Akers Biosciences, Inc.
Form 10-K/A
July 13, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K/A

(Amendment No. 1)

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

For the Fiscal Year Ended: **December 31, 2017**

or

[ ] **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

AKERS BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

New Jersey	**001-36268**	**22-2983783**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification 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: **Common Stock, no par value**

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 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/A or any amendment to this Form 10-K/A. [ ]

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 [ ]
	Smaller reporting company [X]
Non-Accelerated Filer [ ]	
	Emerging growth Company [X]

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. [ ]

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant on June 30, 2017, based on a closing price of $1.25 was $10,201,326. As of March 15, 2018, the registrant had 81,973,964 shares of its common stock, no par value per share, outstanding.

Documents Incorporated By Reference: **None**.

Explanatory Note

This Amendment No. 1 on Form 10-K/A (this "Form 10-K/A") amends and restates certain items noted below in the Annual Report on Form 10-K of Akers Biosciences, Inc. (the "Company") for the fiscal year ended December 31, 2017, as originally filed with the Securities and Exchange Commission on April 3, 2018 (the "Original Filing"). This Form 10-K/A amends the Original Filing to reflect the correction of misstatements in the previously reported fiscal year 2017 financial statements related to the Company's revenue, certain obligations and the value of certain inventory items. See Note 2 to the Consolidated Financial Statements included in Item 8 for additional information and a reconciliation of the previously reported amounts to the restated amounts.

For the convenience of the reader, this Form 10-K/A sets forth the Original Filing, as amended, in its entirety; however, this Form 10-K/A amends and restates only the following financial statements and disclosures that were impacted from the correction of the misstatements:

Part I, Item 1A – Risk Factors

Part II, Item 7 - Management's Discussion and Analysis of Financial Condition and Results of Operations

Part II, Item 8 - Financial Statements and Supplementary Data

Part II, Item 9A - Controls and Procedures

In addition, the Company's Chief Executive Officer and Chief Financial Officer have provided new certifications dated as of the date of this filing in connection with this Form 10-K/A (Exhibits 31.1, 31.2, 32.1 and 32.2), and the Company has provided its revised audited consolidated financial statements formatted in Extensible Business Reporting Language (XBRL) in Exhibit 101.

Except as described above, no other changes have been made to the Original Filing. This Form 10-K/A speaks as of the date of the Original Filing and does not reflect events that may have occurred after the date of the Original Filing, or modify or update any disclosures that may have been affected by subsequent events.

The Company is also concurrently filing amended Quarterly Reports on Form 10-Q for the quarterly periods ended June 30, 2017 and September 30, 2017 to restate the previously issued interim financial statements due to the accounting misstatements described above.

AKERS BIOSCIENCES, INC.

FOR THE FISCAL YEAR ENDED

DECEMBER 31, 2017

TABLE OF CONTENTS

2

FORWARD LOOKING STATEMENTS

This Report and the documents we have filed with the Securities and Exchange Commission (which we refer to herein as the SEC) that are incorporated by reference herein contain forward-looking statements, within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that involve significant risks and uncertainties. Any statements contained, or incorporated by reference, in this Report that are not statements of historical fact may be forward-looking statements. When we use the words "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "p "predict," "project," "will" and other similar terms and phrases, including references to assumptions, we are identifying forward-looking statements. Forward-looking statements involve risks and uncertainties which may cause our actual results, performance or achievements to be materially different from those expressed or implied by forward-looking statements. 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." Moreover, new risks regularly emerge and it is not possible for our management to predict all risks, nor can we assess the impact of all risks on our business or the extent to which any risk, or combination of risks, may cause actual results to differ from those contained in any forward-looking statements. All forward-looking statements included in this Report are based on information available to us on the date hereof. Except to the extent required by applicable laws or rules, we undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise. All subsequent written and oral forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the cautionary statements contained throughout this Report and the documents we have filed with the SEC.

PART I

Item 1. Business.

Overview

Akers Biosciences, Inc. ("Akers," "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. Akers believes it has advanced the science of diagnostics through the development of several innovative proprietary platform technologies that provide product development flexibility.

All of Akers' 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, diabetes, respiratory disease and infectious disease detection, as well as for on and off-the-job alcohol safety initiatives.

Akers believes that low-cost, unit-use testing not only saves time and money, but also allows for more frequent, near-patient testing which may save lives. We believe that Akers' FDA-cleared rapid diagnostic tests help facilitate targeted diagnoses and real-time treatment. We also believe that Akers' 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 from 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 allow for 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 fast, 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.

Recently, the Company has developed tests for non-medical use within the health and wellness industry. These tests will monitor general markers of health and wellness as they relate to diet, nutrition and exercise programs.

Market Overview

Worldwide, healthcare professionals use laboratory tests to support their clinical diagnosis and treatment decisions. According to a Markets and Markets 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 the aging baby boomer 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. In addition, there has been steady growth of the retail health clinic and urgent care center markets.

According to the IVD Market Report, outside of the United States, socialized medicine and/or a general atmosphere of cost-containment and healthcare efficiency are driving 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.

Akers 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 test results can immediately be incorporated into diagnostic and treatment decisions, improving the overall efficiency of the healthcare experience for 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 developing countries that seek to deliver modern medical diagnosis with limited medical infrastructure. 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. Akers believes that the products that emerge from its 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 the global IVD market was estimated $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 and Eastern Europe regions

are projected to be the fastest growing by Frost & Sullivan . The Company's main presence is in the U.S., but the Company has also initiated its strategic move into the China and European Union marketplaces by executing joint venture, distribution and licensing agreements.

Strategy

Akers' strategy is to target carefully chosen, high margin market segments within the diagnostics industry where (i) existing tests do not meet clinical requirements, or (ii) where 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. Akers utilizes its existing platform technologies to internally develop its new products as the Company's proprietary methods.

Akers 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.

Akers 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 and Urgent Care Clinics;

Retail;

Nutraceutical Suppliers; and

Health and Fitness.

The Company plans to target other markets, such as aid organizations seeking rapid infectious disease tests. Additionally, we plan to target 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

Akers' 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. MPC Biosensor-based products contain microparticles that change color to indicate a positive test result. The microparticles are coated with recently discovered agents that both decrease the time to result and exhibit a more defined color change when appropriate. MPC Biosensor-based products are packaged in small, disposable cartridges through which test subjects can easily blow for several seconds. Breath KetoChek has one U.S. and two international patents granted. In addition, Akers 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. Specific to the PIFA Heparin tests, the Company has two international patents and one US patent granted in force.

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. Akers has three U.S. patents for this technology covering our Tri-Cholesterol "Check" test.

Sample Preparation Technology

Rapid Blood Cell Separation Technology

Akers' 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. Akers 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 U.S. patents and three international patents.

Product Portfolio

Akers 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, Akers' commercialized and emerging product portfolio incorporates 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.

Akers 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, Akers' 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 for 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 with limited medical infrastructure. 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 its ISO 13485 quality management system ("QMS-Compliant"). Akers 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, identifies 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	Marketed/Pipeline	Not FDA-regulated; QMS-Compliant Only	FDA Clearance Required *Prescription Use/OTC*	FDA Clearance Status Obtained/Needed	Description
BreathScan ™	MPC	Marketed		OTC	Obtained	Disposable breath alcohol detector
BreathScan ® PRO	MPC	Marketed		OTC	Obtained	Quantitative breath alcohol detection system
Breath Diabetic Ketoacidosis ®	MPC	Pipeline		Prescription Use	Needed	Disposable breath ketone device for diabetic monitoring
METRON ®	MPC	Marketed		Health and wellness	n/a	Disposable breath ketone device to monitor ketosis
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
Lync	MPC	Marketed		Health and wellness	n/a	Non-invasive, quantitative measurement of biological markers for health and wellness

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 ®	PIFA	Marketed		Prescription Use	Obtained	Rapid tests for Heparin/PF4 antibodies to detect an allergy to

PF4					the widely used blood thinner, Heparin
PIFA PLUSS ® Chlamydia	PIFA	Pipeline	Prescription Use	Needed	Rapid tests for the most prevalent sexually transmitted disease
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
BreathScan OxiCHek	MPC	Marketed	Health and wellness	n/a	Breath test for oxidative stress using the Lync reader and digital app
BreathScan KetoChek	MPC	Pipeline	Health and wellness	n/a	Breath test for ketosis using the Lync reader and digital app

MPC Biosensor Technology

The Company's MPC Biosensor breath condensate testing platform forms the basis of a number of Akers' 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 U.S. consumers; CE certification is not required to market the product in the EU because BreathScan ® results are not used to diagnose any medical conditions. The Company's breath alcohol detector technology was granted an Australian Standard certification trademark, which cleared the commercial pathway for product sales in Australia, New Zealand, and South Africa.

The Company's disposable breath alcohol detectors are available in versions designed to detect .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 (the "Analyzer"). After two minutes, the Analyzer's sophisticated optics calculate the subject's BAC; the detectable range spans from 0.00% to .15% 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 U.S. 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. Finally, the .02 Breath Alcohol Detection System has been approved to the Conforming Products List by the U.S. Department of Transportation, and may be sold as a compliance tool to the transportation industry.

Since the appropriate regulatory clearances have been obtained in the U.S. and other major markets requiring specific certifications for specific devices (i.e., 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 at this time.

8

Other Emerging MPC Platform Products

The Company's MPC Biosensor technology is being applied to the development of products that serve the nutraceutical, fitness, 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, Akers has used its proprietary, easy-to-use platform to design disposable breath devices that measure ketone (acid) production associated with fat-burning (METRON ® and KetoChek) and oxidative stress levels that relate to cellular damage and the development of many preventable diseases (OxiChek). The Company believes that personalized health and wellness – and eventually personalized medicine – will become an increasingly significant market. The Company is positioning its tests for fitness, weight loss and oxidative stress for this market by designing a more consumer-focused reagent device, and linking this device to an application for smartphones and tablets that can not only produce a result, but also track progress over time. Initial marketing activities have commenced for these products and the Company is preparing for 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 a 510(k) submission is not required for any 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.

Akers is continuing its clinical development of the BreathScan Diabetic Ketoacidosis "Check" disposable breath tube for the diagnosis of ketoacidosis in diabetics. Breath DKA "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 DKA "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.

The Company is also devoting resources to the research and development of the 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. Akers has chosen to target this trio of conditions due to their significant impact on global health:

- 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 worldwide are 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.

Akers 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 Akers 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 KetoChek 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 Breath KetoChek as compliant with the CE requirements in the EU, and intends to pursue the same designation for each product in the Breath PulmoHealth "Check" trio once the appropriate technical file is assembled.

MPC Biosensor technology is currently protected by one United States patents (8,871,521).

PIFA ® *Technology*

The core products marketed under the PIFA ® platform are the PIFA ® Heparin/PF4 Rapid Assay, and the PIFA PLUSS ® PF4.

PIFA ® Heparin/PF4 Rapid Assay and PIFA PLUSS ® PF4 remain the only FDA-cleared rapid manual assays that quickly determine 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. Patients with HIT are at risk of developing limb- and life-threatening complications, so the timely test result provided by Akers' Heparin/PF4 devices is paramount to effective clinical decision making. In the U.S. 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 improves the standard of care in HIT-testing with its result delivered in less than five minutes after the patient sample has been prepared. Traditional methods required the use of expensive equipment, specialized laboratory personnel and 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.

The Company has also 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 Akers' 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 Akers' 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 other 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.

Other PIFA ® Platform Assays in development

The Company can quickly apply the PIFA PLUSS ® methodology to its infectious disease and emergency-related testing products to further consolidate the test result turn-around time and eliminate the need for any specialized sample preparation personnel or equipment. To date, the Company's custom reagent work has focused on a variety of infectious diseases, markers of cardiovascular disease, and blood typing tests including the following:

Chlamydia

Troponin I

ABOD Battlefield Blood Transfusion Card

REA Technology

Akers' 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 access 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. At present, the Company's Tri-Cholesterol "Check" business strategy is to focus on distribution activities to the OTC and walk-in clinic markets in the U.S. and Europe through strategic alliances, such as Alere in the U.S.

The REA Technology is currently protected by three United States patents (8,808,639; 8,003,061; 8,425,859).

Sample Preparation Technology

Rapid Blood Cell Separation Technology

In addition to the Company's testing platforms, Akers' 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. Currently, seraSTAT ® is integrated into PIFA PLUSS PF4 devices, and will be utilized in the infectious disease products currently under development. Akers 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 Akers' 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 Technologies currently protected by two United States patents (7,896,167; 8,097,171) and one international patent (JP 4,885,134).

Competition

Competitors of Akers 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 Akers to develop a working prototype test ready for clinical trials typically ranges from 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;
- devote resources to the development, production, promotion, support and sale of products;
- acquire other companies to gain new technologies or products that may displace our product lines;
- react to changing customer requirements and expectations;
- manufacture, market and sell 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 Akers and may deter such customers from buying Akers' 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 diagnose 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 may relate to exclusive access to specific markets.

Our Current Target Markets

Regarding the Company's test for the heparin drug allergy, the testing market largely resides within the clinical hospital laboratories of medical facilities. 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. Internationally, Akers provides comprehensive training to its distributor partners which will enable them to implement the same selling and technical training strategies.

The markets for alcohol breathalyzers are reached through a network of large and small distributors. These markets include industrial safety, education, law enforcement, social responsibility and retail.

The health and wellness markets include MLM nutraceutical companies, fitness centers and diet and weight loss centers.

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. U.S. 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.

On February 4, 2015, the Company's quality management system was certified as compliant with the International Standards Organization's ("ISO") 13485:2003 requirements for the design, manufacture and distribution of medical devices including in vitro diagnostic products.

Distribution

We distribute our products through direct and indirect channels of distribution. We have well-developed indirect distribution channels in the U.S. with, among others, Cardinal Health 200, Inc. ("Cardinal Health"), Fisher Healthcare, a Division of Fisher Scientific Company L.L.C. ("Fisher Healthcare") and Typenex Medical L.L.C. ("Typenex") for the Company's PIFA Heparin/PF4 assays. The relationships with Cardinal Health and Fisher Healthcare provide us with access to most U.S. hospitals.

With respect to the Company's breath alcohol franchise, historically Akers 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.

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.

Since 2012, the Company has also had a distribution relationship with Novotek Therapeutics Inc. ("Novotek"), a Beijing-based pharmaceutical and *in vitro* diagnostic business development corporation. The multi-year distribution agreement assigns exclusive sales and marketing rights to Novotek to make Akers' Particle ImmunoFiltration Assay ("PIFA") products available in Mainland China and that market clearance has now been obtained.

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 other international markets in the current fiscal year.

During the year ended December 31, 2017 sales to Cardinal Health, Novotek, and Fisher Healthcare accounted for a significant part of the Company's product revenue. This concentration makes the Company vulnerable to a near-term severe impact should the relationships be terminated.

Joint Venture

On October 24, 2014, the Company entered into a Joint Venture Agreement (the "Joint Venture Agreement") by and among the Company, Hainan Savy Investment Management Ltd. ("Hainan") and Mr. Thomas Knox, a member of the Board at that time, to research, develop, produce and sell certain Akers rapid diagnostic screening and testing products in China (the "Joint Venture"). The Joint Venture is located in Shenzhen, China, and is incorporated as Hainan Savy Akers Biosciences, Ltd ("HSAB").

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 Akers 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 U.S. and international utility patents that currently protect Akers 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
breath ketone detector	US	8,871,521	Manufacture	3/8/2031	Breath KetoChek ®
breath ketone detector	Japan	6023906	Manufacture	3/8/2032	Breath KetoChek ®
breath ketone detector	European Union	2684025	Manufacture	3/8/2032	Breath KetoChek ®
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
	US	8,097,171	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
blood separator and method of separating fluid fraction from whole blood	Japan	4,885,134	Manufacture	8/5/2025	seraSTAT ® ; rapid blood cell separator also integrated into PIFA PLUSS ® PF4 and PIFA PLUSS ® Infectious Diseases Rapid Assays
blood cell separator	European Union	1793906	Manufacture	8/5/2025	seraSTAT ® ; rapid blood cell separator also integrated into PIFA PLUSS ® PF4 and PIFA PLUSS ® Infectious Diseases Rapid Assays

Description	Jurisdiction	Utility Patent No.	Type of Protection	Expiration Date	Product(s) To Which They Relate
blood cell separator	Hong Kong	11004006	Manufacture	8/5/2025	seraSTAT ® ; rapid blood cell separator also integrated into PIFA PLUSS ® PF4 and PIFA PLUSS ® Infectious Diseases Rapid Assays
methods for detecting heparin platelet factor 4	US	9,383,368	Manufacture	10/4/2024	PIFA ® Heparin/PF4 Rapid Assay; PIFA PLUSS ® PF4
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
Methods and kits for detecting heparin platelet factor 4 antibodies	Japan	577579	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®
test strip card	US	8,808,639	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.

Akers’ Tri-Cholesterol “Check”, PIFA Heparin/PF4 Rapid Assay, BreathScan PRO alcohol detection system, and the Breath KetoChek are CE-marked for sale in the EU for professional use. The CE-mark must be affixed to a product that is 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 Akers’ 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 a 510(k) clearance will ever be obtained for any product we propose to market. We have obtained the required FDA clearance for all of our current products that require such 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. The PMA approval process is based on 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 a 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 a 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.

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.

Available information

Our website address is *www.akersbio.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.

Employees

We currently employ 32 full-time equivalent employees, contractors or consultants, which include 12 in research and development, 6 in general and administrative, 5 in sales and marketing and 9 in direct and indirect manufacturing. 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.

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 attributable to common shareholders in most reporting periods since our inception. Our net loss for the years ended December 31, 2017 and 2016 were $7,366,310 and $3,303,538, respectively. Our accumulated deficit at December 31, 2017 was $104,845,847. The Company's go-to-market strategy has been developed to guide the Company to profitability in the near term. We believe Akers Biosciences is properly funded and positioned to realize this goal. There are however no guarantees based on unforeseen market conditions or other factors that could compromise the Company's projected outcomes.

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, 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 ongoing operating costs of being a public reporting company. 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, 2017, we had two principal U.S. customers; Cardinal Health, Inc. (“Cardinal Health”) and Fisher Healthcare (“Fisher”) each has the non-exclusive right to distribute PIFA Heparin/PF4 Rapid Assays within the U.S. NovoTek Pharmaceuticals Ltd (“NovoTek”) has exclusive distribution rights to PIFA Heparin/PF4 Rapid Assays in the Peoples Republic of China.

For the year ended December 31, 2017, Cardinal Health, Fisher and NovoTek accounted for approximately 62% of the Company’s product revenue.

