial statements have been reclassified to conform to the presentation used in 2013.

Quantitative and Qualitative Disclosure About Market Risk

We have limited exposure to market risks from instruments that may impact the *Balance Sheets, Statements of Operations,* and *Statements of Cash Flows.* Such exposure is due primarily to changing interest rates.

Interest Rates

The primary objective for our investment activities is to preserve principal while maximizing yields without significantly increasing risk. This is accomplished by investing excess cash in highly liquid debt and equity investments of highly rated entities which are classified as trading securities.

Off-Balance Sheet Arrangements

We have no significant known off balance sheet arrangements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We do not hold any derivative instruments and do not engage in any hedging activities.

Item 8. Financial Statements and Supplementary Data.

Our financial statements are contained in pages F-1 through F-27 which appear at the end of this Annual Report.

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

There have been no changes in or disagreements with accountants on accounting and financial disclosure.

Item 9A. Controls and Procedures.

(a) Evaluation of Disclosure and Control Procedures

Based on their evaluation as of the end of the period covered by this Annual Report on Form 10-K, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(c) and 15d-15(e) under the Exchange Act) are effective to ensure that information required to be disclosed by us in report that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the U.S. Securities and Exchange Commission’s rules and forms and to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

(b) Management's Assessment of Internal Control over Financial Reporting

This annual report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the Company's registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

(c) Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, during our most recently completed fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance.

Executive Officers and Directors

The following table sets forth the names, ages and positions of all of the directors and executive officers of the Company and the positions they hold as of the date hereof. The directors of the Company serve until their successors are elected and shall qualify. Executive officers are elected by the Board of Directors and serve at the discretion of the directors.

Name	Age	Position
Thomas A. Nicolette(1)	63	Chief Executive Officer, Director, Principal Financial Officer, President
Raymond F. Akers, Jr. PhD	55	Executive Chairman of the Board of Directors, Secretary

Gary M. Rauch	58	Controller and Treasurer
Tom Knox**	72	Independent Director
Brandon Knox**	34	Independent Director
Gavin Moran**	43	Independent Director

1. On March 7, 2013, the Company was informed that effective March 28, 2013, Mr. Nicolette is resigning from his positions as Chief Executive Officer, President and director of the Company, and all other positions to which he may have been assigned, regardless of whether he served in such capacity.

** It is intended that these named persons, who will meet the requirements of “independence” under the pertinent NASDAQ rules.

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Set forth below is a brief description of the background and business experience of each of our executive officers and directors.

Thomas A. Nicolette, age 63, has been our President since February 2007 and our Chief Executive Officer since April 2008. Mr. Nicolette has been a member of the Board since May 2006. Mr. Nicolette has served as the principal of Nicolette Consulting Group Limited, a business management consulting firm, since founding it in 1984. From 1997 through 2012 Mr. Nicolette was the Corporate Secretary, Treasurer and director of Sentech EAS Corp., a designer and manufacturer of electronic security systems for retail, commercial and industrial firms. From 2003 through 2006, Mr. Nicolette was the director of international business development for November AG a developer of methods of authentication for anti-counterfeiting based in Germany. From 2001 to 2004, Mr. Nicolette served as Chairman of Exaqt Sa de CV a manufacturer and installer of electronic security systems. From 2001 through 2003, Mr. Nicolette served as Executive Director of Tri-Mex Group Limited, a developer of monitoring and response solutions to protect high value or hazardous cargo. Mr, Nicolette served as President, Chief Executive Officer and Director of DNA Technologies, Inc., a holder of patented technology providing solutions for counterfeiting, forgery and product diversion, from 2000 through 2003. From 1995 through 2001, Mr. Nicolette was the President, Chief Executive Officer and director of Sentry Technology Corporation which owned Knogo North America, Inc. and Video Sentry Corporation, designers and manufacturers of electronic articles surveillance systems and closed circuit television systems worldwide. Also, Mr. Nicolette served as President, Chief Executive Officer and director of Knogo Corporation, a New York Stock Exchange listed multi company and purveyor of electronic article surveillance, from 1986 through 1994.

Mr. Nicolette is a graduate of Michigan State University School of Criminal Justice.

The Company believes that Mr. Nicolette’s experience in management of various public companies, capital raising strategy, financial planning and the U.S. markets will assist the Company’s development and maintenance of a sound financial strategy going forward.

Raymond F. Akers Jr., Ph.D., age 55, has been Executive Chairman of the Board since December 31, 2009 and was appointed Secretary on August 5, 2013. Dr. Akers founded the Company in 1989. He has over 25 years of experience in the diagnostics industry having co-founded Drug Screening Systems, Inc., a publicly listed company, in 1987, and Akers Medical Technology Inc. in 1984. He was Chief Executive Officer and vice president of research and development of Drug Screening Systems, Inc. until the sale of that company in 1989 and served as President and Chief Executive Officer of Akers Medical Technology Inc. until 1987.

Dr. Akers holds a Ph.D. in Neurochemistry from Northwestern University. Dr. Akers has either invented or directed the research and development of all of the Company’s products and technologies.

The Company believes that Mr. Akers experience in assisting diagnostic companies develop infrastructure; including but not limited to general management and business development will contribute to the Company's development of its own infrastructure and growth as a public company.

Gary M. Rauch, age 58, has over 35 years of experience in accounting, financial and information systems consulting, discrete manufacturing, distribution and administration. Mr. Rauch has been the Company's controller since March, 2010 and was appointed treasurer on August 5, 2013. Mr. Rauch also founded DataSys Solutions, LLC in 2004 and is currently the managing member. DataSys Solutions LLC specializes in financial and information systems consulting and technical support services. From July, 2002 through March, 2010, Mr. Rauch was the controller for Cold Star, Inc., a manufacturer of dairy dispensing equipment and a dairy products distributor. Mr. Rauch also worked for six years as consulting manager with Deloitte & Touche providing financial system selection, development and implementation services for their small to middle market clients.

Mr. Rauch has an associate degree from the University of South Carolina.

Thomas J. Knox, age 72, was appointed to our board of directors effective July 1, 2013. Mr. Knox is currently the Chief Executive Officer of Knox Consulting Group, an advisory and investment firm, as well as Chairman of ORB Automotive Corporation, Ltd. (appointed in 2011), a company focused on the development and manufacture of various components used in the Chinese automotive industry including adhesives and rubber molds. In May of 2007, Mr. Knox was a candidate for Mayor of Philadelphia. From April 2004 to April 2006, Mr. Knox was the Chief Executive Officer of United Healthcare of Pennsylvania, a division of United Healthcare, Inc., the largest health insurance provider in the world. From 1999 to 2004, Mr. Knox was Chairman of the Board and Chief Executive Officer of Fidelity Insurance Group, Inc., a Maryland and Pennsylvania licensed group life and health insurance provider. From 1988 through June 2000, Mr. Knox was the Chairman of the board and Chief Executive Officer of Crusader Holding Corporation, a NASDAQ listed company which was the owner of a multi-branch bank serving the greater Philadelphia area. Mr. Knox is a Chartered Life Underwriter (CLU) and Chartered Financial Consultant (ChFC), and is active in Philadelphia politics having held the position of Deputy Mayor for the Office of Management and Productivity from 1993 to 1999. Mr Knox also currently serves as the Chairman of INDECS Corp, a full service health benefit third party administrator affiliated with Aetna Corporation. From 1999 through the present, Mr. Knox has been a director of Historic Philadelphia Incorporated. Mr. Knox was a candidate for Governor or Pennsylvania from 2008 to 2010.

The Company believes that Mr. Knox extensive expertise in health care and finance will assist the Company’s strategic planning and operations.

Brandon Knox, age 34, Mr. Knox has been a wealth advisor at Raymond James in Philadelphia since December 2012. His practice focuses on investment and estate solutions for high net worth families and individuals as well as public and private institutions both locally and nationally. Prior to joining Raymond James, Mr. Knox was a wealth advisor at Morgan Stanley from July 2008 to October 2012. From 2006 to 2008, Mr. Knox served as Deputy Finance Director for the Philadelphia mayoral campaign of his Father, Thomas Knox. In this role he concentrated on the organization and management of campaign fundraising efforts as well as the planning and execution of campaign events and off-site functions. Mr. Knox was a Leasing Associate for SSH Realty in Philadelphia from 2005 to 2007 handling lease negotiations for both commercial tenants and landlords. Mr. Knox holds a BS in Economics from West Chester University and an MBA in Financial Management from Drexel University. Mr. Knox sits on the Board of Directors of The Committee of Seventy and is a member of the Drexel University Presidents Leadership Council and the Archdiocese of Philadelphia’s OSD Advisory Council.

Mr. Knox holds a B.S. in Economics from West Chester University and an M.B.A. in Financial Management from Drexel University’s LeBow College of Business.

The Company believes that Mr. Knox vast experience with corporate finance and financial management will make him an ideal board member helping the Company to manage its finances as it continues its growth.

Gavin Moran, age 43, has previously worked for Shell International as a Trader, rotating through different departments including Shell chemicals, marketing, finance and International Trading from 1988 to 1995. Mr. Moran held a trading role as a beneficial shareholder at Trafigura Ltd, where he was a Trading Manager based in South Africa and London with responsibility for all the group's activities and with joint responsibility for trading activities in East Africa and Far East, from 1995 to 2008. Since April 2010, Mr. Moran has held a trading role as a beneficial shareholder at Sono International Ltd where he is responsible for the group's commercial activities, investments and strategy. He is based in Ghana and London.

The Company believes that the Mr. Moran's extensive experience in marketing and finance will assist the Company's growth strategy and development as a public company.

Chubeworkx Purchase Agreement/Voting Agreement

On June 19, 2013, the Company and Chubeworkx entered into a purchase agreement (the "Chubeworkx Purchase Agreement") pursuant to which Chubeworkx purchased 512,820 of the Company's common stock for an aggregate purchase price of $1,600,000. As further consideration to induce Chubeworkx to enter into the Chubeworkx Purchase Agreement, the Company, Chubeworkx and Mr. Tom Knox entered into a voting agreement (the "Voting Agreement") whereby Mr. Knox and Chubeworkx agreed to vote their respective shares pursuant to the terms of the Voting Agreement. Amongst other things,

The Company, Mr. Knox and Chubeworkx agreed as follows:

(i) to take all other actions necessary to ensure that at all times, (a) the size of the Board shall be a maximum of five (5) directors and (b) the Company's organizational documents specify that each director has equal rights to each other director;

(ii) on all matters relating to the election of one or more directors of the Company, each of Mr. Knox and Chubeworkx shall vote at regular or special meetings of shareholders and so long as each maintains ten percent (10%) or more of the voting rights with respect to the Company shall be entitled to designate their own directors (each a "Designee and together the "Designees"); and

(iii) Mr. Knox shall vote at a regular or special meeting of stockholders (or by written consent) all of the shares held by him, and the Company and Mr. Knox shall otherwise take all actions necessary to ensure that at all times up to the time which is immediately prior to the consummation of this offering, the unanimous approval of the board of directors of the Company shall be required for any issuance by the Company of any new shares of capital stock of the Company or any instruments convertible into shares of capital stock of the Company (including any such issuance of shares of capital stock of the Company in connection with this offering, including without limitation voting in favor of any amendment to the Certificate of Incorporation or Bylaws, as necessary.

The Voting Agreement shall terminate and be of no further force or effect immediately prior to the consummation of this offering; provided, however, that the parties thereto acknowledge and agree that the termination of the Voting Agreement shall not occur until after the board of directors of the Company has already granted final approval of this offering and the issuance of shares of common stock in connection therewith.