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 any of their distribution agreements would materially 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, 2017, three customers accounted for 72% of our trade receivables as compared to the fiscal year ended December 31, 2016 where 15% of trade receivables are attributed to these customers. In the case of insolvency by one of our significant customers, a trade 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. 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. 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; therefore, we expect cash flows from operations to be inadequate to cover our anticipated expenses. We believe we have sufficient capital to satisfy our needs for at least the next twelve 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. If we cannot secure sufficient additional funding we may be forced to forego strategic opportunities and/or delay, scale back or 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 operating 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 and the European Union ("EU"). 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 the 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 a 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 and 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 KetoChek 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. The Company's quality management system received a certification of compliance with the ISO 13485:2003 requirements on February 4, 2015. The Company's quality management system has been re-certified under the annual requirements. The failure by the Company to maintain this certification may limit Akers' ability to obtain foreign regulatory approval on a timely basis, if at all and to do so may cause Akers to incur additional costs or prevent Akers 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. 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, technical, 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 and the ability to offer rebates or higher discounts and incentives. 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, 2017 research and development expense totaled $1,260,378.

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. If 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. These include 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; 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 applicant.

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 a 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 devices 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 a 510(k) clearance of new products;

withdrawing a 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. The Company has aligned its sales resources with the regional sales segmentation of our clinical products distributors. Although this has positively impacted sales, 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 and Fisher Health. Our sales account executives work in tandem with the distributor's 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, 2017 and 2016, 67% and 87%, respectively of total product revenue from the sale of the Company's Heparin/PF4 Assay products was generated through our U.S. distributors' purchases, with Cardinal Health and Fisher accounting for 85% and 63% of such sales for each year ended December 31, 2017 and 2016. 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 internationally. 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 its joint venture partner in mainland China to register several of its products for eventual sale. Since additional clinical studies must be performed by our joint venture 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 products 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 have an adverse effect 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 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 dependent on the management team of Akers Bio to execute against its business plan. Failure 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 USPTO, 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 USPTO. 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 result in the issue of 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.

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 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.

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 the Company 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, allowances 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 shareholders 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 will remain an emerging growth company until the earliest of (i) December 31, 2019 (the end of the fiscal year in which the fifth anniversary of our initial public offering in the U.S. occurred), (ii) the last day of the first fiscal year in which our annual gross revenue exceed $1.07 billion, (iii) 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 (iv) the date on which we have issued more than $1 billion in non-convertible debt during the preceding three-year period.

We have not 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 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, 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, 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.

Regulatory restrictions in the People’s Republic of China for foreign exchange could adversely affect our ability to transact business with our trade partners.

China maintains a ‘closed’ capital account, meaning companies, banks and individuals cannot move money in or out of the country except in accordance with strict rules. Difficulty making payments to key vendors or in receiving payment from trade partners could have material adverse effects on the Company’s business, financial condition and results of operations.

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

If we fail to continue to meet all applicable NASDAQ requirements and NASDAQ determines to delist our common stock, the delisting could adversely affect the market liquidity of our common stock and the market price of our common stock could decrease.

Our common stock is listed on NASDAQ. In order to maintain our listing, we must meet minimum financial and other requirements, including requirements for a minimum amount of capital and a minimum price per share. On November 28, 2017, we received a notice from the staff (the "Staff") of NASDAQ that, for a period of thirty (30) consecutive business days, the bid price of our common stock had closed below the minimum $1.00 per share requirement for continued inclusion under NASDAQ Rule 5550(a)(2) (the "Bid Price Rule"). The notification had no immediate effect on the listing or trading of the common stock on NASDAQ.

NASDAQ stated in its letter that in accordance with the NASDAQ Listing Rules we have been provided an initial period of 180 calendar days, or until May 29, 2018, to regain compliance. The letter states that the Staff will provide written notification that we have achieved compliance with the minimum bid price listing requirement if at any time before May 29, 2018, the bid price of the common stock closes at $1.00 per share or more for a minimum of ten (10) consecutive business days.

If we are unable to regain compliance by May 29, 2018, we may be eligible for an additional 180 calendar day compliance period to demonstrate compliance with the bid price requirement. To qualify, we will be required to meet the continued listing requirement for market value of publicly held shares set forth in Market Place Rule 5550(a) and

all other initial listing standards for NASDAQ set forth in Marketplace Rule 5505, with the exception of the bid price requirement, and will need to provide written notice to NASDAQ of its intention to cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary. If we do not qualify for the second compliance period or fails to regain compliance during the second 180-day period, then NASDAQ will notify us of its determination to delist the common stock, at which point we would have an opportunity to appeal the delisting determination to a Hearings Panel.

We intend to monitor the closing bid price of the common stock and may, if appropriate, consider implementing available options to regain compliance with the minimum bid price requirement under the NASDAQ Listing Rules. If we fail to continue to meet all applicable NASDAQ requirements, NASDAQ may determine to delist our common stock. If our common stock is delisted for any reason, it could reduce the value of our common stock and its liquidity.

If our common stock is delisted as a result of our failure to comply with the Bid Price Rule or any other NASDAQ continued listing requirement, we would expect our common stock to be traded in the over-the-counter market, which could adversely affect the liquidity of our common stock. Additionally, delisting would substantially impair our ability to raise additional funds to fund our operations, to meaningfully advance the development of our products, and we could face other significant material adverse consequences, including:

a limited availability of market quotations for our common stock;

a reduced amount of news and analyst coverage for us;

reduced liquidity for our shareholders;

potential loss of confidence by employees and potential future partners or collaborators; and

loss of institutional investor interest and fewer business development opportunities.

Negotiations are underway with multiple customers for the Company's products and are anticipated to be completed in the near term, but a significant delay will impact revenue projections.

The Company is awaiting a 510(k) approval from the United States Food & Drug Administration ("FDA") for its PIFA Chlamydia product. An extended delay in receipt of this approval will negatively impact revenue projections.

The Company is actively working with the FDA's examiner to insure requests for additional data and responses to questions are completed as quickly as possible.

The market price of our common stock is 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.

Future sales of our common stock, or the perception that future sales may occur, may cause the market price of our common stock to decline, even if our business is doing well.

Sales by our shareholders of a substantial number of shares of our common stock in the public market could occur in the future. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock.

Exercise of options or warrants or conversion of convertible securities may have a dilutive effect on your percentage ownership and may result in a dilution of your voting power and an increase in the number of shares of common stock eligible for future resale in the public market, which may negatively impact the trading price of our shares of common stock.

The exercise or conversion of some or all of our outstanding options, warrants, or convertible securities could result in significant dilution in the percentage ownership interest of investors in this offering and in the percentage ownership interest of our existing common shareholders and in a significant dilution of voting rights and earnings per share.

As of March 16, 2018, we had outstanding warrants to purchase up to 23,308,805 shares of our common stock at a weighted exercise price of $0.27 per share.

Additionally, the issuance of up to 255,000 shares of our common stock upon exercise of stock options outstanding under our stock incentive plans will further dilute our shareholders' voting interests. To the extent options and/or warrants and/or conversion rights are exercised (including with respect to the warrants), additional shares of common stock will be issued, and such issuance will dilute shareholders.

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".

Shareholders 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.

If we fail to establish and maintain an effective system of internal control, we may not be able to report our financial results accurately or prevent fraud. Any inability to report and file our financial results accurately and timely could harm our reputation and adversely impact the trading price of our common stock.

Effective internal control is necessary for us to provide reliable financial reports and prevent fraud. If we cannot provide reliable financial reports or prevent fraud, we may not be able to manage our business as effectively as we would if an effective control environment existed, and our business and reputation with investors may be harmed. As a result, our small size and any current internal control deficiencies may adversely affect our financial condition, results of operations and access to capital.

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.

There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that expressly authorized or required the SEC to adopt additional rules in these areas, such as an advisory shareholder vote to approve of our executives' compensation (or Say on Pay), proxy access, and an advisory shareholder vote on how often we should include a Say on Pay proposal in our proxy materials for future annual shareholder meetings or any special shareholder meeting for which we must include executive compensation information in the proxy statement for that meeting. Our efforts to comply with these requirements are likely to result in an increase in expenses which is difficult to quantify at this time.

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 $250,000 to $350,000 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. 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 12,500 square feet. For the past eleven 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.

The Company executed a lease for a satellite office in Ramsey, New Jersey on June 23, 2017 which is effective through May 31, 2019. The satellite office supports members of executive management and the sales and marketing team with convenient access to resources in the metro New York area.

The Company executed a lease for warehouse space in Pitman, New Jersey on September 19, 2017 which is effective through December 31, 2019. The warehouse will be utilized for the storage of materials utilized in the production of the Company's products. The addition of the warehouse enables the Company to repurpose a portion of the Thorofare facility to support its expanding operations.

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 August 17, 2016, the Company entered into a Settlement Deed (the "Settlement Agreement") by and among the Company, ChubeWorkx Guernsey Limited ("Chube"), Thirty Six Strategies, LLC ("36S"), Gavin Moran ("Mr. Moran") and Frank Runge ("Mr. Runge") (each, a "Party" and, collectively, the "Parties") to resolve disputes related to (i) the Company's claims brought against Chube in United States District Court, District of New Jersey for outstanding amounts due to the Company pursuant to that certain promissory note (the "Note") issued in favor of Chube on December 31, 2014 ("Dispute 1"); (ii) various claims brought by Chube against the Company brought in The High Court of Justice, Queen's Bench Division Commercial Court, Royal Courts of Justice, United Kingdom arising out that certain Licensing and Supply agreement, as amended (the "License Agreement"), pursuant to which Chube was granted a worldwide, exclusive license to import, offer for sale, sell, distribute, use, promote or label certain products using the Company's intellectual property in a suit brought in The High Court of Justice, Queen's Bench Division Commercial Court, Royal Courts of Justice, United Kingdom ("Dispute 2") and (iii) various claims brought by the Company against 36S, Mr. Moran and Mr. Runge in the United States District Court, District of New Jersey, related to that certain Distribution Agreement entered into by and between the Company and 36S on October 5, 2015 ("Dispute 3" and, together with Dispute 1 and Dispute 2, the "Disputes").

Pursuant to the Settlement Agreement, all of the Disputes have been settled and all of the proceedings related to such have been dismissed. Under the terms of the Settlement Agreement, the Company recovered the full outstanding principal amount of the Note during the 2016 fiscal year in the form of $750,000 worth of BreathScan® Alcohol Detector stock to inventory (which the Company intends to subsequently sell) and $500,000 in prepaid royalty (the "Cash Payment"). In addition, the Settlement Agreement also allows the Company to market and sell all of the Company's breath technology tests worldwide, unencumbered by any past and/or future claims by Chube under the Licensing Agreement. Pursuant to the Settlement Agreement, Chube no longer holds any rights pertaining to the Company's BreathScan® technology.

In return for the Company regaining the full rights to sell its breath technology products, among other things, Chube will receive a royalty of 5% of the Company's gross revenues (the "Chube Royalty") totaling $5,000,000, after which Chube will no longer be entitled to receive any royalties and the Company shall have no further obligations to Chube. The Settlement Agreement further allows the Company to retain 50% of the Chube Royalty until the Cash Payment has been made.

In connection with the Settlement Agreement, on August 17, 2016, the Company and Chube entered into a Security Agreement pledging all of the Company's assets including all inventory and receivables (but excluding the specific assets referred to in the Settlement Agreement) in order to secure the Chube Royalty and the pledge as security of the settlement sum which remains unpaid by the Company to Chube all Company (i) distribution contracts of the Company or any of its affiliates, (ii) customer lists, (iii) manufacturing processes (including all intellectual property required to use those processes and exploit products made thereby), and (iv) all equipment required to perform said manufacturing processes and other equipment. Upon payment of the Chube Royalty to Chube the Security Agreement is terminated and the Company's assets become unencumbered.

On October 17, 2016 the Company was served with a notice that Pulse Health LLC ("Pulse") filed a lawsuit against the Company on September 30, 2016 in United States Federal District Court, District of Oregon, alleging a breach of contract under the Settlement Agreement entered into by the Company and Pulse on April 8, 2011 which settled all claims and disputes between the Company and Pulse arising from a previously executed Technology Development Agreement entered into by the Company and Pulse and damages resulting from said alleged breach. Additionally, Pulse alleges false advertising and unlawful trade practices in connection with the Company's sales activities of the Company's OxiChek products. The Company disputes such allegations. The lawsuit is in an early stage and the Company intends to vigorously defend against all claims.

The Company filed a series of motions with the Court seeking (1) to dismiss the Pulse complaint for lack of jurisdiction or, in the alternative, transfer the matter to the District Court for the District of New Jersey, Camden Vicinage and (2) to dismiss the unfair competition claims for failure to state a claim – on which relief could be granted.

The Company filed a series of motions with the Court seeking (1) to dismiss the Pulse complaint for lack of jurisdiction or, in the alternative, transfer the matter to the District Court for the District of New Jersey, Camden Vicinage and (2) to dismiss the unfair competition claims for failure to state a claim on which relief could be granted. Oral arguments on these motions were heard by the Court on March 10, 2017.

The Court decided by order dated April 14, 2017 in favor of the Company and has dismissed with prejudice the claims brought by Pulse for unfair competition (both federal and state counts). The court decided against the Company in its motions for transfer of venue and for lack of jurisdiction. As such, the case shall proceed in the District Court of Oregon.

Pulse subsequently filed an Amended Complaint, in which Pulse seeks not less than $500,000 in damages and, among other items, an injunction prohibiting the Company from manufacture, use and sale of the OxiChek product. The Company answered the Amended Complaint on May 11, 2017. Discovery concluded on January 22, 2018. The Court has received the Company’s summary judgment motion. A trial date may be set if Pulse’s last remaining claim for breach of contract survives the motion.

The Company intends to establish a rigorous defense of all claims. The Company is unable to assess the potential outcome, so no accrual for losses was made as of December 31, 2017. All legal fees were expensed as and when incurred.

With the exception of the foregoing, we are not currently involved in any litigation that we believe could have a materially adverse effect on our financial condition or results of operations. There is no action, suit, proceeding, inquiry or investigation before or by any court, public board, government agency, self-regulatory organization or body pending or, to the knowledge of the executive officers of our Company, threatened against or affecting our Company or our common stock, in which an adverse decision could have a material adverse effect.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Shareholder 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 on NASDAQ, for our shares since for each fiscal quarter for the two most recent fiscal years. Market prices for our shares have fluctuated significantly since they were listed on NASDAQ and trading volume on NASDAQ have been very small in relation to the number of our total outstanding shares.

Quarter ended	Low Price	High Price
Through March 16, 2018	$0.12	$0.88
December 31, 2017	0.12	1.82
September 30, 2017	0.70	1.30
June 30, 2017	1.15	2.10
March 30, 2017	1.15	2.90
December 31, 2016	1.55	3.60
September 30, 2016	2.47	3.70
June 30, 2016	1.43	3.50
March 31, 2016	1.08	2.47
December 31, 2015	1.12	3.73
September 30, 2015	2.27	4.54
June 30, 2015	3.65	5.28
March 31, 2015	3.08	4.85

The following table shows the high and low market prices per share of our common stock on AIM 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.

	Low Price		High Price		Exchange
Quarter Ended	GBP	USD	GBP	USD	Rate
Through March 16, 2018	£0.15	$0.21	£0.60	$0.83	1.3880
December 31, 2017	0.15	0.20	0.85	1.12	1.3227
September 30, 2017	0.65	0.85	1.02	1.34	1.3092
June 30, 2017	0.90	1.15	1.50	1.92	1.2788
March 30, 2017	0.86	1.07	1.90	2.35	1.2388
December 31, 2016	1.45	1.80	2.55	3.17	1.2429
September 30, 2016	1.94	2.55	2.55	3.35	1.3127
June 30, 2016	1.05	1.51	2.15	3.08	1.4344
March 31, 2016	0.79	1.13	1.50	2.15	1.4324
December 31, 2015	0.83	1.26	2.09	3.17	1.5173
September 30, 2015	1.41	2.18	2.83	4.38	1.5492
June 30, 2015	2.60	3.98	3.30	5.06	1.5320
March 31, 2015	2.10	3.18	2.83	4.29	1.5146

* 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 16, 2018, there were approximately 16,500 holders of record of our common stock. This figure does not include 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, 2017.

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	-	$ -	1,054,893
Equity compensation plans not approved by security holders	255,000	$ 4.25	7,292
Total	255,000	$ 4.25	1,062,185

43

Transfer Agent

Our transfer agent is VStock Transfer LLC, 18 Lafayette Place Woodmere, NY 11598.

Recent Sales of Unregistered Securities

During the year ended December 31, 2017, we have not issued any securities which were not registered under the Securities Act and not previously disclosed in the Company's Quarterly Reports on Form 10-Q or Current Reports on Form 8-K.

Rule 10B-18 Transactions

During the year ended December 31, 2017, 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.

Restatement of Previously Issued Financial Statements

As previously disclosed, we determined that certain revenue transactions did not qualify for revenue recognition under generally accepted accounting principles. In the process of this determination, we discovered information that existed at December 31, 2017 which affected the revenue, certain obligations and the value of certain inventory items reported in the year ended December 31, 2017. We concluded that the impact of applying corrections for these errors and misstatements on the consolidated financial statements as of and for the year ended December 31, 2017 is material. As a result, we are restating our consolidated financial statements as of and for the year ended December 31, 2017. See Note 2 to the Consolidated Financial Statements included in Item 8 for additional information and a reconciliation of the previously reported amounts to the restated amounts.

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 $23,562,181, net of expenses, in public and private offerings since the Company’s initial public offering on the NASDAQ Stock Exchange in 2014. The Company continues to experience recurring losses and negative cash flows from operations. 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;
- Build strategic partnerships within our health and wellness product platform within the multi-level marketing segment;
- 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 preserve our cash position.

Despite our plans, the Company expects to continue to incur losses from operations for the near-term:

- the Company continues to incur expenses related to the initial commercialization and marketing activities for its Wellness products, 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 and sales support programs to increase brand awareness.

At December 31, 2017, Akers had cash of $438,432, working capital of $5,990,862, shareholders’ equity of $7,552,853 and an accumulated deficit of $104,845,847. The Company believes that its current working capital position will be sufficient to meet its estimated cash needs for at least the next twelve months.

The fair value of the Company’s investments in marketable securities as of December 31, 2017 was $5,011,607 (2016: $50,001). The Company restricts its investments to Level I and Level II securities and maturities generally range up to three years. Securities are evaluated with an emphasis on minimizing risk while achieving reasonable rates of return on the investment. These marketable securities are a key component of the Company’s cash management strategy and as such are monitored regularly.

Revenue

The Company’s total revenue for the year ended December 31, 2017 was $3,354,712 a 13% increase compared to the same period in 2016. The table below presents a summary of our sales by product line:

Product Line	Year Ended December 31, 2017 **(restated)**	Year Ended December 31, 2016	Percent Change	
Particle ImmunoFiltration Assay (“PIFA”)	$2,232,684	$2,577,148	(13	)%
MicroParticle Catalyzed Biosensor (“MPC”)	381,228	282,516	35	%
Rapid Enzymatic Assay (“REA”)	133,848	-	-	%
Other	556,952	97,498	471	%
Product Revenue Total	$3,304,712	$2,957,162	12	%
License & Service Fees	50,000	3,750	1,233	%
Total Revenue	$3,354,712	$2,960,912	13	%

Product revenue increased by 12% to $3,304,712 (2016: $2,957,162) during the year ended December 31, 2017. The Company's PIFA Heparin/PF4 Rapid Assay products generated the majority of the product revenue but the growth was driven primarily by sales of BreathScan Alcohol Breathalyzers, BreathScan OxiChek™ and the Company's re-introduced Tri-Cholesterol products. License and service fees increased to $50,000 (2016: $3,750), the result a fee from a potential customer for the Company's BreathScan OxiChek™ products in exchange for the use of equipment, access to product documentation and data, technical support and to restrict the Company from actively pursuing another commercial partner in a specific market segment.