Pursuant to the Voting Agreement, Chubeworkx was granted the right to appoint one director to the Company's board. Chubeworkx nominated Gavin Moran as its representative on the board and Mr. Moran was so appointed effective July 1, 2013.

Family Relationships

Tom Knox and Brandon Knox are father and son, respectively. There are no other family relationships among any of our directors or executive officers.

Board Composition and Committees and Director Independence

Our board of directors consists of 4 members: Raymond F. Akers, Jr. PhD, Thomas Knox, Gavin Moran and Mr. Brandon Knox. The directors will serve until our next annual meeting and until their successors are duly elected and qualified. The Company defines "independent" as that term is defined in Rule 5605(a)(2) of the NASDAQ listing standards.

In making the determination of whether a member of the board is independent, our board considers, among other things, transactions and relationships between each director and his immediate family and the Company, including those reported under the caption “Related Party Transactions”. The purpose of this review is to determine whether any such relationships or transactions are material and, therefore, inconsistent with a determination that the directors are independent. On the basis of such review and its understanding of such relationships and transactions, our board affirmatively determined that Mr. Tom Knox, Mr. Gavin Moran and Mr. Brandon Knox are qualified as independent and that none of them have any material relationship with us that might interfere with his or her exercise of independent judgment.

Board Committees

The Company has established an audit committee, a compensation committee and a nominating and corporate governance committee. Each committee has its own charter, which is available on our website at *www.akersbiosciences.com.* Information contained on our website is not incorporated herein by reference.

Audit Committee

We have a separately-designated standing Audit Committee established in accordance with Section 3(a)(58)(A) of the Exchange Act of 1934, as amended (the Exchange Act”). The members of our Audit Committee are Tom Knox, Gavin Moran and Brandon Knox. Each of these Committee members is “independent” within the meaning of Rule 10A-3 under the Exchange Act and the NASDAQ Stock Market Rules. Our board has determined that Tom Knox is an “audit committee financial expert”, as such term is defined in Item 407(d)(5) of Regulation S-K. Tom Knox serves as Chairman of our Audit Committee.

The Audit Committee oversees our accounting and financial reporting processes and oversee the audit of our financial statements and the effectiveness of our internal control over financial reporting. The specific functions of this Committee include, but are not limited to:

- selecting and recommending to our board of directors the appointment of an independent registered public accounting firm and overseeing the engagement of such firm;
- approving the fees to be paid to the independent registered public accounting firm;
- helping to ensure the independence of the independent registered public accounting firm;
- overseeing the integrity of our financial statements;
- preparing an audit committee report as required by the SEC to be included in our annual proxy statement;
- resolve any disagreements between management and the auditors regarding financial reporting;
- reviewing with management and the independent auditors any correspondence with regulators and any published reports that raise material issues regarding the Company's accounting policies;
- reviewing and approving all related party transactions; and
- overseeing compliance with legal and regulatory requirements.

Compensation Committee

T he members of our Compensation Committee are Tom Knox, Gavin Moran and Brandon Knox. Each such member is "independent" within the meaning of the NASDAQ Stock Market Rules. In addition, each member of our Compensation Committee qualifies as a "non-employee director" under Rule 16b-3 of the Exchange Act. Our Compensation Committee assists the board of directors in the discharge of its responsibilities relating to the compensation of the board of directors and our executive officers. Tom Knox serves as Chairman of our Compensation Committee.

The Committee's compensation-related responsibilities include, but are not limited to:

- reviewing and approving on an annual basis the corporate goals and objectives with respect to compensation for our Chief Executive Officer;
- reviewing, approving and recommending to our board of directors on an annual basis the evaluation process and compensation structure for our other executive officers;
- determining the need for an the appropriateness of employment agreements and change in control agreements for each of our executive officers and any other officers recommended by the Chief Executive Officer or board of directors;
- providing oversight of management's decisions concerning the performance and compensation of other company officers, employees, consultants and advisors;
- reviewing our incentive compensation and other equity-based plans and recommending changes in such plans to our board of directors as needed, and exercising all the authority of our board of directors with respect to the administration of such plans;
- reviewing and recommending to our board of directors the compensation of independent directors, including incentive and equity-based compensation; and
- selecting, retaining and terminating such compensation consultants, outside counsel or other advisors as it deems necessary or appropriate.

Nominating and Corporate Governance Committee

The members of our Nominating and Corporate Governance Committee are Tom Knox, Gavin Moran and Brandon Knox. Each such member is "independent" within the meaning of the NASDAQ Stock Market Rules. The purpose of the Nominating and Corporate Governance Committee is to recommend to the board nominees for election as directors and persons to be elected to fill any vacancies on the board, develop and recommend a set of corporate governance principles and oversee the performance of the board. Mr. Gavin Moran serves as Chairman of our Nominating and Corporate Governance Committee.

The Committee's responsibilities include:

- recommending to the board of directors nominees for election as directors at any meeting of stockholders and nominees to fill vacancies on the board;
- considering candidates proposed by stockholders in accordance with the requirements in the Committee charter;
- overseeing the administration of the Company's Code of Ethics;
- reviewing with the entire board of directors, on an annual basis, the requisite skills and criteria for board candidates and the composition of the board as a whole;
- the authority to retain search firms to assist in identifying board candidates, approve the terms of the search firm's engagement, and cause the Company to pay the engaged search firm's engagement fee;
- recommending to the board of directors on an annual basis the directors to be appointed to each committee of the board of directors;
- overseeing an annual self-evaluation of the board of directors and its committees to determine whether it and its committees are functioning effectively; and
- developing and recommending to the board a set of corporate governance guidelines applicable to the Company.

The Nominating and Corporate Governance Committee may delegate any of its responsibilities to subcommittees as it deems appropriate. The Nominating and Corporate Governance Committee is authorized to retain independent legal

and other advisors, and conduct or authorize investigations into any matter within the scope of its duties.

Code of Ethics

Our board of directors will adopt a Code of Business Ethics and Conduct (the "Code of Ethics") which constitutes a "code of ethics" as defined by applicable SEC rules and a "code of conduct" as defined by applicable NASDAQ rules. We shall require all employees, directors and officers, including our principal executive officer and principal financial officer to adhere to the Code of Ethics in addressing legal and ethical issues encountered in conducting their work. The Code of Ethics requires that these individuals avoid conflicts of interest, comply with all laws and other legal requirements, conduct business in an honest and ethical manner and otherwise act with integrity.

Management-Non-Executive Director Compensation

Messrs. Thomas Knox and Gavin Moran were appointed to serve as non-executive directors in 2013.

Currently, no director of the Company receives any cash compensation for their services as such, but in the future directors may receive stock options pursuant to the Company's stock option plan and grants of the Company's common stock.

Legal Proceedings

To the best of our knowledge, during the past ten years, none of the following occurred with respect to our present or former director, executive officer, or employee: (1) any bankruptcy petition filed by or against any business of which such person was a general partner or executive officer either at the time of the bankruptcy or within two years prior to that time; (2) any conviction in a criminal proceeding or being subject to a pending criminal proceeding (excluding traffic violations and other minor offenses); (3) being subject to any order, judgment or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction, permanently or temporarily enjoining, barring, suspending or otherwise limiting his or her involvement in any type of business, securities or banking activities; and (4) being found by a court of competent jurisdiction (in a civil action), the SEC or the Commodities Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended or vacated.

Compliance with Section 16(A) of the Exchange Act

Section 16(a) of the Exchange Act requires the Company's directors, executive officers and persons who beneficially own 10% or more of a class of securities registered under Section 12 of the Exchange Act to file reports of beneficial ownership and changes in beneficial ownership with the SEC. Directors, executive officers and greater than 10% stockholders are required by the rules and regulations of the SEC to furnish the Company with copies of all reports filed by them in compliance with Section 16(a).

Based solely on our review of certain reports filed with the Securities and Exchange Commission pursuant to Section 16(a) of the Securities Exchange Act of 1934, as amended, the reports required to be filed with respect to transactions in our common stock during the fiscal year ended December 31, 2013, were timely.

Code of Ethics and Business of Conduct

We have adopted a Code of Business Conduct and Ethics, which applies to our board of directors, our executive officers and our employees, outlines the broad principles of ethical business conduct we adopted, covering subject areas such as:

- compliance with applicable laws and regulations,
- handling of books and records,
- public disclosure reporting,

- insider trading,
- discrimination and harassment,
- health and safety,
- conflicts of interest,
- competition and fair dealing, and
- protection of company assets.

A copy of our Code of Business Conduct and Ethics is available without charge, to any person desiring a copy of the Code of Business Conduct and Ethics, by written request to us at our principal offices at 1090 Fountain Street North, Cambridge, Ontario, N3H 4R7.

Item 11. Executive Compensation.

The compensation provided to our “named executive officers” for 2013, 2012 and 2011 is set forth in detail in the Summary Compensation Table and other tables and the accompanying footnotes and narrative that follow this section. This section explains our executive compensation philosophy, objectives and design, our compensation-setting process, our executive compensation program components and the decisions made for compensation in respect of 2012 for each of our named executive officers.

Our named executive officers who appear in the 2013 Summary Compensation Table are:

Thomas A. Nicolette	President and Chief Executive Officer
Raymond F. Akers, Jr., PhD	Executive Chairman, Secretary
Gary M. Rauch	Controller, Treasurer

Summary Compensation Table

The following table summarizes information regarding the compensation awarded to, earned by or paid to, our Chief Executive Officer, and our only other most highly compensated executive officers who earned in excess of $100,000 during 2013, 2012 and 2011.

Name and Principal Position	Year	Salary ($)	Cash Bonus ($)	Stock Awards ($)	Option Awards ($)	All Other Compensation ($)		Total ($)
Raymond F. Akers, Jr. PhD	2013	347,500	26,173	0	0	7,800	(1)	381,473
Executive Chairman,	2012	350,000	0	0	0	7,800	(1)	357,800
Secretary	2011	345,285	0	0	0	7,800	(1)	353,085
Thomas A. Nicolette	2013	0	26,173	0	0	335,004	(2)	361,176
Chief Executive Officer,	2012	0	0	0	0	335,004	(2)	335,004
President(4)	2011	0	0	0	0	333,506	(2)	333,506
Gary M. Rauch,	2013	0	0	0	0	67,500	(3)	67,500
Controller, Treasurer	2012	0	0	0	0	67,500	(3)	67,500
	2011	0	0	0	0	41,700	(3)	41,700

(1) Other compensation for Mr. Akers consisted of a car allowance.

(2) Thomas A. Nicolette is not an employee of the Company and is paid a fee pursuant to his consultant agreement. Fees paid to Mr. Nicolette are recorded as other compensation.

(3) Gary M. Rauch is not an employee of the Company and is paid a fee pursuant to his consultant agreement. Fees paid to Mr. Rauch are recorded as other compensation.

(4) On March 7, 2013, the Company was informed that effective March 28, 2013, Mr. Nicolette is resigning from his positions as Chief Executive Officer, President and director of the Company, and all other positions to which he may have been assigned, regardless of whether he served in such capacity.

Compensation-Setting Process/Role of Our Compensation Committee

During 2013, our board of directors was responsible for overseeing our executive compensation program, establishing our executive compensation philosophy and programs, and determining specific executive compensation, including cash and equity. Unless otherwise stated, the discussion and analysis below is based on decisions by the board of directors.

During 2013, our board of directors considered one or more of the following factors when setting executive compensation, as further explained in the discussions of each compensation element below:

- the experiences and individual knowledge of the members of our board of directors regarding executive compensation, as we believe this approach helps us to compete in hiring and retaining the best possible talent while at the same time maintaining a reasonable and responsible cost structure;
- corporate and/or individual performance, as we believe this encourages our executive officers to focus on achieving our business objectives;

- the executive's existing equity award and stock holdings; and

- internal pay equity of the compensation paid to one executive officer as compared to another — that is, that the compensation paid to each executive should reflect the importance of his or her role to the company as compared to the roles of the other executive officers, while at the same time providing a certain amount of parity to promote teamwork.