Revenue from the Company's PIFA Heparin/PF4 Rapid Assay products decreased 13% to $2,232,684 (2016: $2,577,148) during the year ended December 31, 2017 over the same period of 2016. Additional revenue from PIFA -related components, totaling $500,000, during the year ended December 31, 2017 is included in other revenue. The Company is taking steps to improve its market presence including the use of specialized Independent Sales Representatives and a program to educate the marketplace through the preparation and publication of additional clinical studies and physician seminars on the risks associated with heparin induced thrombocytopenia.

The Company's dedicated technical sales account executives are supporting over 300 sales representatives of Akers' U.S. distribution partners, Cardinal Health ("Cardinal Health"), Fisher HealthCare ("Fisher Healthcare") and Typenex Medical, LLC ("Typenex"). The Company's relationship-building initiative with our partners has delivered a measurable increase in product trials and adoptions. Domestic sales for the year ended December 31, 2017 of our distributors, Cardinal Health and Fisher HealthCare, accounted for $1,902,606 of the total PIFA Heparin/PF4 Rapid Assay sales as compared to $1,820,186 for the same period of 2016.

During the year ended December 31, 2017 the Company recognized $- (2016: $505,380) in PIFA revenue from the Company's distribution partner in the People's Republic of China ("PRC"). During the year ended December 31, 2017, NovoTek purchased PIFA components totaling $500,000 which is included in other revenue. NovoTek will utilize these components along with additional materials to be purchased in a future period to assemble PIFA Heparin/PF4 products in either the PRC or Poland.

The Company's MPC product sales increased by 35% to $381,228 (2016: $282,516) during the year ended December 31, 2017. New distributors for the Company's BreathScan Alcohol Breathalyzer products in Australia, New Zealand and Sri Lanka and the Company's new BreathScan Lync™ and BreathScan OxiChek™ products contributed to the increase for the year ended December 31, 2017.

Demand for the BreathScan Breath Alcohol products is beginning to re-emerge in Western Europe, Australia and the Far East through the efforts of our Independent Manufacturing Representative ("IMR") in Italy working in conjunction with our Corporate staff. The Company expects this trend to continue as the distribution partners in these areas continue to expand their markets.

The Company's re-introduction of its Tri-Cholesterol test generated $133,848 (2016: $-) during the year ended December 31, 2017. The first shipment of this product occurred in September with follow-on shipments in December of 2017.

Revenue from other product lines increased by 471% to $556,952 (2016: $97,498) for the year ended December 31, 2017. The product group consists of fees received for shipping and handling and the sale of components. The significant increase resulted from an initial order, as explained above, for manufacturing components from NovoTek totaling $500,000.

License and service fee revenue increased to $50,000 (2016: $3,750) during the year ended December 31, 2017. The Company received a non-refundable $50,000 fee from a potential customer for the Company's BreathScan OxiChek™ products in exchange for the use of equipment, access to product documentation and data, technical support and to restrict the Company from actively pursuing another commercial partner in a specific market segment.

The table below summarizes our revenue by geographic region for the years ended December 31, 2017 and 2016 as well as the percentage of change year-over-year:

Geographic Region	Year Ended December 31, 2017 (restated)	Year Ended December 31, 2016	Percent Change	
United States	$2,679,549	$2,330,723	15	%
People's Republic of China	502,131	502,998	-	%
Rest of World	173,032	127,191	36	%
Total Revenue	$3,354,712	$2,960,912	13	%

Domestic sales represent the most significant portion of the Company's revenue, contributing 80% (2016: 79%). The primary sales and marketing efforts are concentrated on expanding the Company's domestic market share in the rapid clinical diagnostic and health and wellness segments and the recent introduction of the Tri-Cholesterol test has allowed the Company to re-enter the retail market.

Revenue from China continues to be highly unpredictable. NovoTek Pharmaceuticals ("NovoTek"), our distribution partner for the PIFA Heparin/PF4 Rapid Assay products, continues to pursue approvals for reimbursement rates from the various Provinces and although they anticipate receipt of these approvals, their timing is unknown. Over the past several years, NovoTek has created significant product demand by identifying and working with the key opinion leaders and seeding the marketplace with sample products. As a result, they anticipate strong demand for the PIFA Heparin/PF4 Rapid Assay product once reimbursement rates are approved.

Revenue from the rest of the world consists mostly of the BreathScan Alcohol Breathalyzer products being distributed in Western Europe and Australia.

Cost of sales for the year ended December 31, 2017 totaled $2,406,132 (2016: $1,083,087). Direct cost of sales increased to 19% (2016: 15%) and indirect cost of sales increased to 54% (2016: 21%) of product revenue for year ended December 31, 2017. Overall, cost of sales, as a percentage of product revenue, increased to 73% for the years ended December 31, 2017 and 2016.

Direct costs of sales for the year ended December 31, 2017 were $612,828 (2016: $448,240). Other cost of sales for the year ended December 31, 2017 were $1,793,304 (2016: $634,848).

The initial commercial production of the Company’s Tri-Cholesterol product contributed to the increase in direct costs. One-time costs associated with the transition from Research and Development to Manufacturing as the production plans were implemented and adjusted included engineering, raw material waste as processes were fine-tuned to meet commercial production levels, training of the production staff and increased quality review and testing. The inclusion of several of the Research and Development department’s professional staff as part of the initial production team significantly increased direct labor costs.

Indirect costs were significantly affected by management’s decision to establish a reserve for obsolescence of $1,182,400 for breathalyzer materials produced for the French market during 2013 and 2014 and most of the materials re-acquired as part of the ChubeWorkx settlement agreement in August 2016. The Company has determined that the market for this configuration of the BreathScan Breathalyzer is limited and that existing inventory levels are excessive given the products expiry and projected run rate.

The Company’s gross margin was 28% (2016: 63%) for the year ended December 31, 2017.

General and Administrative Expenses

General and administrative expenses in the year ended December 31, 2017 totaled $4,082,313, which was a 36% increase as compared to $3,008,811 for the year ended December 31, 2016. The table below summarizes our general and administrative expenses for the years ended December 31, 2017 and 2016 as well as the percentage of change year-over-year:

Description	Year Ended December 31, 2017	Year Ended December 31, 2016	Percent Change	
Personnel Costs	$1,173,964	$886,294	32	%
Professional Service Costs	1,358,354	885,746	53	%
Stock Market & Investor Relations Costs	435,937	441,453	(1	)%
Other General and Administrative Costs	1,114,058	795,318	40	%
Total General and Administrative Costs	$4,082,313	$3,008,811	36	%

Personnel costs rose 32% to $1,173,964 (2016: $886,294) for the year ended December 31, 2017. The increase is the result of changes to compensation for the Chief Executive Officer and Vice President of Finance, including base salaries, bonus and equity, and the establishment of a Financial Controller position to support daily operations and assist in the implementation of revised internal and disclosure controls.

Professional service costs increased by 53% for the year ended December 31, 2017 as compared to the same period of 2016. A significant increase in accounting and audit ($258,578 (2016: $182,396)), personnel recruitment ($43,298 (2016: $409)), engineering ($94,472 (2016: $73,405)), legal fees ($899,032 (2016: $613,159)) and general consulting services ($62,975 (2016: $10,138)) accounted for the change.

The Company recognized a small cost savings of 1% for the year ended December 31, 2017 from its stock market and investor relations categories. These include consulting, investor relations, stock exchange fees and transfer agent fees.

The Company's other general and administrative expenses increased by 40% for the year ended December 31, 2017 as compared to the same period of 2016. The Company recognized $494,436 (2016: $146,196) for uncollectable accounts during the year ended December 31, 2017 which were offset by continued efforts to reduce costs resulting in savings across several expense categories, the most significant of which resulted from a reduction in travel expenses for the executive and administrative staff totaled $49,155 (2016: $118,980).

Sales and Marketing Expenses

Sales and marketing expenses in the year ended December 31, 2017 totaled $2,048,571, which was a 4% decrease as compared to $2,137,282 for the year ended 2016. The table below summarizes our sales and marketing expenses for the years ended December 31, 2017 and 2016 as well as the percentage of change year-over-year:

Description	Year Ended December 31, 2017	Year Ended December 31, 2016	Percent Change
Personnel Costs	$1,106,313	$1,129,722	(2)%
Professional Service Costs	256,611	441,632	(42)%
Royalties and Commission Costs	323,817	225,159	44 %
Other Sales and Marketing Costs	361,830	340,769	6 %
Total Sales and Marketing Costs	$2,048,571	$2,137,282	(4)%

Personnel costs decreased 2% in the year ended December 31, 2017 as compared to the same period of 2016. The Company has reduced its sales and marketing staff from 10 members on January 1, 2016 to 5 as of December 31, 2017. The new sales and marketing strategy targets large integrated delivery networks instead of individual facilities. This strategy requires fewer, but more experienced and technically knowledgeable sales personnel to interact with executive management, laboratory and medical directors.

The Company renegotiated or eliminated several consulting arrangements during the years ended December 31 2017 and 2016. The result is a reduction of 42% in professional service fees. General consulting services ($256,450 (2016: $390,386)) and marketing services ($161 (2016: $51,246)) accounted for the savings for the year ended December 31, 2017.

The legal settlement with ChubeWorkx Guernsey, Ltd ("ChubeWorkx"), signed on August 11, 2016, requires the Company to pay a 5% royalty on adjusted gross sales to ChubeWorkx on a quarterly basis. During the year ended December 31, 2017, this royalty totaled $202,126 (2016: $153,854).

The Company has launched an awareness campaign directed at surgeons, pathologists and laboratory and medical directors regarding the risks associated with heparin induced thrombocytopenia (“HIT”) and a campaign directed at health and wellness professionals to introduce the BreathScan Lync™ and OxiChek™ products. In support of the health and wellness project, the Company produced an infomercial in coordination with Balancing Act that aired on May 8, 2017. Expenses related to the production, which occurred in February 2017, totaled $54,700.

Research and Development

Research and development expenses in the year ended December 31, 2017 totaled $1,260,378, which was a 6% increase as compared to $1,188,868 for the year ended 2016. The table below summarizes our research and development expenses for the years ended December 31, 2017 and 2016 as well as the percentage of change year-over-year:

Description	Year Ended December 31, 2017	Year Ended December 31, 2016	Percent Change	
Personnel Costs	$954,632	$745,326	28	%
Professional Service Costs	123,942	113,807	9	%
Clinical Trial Costs	2,453	160,405	(98	)%
Other Research and Development Costs	179,351	169,330	6	%
Total Research and Development Costs	$1,260,378	$1,188,868	6	%

Personnel costs increased 28% during the year ended December 31, 2017 as compared to the same period of 2016. The increase is the result of changes to the compensation for the Chief Scientific Director as he assumed his new expanded responsibilities for the Company.

Clinical trial costs decreased 98% during the year ended December 31, 2017 as compared to the same period of 2016. The Company performed two clinical trials during the year ended December 31, 2016, one to test the effectiveness of the PIFA Chlamydia assay and one for Breath DKA. The trials collected data to support submissions to the U.S. Food and Drug Administration for 510(k) approvals and to support the clinical effectiveness of the products.

A reduction in general consulting services ($39,503 (2016: $71,844)) was offset by an increase in engineering and product design fees ($78,779 (2016: $41,962)) for the year ended December 31, 2017 resulting in a 9% increase in professional service fees.

Moderate decreases in several expense categories were offset by increases in internal resource utilization ($19,176 (2016: $8,595)) and travel expenses ($40,799 (2016 $29,561)) to account for the 6% increase in other research and development expenses.

The following table illustrates research and development costs by project for the years ended December 31, 2017 and 2016, respectively.

	2017	**2016**
Asthma/pH	$52,368	$-
BreathScan	6,885	1,483
Chlamydia Trachomatis	235,803	35,808
H/PF4	67,487	104,436
Diabetic Ketoacidosis	7,154	3,098
KetoChek / OxiChek	461,116	584,585
Metron	1,098	5,832
Other Projects	60,280	149,673
Pulmo Health	11,361	22,069
SeraSTAT	5,610	-
Tri Cholesterol	351,216	281,884
Total R&D Expenses:	$1,260,378	$1,188,868

(Reversal of Allowance for) Bad Debt Expense – Related Party

The Company established an allowance for doubtful accounts for $1,299,609 for a note receivable – related party as a result of an internal assessment indicating a high level of risk of collectability as of December 31, 2015. In August 2016, the two companies reached a settlement agreement which included recovery for the value of the note receivable. As a result, the allowance for doubtful accounts was reversed during the year ended December 31, 2016.

Other Income and Expense

Other income decreased 51% to $12,412 (2016: $25,097) and other expenses totaled $764,932 (2016: $-) for the year ended December 31, 2017. The table below summarizes our other income and expenses for the years ended December 31, 2017 and 2016 as well as the percentage of change year-over-year:

Description	Year Ended December 31, 2017	Year Ended December 31, 2016	Percent Change
Currency Translation Gain	$ (1,659)	$ (3,398)	(51)%
Investment (Gain)/Loss	(3,375)	85	4,071 %
Interest and Dividends	(7,378)	(21,784)	(66)%
Warrant Modification Expenses	764,932	-	- %
Total Other (Income) and Expense	$ 752,520	$ (25,097)	(3,098)%

Gains and losses associated with foreign currency transactions decreased by 51% during the year ended December 31, 2017 as compared to the same period of 2016, primarily a result of the increased strength of the British Pound compared to the US Dollar during 2017.

Realized gains, interest and dividend income declined to $10,753 (2016: $21,699). The Company’s available capital for investment activities was limited during the year ended December 31, 2017 resulting in the decline in investment income.

The Company modified the exercise price for 724,200 warrants issued March 30, 2017 from $1.96 to $1.00 per common share and issued an additional 724,200 warrants to the original holders at an exercise price of $1.26 per common share to raise additional capital. The Company incurred warrant modification expenses of $764,932, which includes the increase in the fair value of the warrants of $93,386 for the reduction in exercise price from $1.96 to $1.00 and the fair value of the new warrants of $671,546 in accordance with FASB ASC 718-20-35.

Income Taxes

As of December 31, 2017 and 2016, the Company had Federal net operating loss carry forwards of approximately $69,001,000 and $60,100,000, respectively, expiring through the year ending December 31, 2036. As of December 31, 2017 and 2016, the Company had New Jersey state net operating loss carry forwards of approximately

$18,168,000 and $9,400,000, respectively, expiring the year ending December 31, 2023.

The principal components of deferred tax assets and valuation allowance as of December 31, 2017 and December 31, 2016 are as follows:

Tax Rates & Benefits

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, 2017 and December 31, 2016 are as follows.

	Years Ended December 31,	
	2017 (restated)	2016
Statutory U.S. Federal Income Tax Rate	(35.0 %)	(35.0%)
New Jersey State income taxes, net of U.S. Federal tax effect	(6.0 %)	(6.0 %)
Tax rate change	122.0%	0.0 %
Change in Valuation Allowance	(81.0)%	41.0 %
Net	0.0 %	0.0 %

In December 2017, the Tax Cuts and Jobs Act was enacted, which reduced the U.S. statutory corporate tax rate to 21% for tax years beginning in 2018. This change resulted in a re-measurement of the federal portion of the Company's deferred tax assets and the valuation allowance as of December 31, 2017 from 35% to the new 21% tax rate.

Deferred Tax Assets

The principle components of the deferred tax assets and related valuation allowances as of December 31, 2017 and 2016 are as follows:

	Year Ended December 31,	
	2017 (restated)	2016
Reserves and other	$718,000	$865,000
Net operating loss carry-forwards	$15,762,000	$21,618,000
Valuation Allowance	$(16,480,000)	$(22,483,000)
Net	$-	$-

The valuation allowance for deferred tax assets as of December 31, 2017 and 2016 was $16,480,000 and $22,483,000. The change in the total valuation for the years ended December 31, 2017 and 2016 were a decrease of $6,003,000 and an increase of $751,000. 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.

Liquidity and Capital Resources

For the years ended December 31, 2017 and 2016, the Company generated a net loss attributable to shareholders of $7,366,310 and $3,303,538, respectively. As of December 31, 2017 and 2016, the Company has an accumulated deficit of $104,845,847 and $97,479,537 and had cash and cash equivalents totaling $438,432 and $72,700, respectively The Company had marketable securities of $5,011,607 and $50,001 available as of December 31, 2017 and 2016.

Currently, our primary focus is to expand the domestic and international distribution of our PIFA Heparin/PF4 rapid assays. The Company continues initial commercialization tasks for METRON and BreathScan Lync, as well as development activities for its PIFA PLUSS® Infectious Disease single-use assays, BreathScan KetoChek, 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. These losses could be attributed to product development, clinical and regulatory activities, contract consulting and other product development and commercialization related expenses. The Company began implementing the 2017-19 Strategic Plan (“Strat Plan”) in January 2017 and management remains confident that the objectives are achievable.

We expect that our primary expenditures will be to continue development of PIFA PLUSS® Infectious Disease single-use assays, BreathScan KetoChek 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 BreathScan Lync) in the U.S. 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.

Capital expenditures, primarily for production, laboratory and facility improvement costs for the year ending December 31, 2017 totaled $54,507 (2016: $123,301). 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.

51

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. The Company executed a lease for a satellite office in Ramsey, New Jersey on June 23, 2017 which is effective through May 31, 2019. The satellite office supports members of executive management and the sales and marketing team with convenient access to resources in the metro New York area. 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

The Company's net cash consumed by operating activities in the year ended December 31, 2017 totaled $5,080,412, which was a 22% increase as compared to $4,173,148 for the year ended December 31, 2016. The table below summarizes our net cash consumed for the years ended December 31, 2017 and 2016 as well as the percentage of change year-over-year:

Description	Year Ended December 31, 2017 (restated)	Year Ended December 31, 2016	Percent Change
Loss from Operations	$(7,366,310)	$(3,303,538)	123 %
Adjustments			
Non-Cash Activities	2,977,645	(738,868)	(343)%
Cash Used in Operating Activities			
Cash Consumed by Operating Activities	(1,136,539)	(531,220)	91 %
Cash Contributed by Operating Activities	444,792	400,478	276 %
Net Cash Used in Operating Activities	$(5,080,412)	$(4,173,148)	(22)%

Net cash consumed by operating activities totaled $5,080,412 during the year ended December 31, 2017. Cash was consumed by the loss of $7,366,310 and $1,412 for accrued income on marketable securities offset by non-cash adjustment of $249,894 for depreciation, amortization of non-current assets, $1,208,522 for a reserve for obsolete inventory, $450,000 reserve for doubtful accounts, $21,103 for amortization of deferred compensation and $284,606

for non-cash share based compensation and services. For the year ended December 31, 2017, decreases in deposits and other receivables of $7,192, prepaid expense of $22,789, prepaid expense – related parties of $101,066, decrease in trade receivables – related parties of $31,892, and an increase in trade and other payables of $281,853 provided cash, primarily related to routine changes in operating activities. A net increase in inventory of $119,613, trade receivables of $813,400, and other assets of $9,280 and a decrease in trade and other payables – related party of $194,246 consumed cash from operating activities.

For the year ended December 31, 2016, cash was consumed by the loss of $3,303,538 and non-operating gains of $1,153,413 offset by a non-cash adjustment of $14,244 for accrued interest and dividends, $286,162 for depreciation, amortization of non-current assets, $32,333 for a reserve for obsolete inventory, $30,153 for amortization of deferred compensation and $51,653 for non-cash share based compensation and services. Decreases in deposits and other receivables ($71,795), prepaid expenses ($17,689), prepaid expenses – related party of ($76,927) and an increase in trade and other payables – related party ($234,067) provided cash. Increases in trade receivables ($138,272), trade receivables – related party ($380), inventories ($187,200) and a decrease in trade and other payables ($205,368) consumed cash. The decrease in net cash used in operating activities was related to improvements to the Company’s budgeting process, termination of several consulting agreements and a significant reduction in legal expenses.

Investing and Financing Activities

The table below summarizes our cash flows from investing and financing activities for the years ended December 31, 2017 and 2016 as well as the percentage of change year-over-year:

Description	Year Ended December 31, 2017	Year Ended December 31, 2016	Percent Change	
Cash Flows from Investing Activities				
Cash Consumed by Investing Activities	(7,763,848)	(159,245)	4,775	%
Cash Contributed by Investing Activities	2,749,147	4,003,034	(31	)%
Cash Flows from Financing Activities				
Cash Consumed by Financing Activities	-	-	-	%
Cash Contributed by Financing Activities	10,460,845	-	-	%

The Company's net cash provided by investing and financing activities totaled $5,446,144 (2016: $3,843,789) during the year ended December 31, 2017. Cash of $7,763,848 (2016: $159,245) was consumed by capital expenditures and the purchase of marketable securities. Proceeds from the sale of marketable securities contributed cash of $2,749,147 (2016: $4,003,034) and net proceeds from the public and private placements of common and Series B preferred stock and the exercise of warrants for common stock contributed $10,460,845 (2016: $-) for the year ended December 31, 2017.

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.

Fair Value Measurement – Marketable Securities:

The framework for measuring fair value provides a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (level 1) and the lowest priority to unobservable inputs (level 3). The three levels of the fair value hierarchy under FASB ASC 820 are described as follows:

Level 1	Inputs to the valuation methodology are unadjusted quoted prices for identical assets or liabilities in active markets that the Company has the Ability to access.
Level 2	Inputs to the valuation methodology include quoted prices for similar assets or liabilities in active markets; quoted prices for identical or similar assets or liabilities in inactive markets; inputs other than quoted prices that are observable for the asset or liability; inputs that are derived principally from or corroborated by observable market data by correlation or other means. If the asset or liability has a specified (contractual) term, the level 2 input must be observable for substantially the full term of the asset or liability.
Level 3	Inputs to the valuation methodology are unobservable and significant to the fair value measurement.

The asset or liability's fair value measurement level within the fair value hierarchy is based on the lowest level of input that is significant to the fair value measurement. Valuation techniques maximize the use of relevant observable inputs and minimize the use of unobservable inputs.

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. 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.

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. As of December 31, 2017, the Company has eleven patents from the United States Patent Office in effect (9,383,368; 7,896,167; 8,097,171; 8,003,061; 8,425,859; 8,871,521; 8,808,639; D691,056; D691,057; D691,058 and D786,872). Other patents are in effect in Australia through the Design Registry (348,310; 348,311 and 348,312), European Union Patents 1793906, 2684025, 002216895-0001; 002216895-0002; 002216895-0003; 3459700-0001 and 3459395-001), United Kingdom and France (2684025), Germany (602012021524.0), Spain (E12755523), China (2016305495829), in Hong Kong (HK11004006) and in Japan (1,515,170; 4,885,134; 4,931,821 5,775,790, and 6023096). 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 US, 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.

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.

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. In cases where the right of return is granted and the Company does not have historical experience to reasonably estimate the sales returns, the revenue is recognized when the return privilege has substantially expired.

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.

New Revenue Recognition Standards

In May 2014 and April 2016, the FASB issued ASU No. 2014-09 and ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606). The core principle of the guidance is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In August 2015, FASB issued ASU 2015-14 which deferred the effective date of Update 2014-09 to annual reporting periods beginning after December 15, 2018 and interim reporting periods within annual reporting periods beginning after December 15, 2019. Early application is permitted as of annual reporting periods beginning after December 15, 2016 including interim reporting periods within that reporting period. The Company is currently evaluating the effect of the amendments but it does not anticipate a material impact of its financial statements. The Company expects to use the modified retrospective adoption method.

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.

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.

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-33 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

The Company maintains “disclosure controls and procedures”, as such terms are defined under Exchange Act Rule 13a-15(e), that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Principal Accounting Officer, as appropriate, to allow timely decisions regarding required disclosures. The Company acknowledges that any controls and procedures can provide only reasonable assurances of achieving the desired control objectives.

We have carried out an evaluation as required by Rule 13a-15(d) under the supervision of and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedure as of December 31, 2017. Based upon their evaluation, the Chief Executive Officer and Principal Accounting Officer concluded that, as of December 31, 2017, the Company’s disclosure controls and procedures were not effective. Although we have determined that the existing controls and procedures are not effective, the deficiencies identified were not initially deemed material to our reporting disclosures.

Subsequent to the initial filing of the Company's annual report on Form 10-K for the year ended December 31, 2017, a special committee of the board of directors of the Company was formed. This special committee engaged independent outside legal counsel who engaged independent outside forensic accountants to assist it with an investigation to gather certain facts relevant to the Company's financial statements. The Audit Committee subsequently identified misstatements relevant to the Company's historical revenue recognition, expense accrual and inventory valuation policies and procedures. These misstatements resulted in a material misstatement of the financial statements and required restatement of the financial statements included in the Company's Form 10-K for the fiscal year ended December 31, 2017 and in the Company's Forms 10-Q for the quarterly periods ended June 30, 2017 and September 30, 2017. These misstatements, which were not detected timely by management, were the result of inadequate design of controls pertaining to the Company's review and ongoing monitoring of its revenue recognition, expense accrual and inventory valuation policies. The deficiency represents a material weakness in the Company's internal control over financial reporting.

Management is actively engaged in the planning for and implementation of remediation efforts to address the material weakness identified above. The remediation plan includes i) hiring and/or engagement of additional qualified personnel, (ii) the implementation of new controls designed to evaluate the appropriateness of revenue recognition, inventory valuation, and expense recognition policies and procedures, iii) the implementation of review and monitoring of transactions to ensure compliance with the new policies and procedures, and iv) the training of personnel responsible for revenue and inventory.

Management believes the measures described above and others that may be implemented will remediate the material weaknesses that we have identified. As management continues to evaluate and improve internal control over financial reporting, it may decide to take additional measures to address control deficiencies or determine to modify, or in appropriate circumstances not to complete, certain of the remediation measures identified.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect all misstatements or fraud. Any control system, no matter how well designed and operated, is based upon certain assumptions and can provide only reasonable, not absolute, assurance that its objectives will be met.

(b) Management's Report on Internal Controls over Financial Reporting

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Internal control over financial reporting refers to the process designed by, or under the supervision of, our principal executive officer and principal financial officer, and effected by our Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Internal control over financial reporting cannot provide absolute assurance of achieving their objectives. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgement and breakdowns resulting from human failures. Due to their inherent limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. It is possible to design safeguards to reduce, but not eliminate, this risk. Management is responsible for establishing and maintaining adequate internal control over financial reporting for the Company.

Management has used the framework set forth in the report entitled Internal Control—Integrated Framework published by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), known as COSO, to evaluate the effectiveness of our internal control over financial reporting.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. Based on such evaluation, our CEO and Principal Financial Officer have concluded that, as of December 31, 2017, our internal controls over financial reporting were not effective.

Management is actively engaged in the planning for and implementation of remediation efforts to address the material weakness identified above. The remediation plan includes i) hiring and/or engagement of additional qualified personnel, (ii) the implementation of new controls designed to evaluate the appropriateness of revenue recognition, inventory valuation, and expense recognition policies and procedures, iii) the implementation of review and monitoring of transactions to ensure compliance with the new policies and procedures, and iv) the training of personnel responsible for revenue and inventory.

Management believes the measures described above and others that may be implemented will remediate the material weaknesses that we have identified. As management continues to evaluate and improve internal control over financial reporting, it may decide to take additional measures to address control deficiencies or determine to modify, or in appropriate circumstances not to complete, certain of the remediation measures identified.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect all misstatements or fraud. Any control system, no matter how well designed and operated, is based upon certain assumptions and can provide only reasonable, not absolute, assurance that its objectives will be met.

The Company's management is composed of a small number of professionals resulting in a situation where limitations on segregation of duties exists. Accordingly, as a result of the material weakness identified above, we have concluded that the control deficiencies result in a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented on a timely basis by the Company's internal controls. The addition of the

Financial Controller will allow the Company to implement the recommended changes to our internal control procedures that were updated or developed with the assistance of an independent accounting firm in 2015-16. Implementation of these procedures will be completed during 2018.

This annual report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act, which permits us to provide only management's report in this annual report.

(c) Changes in Internal Control over Financial Reporting

Other than the weaknesses as described above, 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
John J. Gormally	61	Chief Executive Officer, Director
Raymond F. Akers, Jr. PhD	59	Executive Chairman of the Board of Directors, Chief Scientific Director, Secretary
Gary M. Rauch	62	Vice President, Finance and Treasurer
Bill J. White	56	Independent Director
Richard C. Tarbox	65	Independent Director
Christopher C. Schreiber	52	Independent Director

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

John J. Gormally, age 61, has served as the Company's Chief Executive Officer since appointed to the position on November 16, 2015. Mr. Gormally has over 30 years of experience as a member of senior management in the healthcare industry. He joined Becton, Dickinson and Company ("Becton"), a medical technology company that manufactures and sells a range of medical supplies and diagnostic equipment, in 1978 as a senior sales representative. Mr. Gormally served in a wide range of positions with Becton through 2013, focusing primarily on commercialization of Becton's products and fostering sales growth. From 1999 to 2001, Mr. Gormally served as the Vice President of U.S. Sales and Operations for ConvaTec, a former division of Bristol-Myers Squibb Company. From 2001 to 2002, he served as the Vice President of Global Sales and Marketing for BEI Medical Systems Company, Inc., prior to rejoining Becton from 2002 to 2013. In 2013, Mr. Gormally founded Gormally Elite Medical LLC, a healthcare consulting firm that specializes in human resources and developing go-to-market commercialization strategies.

Mr. Gormally earned an undergraduate degree from DeSales University in 1978 and is currently an MBA candidate at Northeastern University.

Mr. Gormally was selected to serve on the Board in part because of his significant experience running companies operating in the medical device area.

Raymond F. Akers Jr., Ph.D., age 59, has been Executive Chairman of the Board since August 10, 2017, served as Vice Chairman from April 2016 through August 2017, and served as Executive Chairman from December 31, 2009 through April 2016. Dr. Akers 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 62, has over 40 years of experience in accounting, financial and information systems consulting, discrete manufacturing, distribution and administration. Mr. Rauch has been the Company's Controller then Vice President, Finance 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.

Bill J. White, age 56, has more than 30 years of experience in financial management, operations and business development. He currently serves as Chief Financial Officer, Treasurer and Secretary of Intellicheck Mobilisa, Inc., a technology company listed on the NYSE MKT. Prior to working at Intellicheck Mobilisa, Inc., he served 11 years as the Chief Financial Officer, Secretary and Treasurer of FocusMicro, Inc. ("FM"). As co-founder of FM, Mr. White played an integral role in growing the business from the company's inception to over $36 million in annual revenue in a five-year period. Mr. White has broad domestic and international experience including managing rapid and significant growth, import/export, implementing tough cost management initiatives, exploiting new growth opportunities, merger and acquisitions, strategic planning, resource allocation, tax compliance and organization development. Prior to co-founding FM, he served 15 years in various financial leadership positions in the government sector. Mr. White started his career in Public Accounting.

Mr. White holds a Bachelor of Arts in Business Administration from Washington State University and is a Certified Fraud Examiner.

Mr. White was selected to serve on the Board in part because of his significant financial and accounting experience with public companies.

Richard C. Tarbox III, age 65, combines over 40 years of management experience in the medical device and diagnostics sector of the healthcare industry. Mr. Tarbox presently serves as a registered investment banker at Aquilo Partners, L.P., focusing his practice on the needs of clients in the life science tools and diagnostics sectors. Previously, he held executive roles, primarily in business development and operations management, with Becton Dickinson, Thermo Fisher Scientific and Cardinal Health, Baxter International Inc. and American Hospital Supply Corporation. He has also served a number of companies in the industry as an officer and member of the board of directors including; Alverix, Inc., as Chief Executive Officer and board member from 2010 to 2014, Quidel Corporation, as Corporate Development Officer from 2007 to 2009, ClearData Networks, as Chief Operating Officer and a board member from 1999 to 2001, Bioseparations Inc., as Chief Executive Officer and a board member from 1995 to 1998, Metrika Laboratories, as a board member from 1994 to 1995, DenOptix, Inc., as a board member from 1995 to 1998 and Ostex International Inc., as Chief Operating Officer from 1992 to 1995. Mr. Tarbox currently serves as a member of the advisory boards of Qorvo Inc. and Safeguard Scientifics, Inc.

Mr. Tarbox is a graduate of the University of Washington, where he received his Bachelor’s Degree in Clinical Psychology and the Kellogg School of Management at Northwestern University where he earned a Master’s degree in Business Management.

Mr. Tarbox was selected to serve on the Board in part because of his significant experience in the medical device and diagnostics industry, as well as his management experience.

Christopher C. Schreiber, age 52, combines over 30 years of experience in the securities industry. As the Managing Director of Capital Markets at Taglich Brothers, Inc., Mr. Schreiber builds upon his extensive background in capital markets, deal structures, and syndications. Prior to his time at Taglich Brothers, he was a member of the board of directors of Paulson Investment Company, a 40-year-old full service Investment Banking firm. In addition, Mr. Schreiber serves has a director and partner of Long Island Express North, an elite lacrosse training organization for teams and individuals. He also volunteers on the board of directors for Fox Lane Youth Lacrosse, a community youth program.

Mr. Schreiber is a graduate of Johns Hopkins University, where he received a Bachelor's Degree in Political Science.

Mr. Schreiber was selected to serve on the Board in part because of his significant experience in capital markets and knowledge of the Company.

Family Relationships

There are no family relationships between any of our officers or directors.

Board Composition and Committees and Director Independence

On August 7, 2017, the shareholders of the Company reelected Raymond F. Akers, Jr. Ph.D to the Board and elected John J. Gormally, Bill J. White, Richard C. Tardbox III and Christopher C. Shcreiber as members of the Board. Mr. White, Mr. Tarbox and Mr. Schreiber comprise the Board's Audit Committee, Compensation Committee, and Nominating and Corporate Governance Committee. Mr. White acts as Chairman of the Audit Committee, Mr. Tarbox acts as Chairman of the Nominating and Corporate Governance Committee, and Mr. Schreiber acts as Chairman of the Compensation Committee.

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. Bill J. White, Mr. Richard C. Tar box and Mr. Christopher C. Schreiber 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.

Meetings of the Board of Directors and Shareholders

Our board of directors met in person and telephonically ten times during 2017 and also acted by unanimous written consent. Each member of our board of directors was present at least 75% of the board of directors meetings held. It is our policy that all directors must attend all shareholder meetings, barring extenuating circumstances. All directors were present at the 2017 Annual Meeting of Shareholders, either in person or telephonically.

Board Committees

The Company has established an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee. The Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee met in person and telephonically three times, two times and once, respectively, during 2017, and also acted by unanimous written consents. Each committee has its own charter, which is available on our website at *www.akersbio.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 Mr. White, Mr. Tarbox and Mr. Schreiber. 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 Mr. White is an “audit committee financial expert”, as such term is defined in Item 407(d)(5) of Regulation S-K. Mr. White serves as

Chairman of our Audit Committee. Each member of the Audit Committee was present at 100% of the Audit Committee meetings held during such director's tenure as a member of the Audit Committee.

Our Audit Committee oversees our corporate accounting, financial reporting practices and the audits and reviews of financial statements. For this purpose, the Audit Committee has a charter (which is reviewed annually). As summarized below, the Audit Committee:

- evaluates the independence and performance of, and assesses the qualifications of, our independent auditor and engages such independent auditor;
- approves the plan and fees for the annual audit, quarterly reviews, tax and other audit-related services and approves in advance any non-audit service and fees therefor to be provided by the independent auditor;
- monitors the independence of the independent auditor and the rotation of partners of the independent auditor on our engagement team as required by law;
- reviews the financial statements to be included in our Annual Report on Form 10-K and Quarterly Reports on Form 10-Q and reviews with management and the independent auditors the results of the annual audit and reviews of our quarterly financial statements;
- oversees all aspects of our systems of internal accounting and financial reporting control; and
- provides oversight in connection with legal, ethical and risk management compliance programs established by management and the board, including compliance with requirements of Sarbanes-Oxley and makes recommendations to the board of directors regarding corporate governance issues and policy decisions.

Compensation Committee

The members of our Compensation Committee are Mr. Bill J. White, Mr. Richard C. Tarbox and Mr. Christopher C. Schreiber. 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. Mr. Schreiber will serve 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.

The Compensation Committee has the authority to directly engage, at our expense, any compensation consultants or other advisers as it deems necessary to carry out its responsibilities in determining the amount and form of employee, executive and director compensation.

Nominating and Corporate Governance Committee

The members of our Nominating and Corporate Governance Committee are Mr. Bill J. White, Mr. Richard C. Tarbox and Mr. Christopher C. Schreiber. 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. Tarbox 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 shareholders and nominees to fill vacancies on the board;

considering candidates proposed by shareholders 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.