With our transition to being a company listed on NASDAQ, our compensation program following this offering may, over time, vary significantly from our historical practices. For example, we expect that following this offering, in setting executive compensation, the new compensation committee may review and consider, in addition to the items above, factors such as the achievement of predefined milestones, tax deductibility of compensation, the total compensation that may become payable to executive officers in various hypothetical scenarios, the performance of our common stock and compensation levels at public peer companies.

Employment Agreements

Effective January 12, 2011, the Company and Mr. Raymond F. Akers Jr., PhD, our Executive Chairman, entered into a three (3) year (the "Term") employment agreement (the "Employment Agreement"). Mr. Akers shall be responsible for the duties attendant with such position as an executive officer of the Company and is required to devote all of his working time, attention and energies to the affairs of the Company and to use his best efforts to promote its best interests. Mr. Akers shall be paid a base salary of $350,000 (the "Base Salary"), payable in intervals consistent with other executive officers of the Company but in no event less than on a monthly basis. Mr. Akers shall also be entitled to benefits made available to executive officers of the Company, including, but not limited to, participation in incentive compensation plans, pensions and other retirement plans, hospitalization, surgical, dental, major medical coverage and short and long term disability, vacation and sick leave. The Company is required to reimburse of all his reasonable and necessary travel including a car allowance, entertainment or other related expenses incurred by him in carrying out his duties and responsibilities under the Employment Agreement.

In the event that Mr. Akers's employment is terminated by the Company for cause (as defined below) the Company shall pay Mr. Akers his unpaid base salary (excluding bonus compensation) through the month in which the termination occurs. The term "cause" shall mean the entering of a plea of guilty or nolo contendere by Mr. Akers or the conviction of Mr. Akers for a felony or any other criminal act involving moral turpitude.

In the event that Mr. Akers's employment is terminated by the Company for any reason other than death, disability or cause (as such terms are defined in the Employment Agreement, other than in connection with a change in control) the Company shall pay Mr. Akers a severance and non-competition payment equal to the sum of (i) an amount equal to the Base Salary for the remainder of the Term, plus (ii) an amount equal to the Bonus Compensation earned by the Employee in respect of the last full fiscal year immediately preceding the year of termination multiplied by the

number of months remaining in the Term divided by twelve.

Mr. Akers may elect to end his employment with the Company for any reason at any time. Should Mr. Akers end his employment with the Company voluntarily prior to the expiration of the Term, he shall be entitled to his unpaid base salary through the month in which the voluntary termination occurs. For one year following his resignation or termination, Mr. Akers will not work for or provide any services in any capacity to any competitor and will not solicit any of the Company's customers or accounts.

The Compensation Committee is currently working on the terms of a new employment Agreement for Mr. Akers and until such time as the new agreement can be finalized, Mr. Aker continues to work for the Company under the terms of his now expired employment agreement.

Consulting Agreements

Nicolette Consulting Group Limited

Effective January 12, 2011, the Company and Nicolette Consulting Group Limited ("NGC") entered into a three (3) year (the "Term") consulting services agreement (the "Consulting Agreement") whereby Mr. Thomas A. Nicolette, Managing Director of NGC, shall serve the Company in the capacity of Chief Executive Officer. Mr. Nicolette is responsible for the duties attendant with his position as Chief Executive Officer of the Company and is required to devote all of his working time, attention and energies to the affairs of the Company and to use his best efforts to promote its best interests. In consideration for such services, NGC is paid a monthly fee (the "Monthly Fee") of $27,916.67. The Company is required to reimburse NGC for all approved, reasonable and necessary travel, entertainment or other related expenses up to $10,000 per month (the "Approved Expenses") incurred in carrying out duties and responsibilities under the Consulting Agreement. NGC must submit appropriate, written, audit-worthy documentation to the Company supporting Approved Expenses (including receipts) and the Company must authorize the same, which shall not be unreasonably withheld.

In the event that NGC or Mr. Nicolette is terminated by the Company for cause (as defined below), the Company is required to pay NGC any unpaid Monthly Fee or Approved Expenses earned but unpaid through the termination date. The term “cause” shall mean (a) Mr. Nicolette’s conviction or guilty plea admitting guilt of any felony; (ii) the deliberate engaging by NGC or Mr. Nicolette in fraud or embezzlement which is demonstrably proven and materially injurious to the Company; or (iii) NGC’s or Mr. Nicolette’s refusal to observe or perform any of the terms and provisions of the Consulting Agreement, which refusal remains uncured following thirty (30) days prior written notice from the Company.

In the event that the Consulting Agreement is terminated without cause the Company shall pay NGC any unpaid Monthly Fee or Approved Expenses earned but unpaid through the termination date.

The Company, NGC and NGC’s personnel, including Mr. Nicolette, have agreed to indemnify each other from and against any and all claims, liabilities losses, damages, and expenses incurred, arising in connection with any litigation related to services performed under the Consulting Agreement.

The relationship created by the Consulting Agreement is one of an independent contractor. Neither NGC nor its personnel, including Mr. Nicolette, are entitled to any rights and or benefits that the Company provides for the Company’s employees (including any employee pension, health, vacation pay, sick pay or other fringe benefits offered by the Company under plan or practice) by virtue of the services being rendered by NGC or otherwise.

During the Term, NGC and Mr. Nicolette shall not provide services to any direct competitor of the Company.

In March 2014, the Term of the Consulting Agreement was extended through March 28, 2014.

DataSys Solutions, LLC

Effective January 11, 2012, the Company and DataSys Solutions, LLC (“DS”) entered into a two (2) year (the “Term”) consulting services agreement (the “DS Consulting Agreement”) whereby Mr. Gary M. Rauch, Managing Member of DS, shall serve the Company in the capacity of Controller and/or other such positions designated by the Company’s CEO. Mr. Rauch is responsible for the duties attendant with his position as Controller of the Company and/or other such positions designated by the Company’s CEO and is required to devote all of his working time, attention and energies to the affairs of the Company and to use his best efforts to promote its best interests. In consideration for such services, DS is paid an annual fee of $67,500 in compensation payable in twelve monthly installments of $5,625 for seventeen (17) days per month devoted to the engagement (the “DS Monthly Fee”). The Company is required to reimburse DS for all reasonable expenses directly attributable to and incurred in connection with the engagement with prior approval by the CEO.

The Company may terminate the DS Consulting Agreement for cause (as defined below) by action of its CEO, without notice and without liability. The term “cause” shall mean (a) Mr. Rauch’s conviction, guilty plea, plea of nolo contender, or entering into any other plea admitting guilt of any felony; (ii) the deliberate engaging by DS or Mr. Rauch in fraud or embezzlement which is demonstrably proven and materially injurious to the Company; or (iii) DS’s or Mr. Rauch’s refusal to observe or perform any of the terms and provisions of the DS Consulting Agreement, or services thereunder.

The Company or DS may terminate the DS Consulting Agreement for any reason without cause, upon ninety (90) days advance written notice.

In the event that the DS Consulting Agreement is terminated without cause the Company shall pay DS any unpaid DS Monthly Fee or approved expenses earned but unpaid through the termination date.

The Company, DS and DS's personnel, including Mr. Rauch, have agreed to indemnify each other from and against any and all claims, liabilities losses, damages, and expenses incurred, arising in connection with any litigation related to services performed under the DS Consulting Agreement.

During the Term, DS and Mr. Rauch shall not provide services to any direct competitor of the Company.

Outstanding Equity Awards at Fiscal Year-End 2013

There were no outstanding equity awards at Fiscal Year-End 2013.

DIRECTOR COMPENSATION

The following sets forth the compensation awarded to, earned by, or paid to the named director by us during the year ended December 31, 2013.

Name	Fees earned or paid in cash ($)	Stock awards ($)	Option awards ($)	Non-equity incentive plan compensation ($)	Change in pension value and nonqualified deferred compensation earnings	All other compensation ($)	Total ($)
Thomas Nicolette(4)	0	0	0	0	0	0	0
Raymond Akers Jr.	0	0	0	0	0	0	0
Gavin Moran(1)	0	0	0	0	0	0	0
Tom Knox (2)	0	0	0	0	0	0	0
Brandon Knox(3)	0	0	0	0	0	0	0

(1) Effective July 1, 2013, Mr. Gavin Moran was appointed as Director.

(2) Effective July 1, 2013, Mr. Tom Knox was appointed as Director.

(3) Effective January 23, 2014, Mr. Brandon Knox was appointed as Director.

(4) Effective, March 28, 2013, Mr. Nicolette is resigning from his positions as Chief Executive Officer, President and director of the Company, and all other positions to which he may have been assigned, regardless of whether he served in such capacity.

Item 13. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The following table sets forth, as of December 30, 2013, information regarding beneficial ownership of our capital stock by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock;
- each of our named executive officers;
- each of our directors; and
- all of our current executive officers and directors as a group.

Beneficial ownership is determined according to the rules of the SEC and generally means that a person has beneficial ownership of a security if he, she or it possesses sole or shared voting or investment power of the applicable security, including options that are currently exercisable or exercisable within 60 days of March 28, 2014. Except as indicated by the footnotes below, we believe, based on the information furnished to us, that the persons named in the table below have sole voting and investment power with respect to all shares of common stock shown that they beneficially own, subject to community property laws where applicable.

Our calculation of the percentage of beneficial ownership prior to this offering is based on 4,894,837 shares of our common stock issued and outstanding as of March 25, 2014.

Common stock subject to stock options currently exercisable or exercisable within 60 days of December 30, 2013, are deemed to be outstanding for computing the percentage ownership of the person holding these securities and the percentage ownership of any group of which the holder is a member but are not deemed outstanding for computing the percentage of any other person.

Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o Akers Biosciences, Inc., 201 Grove Road, Thorofare, New Jersey USA 08086.

	Voting Rights held Prior to this Offering	Percentage of Ownership as of September 30		Percentage Immediately following the Offering	
Name of Beneficial Owner:					
5% Stockholders:					
Chubeworkx Guernsey Limited[(1)]	512,820	23.66	%	10.5	%
Act Capital Management, LLLP	280,100	-		5.7	%
Named Executive Officers and Directors:					
Thomas A. Nicolette	38,464	1.77	%	0.8	%
Raymond F. Akers, Jr. Phd	—				
Tom Knox	358,150	16.52	%	7.3	%
Brandon Knox	48,076	2.22	%	1.0	%
Gavin Moran	—	—		—	
Gary M. Rauch	480	0.02	%	0.0	%
All executive officers and directors as a group (6 persons)	445,170	20.54	%	9.1	%

(1) Mark Chasey is the Chairman of Chubeworkx Guernsey Limited and has beneficial ownership of the shares.

Changes in Control

We are not aware of any arrangements that may result in “changes in control” as that term is defined by the provisions of Item 403(c) of Regulation S-K.

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

Other than compensation arrangements, the following is a description of transactions to which we were a participant or will be a participant to, in which:

- the amounts involved exceeded or will exceed the lesser of 1% of our total assets or $120,000; and
- any of our directors, executive officers or holders of more than 5% of our capital stock, or any member of the immediate family of the foregoing persons, had or will have a direct or indirect material interest.