Management-Non-Executive Director Compensation

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, none of our directors or executive officers has, during the past ten years:

been convicted in a criminal proceeding or been subject to a pending criminal proceeding (excluding traffic violations and other minor offenses);

had any bankruptcy petition filed by or against the business or property of the person, or of any partnership, corporation or business association of which he was a general partner or executive officer, either at the time of the bankruptcy filing or within two years prior to that time;

been subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction or federal or state authority, permanently or temporarily enjoining, barring, suspending or otherwise limiting, his involvement in any type of business, securities, futures, commodities, investment, banking, savings and loan, or insurance activities, or to be associated with persons engaged in any such activity;

been found by a court of competent jurisdiction in a civil action or by the Securities and Exchange Commission or the Commodity Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended, or vacated;

been the subject of, or a party to, any federal or state judicial or administrative order, judgment, decree, or finding, not subsequently reversed, suspended or vacated (not including any settlement of a civil proceeding among private litigants), relating to an alleged violation of any federal or state securities or commodities law or regulation, any law or regulation respecting financial institutions or insurance companies including, but not limited to, a temporary or permanent injunction, order of disgorgement or restitution, civil money penalty or temporary or permanent cease-and-desist order, or removal or prohibition order, or any law or regulation prohibiting mail or wire fraud or fraud in connection with any business entity; or

been the subject of, or a party to, any sanction or order, not subsequently reversed, suspended or vacated, of any self-regulatory organization (as defined in Section 3(a)(26) of the Exchange Act), any registered entity (as defined in Section 1(a)(29) of the Commodity Exchange Act), or any equivalent exchange, association, entity or organization that has disciplinary authority over its members or persons associated with a member.

Except as set forth in our discussion below in “Certain Relationships and Related Transactions,” none of our directors or executive officers has been involved in any transactions with us or any of our directors, executive officers, affiliates or associates which are required to be disclosed pursuant to the rules and regulations of the Commission.

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% shareholders 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 upon a review of copies of Section 16(a) reports and representations received by us from reporting persons, and without conducting any independent investigation of our own, in fiscal year 2017, all Forms 3, 4 and 5 were timely filed with the SEC by such reporting persons, with exceptions of Mr. Bill J. White, Mr. Richard C. Tarbox and Mr. Christopher C. Schreiber, each of which did not file a Form 3, which were each due on August 7, 2017. Mr. Bill J. White, Mr. Richard C. Tarbox and Mr. Christopher C. Schreiber will each file a Form 3 as soon as possible.

Shareholder Communications with Directors

Shareholders and other interested parties may send correspondence by mail to the full Board or to individual directors. Shareholders should address such correspondence to the Board or the relevant Board members in care of: Akers Biosciences, Inc., 201 Grove Road Thorofare, New Jersey USA 08086, Attention: Secretary.

All such correspondence will be compiled by our Secretary and forwarded as appropriate. In general, correspondence relating to corporate governance issues, long-term corporate strategy or similar substantive matters will be forwarded to the Board, one of the committees of the Board, or a member thereof for review. Correspondence relating to the ordinary course of business affairs, personal grievances, and matters as to which we tend to receive repetitive or duplicative communications are usually more appropriately addressed by the officers or their designees and will be forwarded to such persons accordingly.

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 201 Grove Road, Thorofare, New Jersey USA 08086.

Item 11. Executive Compensation.

The compensation provided to our “named executive officers” for 2017 and 2016 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 2017 for each of our named executive officers.

Our named executive officers who appear in the 2017 Summary Compensation Table are:

John J. Gormally	Chief Executive Officer
Raymond F. Akers, Jr., PhD	Vice Chairman, Secretary, Chief Scientific Director
Gary M. Rauch	Vice President of Finance, 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 other most highly compensated executive officers who earned in excess of $100,000 during 2017, 2016 and 2015.

Name and Principal Position	Year	Salary $	Cash Bonus $	Stock Awards $	Option Awards $	All Other $	Total $
John J. Gormally (1)	2017	322,115	50,000	132,000	-	7,800 (2)	511,915
Chief Executive Officer	2016	248,500	-	54,725	-	7,800 (2)	311,025
	2015	24,038	-	-	-	650 (2)	24,688
Gary M. Rauch	2017	111,031	18,900	31,924	-	-	161,855
Vice President of Finance and Treasurer	2016	95,000	-	-	-	-	95,000
	2015	95,000	-	27,675	-	-	122,675
Raymond F. Akers, Jr PhD (3)	2017	288,462	-	-	-	7,800 (4)	296,262
Secretary and Chief Scientific Director	2016	269,231				7,800 (4)	277,031
	2015	397,450	-	256,900	-	7,800 (4)	662,150

(1) Mr. Gormally was appointed as Chief Executive Officer on December 2, 2015.

(2) Other Compensation for Mr. Gormally consisted of a car allowance.

(3) Effective October 5, 2016, the Board approved certain incentive based salary adjustments (the "Salary Adjustments") for Raymond Akers, the Company's Chief Scientific Director and member of the Board. The Salary Adjustments will, upon the achievement of certain milestones by Dr. Akers between October 5, 2016 and December 31, 2016, cause Dr. Akers' salary to increase up to $200,000 above his current salary. Dr. Akers will receive his increased salary on a prorated basis in 2016 only to the extent Dr. Akers achieves said milestones prior to December 31, 2016, each milestone representing a portion of the $200,000 salary increase, and his increased salary will remain in effect going forward.

(4) Other Compensation for Dr. Akers consisted of a car allowance.

Employment Agreements

On December 2, 2015, the Company and John J. Gormally finalized the terms of his employment and entered into an employment agreement (the "Employment Agreement"), pursuant to which Mr. Gormally will serve as the Company's

Chief Executive Officer. Mr. Gormally shall have such duties, responsibilities and authority as are commensurate and consistent with the position of Chief Executive Officer of a public company.

The Company shall pay Mr. Gormally a salary at a rate of Two Hundred Fifty Thousand and 00/100 Dollars ($250,000) per year (the "Base Salary"). On January 31, 2017, pursuant to the terms of the Employment Agreement, the Board adjusted Mr. Gormally's salary to Three Hundred Twenty-Five Thousand and 00/100 Dollars ($325,000) effective as of January 1, 2017. In addition, subject to the discretion of the Company's Compensation Committee and the Board, provided that the Employment Agreement has not been terminated, Mr. Gormally shall be eligible for an annual performance-based cash bonus of up to 100% of the Base Salary (the "Cash Incentive Bonus"). Mr. Gormally shall receive certain grants of the Company's restricted common stock (each an "Incentive Award" and together with the Cash Incentive Bonus, the "Incentive Compensation") on a bi-annual basis, with such awards expected to be made on or about February 15 and August 15 of each year, under the Company's Amended and Restated 2013 Incentive Stock and Award Plan. Each Incentive Award will vest or has vested as follows: (i) 1/3 vested on the date of grant; (ii) 1/3 vest on the first anniversary of the date of grant and (iii) 1/3 shall vest on the second anniversary of the date of grant. The Incentive Awards will be made within the following ranges, in the aggregate, for each such year: (i) for 2016, up to 140,000 shares of restricted common stock, but no less than 27,500 shares of restricted common stock; (ii) for 2017, up to 125,000 shares of restricted common stock, but no less than 25,000 shares of restricted common stock; (iii) for 2018, up to 125,000 shares of restricted common stock, but no less than 25,000 shares of restricted common stock; (iv) for 2019, up to 125,000 shares of restricted common stock, but no less than 25,000 shares of restricted common stock; and (v) for 2020, up to 125,000 shares of restricted common stock, but no less than 25,000 shares of restricted common stock.

The Employment Agreement may be terminated by either party upon thirty (30) days' written notice to the other party or sooner upon the parties' mutual written consent. In the event that Mr. Gormally is terminated without Cause (as defined in the Employment Agreement), including termination pursuant to thirty (30) days' written notice, or Mr. Gormally terminates his employment for Good Reason (as defined in the Employment Agreement) the Company shall pay Mr. Gormally severance in accordance to the following: (i) if the date of termination is prior to the four month anniversary of the effective date of the Employment Agreement (the "Four Month Anniversary"), Mr. Gormally shall receive no severance; (ii) if the date of termination is after the Four Month Anniversary but prior to the one year anniversary (the "One Year Anniversary") of the effective date of the Employment Agreement, the Company shall pay Mr. Gormally severance equal to one third (1/3) of his Base Salary; (iii) if the date of termination is on or after the One Year Anniversary but prior to the two year anniversary (the "Two Year Anniversary") of the effective date of the Employment Agreement, the Company shall pay Mr. Gormally severance equal to one half (1/2) of the Mr. Gormally's then current Base Salary; and (iv) if the date of termination is on or after the Two Year Anniversary, the Company shall pay Mr. Gormally severance equal to one year of Mr. Gormally's then current Base Salary. If Mr. Gormally is terminated for Cause the Company will not pay any severance.

STOCK AWARDS

Name (a)	Number of Securities Underlying Unexercised Options (#) Exercisable (b)	Number of Securities Underlying Unexercised Options (#) Unexercisable (c)	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#) (d)	Option Exercise Price ($) (e)	Option Expiration Date (f)	Number of Shares or Units of Stock That Have Not Vested (#) (g) (9)	Market Value of Shares or Units of Stock That Have Not Vested ($) (h)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#) (i)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested (#) (j)
Raymond F. Akers Jr.									
Chief Scientific Officer, Executive Chairman, Secretary	40,000	(1) -	-	5.50	06/30/2019	-	-	-	-

John J. Gormally *Chief Executive Officer, Director*	-	-	-	-	n/a	9,166	1,192	-	-
Gary Rauch *VP of Finance, Treasurer*	15,000	-	-	5.50	06/30/2019	-	-	-	-
Christopher C. Scheiber *Director*									
Bill J. White *Director*									
Richard C. Tarbox *Director*									

(1) Dr. Akers gifted such options to the Akers Family Trust, a trust to which he is not a named beneficiary.

Effective October 5, 2016, the Board of Directors (the "Board") of Akers Biosciences, Inc. (the "Company") amended (the "Amendment"), upon recommendation from the Compensation Committee of the Board, the Akers Biosciences, Inc. First Amended and Restated 2013 Incentive Stock and Award Plan (the "Plan"). The Amendment increases the number of authorized shares of common stock subject to the Plan by 30,000 shares, or 3.75% of the amount of shares previously authorized under the Plan.

Effective August 7, 2017, the shareholders of the Company, upon the recommendation of the Board of Directors of the Company, approved and adopted the Akers Biosciences, Inc. 2017 Equity Incentive Plan (the "Plan") which supplemented the Company's existing Amended and Restated 2013 Incentive Stock and Award Plan. The Plan provides for the issuance of up to 1,350,000 shares of the Company's common stock, no par value per share (the "Common Stock"), through the grant of non-qualified options (the "Non-qualified Options"), incentive options (the "Incentive Options" and together with the Non-qualified Options, the "Options"), restricted stock (the "Restricted Stock") and unrestricted stock to directors, officers, consultants, attorneys, advisors and employees. Through December 31, 2017, 1,054,893 are shares reserved for future issuances under our Plan. All future grants will be made pursuant to the Plan at the market price per share on the date of issuance.

CEO Pay Ratio– 9.27

We believe our executive compensation program must be consistent and internally equitable to motivate our employees to perform in ways that enhance shareholder value. We are committed to internal pay equity, and the Compensation Committee monitors the relationship between the pay of our executive officers and the pay of our non-executive employees. The Compensation Committee reviewed a comparison of John J. Gormally's, our Chief Executive Officer (which we refer to for these purposes as the CEO), annual total compensation in fiscal year 2017 to that of all other company employees for the same period. The calculation of annual total compensation of all employees was determined in the same manner as the "Total Compensation" shown for our CEO in the "Summary Compensation Table" on page 66 of this Report. Pay elements that were included in the annual total compensation for each employee are:

- salary received in fiscal year 2017;
- annual bonus payment received for performance in fiscal year 2017;
- grant date fair value of stock option exercises and RSU awards vested in fiscal year 2017;
- company-paid insurance premiums during fiscal year 2017; and

auto allowance paid in fiscal year 2017.

Our calculation includes all employees as of December 31, 2017. We determined the compensation of our median employee by: (i) calculating the annual total compensation described above for each of our employees, (ii) ranking the annual total compensation of all employees except for the CEO from lowest to highest), and (iii) since we have an even number of employees when not including the CEO, determining the average of the annual total compensation of the two employees ranked 13 and 15 on the list ("Median Employee")].

The annual total compensation for fiscal year 2017 for our CEO was $518,338 and for the Median Employee was $55,937. We estimate that the resulting ratio of our CEO's pay to the pay of our Median Employee for fiscal year 2017 is 9.27 to 1.

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, 2017.

Name	Fees earned or paid in cash ($)	Stock Awards ($)	Option Awards ($)	Non-equity incentive plan compensation ($)	All other compensation ($)	Total ($)
Raymond Akers, Jr. (1)	-	-	-	-	-	-
John J. Gormally	-	-	-	-	-	-
Christopher Schreiber	-	-	-	-	-	-
Richard Tarbox	-	-	-	-	-	-
William White	-	-	-	-	-	-
Thomas Knox (2)	-	-	-	-	-	-
Brandon Knox (3)	-	-	-	-	-	-
Robert E. Andrews (4)	-	-	-	-	-	-
Dr. Raza Bokhari (5)	-	-	-	-	-	-

(1) Effective April 22, 2016, Dr. Akers resigned as Executive Chairman of the Board. Dr. Akers was Vice Chairman from April 22, 2016 through August 10, 2017 when he resumed his position as Executive Chairman.

(2) Effective July 1, 2013, Mr. Thomas Knox was appointed as Director and, on April 22, 2016, was appointed sole Non-Executive Chairman of the Board. Mr. T. Knox did not seek reelection to the Board and his term ended on August 10, 2017.

(3) Effective January 23, 2014, Mr. Brandon Knox was appointed as Director. Mr. B. Knox did not seek reelection to the Board and his term ended on August 10, 2017.

(4)

Effective June 29, 2015, Mr. Robert E. Andrews was appointed as Director. Mr. Andrews did not seek reelection to the Board and his term ended on August 10, 2017.

(5) Effective November 11, 2015, Dr. Raza Bokhari was appointed as Director. Mr. Bokhari did not seek reelection to the Board and his term ended on August 10, 2017.

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

The following table sets forth, as of March 15, 2018, 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 April 5, 2017. 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 is based on 81,973,964 shares of our common stock issued and outstanding as of March 15, 2018.

Common stock subject to stock options currently exercisable or exercisable within 60 days of April 5, 2017, 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.

	Shares Beneficially Owned as of March 15, 2018	**Percentage of Ownership as of March 15, 2018**	
Name of Beneficial Owner:			
5% Shareholders:			
Empery Asset Management, LP	4,656,859	5.70	%
Alpha Capital Anstalt	2,516,635	3.08	%
Bigger Capital Funds, LP	1,953,006	2.39	%
Named Executive Officers and Directors:*			
Raymond F. Akers, Jr. Phd[(1)]	-	-	%
Bill J. White	-	-	%
Richard C. Tarbox III	-	-	%
Christopher C. Schreiber	-	-	%
John J. Gormally	180,000	0.22	%
Gary M. Rauch[(2)]	78,777	0.10	%
All executive officers and directors as a group (6 persons)	258,777	0.32	%

(1) Dr. Akers previously gifted 70,000 shares of Common Stock to the Akers Family Trust, a trust to which he is not a named beneficiary. On January 5, 2016, Dr. Akers' wife purchased 2,100 shares of Common Stock.

(2) Mr. Rauch owns 63,777 shares of common stock and has 15,000 vested options.

* Aside from Mr. Rauch, all other named executive officers and directors in the table above only hold shares of common stock and do not have any options outstanding.

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.

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.

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.

Audit-Related fees include services for the review of interim financial statements, tax fees include the preparation of tax returns and other fees include services performed in relation to the preparation of various SEC Forms and advisory services.

All Other Fees includes services in support of the preparation of the Company's Form S-1 and S-3. The firm performed due diligence review and preparation of the Audit Comfort Letter for the underwriter for the Company's public offering and shelf registration filings.

	2017	2016
Audit Fees	$113,000	$100,000
Audit-Related Fees	$97,000	$69,000
Tax Fees	$9,500	$9,500
All Other Fees	$44,795	$15,144
TOTAL	$264,295	$193,644

PART IV

Item 15. Exhibits, Financial Statement Schedules.

Exhibit Number	**Description of Exhibit**
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).
3.6	Amendment to Restated By-laws dated May 11, 2016 (incorporated herein by reference to Exhibit 3.6 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 18, 2016).
3.7	Certificate of Amendment to Certificate of Incorporation, Certificate of Designation of Series B Convertible Preferred Stock, dated December 19, 2017 (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 26, 2017).

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).
4.2	Form of Warrant (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 10, 2017).
4.3	Form of Purchaser Warrant (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 5, 2017).
4.4	Form of Placement Agent Warrant (incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 5, 2017).
4.5	Form of Purchaser Warrant (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 13, 2017).
4.6	Form of Underwriter's Warrant (incorporated herein by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on December 15, 2017).
4.7	Form of Common Stock Purchase Warrant (incorporated herein by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on December 15, 2017).
10.1	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).
10.2	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).
10.3	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).
10.4	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).
10.5	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).
10.6	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).

71

10.7	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).
10.8	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).
10.9	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).
10.10	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).
10.11	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).
10.12	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).
10.13	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).
10.14	Letter Agreement, dated December 3, 2013, by and between the Company and Mr. Thomas 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).
10.15	Joint Venture Agreement, dated October 24, 2014, by and between Akers Biosciences, Inc., Hainan Savy Investment Management Ltd, and Thomas Knox (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 29, 2014).
10.16	Amended and Restated 2013 Incentive Stock and Award Plan (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 9, 2015).
10.17	Form of Lock Up Agreement (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 9, 2015).
10.18	

Employment Agreement between the Company and John J Gormally, dated December 1, 2015. (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 3, 2015).

10.19	First Amendment to the Amended and Restated 2013 Incentive Stock and Award Plan (incorporated by referenced to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 12, 2016).
10.20	Form of Placement Agency Agreement, dated March 30, 2017, by and between Akers Biosciences, Inc. and Joseph Gunnar and Co., LLC (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 5, 2017).
10.21	Form of Securities Purchase Agreement, dated March 30, 2017, by and between Akers Biosciences, Inc. and various purchasers. (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 5, 2017).
10.22	Form Registration Rights Agreement, dated March 30, 2017, by and between Akers Biosciences, Inc. and various purchasers (incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 5, 2017).
10.23	Akers Biosciences, Inc. 2017 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 8, 2017).
10.24	Form Warrant Exercise Agreement, dated October 12, 2017 by and between Akers Biosciences, Inc. and various holders (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 13, 2017).
23.1*	Consent of Independent Registered Accounting Firm.
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 Financial Officer pursuant to 18 U.S.C. 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase

101.PRE XBRL Taxonomy Extension Presentation Linkbase

* Filed herewith

Item 16. Form 10-K Summary.

Not applicable

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: July 13, 2018 By: */s/ John J. Gormally*
Name: John J. Gormally
Title: Chief Executive Officer (Principal Executive Officer)

Date: July 13, 2018 By: */s/ Gary M. Rauch*
Name: Gary M. Rauch
Vice President, Finance & Treasurer
Title:
(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/ John J. Gormally John J. Gormally	Chief Executive Officer and Director (Principal Executive Officer)	July 13, 2018
/s/ Gary M. Rauch Gary M. Rauch	Vice President, Finance & Treasurer (Principal Financial Officer and Principal Accounting Officer)	July 13, 2018
/s/ Christopher C. Schreiber Christopher C. Schreiber	Director	July 13, 2018
/s/ Bill J. White Bill J. White	Director	July 13, 2018
/s/ Richard C. Tarbox III Richard C. Tarbox III	Director	July 13, 2018

FINANCIAL STATEMENTS

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Shareholders of Akers Biosciences, Inc. and Subsidiaries

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Akers Biosciences, Inc. and Subsidiaries (the Company) as of December 31, 2017 and 2016, and the related consolidated statements of operations and comprehensive loss, changes in shareholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2017, and the related notes (collectively referred to as the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

Restatement of 2017 consolidated financial statements

As discussed in Note 2 to the consolidated financial statements, the accompanying December 31, 2017 consolidated financial statements have been restated to correct misstatements.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. 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, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Morison Cogen LLP

We have served as the Company's auditor since 2010.

Blue Bell, Pennsylvania

April 2, 2018, (except for the effects of the restatement described in Note 2, to which the date is July 13, 2018)

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Consolidated Balance Sheets

December 31, 2017 and 2016

	2017 (restated)	2016
ASSETS		
Current Assets		
Cash	$438,432	$72,700
Marketable Securities	5,011,607	50,001
Trade Receivables, net	964,671	601,271
Trade Receivables - Related Party, net	-	31,892
Deposits and other receivables	16,590	23,782
Inventories, net	947,612	2,036,521
Prepaid expenses	145,488	168,277
Prepaid expenses - Related Party	251,499	202,500
Total Current Assets	7,775,899	3,186,944
Non-Current Assets		
Prepaid expenses - Related Party	120,118	270,183
Property, Plant and Equipment, net	235,113	259,392
Intangible Assets, net	1,130,667	1,301,775
Other Assets	76,093	66,813
Total Non-Current Assets	1,561,991	1,898,163
Total Assets	$9,337,890	$5,085,107
LIABILITIES		
Current Liabilities		
Trade and Other Payables	$1,745,216	$1,463,363
Trade and Other Payables - Related Party	39,821	234,067
Total Current Liabilities	1,785,037	1,697,430
Total Liabilities	1,785,037	1,697,430
SHAREHOLDERS ' EQUITY		
Convertible Preferred Stock, No par value, 50,000,000 shares authorized, 1,755 and 0 shares issued and outstanding as of December 31, 2017 and 2016	1,755,000	-
Common Stock, No par value, 500,000,000 shares authorized, 44,220,552 and 5,452,545 issued and outstanding as of December 31, 2017 and 2016	110,647,169	100,891,786

Deferred Compensation	(3,469)	(24,572)
Accumulated Deficit	(104,845,847)	(97,479,537)
Accumulated Other Comprehensive Income	-	-
Total Shareholders' Equity	7,552,853	3,387,677
Total Liabilities and Shareholders' Equity	$9,337,890	$5,085,107

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

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Consolidated Statements of Operations and Comprehensive Loss

For the years ended December 31, 2017 and 2016

	Year ended December 31,	
	2017 (restated)	2016
Revenues :		
Product Revenue	$3,304,712	$2,956,782
Product Revenue - Related party	-	380
License & Service Revenue	50,000	3,750
Total Revenues	3,354,712	2,960,912
Cost of Sales:		
Product Cost of Sales	(2,406,132)	(1,083,087)
Gross Income	948,580	1,877,825
Administrative Expenses	4,082,313	3,008,811
Sales and Marketing Expenses	1,846,445	1,983,428
Sales and Marketing Expenses - Related Party	202,126	153,854
Research and Development Expenses	1,237,384	1,188,868
Research and Development Expenses - Related Party	22,994	-
Reversal of Allowance - Related parties	-	(1,299,609)
Amortization of Non-Current Assets	171,108	171,108
Loss from Operations	(6,613,790)	(3,328,635)
Other (Income)/Expenses		
Foreign Currency Transaction Gain	(1,659)	(3,398)
Interest and Dividend Income	(10,753)	(21,699)
Warrant Modification Expense	764,932	-
Total Other (Income)/Expense	752,520	(25,097)
Loss Before Income Taxes	(7,366,310)	(3,303,538)
Income Tax Benefit	-	-
Net Loss Attributable to Common Shareholders	(7,366,310)	(3,303,538)
Other Comprehensive Income		
Net Unrealized Gain on Marketable Securities	-	6,231
Total Other Comprehensive Income	-	6,231

Comprehensive Loss	$(7,366,310)	$(3,297,307)
Basic and Diluted loss per common share	$(0.78)	$(0.61)
Weighted average basic and diluted common shares outstanding	9,494,977	5,430,205

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

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Consolidated Statement of Changes in Shareholder's Equity

For the years ended December 31, 2017 and 2016

	Preferred Shares Issued and Outstanding	Preferred Stock	Common Shares Issued and Outstanding	Common Stock	Deferred Compensation	Accumulated Deficit	Accumulated Other Comprehensive Income/(Loss)	Total Equity
Balance at December 31, 2015	-	$-	5,425,045	$100,785,408	$-	$(94,175,999)	$(6,231)	$6,603,178
Net loss	-	-	-	-	-	(3,303,538)	-	(3,303,538)
Issuance of restricted common stock to officers	-	-	27,500	54,725	(54,725)	-	-	-
Amortization of deferred compensation	-	-	-	-	30,153	-	-	30,153
Issuance of non-qualified stock options to key employees	-	-	-	27,977	-	-	-	27,977
Issuance of non-qualified stock options for services from non-employees	-	-	-	23,676	-	-	-	23,676
Net unrealized gain on marketable securities	-	-	-	-	-	-	6,231	6,231
Balance at December 31, 2016	-	$-	5,452,545	$100,891,786	$(24,572)	$(97,479,537)	$-	$3,387,677
Net loss (restated)	-	-	-	-	-	(7,366,310)	-	(7,366,310)

Share register adjustment	-	-	(1)	-	-	-	-	-
Public offering of common stock, net of offering costs of $494,406	-	-	1,789,500	1,652,994	-	-	-	1,652,994
Private offering of common stock, net of offering costs of $267,443	-	-	1,448,400	1,760,317	-	-	-	1,760,317
Public offering of common and preferred stock, net of offering costs of $834,414	3,675	3,675,000	21,500,000	2,390,586	-	-	-	6,065,586
Warrant Modification				764,932				764,932
Exercise of warrants for common stock	-	-	925,000	981,948	-	-	-	981,948
Conversion of preferred stock to common stock	(1,920)	(1,920,000)	12,800,001	1,920,000				
Amortization of deferred compensation	-	-	-	-	21,103	-	-	21,103
Issuance of stock grants to officers			186,277	163,924				163,924
Issuance of stock grants to key employees			108,830	95,770				95,770
Issuance of non-qualified stock options to key employees	-	-	-	17,274	-	-	-	17,274
Issuance of non-qualified stock options for services to non-employees	-	-	-	2,183	-	-	-	2,183
Issuance of restricted stock for services for non-employees	-	-	10,000	5,455	-	-	-	5,455
	1,755	$1,755,000	44,220,552	$110,647,169	$(3,469)	$(104,845,847)	$-	$7,552,853

Balance at
December 31,
2017(restated)

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

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

For the years ended December 31, 2017 and 2016

	2017 (restated)	2016
Cash flows from operating activities		
Net loss	$(7,366,310)	$(3,303,538)
Adjustments to reconcile net loss to net cash used in operating activities:		
Accrued income on marketable securities	(1,412)	14,244
Depreciation and amortization	249,894	286,162
Reserve and write-off for obsolete inventory	1,208,522	32,333
Allowance for /(Reversal) of doubtful accounts	450,000	(1,153,413)
Expenses related to modification of warrants	764,932	-
Amortization of deferred compensation	21,103	30,153
Share based compensation to employees - options	17,274	27,977
Share based compensation to employees - restricted stock	95,770	-
Share based compensation to officers - restricted stock	163,924	-
Share based compensation to non-employees - options	2,183	23,676
Share based compensation to non-employees - restricted stock	5,455	-
Changes in assets and liabilities:		
Increase in trade receivables	(813,400)	(138,272)
Increase/(Decrease) in trade receivables - related party	31,892	(380)
Decrease in deposits and other receivables	7,192	71,795
Increase in inventories	(119,613)	(187,200)
Decrease in prepaid expenses	22,789	17,689
Decrease in prepaid expenses - related party	101,066	76,927
Increase in other assets	(9,280)	-
Increase/(decrease) in trade and other payables	281,853	(205,368)
Increase/(decrease) in trade and other payables - related party	(194,246)	234,067
Net cash used in operating activities	(5,080,412)	(4,173,148)
Cash flows from investing activities		
Purchases of property, plant and equipment	(54,507)	(123,301)
Purchases of marketable securities	(7,709,341)	(35,944)
Proceeds from sale of marketable securities	2,749,147	4,003,034
Net cash provided by/(used in) investing activities	(5,014,701)	3,843,789
Cash flows from financing activities		
Net proceeds from issuance of common stock	5,803,897	-
Proceeds from issuance of preferred stock	3,675,000	-
Net proceeds from exercise of warrants for common stock	981,948	-
Net cash provided by financing activities	10,460,845	-

Net increase/(decrease) in cash	365,732	(329,359)
Cash at beginning of year	72,700	402,059
Cash at end of year	$438,432	$72,700
Supplemental Schedule of Non-Cash Financing and Investing Activities		
Issuance of restricted common stock grants to officers	$-	$54,725
Net unrealized gains on marketable securities	$-	$6,231
Settlement of note receivable in the form of inventory	$-	$750,000
Settlement of note receivable in the form of prepaid expense	$-	$549,609

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 financial statements have been prepared by Akers Biosciences, Inc. ("Akers" 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'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 typically requires an upfront licensing fee to be paid for the right to sell the Company's products in specific markets.

Note 2 – Restatement of Previously Issued Financial Statements

As previously disclosed, the Company determined that certain revenue transactions did not qualify for revenue recognition under generally accepted accounting principles. In the process of this determination, the Company discovered information that existed at December 31, 2017 which affected the revenue, certain obligations and the value of certain inventory items reported in the year ended December 31, 2017. The Company concluded that the impact of applying corrections for these errors and misstatements on the consolidated financial statements as of and for the year ended December 31, 2017 is material. As a result, the Company is restating its consolidated financial

statements as of and for the year ended December 31, 2017. See below for a reconciliation of the previously reported amounts to the restated amounts.

The table below sets forth the consolidated balance sheets, including the balances originally reported, corrections and the as restated balances:

	As of December 31, 2017		
	As Reported	Correction	As Restated
Trade Receivables, net	$1,490,985	$(526,314)	$964,671
Trade Receivables – Related Party, net	125,001	(125,001)	-
Inventories, net	1,845,281	(897,669)	947,612
Total Current Assets	9,324,883	(1,548,984)	7,775,899
Total Assets	10,886,874	(1,548,984)	9,337,890
Trade and Other Payables	1,733,216	12,000	1,745,216
Total Current Liabilities	1,773,037	12,000	1,785,037
Total Liabilities	1,773,037	12,000	1,785,037
Accumulated Deficit	(103,284,863)	(1,560,984)	(104,845,847)
Total Stockholder's Equity	9,113,837	(1,560,984)	7,552,853
Total Liabilities and Stockholders' Equity	10,886,874	(1,548,984)	9,337,890

The table below sets for the consolidated statements of income, including the balances originally reported, corrections, and the restated amounts:

	For the year ended December 31, 2017		
	As Reported	Correction	As Restated
Product revenue	$3,754,896	$(450,184)	$3,304,712
Product revenue – Related party	124,631	(124,631)	-
Product Cost of Sales	(1,419,963)	(986,169)	(2,406,132)
Gross Income	2,509,564	(1,560,984)	948,580
Loss from Operations	(5,052,806)	(1,560,984)	(6,613,790)
Loss Before Income Taxes	(5,805,326)	(1,560,984)	(7,366,310)
Net Loss Attributable to Common Stockholders	(5,805,326)	(1,560,984)	(7,366,310)
Comprehensive Loss	(5,805,326)	(1,560,984)	(7,366,310)
Loss per Share	(0.61)	(0.17)	(0.78)

The table below sets forth the consolidated statements of shareholders' equity, including the balances originally reported, corrections and the as restated balances:

	As Reported	Correction	As Restated
Net loss, for the year ended December 31, 2017	$(5,805,326)	$(1,560,984)	$(7,366,310)
Accumulated Deficit, as of December 21, 2017	(103,284,863)	(1,560,984)	(104,845,847)
Total Equity, as of December 31, 2017	9,113,837	(1,560,984)	7,552,853

The table below sets forth the consolidated statements of cash flows from operating activities, including the balances originally reported, corrections and the as restated balances:

	For the year ended December 31, 2017		
	As Reported	Correction	As Restated
Net loss	$(5,805,326)	$(1,560,984)	$(7,366,310)
Reserve and write-off for absolute inventory	26,122	1,182,400	1,208,522
Increase in trade receivables	(1,339,714)	526,314	(813,400)
(Increase)/decrease in trade receivables – related party	(93,109)	125,001	31,892
Increase/(decrease) in inventories	165,118	(284,731)	(119,613)
Increase/(decrease) in trade and other payables	269,853	12,000	281,853
Net cash used in operating activities	5,080,412	-	5,080,412

The restatement had no impact on cash flows from investing activities or financing activities.

In addition to the restated consolidated financial statements, the information contained in Notes 4, 7, 9, 12, 15, 16, 17, 18, 19, and 22 has been restated.

Note 3 - 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. 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, 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 consolidated statement of operations and comprehensive loss.

(d) Comprehensive Income (Loss)

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.

Note 4 - Significant Accounting Policies (restated)

(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 consolidated balance sheet.

(b) Fair Value of Financial Instruments

The Company's financial instruments consist of cash and cash equivalents, marketable securities, receivables and trade and other payables. The carrying value of cash and cash equivalents, receivables and trade and other payables approximate their fair value because of their short maturities. The fair value of marketable securities is described in Note 3(c).

(c) Fair Value Measurement – Marketable Securities

The framework for measuring fair value provides a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (level 1) and the lowest priority to unobservable inputs (level 3). The three levels of the fair value hierarchy under FASB ASC 820 are described as follows:

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

Level 1	Inputs to the valuation methodology are unadjusted quoted prices for identical assets or liabilities in active markets that the Company has the ability to access.
Level 2	Inputs to the valuation methodology include

quoted prices for similar assets or liabilities in active markets;

quoted prices for identical or similar assets or liabilities in inactive markets;

inputs other than quoted prices that are observable for the asset or liability;

inputs that are derived principally from or corroborated by observable market data by correlation or other means.

If the asset or liability has a specified (contractual) term, the level 2 input must be observable for substantially the full term of the asset or liability.

Level 3	Inputs to the valuation methodology are unobservable and significant to the fair value measurement.

The asset or liability's fair value measurement level within the fair value hierarchy is based on the lowest level of input that is significant to the fair value measurement. Valuation techniques maximize the use of relevant observable inputs and minimize the use of unobservable inputs.

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

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. Credit terms longer than these may be extended after considering the credit worthiness of the customers and the business requirements. 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, 2017 and 2016, allowances for doubtful accounts for trade receivables were $596,196 and $1,010,196. Bad debt expenses for trade receivables were $494,436 and $146,196 for the years ended December 31, 2017 and 2016. The credit comprises the reversal of an allowance for bad debts expense – related party of $1,299,609 and an allowance for bad debts for an external party of $146,195 included in the administrative expenses for the year ended December 31, 2016. Included in the allowance for doubtful accounts as of December 31, 2016 is $864,000 being an allowance for doubtful account of a trade receivable from a related party written off against the trade receivable in the year ended December 31, 2017.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

As of December 31, 2017 and 2016, the aging of trade receivables and trade receivables – related party was as follows:

Aging Period	December 31, 2017 (restated)	%	2016	%
Current (Notes 6 & 16)	1,181,335	76%	464,365	28%
01-30 Days	79,535	5 %	43,223	3 %
31-60 Days	20,154	1 %	39,203	2 %
61-90 Days	25,100	2 %	6,150	0 %
>90 Days	254,743	16%	1,090,418	67%
Subtotal	1,560,867		1,643,359	
Bad Debts Allowance	(596,196)		(1,010,196)	
Total	$964,671		$633,163	
Average Days in Receivable	169.83		202.58	

The aging above represents the number of days that the account receivable balance exceeds the credit terms. Included in the current category is accounts receivable of $470,000 and $- as of December 31, 2017 and December 31, 2016 with payment terms extended to 180 days.

(e) Concentration of Credit Risk (restated)

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

All of the Company's cash is maintained with Fulton Bank of New Jersey, Bank of America, NA and PayPal. The funds are insured by the FDIC up to a maximum of $250,000, but are otherwise unprotected. The Company placed $426,927 and $67,865 with Fulton Bank of New Jersey, $7,915 and $795 with Bank of America, NA and $3,590 and $4,040 with PayPal as of December 31, 2017 and 2016. No losses have been incurred in these accounts.

Concentration of credit risk with respect to trade receivables exists as approximately 73% of the Company's product revenue is generated by three customers. These customers accounted for 72% of trade receivables as of December 31,

2017. To limit such risks, the Company performs ongoing credit evaluations of its customers' financial condition.

(f) Inventories

Inventories are measured at the lower of cost or net realizable value. 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.

(g) 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 consolidated statement of operations and comprehensive loss.

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
Leasehold Improvements	Shorter of the remaining lease or estimated useful life

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

(h) 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. As of December 31, 2017, the Company has ten patents from the United States Patent Office in effect (9,383,368; 7,896,167; 8,097,171; 8,003,061; 8,425,859; 8,871,521; 8,808,639; 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), European Union Patents 1793906, 2684025, 002216895-0001; 002216895-0002 and 002216895-0003), in Hong Kong (HK11004006) and in Japan (1,515,170; 4,885,134; 4,931,821 5,775,790, and 6023096). 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.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

(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.

(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

(i) 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.

(j) Investments

In accordance with FASB ASC 323, the Company recognizes investments in joint ventures based upon the Company's ability to significantly influence the operational or financial policies of the joint venture. An objective judgment of the level of influence is made at the time of the investment based upon several factors including, but not limited to the following:

a) Representation on the Board of Directors

b) Participation in policy-making processes

c) Material intra-entity transactions

d) Interchange of management personnel

e) Technological dependencies

f) Extent of ownership and the ability to influence decision making based upon the makeup of other owners when the shareholder group is small.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

The Company follows the equity method for valuating investments in joint ventures when the existence of significant influence over operational and financial policy has been established, as determined by management; otherwise, the Company will valuate these investments using the cost method.

Investments recorded using the cost method will be assessed for any decrease in value that has occurred that is other than temporary and the other than temporary decrease in value shall be recognized. As and when circumstances and facts change, the Company will evaluate the Company's ability to significantly influence operational and financial policy to establish a basis for converting the investment accounted for using the cost method to the equity method of valuation.

On March 9, 2015, the Company contributed capital of $64,675 in Hainan Savy Akers Biosciences, Ltd., a company incorporated in the People's Republic of China, resulting in a 19.9% ownership interest. The contribution was adjusted downward to $64,091 on April 8, 2015; the net effect of the currency conversion when the contribution was processed in Hainan. This is included in other assets in the Consolidated Balance Sheet as of December 31, 2017 and 2016 and is accounted for using the cost method.