On September 14, 2012, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with Mr. Thomas J. Knox. Pursuant to the Purchase Agreement, Mr. Knox purchased 192,305 shares of the Company's common stock for a purchase price of $450,000. Additionally, Mr. Knox received 10,000,000 shares of the Company's Series A Cumulative Preferred Stock (the Series A Preferred Stock") in consideration for a $225,000 promissory note issued to the Company by Mr. Knox. The note bears interest at the rate of 3% per annum. The Series A Preferred Stock pays a $0.00135 dividend per annum. The Series A Preferred Stock were convertible at any time into 320,512 common stock, at the rate of 0.0320512 common stock for each preferred share, for an additional payment of $0.05 per converted share.

On June 12, 2013, the Company entered into a purchase agreement with Chubeworkx Guernsey Limited ("Chubeworkx") whereby the Company sold all of its equity interest, 20 ordinary shares, in (EN)10 (Guersney) Limited to Chubeworkx for a purchase price of $100,000.

On December 19, 2012, Chubeworkx placed an order for 3,500,000 Breathalyzers for a purchase price of $1,050,000 or $0.30 per unit. Additional orders were received in 2013 totaling 4,620,000 units. As of December 31, 2013, 5,000,000 units have shipped and 2,500,000 units are packaged awaiting delivery instructions. During 2013, the Company had product sales of $1,719,340 to Chubeworkx and recognized $333,333 of licensing fees. The Company received $519,964 during 2013 and has an account receivable of $1,209,388 from Chubeworkx as of December 31, 2013. The Company received an additional payment of $500,000 from Chubeworkx on March 7, 2014.

On November 15, 2013, Mr. Knox converted all 10,000,000 shares of Series A Preferred Stock into 320,512 shares of common stock. In order to satisfy the required one time payment of $500,000 (the "Purchase Price") due upon conversion as set forth in the Purchase Agreement, Mr. Knox issued a promissory note in favor of the Company for the principal aggregate amount of $500,000 (the "2013 Knox Note"). The 2013 Knox Note required payment of the principal in full prior to maturity date of November 15, 2014 (the "Maturity Date") with interest on the unpaid principal balance at the rate of the thirty day average LIBOR per annum commencing on November 15, 2013. The 320,512

shares of common stock were to be held by the Company as collateral until all amounts owing under the 2013 Knox Note were paid in full.

On December 3, 2013 the Company entered into a letter agreement with the Knox whereby the 2013 Knox Note was cancelled and the Company issued Mr. Knox 261,997 shares of common stock and cancelled the remaining shares issuable to him under the terms of the Series A Preferred Stock in full satisfaction of the Purchase Price.

Item 14. Principal Accounting Fees and Services.

The following table sets forth the aggregate fees billed for each of the last two fiscal years for professional services rendered by the principal accountant for the audit of the Company's annual financial statements and review of financial statements included in the Company's quarterly reports or services that are normally provided by the accountant in connection with statutory and regulatory filings or engagements for those fiscal years.

	2013	2012
Audit Fees	$50,340	$50,490
Audit-Related Fees	$39,500	$-
Tax Fees	$7,500	$7,800
All Other Fees [(1)]	$22,900	$-
TOTAL	$120,240	$58,290

[(1)] All other fees includes services performed in association with document reviews during the preparation of the Company’s S/1 filing.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

Exhibit Number	Description of Exhibit
1.1	Form of Underwriting Agreement (incorporated by reference to Exhibit 1.1 to the to the Company's Registration Statement on Form S-1 filed with the Securities Exchange Commission on November 18, 2013).
3.1	Amended & Restated Certificate of Incorporation (incorporated herein by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013).
3.2	Amendment to Certificate of Incorporation dated June 2, 2008 (incorporated herein by reference to Exhibit 3.2 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013).
3.3	Amendment to Certificate of Incorporation, Certificate of Designation of Series A Preferred Stock, dated September 21, 2012. (incorporated herein by reference to Exhibit 3.3 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013).
3.4	Amendment to Certificate of Incorporation dated January 22, 2013 (incorporated herein by reference to Exhibit 3.4 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013).
3.5	Amended and Restated By-laws dated August 5, 2013(incorporated herein by reference to Exhibit 3.5 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013).
4.1	Form of Underwriters' Warrant (incorporated by reference to Exhibit 4.1 to the to the Company's Registration Statement on Form S-1 filed with the Securities Exchange Commission on November 18, 2013).
5.1	Opinion of Lucosky Brookman LLP (incorporated by reference to exhibit 5.1 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on December 30, 2013).
10.1	Employment Agreement, dated January 12, 2011 between Raymond F. Akers, Jr. Phd and Akers Biosciences, Inc. and letter of amendment dated August 3, 2013. (incorporated herein by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013).
10.2	Consulting Agreement between Akers Biosciences, Inc. and Nicolette Consulting Group, dated January 12, 2011(incorporated herein by reference to Exhibit 10.2 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013).
10.3	Consulting Agreement between Akers Biosciences, Inc. and DataSys Solutions, LLC, dated January 1, 2012. (incorporated herein by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013).
10.4	Amended License and Supply Agreement by and between Akers Biosciences, Inc. and Chubeworkx Guernsey Limited (as successor to Sono International Limited) ("Chubeworkx"), (EN)10 (Guernsey) Limited (formerly BreathScan International (Guernsey) Limited) and (EN)10 Limited (formerly BreathScan International Limited), dated June 12, 2013 (incorporated herein by reference to Exhibit 10.4

	to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013).
10.5	Share Purchase Agreement by and between Akers Biosciences, Inc. and Chubeworkx, dated June 12, 2013. (incorporated herein by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013)
10.6	Voting Agreement by and between Akers Biosciences, Inc., Chubeworkx and Thomas J. Knox, dated June 12, 2013(incorporated herein by reference to Exhibit 10.6 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013).
10.7	Subscription Agreement by and between Akers Biosciences, Inc. and Chubeworkx, dated June 12, 2013(incorporated herein by reference to Exhibit 10.7 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013).
10.8	Subscription Agreement by and between Akers Biosciences, Inc. and Thomas J. Knox, dated September 14, 2012(incorporated herein by reference to Exhibit 10.8 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013).
10.9	Promissory Note entered into by Thomas J Knox issued in favor of Akers Biosciences, Inc., dated September 14, 2012. (incorporated herein by reference to Exhibit 10.9 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013).
10.10	License and Supply Agreement by and among the Company, Sono International Limited ("SIL"), BreathScan International (Guersney) Limited and BreathScan International Limited, dated June 19, 2012 (incorporated herein by reference to Exhibit 10.10 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on October 8, 2013).
10.11	Distribution Agreement by and among the Company and Fisher Healthcare, and Amendment thereto, dated June 15, 2010 and May 1, 2012, respectively. (incorporated herein by reference to Exhibit 10.11 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on October 8, 2013).
10.12	National Brand Distribution Agreement by and among the Company and Cardinal Health 2000, and Amendment thereto, dated May 1, 2007 and June 1, 2008, respectively. (incorporated herein by reference to Exhibit 10.12 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on October 8, 2013).
10.13	Promissory Note entered into by Thomas J. Knox issued in favor of Akers Biosciences, Inc, dated November 15, 2013(incorporated herein by reference to Exhibit 10.13 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on November 18, 2013).
10.14	2013 Incentive Stock and Award Plan (incorporated herein by reference to Exhibit 10.14 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on December 6, 2013).
10.15	Form of Nonqualified Stock Option Agreement (Non-Employee) (incorporated herein by reference to Exhibit 10.15 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on December 6, 2013).
10.16	Form of Nonqualified Stock Option Agreement (Employee) (incorporated herein by reference to Exhibit 10.16 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on December 6, 2013).
10.17	Form of Restricted Stock Agreement (incorporated herein by reference to Exhibit 10.17 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on December 6, 2013).
10.18	Form of Incentive Stock Option (incorporated herein by reference to Exhibit 10.18 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on December 6, 2013).
10.19	Letter Agreement, dated December 3, 2013, by and between the Company and Mr. Tom Knox (incorporated herein by reference to Exhibit 10.19 to the Company's Registration Statement on Form S-1/A filed with the

	Securities and Exchange Commission on December 6, 2013).
17.1	Letter of Resignation from Thomas Nicolette dated March 7, 2014 (incorporated herein by reference to Exhibit 17.1 to the Company's Current Report on Form 8-K filed March 12, 2014).
31.1*	Certification by the Principal Executive Officer of Registrant pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Rule 13a-14(a) or Rule 15d-14(a))
31.2*	Certification by the Principal Financial Officer of Registrant pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Rule 13a-14(a) or Rule 15d-14(a))
32.1*	Certification by the Principal Executive Officer pursuant to 18 U.S.C. 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification by the Principal Executive Officer pursuant to 18 U.S.C. 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

* Filed herewith

Unless otherwise indicated, exhibits were previously filed with this registration statement.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AKERS BIOSCIENCES, INC.

Date: March 28, 2014 By: */s/ Raymond Akers Jr.*
Name: Raymond Akers Jr.
Title: Executive Chairman

(Principal Executive Officer)

Date: March 28, 2014 By: */s/ Raymond Akers Jr*

Name: Raymond Akers Jr.
(Principal Financial Officer)

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

Name	**Position**	**Date**
/s/ Thomas Nicolette Thomas Nicolette	Chief Executive Officer, President and Director	March 28, 2014
/s/ Raymond Akers Jr. Raymond Akers Jr.	Executive Chairman	March 28, 2014
/s/Thomas Knox Thomas Knox	Director	March 28, 2014
/s/ Brandon Knox Brandon Knox	Director	March 28, 2014
/s/ Gavin Moran Gavin Moran	Director	March 28, 2014

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

Akers Biosciences, Inc. and Subsidiaries

We have audited the accompanying consolidated balance sheets of Akers Biosciences, Inc. and Subsidiaries (the "Company") as of December 31, 2013 and 2012, and the related consolidated statements of operations, stockholders' equity, and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such an opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Akers Biosciences, Inc. and Subsidiaries at December 31, 2013 and 2012, and the consolidated results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

/s/ Morison Cogen LLP

Bala Cynwyd, Pennsylvania

March 28, 2014

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AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Consolidated Balance Sheets

December 31, 2013 and 2012

	2013	2012
ASSETS		
Current Assets		
Cash and Cash Equivalents	$103,634	$633,022
Trade Receivables (net)	118,404	101,213
Trade Receivables - Related Party	1,209,388	10,013
Other Receivables	748,962	4,497
Note Receivable - Related Parties	-	225,000
License Fee Receivable - Related Party	-	450,000
Inventories (net)	1,025,104	987,853
Other Current Assets	163,890	67,898
Total Current Assets	3,369,382	2,479,496
Non-Current Assets		
Property, plant and equipment, net	267,321	240,014
Intangible assets, net	2,434,637	2,693,209
Other Assets	4,282	4,572
Total Non-Current Assets	2,706,240	2,937,795
Total Assets	$6,075,622	$5,417,291
LIABILITIES		
Current Liabilities		
Trade and Other Payables	$1,000,413	$1,082,504
Other Payables - Related Party	6,586	58,542
Short-Term Notes Payable - Related Party	307,500	-
Deferred Revenue - Related Party	638,889	972,222
Total Current Liabilities	1,953,388	2,113,268
Total Liabilities	1,953,388	2,113,268
EQUITY		
Convertible Preferred Stock, No par value, 50,000,000 shares authorized, 0 and 10,000,000 shares issued and outstanding as of December 31, 2013 and 2012	-	225,000
Common Stock, No par value, 500,000,000 shares authorized, 2,167,837 and 1,278,948 issued and outstanding as of December 31, 2013 and 2012	85,843,360	83,273,376
Accumulated Deficit	(81,721,126)	(80,194,353)

Total Equity	4,122,234	3,304,023
Total Liabilities and Equity	$6,075,622	$5,417,291