(k) Revenue Recognition (restated)

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. The accrual for estimated sales returns was $- as of December 31, 2017 and 2016. In cases where the right of return is granted and the Company does not have historical experience to reasonably estimate the sales returns, the revenue is recognized when the return privilege has substantially expired.

The Company implemented a standard dealer cost model during the year ended December 31, 2016 which includes a provision for rebates to the distributors under limited circumstances. The Company established an accrual of $126,471 and $41,120, which is a reduction of revenue as of December 31, 2017 and 2016. Accounts receivable will be reduced when the rebates are applied by the customer. The Company recognized $296,164 and $471,949 during the years ended December 31, 2017 and 2016 for rebates, which is included as a reduction of product revenue in the

Consolidated Statement of Operations and Comprehensive Loss.

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.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

(l) 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.

(m) Shipping and Handling Fees and Costs (restated)

The Company charges actual shipping plus a handling fee to customers, which amounted to $59,985 and $54,928 for the years ended December 31, 2017 and 2016. These fees are classified as part of product revenue in the Consolidated Statement of Operations and Comprehensive Loss. 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 $136,145 and $138,662 for the years ended December 31, 2017 and 2016.

(n) Research and Development Costs

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

(o) 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.

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.

The Company estimates the fair value of stock-based awards to non-employees 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. At the end of each financial reporting period, prior to vesting or prior to completion of services, the fair value of equity based payments will be re-measured and the non-cash expense recognized during the period will be adjusted accordingly. Since the fair value of equity based payments granted to non-employees is subject to change in the future, the amount of the future expense will include fair value re-measurement until the equity based payments are fully vested or the service is completed.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

(p) 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.

(q) Recently Adopted Accounting Pronouncements

As of December 31, 2017 and for the year then ended, there were no recently adopted accounting pronouncements that had a material effect on the Company’s financial statements.

(r) Recently Issued Accounting Pronouncements Not Yet Adopted

As the Company is an emerging growth company, it has elected to adopt recently issued standards based on effective dates applicable to nonpublic entities. All effective dates as mentioned in the following paragraphs refer to that applicable to nonpublic entities.

In May 2014 and April 2016, the FASB issued ASU No. 2014-09 and ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606). The core principle of the guidance is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In August 2015, FASB issued ASU 2015-14 which deferred the effective date of Update 2014-09 to annual reporting periods beginning after December 15, 2018 and interim reporting periods within annual reporting periods beginning after December 15, 2019. Early application is permitted as of annual reporting periods beginning after December 15, 2016 including interim reporting periods within that reporting period. The Company is currently evaluating the effect of the amendments but it does not anticipate a material impact of its financial statements. The Company expects to use the modified retrospective adoption method.

In November 2015, the FASB issued ASU No. 2015-17, *Income Taxes (Topic 740), Balance Sheet Classification of Deferred Taxes*. The amendments in this Update require that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. The amendments in this Update are effective for financial statements issued for annual periods beginning after December 15, 2017, and interim periods within annual periods beginning after December 31, 2018. Earlier application is permitted for all entities as of the beginning of an interim or annual reporting period. The Company has no deferred tax balances as a 100% valuation allowance has been made. No material impact is expected.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

In January 2016, the FASB issued ASU No. 2016-01, *Financial Instruments – Overall (Subtopic 825-10)*, *Recognition and Measurement of Financial Assets and Financial Liabilities*. The amendments in this Update require all equity investments to be measured at fair value with changes in the fair value recognized through net income (other than those accounted for under the equity method of accounting or those that result in consolidation of the investee). The amendments in this Update also require an entity to present separately in other comprehensive income the portion of the total change in the fair value of a liability resulting from a change in the instrument-specific credit risk when the entity has elected to measure the liability at fair value in accordance with the fair value option for financial instruments. The amendments in this Update are effective for fiscal years beginning after December 15, 2018, and interim periods within fiscal years beginning after December 15, 2019. The Company is evaluating the effect of the adoption of this Update on its financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*. The amendments in this Update specify the accounting for leases. The core principle of Topic 842 is that a lessee should recognize the assets and liabilities that arise from leases. The amendments in this Update are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early application of the amendments in this Update is permitted. The Company is currently evaluating the effect the amendments in this Update will have on its financial statements and related disclosures.

In March 2016, the FASB issued ASU No. 2016-08, *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net)*, which clarifies certain aspects of the principal versus agent guidance in the new revenue recognition standard. The effective date and transition requirement for this ASU are the same as the effective date and transition requirements of ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*, as amended by ASU 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*, which deferred the effective date to annual reporting periods beginning after December 15, 2018. The Company is currently evaluating the effect the amendments in this Update will have on its financial statements and related disclosures.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*, which simplifies several aspects of the accounting for share-based payment award transactions, including: (1) income tax consequences; (2) classification of awards as either equity or liabilities, and (3) classification on the statement of cash flows. The amendments in this ASU are effective for annual periods beginning after December 15, 2017, and interim periods within annual periods beginning after December 15, 2018. Early adoption is permitted in any interim or annual period. The Company is currently evaluating the effect the amendments in this Update will have on its financial statements and related disclosures.

F-17

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230), Classification of Certain Cash Receipts and Cash Payments*. The Update addresses eight specific changes to how cash receipts and cash payments are presented and classified in the statement of cash flows. The amendments in this Update are effective for fiscal years beginning after December 15, 2018, and interim periods within fiscal years beginning after December 15, 2019. Early adoption is permitted. An entity that elects early adoption must adopt all of the amendments in the same period. The amendments in this Update should be applied using a retrospective transition method to each period presented. If it is impracticable to apply the amendments retrospectively for some of the issues, the amendments for those issues would be applied prospectively as of the earliest date practicable. The Company is currently evaluating the effect the amendments in this Update will have on its financial statements and related disclosures.

In May 2017, the FASB issued ASU 2017-09, *Compensation - Stock Compensation* (Topic 718), Scope of Modification Accounting. The amendments in this Update provide guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. The amendments in this Update are effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. Early adoption is permitted, including adoption in any interim period, for (1) public business entities for reporting periods for which financial statements have not yet been issued and (2) all other entities for reporting periods for which financial statements have not yet been made available for issuance. The amendments in this Update should be applied prospectively to an award modified on or after the adoption date.

Note 5 – Management Plan

Historically, the Company has relied upon public offerings and private placements of common stock to raise operating capital. During the year ended December 31, 2017, the Company raised $9,478,897, net of expenses, in public and private offerings and an additional $981,948, net of expenses, from the exercise of warrants (Note 13). As of March 16, 2018, the Company had realized an additional $4,909,081 from the exercise of warrants, had cash and marketable securities of approximately $8.94 million and working capital of approximately $11.19 million.

The 2017-19 Strategic Business Plan (“Strat Plan”) was presented to and approved by the Board of Directors on December 12, 2016. The plan outlines the Company’s business objectives for the next three years and sets measurable targets for new product releases, sales and marketing programs to increase market penetration for the Company’s products and operational expense management.

Implementation of the Strat Plan began in January 2017 and management remains confident that the objectives are achievable. The Company's Go To Market ("GTM") plan, revised annually, supports the implementation of the Strat Plan by defining specific tasks, products and customer targets designed to achieve the Plan's revenue goals. The Company anticipates achieving a cash-flow positive position during the second quarter of 2018 based upon the revenue targets as outlined in the GTM and Strat Plan.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

During the year ended December 31, 2016, the Company significantly reduced operating expenses through a systematic review of operations throughout the organization. As a result, the Company achieved a reduction in its weekly operating cash requirements of approximately 19% to $80,253 (2015: $98,699).

The Company has achieved the reduction in weekly cash requirements by renegotiating contracts with key consultants and canceling consulting agreements where the cost-benefits are negligible, working with vendors to reduce or eliminate minimum purchasing requirements, to extend payment terms and re-sourcing materials when necessary to reduce costs.

Production cost savings, especially direct manufacturing costs, have been realized by utilizing sub-contractors to perform labor intensive production processes. This improves efficiency for our manufacturing staff, allowing them to concentrate their efforts on more complex assembly and production tasks.

During the year ended December 31, 2017, the Company’s average weekly operating cash requirement increased to $97,700 (2016: $80,253). The increase resulted from payments to vendors and sub-contractors included in the December 31, 2016 accounts payable balance, a significant royalty payment that had been deferred in 2016 as part of a legal settlement, significantly higher professional service fees and other payments for contractual obligations. The Company anticipates the cash requirements to remain in the range of $95,000 to $100,000 per week throughout 2018.

Barring any unforeseen circumstances, the Company believes that it is probable that it will be able to meet its obligations as they fall due within one year after the financial statements are issued.

Note 6 - Fair Value Measurement - Marketable Securities

Following is a description of the valuation methodologies used for assets measured at fair value as of December 31, 2017 and 2016.

U.S. Agency Securities and Corporate and Municipal Securities: Valued using pricing models maximizing the use of observable inputs for similar securities. This includes basing value on yields currently available on comparable securities of issuers with similar credit ratings.

	As of December 31, 2017				
	Cost	Accrued Income	Unrealized Gains	Unrealized Losses	Fair Value
Level 2:					
Money market funds	$5,165	$ 161	$ -	$ -	$5,326
Municipal securities	5,005,000	1,281	-	-	5,006,281
Total Level 2:	5,010,165	1,442	-	-	5,011,607
Total:	$5,010,165	$ 1,442	$ -	$ -	$5,011,607

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

	As of December 31, 2016				
	Cost	Accrued Income	Unrealized Gains	Unrealized Losses	Fair Value
Level 2:					
Money market funds	$29,657	$ 15	$ -	$ -	$29,672
Municipal securities	20,314	15	-	-	20,329
Total Level 2:	49,971	30	-	-	50,001
Total:	$49,971	$ 30	$ -	$ -	$50,001

Marketable securities are classified as available for sale. The securities are valued at fair market value. Maturities of the securities are less than one year. Unrealized gains relating to the available for sale investment securities were recorded in the Consolidated Statement of Changes in Shareholders' Equity as comprehensive income. These amounts were an unrealized gain of $- and $6,231 (net of effect of income tax expense of $-) for the years ended December 31, 2017 and 2016.

Proceeds from the sale of marketable securities in the years ended December 31, 2017 and 2016 were $2,749,147 and $4,003,034. Net gains of $3,375 and net losses of $85 resulted from these sales for the years ended December 31, 2017 and 2016.

Note 7 - Trade Receivables – Related Party (restated)

Trade receivables – related party are made up of amounts due from Hainan Savy Akers Biosciences Ltd ("Hainan"), a joint venture between Akers, Thomas Knox, Akers' former Board Chairman, and Hainan Savy Investment Management Ltd, located in the People's Republic of China. The Company holds a 19.9% position in the joint venture. The amount due is non-interest bearing, unsecured and generally has a term of 30-90 days (Note 17).

Note 8 - Note Receivable – Related Parties

On December 31, 2014, a note of $1,475,766 was issued to the Company in exchange for the Company's open trade receivables from ChubeWorkx Guernsey Limited ("ChubeWorkx"), a major shareholder. It is payable in sixty equal installments of $27,734 commencing January 1, 2015 and has an interest rate of 5% per annum.

As of December 31, 2015, the Company established an allowance for doubtful accounts for notes receivable – related party of $1,299,609 which is reported as bad debt expense – related parties in the Consolidated Statement of Operations and Comprehensive Loss for the year ended December 31, 2015.

On August 17, 2016, the Company entered into a Settlement Agreement with ChubeWorkx which settled all pending claims between the companies. Under the terms of the Settlement Agreement, the Company recovered the full outstanding principal amount in the current fiscal year in the form of $750,000 of BreathScan® Alcohol Detector inventory – which the Company intends to subsequently sell – and the balance of $549,609 as a prepaid royalty (Note 16). As a result of the Settlement Agreement, the Company reversed the allowance for doubtful note in the amount of $1,299,609 which is included in the Consolidated Statement of Operations and Comprehensive Loss for the year ended December 31, 2016.

For the year ended December 31, 2017 and 2016, the Company has invoiced $21,600 and $- for the BreathScan® Alcohol Detector inventory that was recovered as part of the Settlement.

Note 9 – Inventories (restated)

Inventories consists of the following categories:

	December 31,	
	2017	2016
	(restated)	
Raw Materials	$458,441	$440,316
Sub-Assemblies	886,274	907,989
Finished Goods	815,505	749,488
Reserve for Obsolescence	(1,212,608)	(61,272)
	$947,612	$2,036,521

The Company has been actively marketing, on a global basis, the BreathScan Breath Alcohol products that were produced for and/or acquired as part of the ChubeWorkx settlement agreement in August 2016. Unfortunately, the Company has not been successful in securing buyers in sufficient volumes.

An extensive analysis of the market opportunity has been performed and it was determined that the on-hand quantity of this group of products exceeded the expected near term demand for the product prior to its expiration. As such, the Company's management elected to establish a reserve of $1,182,400 for the year ended December 31, 2017.

Obsolete inventory charged to cost of goods during the years ended December 31, 2017 and 2016 totaled $1,208,522 and $32,333.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

Note 10 - Property, Plant and Equipment

Property, plant and equipment consists of the following:

	December 31, 2017	2016
Computer Equipment	$114,771	$114,771
Computer Software	40,681	40,681
Office Equipment	39,959	39,959
Furniture & Fixtures	38,356	29,939
Machinery & Equipment	1,138,134	1,126,134
Molds & Dies	868,570	834,480
Leasehold Improvements	222,593	222,593
	2,463,064	2,408,557
Less Accumulated Depreciation	2,227,951	2,149,165
	$235,113	$259,392

Depreciation expenses totaled $78,786 and $115,054 for the years ended December 31, 2017 and 2016.

Note 11- Intangible Assets

Intangible assets as of December 31, 2017 and 2016 and the movements for the periods then ended are as follows:

	Patents & Trademarks	Distributor & Customer Relationships	Totals
Cost or Deemed Cost At December 31, 2015	$2,626,996	$ 1,270,639	$3,897,635

Additions	-	-	-
Disposals	-	-	-
At December 31, 2016	$2,626,996	$1,270,639	$3,897,635
Accumulated Amortization			
At December 31, 2015	$1,154,113	$1,270,639	$2,424,752
Amortization Charge	171,108	-	171,108
Disposals	-	-	-
At December 31, 2016	$1,325,221	$1,270,639	$2,595,860
Net Book Value			
At December 31, 2015	$1,472,883	$-	$1,472,883
At December 31, 2016	$1,301,775	$-	$1,301,775
Cost or Deemed Cost			
At December 31, 2016	$2,626,996	$1,270,639	$3,897,635
Additions	-	-	-
Disposals	-	-	-
At December 31, 2017	$2,626,996	$1,270,639	$3,897,635
Accumulated Amortization			
At December 31, 2016	$1,325,221	$1,270,639	$2,595,860
Amortization Charge	171,108	-	171,108
Disposals	-	-	-
At December 31, 2017	$1,496,329	$1,270,639	$2,766,968
Net Book Value			
At December 31, 2016	$1,301,775	$-	$1,301,775
At December 31, 2017	$1,130,667	$-	$1,130,667

Amortization expense totaled $171,108 for the years ended December 31, 2017 and 2016.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

The estimated aggregate amortization expense for each of the five succeeding fiscal years is as follows:

Period	Amount
2018	$171,108
2019	171,108
2020	171,108
2021	171,108
2022	171,108

Note 12 - Trade and Other Payables (restated)

Trade and other payables consists of the following:

	December 31,	
	2017	2016
	(**restated**)	
Trade Payables	$948,951	$923,311
Accrued Expenses	736,515	480,302
Deferred Compensation	59,750	59,750
	$1,745,216	$1,463,363

Trade and other payables – related party are as follows:

	December 31,	
	2017	2016
Trade Payables	$39,821	$182,001
Accrued Expenses	-	52,066
	$39,821	$234,067

As of December 31, 2017 the Company owed ChubeWorkx Guernsey Limited, previously a major shareholder, royalties of $36,661 (Note 16) which was paid on February 12, 2018.

As of December 31, 2017, the Company owed Hainan $670. Senior management at Hainan are actively involved in Shenzhen Savy-Akers Biosciences (“Shenzhen”) which is therefore being included as a related party. The Company owed Shenzhen $2,490 as of December 31, 2017.

Trade and other payables are non-interest bearing and are normally settled on 30 – 60 day terms.

Note 13 - Share-based Payments

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.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

On January 9, 2015, the Board of Directors of the Company approved, upon recommendation from the Compensation Committee of the Board, by unanimous written consent the Amended and Restated 2013 Incentive Stock and Award Plan (the "Amended Plan"), which increases the number of authorized shares of common stock subject to the Plan to 800,000 shares.

On September 30, 2016, the Board of Directors increased the number of authorized shares of common stock subject to the Amended Plan to 830,000 shares. As of December 31, 2017, under the 2013 Amended Plan, grants of restricted stock and options to purchase 264,166 shares of common stock have been issued and are unvested or unexercised and 7,292 shares of common stock remain available for grants.

On August 7, 2017, the Shareholders approved and the Company adopted the 2017 Equity Incentive Plan (the "Plan") which will provide for the issuance of up to 1,350,000 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. As of December 31, 2017, under the 2017 Plan, grants totaling 295,107 shares of restricted common stock have been issued and 1,054,893 shares of common stock remain available for grants.

The 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, the Company's common stock.

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.

On January 1, 2016, the Company approved the issuance of 12,500 options to purchase common shares to a key consultant for services at an exercise price of $3.70 per common share with vesting over one year. The options carry a five-year expiration.

On August 9, 2016 the Company approved the issuance of 26,000 options to purchase common shares to two key employees at an exercise price of $3.25 per common share with vesting over two years. The options carry a five-year expiration.

The options issued under the above plan were valued using a Black Scholes option pricing model. The assumptions utilized in calculating the value of the issued options under Black Scholes are as follows:

	2017	**2016**
Expected option term	-	5 yrs
Expected volatility	-	95.02%
Expected divident yeild	-	0.00 %
Risk free interest rate	-	1.76 %

The Company did not issue any options or warrants under the above plan during the year ended December 31, 2017.

The following table summarizes the option activities for the years ended December 31, 2017 and 2016:

	Number of Shares	**Weighted** Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Balance at December 31, 2015	220,500	$ 4.38	3.81	$ -
Granted	38,500	3.40	4.43	-
Exercised	-	-	-	-
Forfeited	-	-	-	-
Canceled/Expired	-	-	-	-
Balance at December 31, 2016	259,000	$ 4.23	3.05	$ 20,100
Exercisable as of December 31, 2016	239,167	$ 4.31	2.92	$ 20,100
Balance at December 31, 2016	259,000	$ 4.23	3.05	$ 20,100
Granted	-	-	-	-
Exercised	-	-	-	-
Forfeited	(4,000)	3.25	3.63	-
Canceled/Expired	-	-	-	-
Balance at December 31, 2017	255,000	$ 4.25	2.02	$ -
Exercisable as of December 31, 2017	250,334	$ 4.27	1.99	$ -

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the closing stock price of $0.13 and $1.90 for our common shares on December 31, 2017 and 2016.