The accompanying notes are an integral part of these consolidated financial statements

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Consolidated Statements of Operations

Years ended December 31, 2013 and 2012

	2013	2012
Revenues:		
Product Revenue	$1,325,178	$1,523,650
Product Revenue - Related party	1,719,340	12,673
License Revenue	200,000	-
License Revenue - Related party	333,333	27,778
Total Revenue	3,577,851	1,564,101
Cost of Sales:		
Product Cost of Sales	(1,913,844)	(1,007,951)
Gross Profit	1,664,007	556,150
Administrative Expenses	1,095,950	1,009,803
Administrative Expenses - Related parties	428,676	483,904
Sales and Marketing Expenses	684,720	638,732
Research and Development Expenses	1,006,800	900,380
Amortization of Non-Current Assets	258,572	258,572
Loss from Operations	(1,810,711)	(2,735,241)
Other Income/Expenses		
Foreign Currency Transaction (Income)/Expense	57	(6,859)
Gain on sale of equity investment - Related party	(99,710)	-
Gain from demutualization of insurance carrier	(91,286)	-
Other Income	(92,999)	(3,154)
Total Other income	(283,938)	(10,013)
Loss Before Income Taxes	(1,526,773)	(2,725,228)
Income Tax Benefit	-	167,408
Net Loss	$(1,526,773)	$(2,557,820)
Basic & diluted loss per common share	$(0.96)	$(2.24)
Weighted average basic & diluted common shares outstanding	1,596,722	1,143,058

The accompanying notes are an integral part of these consolidated financial statements

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AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Consolidated Statement of Changes in Stockholder's Equity

Years ended December 31, 2013 and 2012

	Convertible Preferred Stock	Common Stock	Accumulated Deficit	Total Equity
Balance at December 31, 2011	$ -	$82,822,308	$(77,636,533)	$5,185,775
Net loss for the year	-	-	(2,557,820)	(2,557,820)
Issuance of shares	225,000	451,068	-	676,068
Balance at December 31, 2012	225,000	83,273,376	(80,194,353)	3,304,023
Net loss for the year	-	-	(1,526,773)	(1,526,773)
Conversion of Series A Preferred Shares	(225,000)	225,000	-	-
Issuance of shares, net of offering costs	-	2,344,984	-	2,344,984
Balance at December 31, 2013	$ -	$85,843,360	$(81,721,126)	$4,122,234

The accompanying notes are an integral part of these consolidated financial statements

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Consolidated Cash Flow Statements

Years ended December 31, 2013 and 2012

	2013	2012
Cash flows from operating activities		
Net loss for the year	$(1,526,773)	$(2,557,820)
Adjustments to reconcile net loss to net cash used by operating activities:		
Gain from demutualization of insurer	(91,286)	-
Gain on sale of equity investment - related party	(99,710)	-
Reversal of old trade payables	(91,905)	-
Depreciation and amortization of non-current assets	354,397	371,676
Provisions for bad debts	-	9,047
Provision for inventory obsolesence	-	32,000
Write-off of note receivable	-	148,900
Changes in assets and liabilities		
(Increase)/Decrease in trade receivables	(17,191)	95,287
(Increase)/decrease in trade receivables - related party	(1,199,375)	11,829
Decrease in other receivables	559	258,939
Decrease in license fees receivable - related party	450,000	-
Increase in inventories	(37,251)	(334,178)
(Increase)/decrease in other assets	(95,992)	16,669
Increase in trade and other payables	116,739	281,422
Increase/(decrease) in other payables - related party	(51,957)	37,917
Increase/(decrease) in legal settlement liabilities	(106,924)	106,924
Increase/(decrease) in deferred revenue - related party	(333,333)	522,222
Net cash used in operating activities	(2,730,002)	(999,166)
Cash flows from investing activities		
Purchases of property, plant and equipment	(123,132)	(11,685)
Proceeds from sale of equity investment - related party	100,000	-
Proceeds from demutualization of insurance carrier	91,286	-
Net cash provided from/(used in) investing activities	68,154	(11,685)
Cash flows from financing activities		
Proceeds from note receivable - related party for Series A Convertible Preferred Stock	225,000	-
Proceeds from short-term note payable - related party	307,500	-
Proceeds from issuance of common stock	1,599,960	451,068
Net cash provided by financing activities	2,132,460	451,068

Net decrease in cash and cash equivalents	(529,388)	(559,783)
Cash and cash equivalents at beginning of year	633,022	1,192,805
Cash and cash equivalents at end of year	$103,634	$633,022
Supplemental Disclosure of Cash Flow Information		
Non-cash financing activities		
Other receivable for proceeds of London Private Placement	$745,024	$-
Issuance of convertible preferred stock for note receivable - related party	$-	$225,000
License fee receivable - related party included in deferred revenue - related party	$-	$450,000

The accompanying notes are an integral part of these consolidated financial statements

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

Note 1 – Nature of Business

(a) Reporting Entity

The accompanying audited financial statements have been prepared by Akers Biosciences, Inc. ("ABI" or the "Company"), a company domiciled in the United States of America. The address of the Company's registered office is 201 Grove Road, West Deptford, New Jersey, 08086. The Company is incorporated in the United States of America under the laws of the State of New Jersey.

The consolidated financial statements include two dormant subsidiaries, Akers Acquisition Sub, Inc. and Bout Time Marketing Corporation. All material intercompany transactions have been eliminated upon consolidation.

(b) Nature of Business

The Company commenced research and development operations in September 1989, and until 2005 had devoted substantially all its efforts to establishing the new business.

The Company's primary focus is the development and sale of disposable diagnostic testing devices that can be performed in minutes, to facilitate time sensitive therapeutic decisions. The Company's main products are a disposable breathalyzer test that measures the blood alcohol content of the user, a rapid test detecting the antibody causing an allergic reaction to Heparin and a disposable breathalyzer test that measures Free Radical activity in the human body. When the Company enters into an agreement with a new distributor it requires an upfront licensing fee to be paid for the right to sell the Company's products in specific markets.

Note 2 - Basis of Presentation

(a) Statement of Compliance

The consolidated financial statements of the Company are prepared in U.S. Dollars and in accordance with accounting principles generally accepted in the United States of America (US GAAP).

The Company is an emerging growth company as the term is used in The Jumpstart Our Business Startups Act enacted on April 5, 2012 and has elected to comply with certain reduced public company reporting requirements.

(b) Use of Estimates and Judgments

The preparation of financial statements in conformity with US GAAP requires management to make judgments, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets, liabilities, income and expenses. Actual results may differ from these estimates. Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimates are revised and in any future periods affected. In particular, information about significant areas of estimation, uncertainty and critical judgments in applying accounting policies that have the most significant effect on the amounts recognized in the financial statements is included in the following notes for revenue recognition, preferred stock, allowances for doubtful accounts, inventory write-downs, impairment of intangible assets and valuation of share based payments.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

(c) Functional and Presentation Currency

These consolidated financial statements are presented in U.S. Dollars, which is the Company's functional currency. All financial information presented in U.S. Dollars has been rounded to the nearest dollar. Foreign Currency Transaction Gains or Losses, resulting from loans and cash balances denominated in Foreign Currencies, are recorded in the statement of operations.

(d) Comprehensive Income

The Company follows Financial Accounting Standards Board Accounting Standards Codification (FASB ASC) 220 in reporting comprehensive income (loss). Comprehensive income is a more inclusive financial reporting methodology that includes disclosure of certain financial information that historically has not been recognized in the calculation of net income. Since the Company has no items of other comprehensive income (loss), comprehensive income (loss) is equal to net income (loss).

Note 3 - Significant Accounting Policies

(a) Cash and Cash Equivalents

Cash and cash equivalents comprise cash balances. The Company considers all highly liquid investments, which include short-term bank deposits (up to 3 months from date of deposit) that are not restricted as to withdrawal date or use, to be cash equivalents. Bank overdrafts are shown as part of trade and other payables in the balance sheet.

(b) Fair Value of Financial Instruments

The Company's financial instruments consist of cash and cash equivalents, receivables and trade and other payables. The carrying value of cash and cash equivalents, trade receivables and trade and other payables approximate their fair value because of their short maturities. The Company believes the carrying amount of its note receivable and notes payable approximates their fair value based on rates and other terms.

(c) Trade Receivables, Trade Receivables – Related Party and Allowance for Doubtful Accounts

The carrying amounts of current trade receivables is stated at cost, net of allowance for doubtful accounts and approximate their fair value given their short term nature.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

The normal credit terms extended to customers ranges between 30 and 90 days. The Company reviews all receivables that exceed terms and establishes an allowance for doubtful accounts based on management's assessment of the collectability of trade and other receivables. A considerable amount of judgment is required in assessing the amount of allowance. The Company considers the historical level of credit losses, makes judgments about the credit worthiness of each customer based on ongoing credit evaluations and monitors current economic trends that might impact the level of credit losses in the future.

As of December 31, 2013 and 2012, allowances for doubtful accounts were $- and $-. Allowances charged for doubtful accounts amounted to $- and $9,047 for the years ended December 31, 2013 and 2012.

(d) Concentration of Credit Risk

The Company is exposed to credit risk in the normal course of business primarily related to trade receivables and cash and cash equivalents.

Substantially all of the Company's cash and cash equivalents are maintained with Bank of America, NA. The funds are insured by the FDIC up to a maximum of $250,000, but are otherwise unprotected. The Company placed $99,418 and $630,337 with this institution as of December 31, 2013 and 2012. No losses have been incurred in these accounts.

Concentration of credit risk with respect to trade receivables exists as approximately 85% of its revenue is generated by three customers. These customers accounted for 97% of trade receivables as of December 31, 2013. One customer generated 49% of its revenue and accounted for 40% of trade receivables as of December 31, 2012. In order to limit such risks, the Company performs ongoing credit evaluations of its customers' financial condition.

(e) Inventories

Inventories are measured at the lower of cost or market. The cost of inventories is based on the weighted-average principle, and includes expenditures incurred in acquiring the inventories, production or conversion costs and other costs incurred in bringing them to their existing location and condition. In the case of manufactured inventories and work in progress, costs include an appropriate share of production overheads based on normal operating capacity.

(f) Property, Plant and Equipment

Items of property, plant and equipment are measured at cost less accumulated depreciation and accumulated impairment losses. Costs include expenditures that are directly attributable to the acquisition of the asset.

Gains and losses on disposal of an item of property, plant and equipment are determined by comparing the proceeds from disposal with the carrying amount of property, plant and equipment and are recognized within “other income” in the statement of operations.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

Depreciation is recognized in profit and loss on the accelerated basis over the estimated useful lives of the property, plant and equipment. Leased assets are depreciated over the shorter of the lease term or their useful lives.

The estimated useful lives for the current and comparative periods are as follows:

	Useful Life (in years)
Plant and equipment	5-12
Furniture and fixtures	5-10
Computer equipment & software	3-5

Depreciation methods, useful lives and residual values are reviewed at each reporting date.

(g) Intangible Assets

(i) Patents and Trade Secrets

The Company has developed or acquired several diagnostic tests that can detect the presence of various substances in a person’s breath, blood, urine and saliva. Propriety protection for the Company’s products, technology and process is important to its competitive position. To date, the Company has eleven patents from the United States Patent Office in effect (7,896,167, 8,097,171, 7,285,246, 7,837,936, 8,003,061, 8,425,859, 5,565,366, 5,827,749, D691,056, D691,057 and D691,058). Other patents are in effect in Australia through the Design Registry (348,310, 348,311 and 348,312), the Community Trade Mark in the European Union ((OHIM) 002216895-0001, 002216895-0002 and 002216895-0003) and in Japan (4,885,134 and 4,931,821). Patents are in the national phase of prosecution in many Patent Cooperation Treaty participating countries. Additional proprietary technology consists of numerous different inventions. The Company intends to file additional patent applications, where appropriate, relating to new products, technologies and their use in the U.S., European and Asian markets. Management intends to protect all other intellectual property (e.g. copyrights, trademarks and trade secrets) using all legal remedies available to the Company.

(ii) Patent Costs

Costs associated with applying for patents are capitalized as patent costs. Once the patents are approved, the respective costs are amortized over their estimated useful lives (maximum of 17 years) on a straight-line basis. Patent pending costs for patents that are not approved are charged to operations the year the patent is rejected.

In addition, patents may be purchased from third parties. The costs of acquiring the patent are capitalized as patent costs if it represents a future economic benefit to the Company. Once a patent is acquired it is amortized over its remaining useful life.

(iii) Other Intangible Assets

Other intangible assets that are acquired by the Company, which have definite useful lives, are measured at cost less accumulated amortization and accumulated impairment losses.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

(iv) Amortization

Amortization is recognized on a straight-line basis over the estimated useful lives of intangible assets, other than goodwill, from the date that they are available for use. The estimated useful lives for the current and comparative periods are as follows:

	Useful Life (in years)
Patents and trademarks	12-17
Customer lists	5

(h) Recoverability of Long Lived Assets

In accordance with FASB ASC 360-10-35 “Impairment or Disposal of Long-lived Assets”, long-lived assets to be held and used are analyzed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be fully recoverable or that the useful lives of those assets are no longer appropriate. The Company evaluates at each balance sheet date whether events and circumstances have occurred that indicate possible impairment.

The Company determines the existence of such impairment by measuring the expected future cash flows (undiscounted and without interest charges) and comparing such amount to the carrying amount of the assets. An impairment loss, if one exists, is then measured as the amount by which the carrying amount of the asset exceeds the discounted estimated future cash flows. Assets to be disposed of are reported at the lower of the carrying amount or fair value of such assets less costs to sell. Asset impairment charges are recorded to reduce the carrying amount of the long-lived asset that will be sold or disposed of to their estimated fair values. Charges for the asset impairment reduce the carrying amount of the long-lived assets to their estimated salvage value in connection with the decision to dispose of such assets.

(i) Revenue Recognition

In accordance with FASB ASC 605, the Company recognizes revenue when (i) persuasive evidence of a customer or distributor arrangement exists, (ii) a retailer, distributor or wholesaler receives the goods and acceptance occurs, (iii) the price is fixed or determinable, and (iv) the collectability of the revenue is reasonably assured. Subject to these criteria, the Company recognizes revenue from product sales when title passes to the customer based on shipping

terms. The Company typically does not accept returns nor offer charge backs or rebates except for certain distributors. Revenue recorded is net of any discount, rebate or sales return. No accrual for estimated sales returns and rebate incentives are necessary as of December 31, 2013 and 2012.

License fee revenue is recognized on a straight-line basis over the term of the license agreement.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

When the Company enters into arrangements that contain more than one deliverable, the Company allocates revenue to the separate elements under the arrangement based on their relative selling prices in accordance with FASB ASC 605-25.

(j) Income Taxes

The Company follows FASB ASC 740 when accounting for income taxes, which requires an asset and liability approach to financial accounting and reporting for income taxes. Deferred income tax assets and liabilities are computed annually for temporary differences between the financial statements and tax bases of assets and liabilities that will result in taxable or deductible amounts in the future based on enacted tax laws and rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. Income tax expense or benefit is the tax payable or refundable for the period plus or minus the change during the period in deferred tax assets and liabilities.

(k) Shipping and Handling Fees and Costs

The Company charges actual shipping plus a handling fee to customers, which amounted to $40,714 and $41,738 for December 31, 2013 and 2012. These fees are classified as part of product revenue in the statement of operations. Shipping and other related delivery costs, including those for incoming raw materials are classified as part of the cost of net revenue, which amounted to $96,187 and $72,305 for December 31, 2013 and 2012.

During 2013, the Company reclassified shipping and handling fees included in other income of $44,892 in the year ended December 31, 2012 to product revenue to match the revenue with the related expenses.

(l) Research and Development Costs

In accordance with FASB ASC 730, research and development costs are expensed when incurred.

(m) Stock-based Payments

The Company accounts for stock-based compensation under the provisions of FASB ASC 718, Compensation—Stock Compensation, which requires the measurement and recognition of compensation expense for all stock-based awards made to employees and directors based on estimated fair values on the grant date. The Company estimates the fair value of stock-based awards on the date of grant using the Black-Scholes model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over shorter of the period over which services are to be received or the vesting period.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

The Company accounts for stock-based compensation awards to non-employees in accordance with FASB ASC 505-50, Equity-Based Payments to Non-Employees. Under FASB ASC 505-50, the Company determines the fair value of the stock warrants or stock-based compensation awards granted as either the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measurable.

All issuances of stock warrants or other equity instruments to non-employees as consideration for goods or services received by the Company are accounted for based on the fair value of the equity instruments issued. The Company estimates the fair value of stock-based awards on the date of grant using the Black-Scholes model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the period which services are to be received.

(n) Basic and Diluted Earnings per Share of Common Stock

Basic earnings per common share are based on the weighted average number of shares outstanding during the periods presented. Diluted earnings per share are computed using the weighted average number of common shares plus dilutive common share equivalents outstanding during the period. Potential common shares that would have the effect of increasing diluted earnings per share are considered anti-dilutive, i.e. the exercise prices of the outstanding stock options were greater than the market price of the common stock.

(o) Recently Adopted Accounting Pronouncements

As of December 31, 2013 and for the year then ended, there were no recently adopted accounting pronouncements that had a material effect on the Company’s financial statements.

(p) Recently Issued Accounting Pronouncements not Yet Adopted

As of December 31, 2013, there are no recently issued standards not yet adopted which would have a material effect on the Company’s financial statements.

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AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

Note 4 - Note Receivable – Related Parties

The note of $225,000 was issued to the Company in connection with the subscription of 10,000,000 series A convertible preferred stock entered into on September 14, 2012 (Note 12). It is due September 14, 2027 and has an interest rate of 3% per annum. For the year ended December 31, 2013, interest income of $1,054 and $1,997 was recorded. The note was fully settled in cash on February 26, 2013 and hence the note is recorded as a receivable instead of being shown as a contra account against the preferred stock as of December 31, 2012.

As of December 31, 2011 BreathScan International Ltd owed the Company $148,900 for products related to the licensing agreement dated March 17, 2010. This note was written-off on June 19, 2012 as part of the 3 year exclusive License & Supply agreement with Chubeworkx Guernsey Limited (as a successor to SONO International Limited)(“Chubeworkx”).

Note 5 - License Fee Receivable – Related Party

On June 19, 2012, the Company entered into a 3-year exclusive License & Supply Agreement with Chubeworkx Guernsey Limited (as a successor to SONO International Limited) (“Chubeworkx”) for the purchase and distribution of the Company’s proprietary breathalyzers outside North America (Note 15). Chubeworkx agreed to pay a licensing fee of $1,000,000. The final payment of $450,000 was received on March 6, 2013.

On June 12, 2013, Chubeworkx became a shareholder of the Company (Note 18)

Note 6 - Inventories

Inventories at December 31, 2013 and 2012 consists of the following categories:

	2013	2012
Raw Materials	$299,464	$516,497
Sub-Assemblies	335,229	464,107
Finished Goods	422,411	39,249
Reserve for Obsolescence	(32,000)	(32,000)
	$1,025,104	$987,853

For the years ended December 31, 2013 and 2012 $- and $32,000 was charged to cost of goods sold for obsolete inventory.

Certain items in sub-assemblies in 2012 were reclassified to finished goods to conform to the 2013 presentation.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

Note 7 - Property, Plant and Equipment

Property, plant and equipment as of December 31, 2013 and 2012 are as follows:

	2013	2012
Computer Equipment	$100,405	$100,405
Computer Software	22,930	22,930
Office Equipment	50,049	50,049
Furniture & Fixtures	29,939	29,939
Machinery & Equipment	1,098,503	1,021,061
Molds & Dies	649,647	603,957
Leasehold Improvements	222,594	222,594
	2,174,067	2,050,935
Less		
Accumulated Depreciation	1,906,746	1,810,921
	$267,321	$240,014

During the years ended December 31, 2013 and 2012 depreciation expense was $95,825 and $113,104.

Note 8 - Intangible Assets

Intangible assets as of December 31, 2013 and 2012 and the movements for the years then ended are as follows:

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

	Patents & Trademarks	Distributor & Customer Relationships	Totals
Cost or Deemed Cost			
At December 31, 2011	$3,851,494	$ 1,270,639	$5,122,133
Additions	-	-	-
Disposals	-	-	-
At December 31, 2012	3,851,494	1,270,639	5,122,133
Accumulated Amortization			
At December 31, 2011	899,713	1,270,639	2,170,352
Amortization Charge	258,572	-	258,572
Disposals	-	-	-
At December 31, 2012	1,158,285	1,270,639	2,428,924
Net Book Value			
At December 31, 2011	2,951,781	-	2,951,781
At December 31, 2012	2,693,209	-	2,693,209
Cost or Deemed Cost			
At December 31, 2012	3,851,494	1,270,639	5,122,133
Additions	-	-	-
Disposals	-	-	-
At December 31, 2013	3,851,494	1,270,639	5,122,133
Accumulated Amortization			
At December 31, 2012	1,158,285	1,270,639	2,428,924
Amortization Charge	258,572	-	258,572
Disposals	-	-	-
At December 31, 2013	1,416,857	1,270,639	2,687,496
Net Book Value			
At December 31, 2012	2,693,209	-	2,693,209
At December 31, 2013	$2,434,637	$ -	$2,434,637

During the years ended December 31, 2013 and 2012 amortization expense was $258,572 and $258,572.

Note 9 - Trade and Other Payables

Trade and other payables as of December 31, 2013 and 2012 are as follows:

	2013	2012
Trade Payables	$623,157	$608,836
Other Payables	377,256	366,744
Legal Settlement Payable	-	106,924
	$1,000,413	$1,082,504

Trade and other payables are non-interest bearing and are normally settled on 30 – 60 day terms. The legal settlement is non-interest bearing and has a term of 12 equal monthly installments, which commended on October 31, 2012.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

The legal settlements payable comprises two arbitration settlements as follows:

(a) On January 9, 2012, the Company was notified of an action to recover unpaid royalties for the exclusive use of a patent used in the production of our MPC Biosensor products (MicroParticle Catalyzed Biosensor). The dispute related to the method used to calculate royalty payments and the scope of the products involved for the period dated March 17, 2007 through March 19, 2012.

On April 23, 2012, the Company agreed to an arbitration settlement of $137,791. The settlement is to be paid over 12 months, with an initial payment of $50,000 and 11 equal payments of $7,981. As of December 31, 2013 the amount due was $-.

The Company recorded an amount of $131,376 in Sales and Marketing expenses in 2011. Upon agreement of the settlement on April 23, 2012, an additional amount of $6,425 was accrued and recorded as Sales and Marketing expenses in 2012.

(b) On January 11, 2012, the Company was notified of a demand for arbitration from Trinity Biotech Manufacturing Limited related to the distributor agreement between the parties dated June 19, 2008.

On October 15, 2012, the Company agreed to an arbitration settlement of $118,000. The settlement is to be paid over 13 months, with an initial payment of $18,000 and 12 equal payments of $8,333. As of December 31, 2013 the amount due was $-.

The Company recorded $118,000 in Administrative expense in 2012.

Note 10 - Deferred Revenue – Related Party

Deferred revenue represents the unearned revenue from the 3-year exclusive License and Supply Agreement with Chubeworkx Guernsey Limited (Note 15) for the purchase and distribution of the Company’s proprietary breathalyzer

that was signed in June, 2012. The first order for the proprietary breathalyzers was received in December 2012 for 3,500,000 units and additional orders were received in 2013 totaling 4,620,000 units. As of December 31, 2013, 5,000,000 units have shipped and 2,500,000 units are packaged awaiting delivery instructions. The license revenue is being recognized monthly on a straight line basis over the 3-year term of the agreement.

Note 11 - Share-based Payments

(a) Stock Warrants

The Company has issued warrants to various employees, consultants and members of the Board of Directors of the Company for their services either in connection with the Company's ongoing efforts to raise capital or the development of the Company's products. In addition, the Company has granted warrants to lenders in connection with the issuance of debt. Each warrant granted may be exchanged for a prescribed number of shares of common stock. The warrants expire March 18, 2015.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

	2013		2012	
	Warrants	Weighted Average Exercise Price	Warrants	Weighted Average Exercise Price
Outstanding at January 1	47,211	$ 48.54	60,031	$ 61.91
Cancelled during year	(44,870)	46.80	-	-
Expired during year	(352)	138.84	(12,820)	111.15
Outstanding at December 31	1,989	$ 71.76	47,211	$ 48.54

The Company has adopted two option plans that permit the granting of options to purchase shares of common stock. The plans provide for the granting of both incentive stock options ("Incentive Stock Plan"), as defined in Section 422 of the U.S. Internal Revenue Code (the "Code"), and options defined by Section 422 of the Code ("Non-qualified options").

The plans are administered by a Compensation Committee, which is appointed by the Board of Directors, who grants all options and determines their terms. Options are non-transferable and are only granted to employees, officers and directors, and advisors or consultants who agree to be employed or to provide services to the Company for a period of at least one year after the grant date. The maximum term of any option under the plans is ten years, and generally vest over three years.

(b) Stock options

Qualified option holders may exercise their options at their discretion. Each option granted may be exchanged for a prescribed number of shares of common stock.

Employee's Plan	2013		2012	
	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
Outstanding at January 1	1,579	$ 42.12	2,860	$ 42.12
Forfeited during year	-	-	(1,281)	42.12
Expired during year	(1,579)	42.12	-	-
Outstanding at December 31	-	$ -	1,579	$ 42.12

Director's Plan	2013		2012	
	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
Outstanding at January 1	352	$ 312.00	5,639	$ 69.59
Cancelled during year	(352)	312.00	-	-
Expired during year	-	-	(5,287)	53.45
Outstanding at December 31	-	$ -	352	$ 312.00

The options and warrants issued under the above three plans were valued using a Black Scholes option pricing model on the date of measurement. There were no options or warrants granted during 2013 or 2012.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

A summary of warrants and stock options outstanding and exercisable as of December 31, 2013 follows:

			Outstanding			Exercisable	
			Wgtd Avg Life	Wgtd Avg Exercise		Wtgt Avg Exercise	
	Low	High	Shares	Remaining	Price	Shares	Price
Warrants	$71.76	$71.76	1,989	1.23	$ 71.76	1,989	$ 71.76

Note 12 - Equity

The holders of common shares are entitled to one vote per share at meetings of the Company. Holders of Series A convertible preferred shares are entitled to five votes per share at meetings of the Company.

At December 31, 2013 and 2012, the Company has an undeclared dividend due to series A convertible preferred shareholders in the amount of $15,793 and $3,995.

On July 7, 2012, the Company issued 641 common shares to an investor for $1,068.

On September 14, 2012, the Company, in a private placement to an investor, issued 192,305 common shares for $450,000 and 10,000,000 series A convertible preferred shares to an investor for a promissory note of $225,000 (Note 4). The series A convertible preferred shares have the following rights:

Voting Rights. Preferred stockholders have voting rights equal to the number of common shares stockholder would own upon conversion of shares of preferred stock. The preferred stock is convertible into 320,512 shares of common stock.

Dividends. The holders of the Convertible Preferred Stock are entitled to receive preferential dividends at a rate of $0.00135 per share. Such dividends compound annually and are fully cumulative and have priority to any dividends on common stock.

Liquidation Preferences. The holders of the Convertible Preferred Stock are entitled to receive liquidation preferences for payment of any dividends due the holders. After payment of the liquidation preferences, the remaining assets, if any, are to be distributed to the holders of the Convertible Preferred Stock and common stock on a pro rata basis.

Conversion. One share of the Convertible Preferred Stock is convertible into five shares of the Company's common stock at the option of the holder. In order to convert, the holders of the Convertible Preferred Stock must make a one-time payment to the Company of $500,000.

The Convertible Preferred Stock is recorded as equity in accordance with FASB ASC 480. In accordance with FASB ASC 815, it was determined that the conversion feature was not required to be bifurcated from the equity host.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

On December 20, 2012 the Company increased its authorized number of preferred stock to 50,000,000 and its authorized number common stock to 500,000,000

On June 12, 2013 the Company, in a private placement to ChubeWorkx, issued 512,820 common shares for $1,600,000.

On August 8, 2013, the Company filed a registration statement with the Security and Exchange Commission seeking authority to begin trading the Company's common shares on the NASDAQ stock exchange.

On November 6, 2013, the Company approved a 156-to-1 reverse stock split of the Company's common shares to raise the price per share to $10.11 as calculated using the November 6, 2013 closing AIM London Stock Exchange ("LSE") market price of £0.0405 or $0.0648 per share to facilitate the NASDAQ initial public offering. All shares and per share amounts in the consolidated financial statements have been adjusted to give retroactive effect to the 156-1 reverse stock split.

On November 15, 2013, Thomas Knox executed the conversion of 10,000,000 shares of Series A convertible preferred stock to 320,512 shares of common stock (50,000,000 pre-split shares) and entered into a promissory note of $500,000 as a basis to provide the required onetime payment due upon conversion as set forth in the subscription agreement dated September 14, 2012. The promissory note requires payment of the principal in full prior to maturity date of November 15, 2014 (the "Maturity Date") with interest on the unpaid principal balance at the rate of the thirty day average LIBOR per annum commencing on November 15, 2013. The interest is to be paid in one lump sum on or before December 31 of each calendar year. The 320,512 shares of common stock will be held by the Company as collateral until all amounts owing under this note are paid. In the event that Mr. Knox does not pay in full all amounts due and owing under the note within 15 business days of the Maturity Date the Company has the right to cancel the 320,512 shares of common stock; provided however, the Company provides Mr. Knox no less than thirty (30) day written notice prior to cancelling the common stock. Mr. Knox shall have no less than sixty (60) days from the date the notice is received to pay all amount due and owing under the note.

On December 3, 2013, the note receivable received for the conversion of the Series A convertible preferred stock was cancelled in exchange of 58,515 shares of common stock at the AIM:LSE market closing price of £5.2250 using the exchange rate of $1.6355 or $8.5455 per share. The Company has recorded the receipt of the 58,515 shares as a reduction of the issued and outstanding common stock, as the shares were retired upon receipt.

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Notes to Consolidated Financial Statements

On December 23 2013, the Company issued 114,072 common shares in a private placement offering. The transaction was recorded at the value of the net proceeds. The proceeds were recorded in Other Receivables at December 31, 2013. The cash proceeds from the sale were received on January 2, 2014. The expenses related to this private placement are detailed below:

	$	$
Gross Proceeds:		800,732
Broker Commission	40,037	
Legal Fees	15,672	
Total Expenses		55,708
Net Proceeds:		745,024

As of December 31, 2013 and 2012 the Company has reserved shares of its common stock as follows:

	2013	2012
Reserves for:		
Convertible Preferred Stock	-	320,512
Outstanding Warrants	1,989	47,211
Outstanding Employee Options	-	1,579
Outstanding Directors Options	-	352
Total Reserves	1,989	369,654

The following is a reconcilement of the movement of shares of Series A Convertible Preferred stock (preferred stock) and common stock:

	Authorized Preferred Stock	Common Stock	Issued Preferred Stock	Common Stock
Balance at December 31, 2011	15,000,000	200,000,000	-	1,086,002
Shares Issued:				
July 7, 2012	-	-	-	641
September 14, 2012	-	-	10,000,000	192,305
Increase in Authorization:				

December 20, 2012	35,000,000	300,000,000	-	-
Balance at December 31, 2012	50,000,000	500,000,000	10,000,000	1,278,948
Preferred Share Conversion:				
November 15, 2013	-	-	(10,000,000)	320,512
Shares Cancelled:				
December 3, 2013	-	-	-	(58,515)
Shares Issued:				
June 12, 2013	-	-	-	512,820
December 23, 2013	-	-	-	114,072
Balance at December 31, 2013	50,000,000	500,000,000	-	2,167,837

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

Note 13 - Loss per share

The calculation of basic and diluted loss per share at December 31, 2013 and 2012 was based on the loss attributable to common shareholders of $1,526,773 and $2,557,820. The basic and diluted weighted average number of common shares outstanding for 2013 and 2012 was 1,596,722 and 1,143,058.

Diluted net loss per share is computed using the weighted average number of common and dilutive potential common shares outstanding during the period.

Potential common shares consist of preferred stocks, options and warrants. Diluted net loss per common share was the same as basic net loss per common share for the years ended December 31, 2013 and 2012 since the effect of preferred stocks, options and warrants would be anti-dilutive due to the net loss attributable to the common shareholders for the years. Instruments excluded from dilutive earnings per share, because their inclusion would be anti-dilutive, were as follows: series A convertible preferred stock – nil (2012: 320,512), employee and consulting stock options – nil (2012: 1,931); warrants 1,989 (2012: 47,211).

Note 14 - Income Tax Expense

The Company’s income tax benefit is as follows:

	Years Ended December 31	
	2013	2012
Current	$-	$167,408
Deferred	939,998	$1,108,127
Change in Valuation Allowance	(939,998)	$(1,108,127)
Income Tax Benefit	$-	$167,408

During 2012, the Company was approved by the State of New Jersey to sell a portion of its state tax benefits that existed as of December 31, 2011, pursuant to the Technology Tax Certificate Transfer Program. The Company received net proceeds of $- in 2013 (2012: $167,408) as a result of the sale of the tax benefits, which has been included when received as an income tax benefit in the consolidated statement of operations.

As of December 31, 2013 and 2012, the Company had Federal net operating loss carry forwards of approximately $47,600,000 and $46,500,000, expiring through the year ending December 31, 2033. As of December 31, 2013 and 2012, the Company had New Jersey state net operating loss carry forwards of approximately $8,100,000 and $5,600,000, expiring through the year ending December 31, 2020.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

The principle components of the deferred tax assets and related valuation allowances as of December 31, 2013 and 2012 are as follows:

	Years Ended December 31	
	2013	2012
Reserves and other	$844,729	$921,068
Net operating loss carry-forwards	17,165,809	16,149,472
Valuation Allowance	(18,010,538)	(17,070,540)
Net	$-	$-

The reconciliation of income taxes using the statutory U.S. income tax rate and the benefit from income taxes for the years ended December 31, 2013 and 2012 are as follows:

	Years Ended December 31	
	2013	2012
Statutory U.S. Federal Income Tax Rate	(35.0)%	(35.0)%
New Jersey State income taxes, net of U.S. Federal tax effect	(5.9)%	(6.0)%
Change in Valuation Allowance	40.9 %	35.0 %
Net	(0.0)%	(6.0)%

The valuation allowance for deferred tax assets as of December 31, 2013 and 2012 was 18,010,538 and $17,070,540. The change in the total valuation for the years ended December 31, 2013 and 2012 were increases of $939,998 and $1,108,127. In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which the net operating losses and temporary differences become deductible. Management considered projected future taxable income and tax planning strategies in making this assessment. The value of the deferred tax assets was fully offset by a valuation allowance, due to the current uncertainty of the future realization of the deferred tax assets.

The Company’s policy is to record interest and penalties associated with unrecognized tax benefits as additional income taxes in the statement of operations. As of January 1, 2013, the Company had no unrecognized tax benefits and no charge during 2013, and accordingly, the Company did not recognize any interest or penalties during 2013

related to unrecognized tax benefits. There is no accrual for uncertain tax positions as of December 31, 2013.

The Company files U.S. federal income tax returns and a state income tax returns. With few exceptions, the U.S. and state income tax returns filed for the tax years ending on December 31, 2010 and thereafter are subject to examination by the relevant taxing authorities.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

Note 15 - Related Party Transactions

On January 12, 2011, the Company entered into a consulting agreement with Nicolette Consulting Group Limited (NCG) for a period of three years under which the Company must pay NCG $27,917 per month in fees and up to $10,000 in reimbursement for monthly expenses (2013: $110,000; 2012: $100,000) for the services of Mr. Nicolette as President and Chief Executive Officer of the Company. The consulting agreement was extended through February 11, 2014 on December 23, 2013 and extended through March 31, 2014 on March 15, 2014. Mr. Nicolette has decided to step down from the Board and resigned from the Company effective March 28, 2014. The total amount of consulting fees accrued for NCG as of December 31, 2013 and 2012 was $- and $58,542 and is shown as Other Payables – Related Party in the Consolidated Balance Sheet.

On March 17, 2010, in exchange for an exclusive licensing agreement, ABI received a 20 percent equity stake in BreathScan International Ltd (BIL). During 2012, BreathScan International Limited changed its name to en(10) Guernsey Limited (“en(10)”). Thomas A. Nicolette, President and Chief Executive Officer of the Company, was also appointed to en(10)’s Board of Directors. The equity stake is accounted for using the equity method of accounting in accordance with the Financial Accounting Standards Board Accounting Standards Codification. The equity investment was initially recorded at cost, which was nil. During the years ended December 31, 2013 and 2012 no profit or loss is recorded for en(10)’s results as en(10) recorded a net loss and the Company is not required to equity account any losses in excess of its carrying value on the books. On June 13, 2013 the Company sold its interest in en(10) to ChubeWorkx for $100,000 and Mr. Nicolette resigned from en(10)’s Board of Directors. A realized gain of $99,710 is recognized for the disposal of the investment in the statement of operations for the year ended December 31, 2013.

On June 19, 2012, the Company entered into a 3 year exclusive License & Supply Agreement with Chubeworkx Guernsey Limited (as successor to SONO International Limited) (“Chubeworkx”) for the purchase and distribution of ABI’s proprietary breathalyzers outside North America. Chubeworkx paid a licensing fee of $1,000,000, of which $333,333 and $27,776 was recognized as income for the years ended December 31, 2013 and 2012, with the deferral to be recognized over the remaining term of the agreement (Note 5).

On June 13, 2013, the Company announced an expansion of the License and Supply Agreement with Chubeworkx to include worldwide marketing and distribution of the “Be CHUBE” program using the Company’s breathalyzer.

On June 14, 2013, the Company announced that Chubeworkx has agreed to subscribe for 512,820 new common shares in the Company for a total price of $1,600,000. The proceeds were received by the Company on June 14, 2013.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

In accordance with FASB ASC 605-25, Revenue *Recognition, Multiple-Element Arrangements*, since the Amended License and Supply Agreement with Chubeworks was entered into simultaneously with the sale of the Company's 20% interest in en(10) to Chubeworks and Chubeworks purchase of 512,820 shares of the Company's common stock, the Company evaluated the separate agreements as a single arrangement with multiple deliverables in considering whether there were one or more units of accounting. The three arrangements were considered to be separate units of accounting since the three transactions have value to Chubeworks on a stand-alone basis and the transactions were consummated with no right of return. The entire consideration of the three arrangements was allocated at the inception of the arrangements on the basis of their relative selling price. The proceeds of $1,600,000 were allocated to the sale of the 80 million shares of the Company's common stock based on third party selling price. The third party selling price was based on the selling price of the stock on the AIM Market of the London Stock Exchange on date of the arrangement. The Amended License and Supply agreement was allocated zero value based on the Company's best estimate of the selling price for that deliverable. This best estimate was based on the fact that the Company and Chubeworks are in the process of developing an appropriate marketing plan for the region and that there is no current active market for the Company's CHUBE products in the expanded region. $100,000 of the proceeds were allocated to the sale of the Company's 20% interest in en(10) based on the Company's best estimate of the selling price for this deliverable. This best estimate was based on the negotiation of the sale with Chubeworks.

On August 5, 2013, the Board of Directors appointed Gary M Rauch, the principle of DataSys Solutions, LLC (DS), as the Corporate Treasurer. The Company entered into a consulting agreement with DS on January 1, 2011, with a term of three years, under which the Company agreed to pay $5,625 per month for Mr. Rauch's services as Controller of the Company.

On December 23, 2013, the Company entered into a short-term bridge loan with Nicolette Consulting Group for $307,500, payable on January 15, 2014 with a 5% per annum interest rate. The transaction was recorded as a Short-Term Notes Payable – Related Party. The loan, with interest amounting to $969, was paid in full on January 15, 2014.

Trade receivables – related party for the years ended December 31, 2013 and 2012 are amounts due from Chubeworkx Guernsey Limited, a major shareholder of the Company of $1,209,388 and $10,013. The amount due is non-interest bearing, unsecured and has a term of 90 days generally.

Product revenue – related parties for the years ended December 31, 2013 and 2012 are $1,719,340 and $12,673 from Chubeworkx Guernsey Limited, a major shareholder of the Company.

Administrative expenses – related parties for the years ended December 31, 2013 and 2012 are $361,176 and $335,004 for Nicolette Consulting Group, $67,500 and $67,500 for DataSys Solutions and $- and $148,900 for the write-off of the ChubeWorkx note receivable as part of the June 2012 licensing agreement.

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Notes to Consolidated Financial Statements

Note 16 - Commitments

The Company leases its facility in West Deptford, New Jersey under an operating lease with annual rentals of $130,200 plus common area maintenance (CAM) charges. The lease, which took effect on January 1, 2008, reduced the CAM charges allowing the Company to reach their own agreements with utilities and other maintenance providers.

On January 7, 2013, the Company extended its lease agreement for a term of 7 years, expiring December 31, 2019. Under the terms of the lease, The Company will pay $132,000 per year.

	$
Next 12 Months	132,000
Next 13-24 Months	132,000
Next 25-36 Months	132,000
Next 37-48 Months	132,000
Next 49-60 Months	132,000
Thereafter	132,000

Rent expense, including related CAM charges for the years ended December 31, 2013 and 2012 were $148,593 and $160,207.

Note 17 – Major Customers

For the year ended December 31, 2013, two customers each generated more than 10% of the Company’s revenue. In aggregate, sales to these customers accounted for 79% of the Company’s revenue. As of December 31, 2013, the amount due from these two customers was $1,269,769. This concentration makes the Company vulnerable to a near-term severe impact should the relationships be terminated.

For the year ended December 31, 2012, one customer generated more than 10% of the Company's revenue. Sales to this customer accounted for 49% of the Company's revenue. As of December 31, 2012, the amount due from the customer was $44,629.

Note 18 – Major Suppliers

For the year ended December 31, 2013, three suppliers each accounted for more than 10% of the Company's purchases. In aggregate, these suppliers accounted for 60% of the Company's total purchases. As of December 31, 2013, the amount due to these three suppliers was $167,616. This makes the Company vulnerable to a near-term severe impact should the relationships be terminated.

For the year ended December 31, 2012, one supplier accounted for more than 10% of the Company's purchases. This supplier accounted for 42% of the Company's total purchases. As of December 31, 2012, the amount due to the supplier was $252,368.

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Notes to Consolidated Financial Statements

Note 19 - Other Income

Other income consists of interest income and other miscellaneous income items. As of December 31, 2013 and 2012 the earnings were as follows:

	2013	2012
Interest Income	$1,094	$2,366
Miscellaneous Income	91,905	788
Total:	$92,999	$3,154

Note 20 – Contingencies

On November 7, 2013, the Company received a letter from the counsel of Rapid Breath Diagnostics, LLC ("RBD") alleging, among other things, the Company entered into a purported Authorized Distributor and License Agreement with RBD which was materially altered without RBD's consent. Additionally, RBD claims that the Company has violated certain intellectual property rights of RBD with respect to its Ketone Check and Metron products. RBD is alleging that it has suffered $250,000 in damages and that it has development and ownership of the market use of Ketone Check for the management of neurological diseases as well as intellectual property rights to the name Metron. The Company informed RBD that the alleged agreement was not fully executed, and that the Company's offer to enter into the agreement was void. See Note 21 – "Subsequent Events".

Note 21 - Subsequent events

On January 9, 2014, the Company commenced a lawsuit in the United States Federal Court, District of New Jersey, against Rapid Breath Diagnostics, LLC and David A. Urman (collectively, "the RBD Parties"). The Complaint requests that the Court declare the rights of the parties with respect to an alleged Distributor and License Agreement and to preliminary enjoin the RBD Parties from continuing to prosecute an arbitration filed with the American Arbitration Association with respect to the same subject matter ("the Arbitration"). Pursuant to stipulation of the parties, the Arbitration has since been discontinued in anticipation of the RBD Parties' agreement to litigate the dispute in the court action. The Company is not able to assess its position in the court action in terms of favorable or unfavorable position and intends to vigorously defend against any counterclaims, if asserted.

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AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

On January 23, 2014 the Company completed its initial public offering on the NASDAQ stock exchange, placing 2,727,000 common shares. The transaction was recorded at the value of the net proceeds. The cash proceeds from the sale were received on January 28, 2014. The estimated expenses related to this private placement are detailed below:

	$	$
Gross Proceeds:		14,998,500
Underwriter/Aegis Expenses		
Underwriter Commission	1,049,895	
Underwriter Expenses	149,985	
Aegis Legal Fees	80,000	
Aegis Registration Expenses	7,500	
Aegis Miscellaneous Expenses	36,775	
Aegis Road Show Expenses	20,000	
Total		1,344,155
Akers Biosciences Expenses		
Legal & Accounting Expenses	393,298	
Printing & Document Prep	60,564	
Registration Expenses	55,946	
Road Show Expenses	29,411	
Total		539,219
Net Procceds:		13,115,126

On January 23, 2014, upon effectiveness of the registration statement filed with the Securities and Exchange Commission (“SEC”), the Board of Directors appointed Brandon Knox as a non-executive director.

On January 23, 2014, upon effectiveness of the registration statement filed with the SEC, the Company adopted the 2013 Stock Incentive Plan (the “Plan”) which will provide for the issuance of up to 400,000 shares. The purpose of the Plan is to provide additional incentive to those officers, employees, consultants and non-employee directors of the Company and its parents, subsidiaries and affiliates whose contributions are essential to the growth and success of the Company’s business. The 2013 Plan may be administered by the board or a board-appointed committee. Eligible recipients of option awards are employees, officers, consultants or directors (including non-employee directors) of the Company or of any parent, subsidiary or affiliate of the Company. The board has the authority to grant to any eligible recipient any options, restricted stock or other awards valued in whole or in part by reference to, or otherwise based on, our common stock.

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