A summary of the Company's non-vested shares as of December 31, 2017 and the changes during the period then ended are as follows:

Non-Vested Shares	Shares	Weighted Average Grant Date Fair Value
Non-vested at December 31, 2015	-	$ -
Granted	38,500	1.98
Vested	(18,666)	1.90
Forfeited	-	-
Non-vested at December 31, 2016	19,834	$ 2.36
Non-vested at December 31, 2016	19,834	$ 2.36
Granted	-	-
Vested	(11,168)	2.07
Forfeited	(4,000)	2.36
Non-vested at December 31, 2017	4,666	$ 2.36

Unrecognized compensation cost related to non-vested employee stock options totaled $6,930 as of December 31, 2017. The cost is to be recognized over a weighted average period of 0.62 years.

During the years ended December 31, 2017 and 2016, the Company incurred stock option expenses totaling $19,457 and $51,653.

During the year ended December 31, 2017, the Company issued 50,415,571 warrants in conjunction with two public offerings and a private placement of the Company's common shares. All warrants carry a five-year expiration term. The table below summarizes the warrant activity for the year ended December 31, 2017:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)
Balance at December 31, 2016	-	$ -	-
Granted	50,415,571	0.24	4.94
Exercised	(925,000)	1.11	-
Forfeited	-	-	-
Canceled/Expired	-	-	-
Balance at December 31, 2017	49,490,571	$ 0.22	4.95
Exercisable as of December 31, 2017	48,766,371	$ 0.22	4.95

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

Note 14 - Equity

The holders of common shares are entitled to one vote per share at meetings of the Company. Holders of Series B convertible preferred shares have no voting rights at meetings of the Company.

A restricted stock award is an award of common shares that are subject to certain restrictions during a specified period. Restricted stock awards are independent of option grants and are generally subject to forfeiture if employment terminates prior to the release of the restrictions. The grantee cannot transfer the shares before the restricted shares vest. Shares on non-vested restricted stock have the same voting rights as common stock, are entitled to receive dividends and other distributions thereon and are considered to be currently issued and outstanding. The Company expenses the cost of the restricted stock awards, which is determined to be the fair market value of the shares at the date of grant, straight-line over the period during which the restrictions lapse. For these purposes, the fair market value of the restricted stock is determined based on the closing price of the Company's common stock on the grant date.

On June 8, 2016, the Company issued 27,500 restricted common shares to an officer in connection with his employment agreement. These shares vest 1/3 immediately on the date of the grant and the remaining 2/3 vests equally on March 1, 2017 and March 1, 2018. The fair value of these shares was $54,725 and was based on the share price on the date of the grant. $21,103 and $30,153 was recorded during the years ended December 31, 2017 and 2016 as administrative expense on the Consolidated Statement of Operations and Comprehensive Loss and the remaining $3,469 is reported as deferred compensation, a contra equity account, on the Condensed Consolidated Balance Sheet as of December 31, 2017.

On January 13, 2017, the Company completed a public offering of 1,789,500 common shares, raising net proceeds of $1,652,994. Below is a summary of the gross proceeds to net proceeds calculation.

	Shares	**$**	**$**
Common Shares			
Base Offering	1,667,000	2,000,400	
Over-Allotment	122,500	147,000	
Gross Proceeds			2,147,400
Underwriter/Gunnar Expenses			
Discount		150,318	

Legal Fees	60,000	
Roadshow	1,783	
Miscellaneous	34,005	
Total		246,106
Akers Biosciences Expenses		
Legal & Accounting	197,813	
Registration/Regulatory	50,487	
Total		248,300
Net Proceeds		1,652,994

In addition to the common shares issued, the Company also issued 894,750 warrants with an exercise price of $1.50 per common share. All of the warrants issued have a five-year term.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

On March 30, 2017, the Company completed a private placement of 1,448,400 unregistered shares of common stock, raising net proceeds of $1,760,317. The unregistered shares were admitted to trading on September 30, 2017 upon notification from the Securities and Exchange Commission that the Registration Statement, filed April 19, 2017, had been deemed effective. Below is a summary of the gross proceeds to net proceeds calculation.

	Shares	**$**	**$**
Common Shares			
Base Offering	1,448,400	2,027,760	
Gross Proceeds			2,027,760
Underwriter/Gunnar Expenses			
Discount		141,943	
Legal Fees		50,000	
Total			191,943
Akers Biosciences Expenses			
Legal & Accounting		75,000	
Filing Fees		500	
Total			75,500
Net Proceeds			1,760,317

In addition to the common shares issued, the Company also issued 796,620 warrants with an exercise price of $1.96 per common share with a five-year term.

On April 11, 2017, the Company issued 10,000 restricted shares to a consultant for services to be rendered during the year ending December 31, 2017. These shares vested on the date of the grant. The fair value of these shares was $18,000 and was based on the share price on the date of the grant. The company recorded $5,455 during the year ended December 31, 2017 as sales and marketing expenses on the Consolidated Statement of Operations and Comprehensive Loss. The Company will recognize the remaining expense of $12,545 during the year ending December 31, 2018.

On October 12, 2017, the Company entered into Warrant Exercise Agreements with the existing holders of 724,200 warrants from the March 2017 private placement with an original exercise price of $1.96 per share to exercise their current warrants at $1.00 per share and receive a new warrant which would be convertible into the same number of common shares as the original warrant. The new warrant has an exercise price of $1.26 and expire five years from the date of issuance. The increase in fair value of the reduction in the exercise price of the warrants from $1.96 to $1.00

was $93,386. The Company used the Black-Scholes option pricing model to calculate the increase in fair value with the following assumptions for the decrease in exercise price: no dividend yield, expected volatility of 97.16%, risk free interest rate of 1.95%, and expected warrant life of 4.47 years. The fair value of the new warrants issued of 724,200 was $671,546. The Company used the Black-Scholes option pricing model to calculate the fair value with the following assumptions for the issuance of the new warrants: no dividend yield, expected volatility of 97.16%, risk free interest rate of 1.95%, and expected warrant life of 5 years. In accordance with FASB ASC 718-20-35, expenses related to the modification and re-issue of the warrants totaled $764,932 which are included as warrant modification expenses on the Consolidated Statement of Operations and Comprehensive Loss. The Company received net proceeds of $680,748 net of a solicitation fee of $43,452 from the exercise of 724,200 warrants.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

On October 17, 2017, the Board of Directors issued 295,107 restricted shares of common stock to key employees and officers of the Company as part of the 2017 Equity Incentive Plan. The restricted stock vested immediately and were valued at the closing stock price of $0.88 per share. The fair value of the restricted shares totaled $259,694 and were expensed immediately. The expense is included in the Consolidated Statement of Operations and Comprehensive Loss for the year ending December 31, 2017 as follows:

Expense Category	**2017**	**2016**
General & Administrative	$163,924	—
Sales & Marketing	95,770	—
	$259,694	$ —

On December 21, 2017, the Company completed a public offering of 21,500,000 common shares and 3,675 Series B convertible preferred shares, raising net proceeds of $6,065,586. Below is a summary of the gross proceeds to net proceeds calculation.

	Public Offering - December 21, 2017		
	Shares	$	$
Common Shares			
Base Offering	15,500,000	2,325,000	
Over-Allotment	6,000,000	900,000	
Series B Preferred Shares			
Base Offering	3,675	3,675,000	
Gross Proceeds			6,900,000
Underwriter/Gunnar Expenses			
Discount		483,000	
Non-Accountable Allowance		60,000	
Legal Fees		75,000	
Roadshow		2,558	
Miscellaneous		36,500	
Total			657,058
Akers Biosciences Expenses			
Legal & Accounting		160,000	
Registration/Regulatory		17,356	
Total			177,356
Net Proceeds			6,065,586

In addition to the common shares issued, the Company also issued 46,000,001 warrants with an exercise price of $0.1875 per common share in support of the base offering. All the warrants issued have a five-year term.

During the year ended December 31, 2017, warrant holders from the January 13, 2017 public offering executed 200,800 warrants with an exercise price of $1.50 per common share, raising net proceeds of $301,200.

Note 15 - Loss per share (restated)

The calculation of basic and diluted loss per share at December 31, 2017 and 2016 was based on the loss attributable to common shareholders of $7,366,310 and $3,303,538. The basic and diluted weighted average number of common shares outstanding for 2017 and 2016 was 9,494,977 and 5,430,205.

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 options, warrants and unvested restricted stock. Diluted net loss per common share was the same as basic net loss per common share for the years ended December 31, 2017 and 2016 since the effect of options and warrants would be anti-dilutive due to the net loss attributable to the common shareholders. Instruments excluded from dilutive earnings per share, because their inclusion would be anti-dilutive, were as follows: incentive and award stock options – 255,000 and 259,000; unvested restricted shares of common stock – 9,166 and 18,333; warrants – 48,766,371 and - as of December 31, 2017 and 2016.

Note 16 - Income Tax Expense (restated)

The Company utilizes the asset and liability method of accounting for income taxes in accordance with FASB ASC 740.

The Company’s income tax (benefit)/provision is as follows:

	Years Ended December 31,	
	2017 (restated)	2016
Current	$-	$-
Deferred	(6,003,000)	$(751,000)
Change in Valuation Allowance	6,003,000	$751,000

Income Tax Benefit	$-	$-

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

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, 2017 and 2016 are as follows:

	Years Ended December 31,	
	2017 (restated)	2016
Statutory U.S. Federal Income Tax Rate	(35.0 %)	(35.0%)
New Jersey State income taxes, net of U.S. Federal tax effect	(6.0 %)	(6.0 %)
Tax rate change	122.0%	0.0 %
Change in Valuation Allowance	(81.0)%	41.0 %
Net	0.0 %	0.0 %

In December 2017, the Tax Cuts and Jobs Act was enacted, which reduced the U.S. statutory corporate tax rate to 21% for tax years beginning in 2018. This change resulted in a re-measurement of the federal portion of the Company's deferred tax assets and the valuation allowance as of December 31, 2017 from 35% to the new 21% tax rate.

As of December 31, 2017 and 2016, the Company had Federal net operating loss carry forwards of approximately $69,001,000 and $60,100,000, expiring through the year ending December 31, 2037. As of December 31, 2017 and 2016, the Company had New Jersey state net operating loss carry forwards of approximately $18,168,000 and $9,400,000, expiring through the year ending December 31, 2024.

The principle components of the deferred tax assets and related valuation allowances as of December 31, 2017 and 2016 are as follows:

	Years Ended December 31,	
	2017 (restated)	2016
Reserves and other	$718,000	$865,000
Net operating loss carry-forwards	15,762,000	21,618,000
Valuation Allowance	(16,480,000)	(22,483,000)
Net	$-	$-

The valuation allowance for deferred tax assets as of December 31, 2017 and 2016 was $16,480,000 and $22,483,000. The change in the total valuation for the years ended December 31, 2017 and 2016 were a decrease of $6,003,000 and an increase of $751,000. 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, 2017, the Company had no unrecognized tax benefits and no charge during 2017, and accordingly, the Company did not recognize any interest or penalties during 2017 related to unrecognized tax benefits. There is no accrual for uncertain tax positions as of December 31, 2017.

The Company files U.S. federal income tax returns and a state income tax returns. The U.S. and state income tax returns filed for the tax years ending on December 31, 2014 and thereafter are subject to examination by the relevant taxing authorities.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

Note 17 - Related Party Transactions (restated)

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 Akers' proprietary breathalyzers outside North America. ChubeWorkx paid a licensing fee of $1,000,000 which was recognized over the term of the agreement through September 30, 2015.

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 August 17, 2016, the Company entered into a Settlement Agreement (the "Settlement Agreement") with ChubeWorkx Guernsey Limited ("ChubeWorkx"), a major shareholder, which settled all pending claims between the Company and ChubeWorkx. Specifically, the Company and ChubeWorkx agreed to voluntarily dismiss (i) the action in the United States Federal Court, District of New Jersey brought by the Company against ChubeWorkx for outstanding amounts due to the Company under a promissory note and (ii) the action in The High Court of Justice, Queen's Bench Division Commercial Court, Royal Courts of Justice, United Kingdom brought by ChubeWorkx against the Company arising from an exclusive licensing agreement between ChubeWorkx and the Company ("Licensing Agreement").

Under the terms of the Settlement Agreement, the Company will recover the full outstanding principal amount in the current fiscal year in the form of $750,000 of BreathScan® Alcohol Detector inventory – which the Company intends to subsequently sell – and the balance of $549,609 as prepaid royalty. Akers' established an allowance for this doubtful note in the Company's financial statements for the year ended December 31, 2015. As a result of the Settlement Agreement, the Company reversed the allowance for doubtful note in the amount of $1,299,609 which was included in the Consolidated Statement of Operations and Comprehensive Loss for the year ended December 31, 2016. As of December 31, 2017, the Company evaluated the net realizable value of this inventory and recorded a reserve of $690,190, which is included in cost of goods sold in the Consolidated Statement of Operations, and Comprehensive Loss for the year ended in December 31, 2017.

In addition to addressing the promissory note described above, the Settlement Agreement also allows the Company to market and sell all of the Company's breath technology tests worldwide, unencumbered by any past/future claims by ChubeWorkx under the Licensing Agreement (entered into with ChubeWorkx in 2012 and subsequently amended in

2013). Under the terms of the Settlement Agreement, ChubeWorkx no longer holds any rights pertaining to Akers' BreathScan® technology, which serves as the basis for a number of commercialized products including BreathScan® Alcohol Detector and BreathScan OxiChek™; and a number of products in development.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

In return for the Company regaining the full rights to sell breath technology products, under the terms of the Settlement Agreement, ChubeWorkx is entitled to receive a royalty of 5% of the Company's gross revenues (the "ChubeWorkx Royalty") until ChubeWorkx has earned an aggregate $5,000,000, after which point ChubeWorkx will no longer be entitled to receive any royalties from the Company and the Company shall have no further obligation to ChubeWorkx. The Settlement Agreement further allows the Company to retain 50% of the ChubeWorkx Royalty until the full $549,609 cash component of the monies owed by ChubeWorkx to the Company as described above has been satisfied. The Company recorded royalty expenses of $202,126 and $153,854 for the years ended December 31, 2017 and 2016 which are included in sales and marketing expenses – related party on the Consolidated Statement of Operations and Comprehensive Loss. As of December 31, 2017 and 2016, the Company owed ChubeWorkx royalties of $36,661 and $17,953. The royalty owing is subject to a monthly interest rate of 4.0% and is due in the month following the end of each quarter.

Other terms of the Settlement include: 1) the pledge as security of all earned but unpaid royalties by the Company to ChubeWorkx all Company assets, worthy to satisfy its obligations, including all inventory and receivables, with the exception of (i) distribution contracts of the Company or any of its affiliates, (ii) customer lists, (iii) manufacturing processes (including all intellectual property required to use those processes and exploit products made thereby), and (iv) all equipment required to perform said manufacturing processes and other equipment; 2) the pledge as security of the settlement sum which remains unpaid by the Company to ChubeWorkx all Company (i) distribution contracts of the Company or any of its affiliates, (ii) customer lists, (iii) manufacturing processes (including all intellectual property required to use those processes and exploit products made thereby), and (iv) all equipment required to perform said manufacturing processes and other equipment; and 3) the grant of voting proxy by ChubeWorkx to the Company which allows the Company to vote ChubeWorkx's shares for corporate formalities under certain conditions.

The pledged assets are only at risk in the event that the Company cannot satisfy any outstanding royalty payment obligations subject to various cure periods and/or through a restructuring and/or liquidation under the United States Bankruptcy laws of the Company in favor of payment of said obligation.

The Company began purchasing manufacturing molds, plastic components and the assembled BreathScan Lync™ device through Hainan and its related party during the year ended December 31, 2016 (Note 11). The Company purchased a total of $41,731 and $207,135 during the years ended December 31, 2017 and 2016. As of December 31, 2017, the Company owed the Hainan and its related party $3,160 which is included in trade and other payables – related party on the Consolidated Balance Sheet. The amount owed is interest free and has similar credit terms as other suppliers.

Trade receivables – related party as of December 31, 2017 and 2016 were $- and $31,892. The amounts due are non-interest bearing, unsecured and generally have a term of 30-180 days (Note 6).

Product revenue – related party for the years ended December 31, 2017 and 2016 were $- and $380. The revenue was the result of sales to Hainan and its related party.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

Note 18 – Commitments (restated)

The Company leases its facility in West Deptford, New Jersey under an operating lease (“Thorofare Lease”) with annual rentals of $132,000 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.

Rent expense for the Thorofare Lease, including related CAM charges for the years ended December 31, 2017 and 2016 totaled $161,807 and $161,160, respectively.

The Company entered into a 24-month lease for a satellite office located in Ramsey, New Jersey (“Ramsey Lease”) with annual rents of $25,980 plus common area maintenance (CAM) charges. The lease took effect on June 1, 2017 and runs through May 31, 2019.

Rent expenses for the Ramsey Lease, including related CAM charges totaled $15,166 and $- for the years ended December 31, 2017 and 2016. The Company posted a security deposit of $4,330 which is included in other assets on the Consolidated Balance Sheet.

The Company entered into a 29-month lease for warehouse space located in Pitman, New Jersey (“Pitman Lease”) with annual rents of $39,650. The lease took effect on August 1, 2017 and runs through December 31, 2019.

Rent expenses for the Pitman Lease totaled $16,670 and $- for the years ended December 31, 2017 and 2016. A security deposit of $4,950 is included in other assets on the Consolidated Balance Sheet.

The Company entered into a 60-month operating lease for equipment with annual rentals of $6,156 on September 29, 2014. The lease commenced on October 21, 2014 upon the delivery of the equipment.

The schedule of lease commitments is as follows:

	Thorofare Lease $	Ramsey Lease $	Pitman Lease $	Equipment Lease $	Total $
Next 12 Months	132,000	25,980	39,650	6,156	203,786
Next 13-24 Months	132,000	10,825	39,650	5,130	187,605

On June 30, 2017, the Company signed the Third Amendment to the exclusive Distribution Agreement with NovoTek Pharmaceuticals Limited (‘NovoTek’) which expanded the geographic area of coverage to include Poland and grants NovoTek the right to assemble certain PIFA Heparin PF/4 products in their facilities from components acquired from the Company.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

The Company has agreed to provide PIFA Heparin/PF4 devices, valued at approximately $88,500, at no charge to NovoTek for their use and are to be shipped upon their request. During the year ended December 31, 2017, the Company incurred a charge to product cost of sales of $88,500 in connection with this product obligation and included this amount as an accrued expense in trade and other payables within the Company's consolidated balance sheets as of December 31, 2017.

As of December 31, 2017, the Company had not shipped any goods related to the program.

Note 19 - Major Customers (restated)

For the year ended December 31, 2017, three customers generated 10% or more of the Company's revenue. Sales to these customers accounted for 73% of the Company's revenue. As of December 31, 2017, the amount due from these customers was $1,123,920. This concentration makes the Company vulnerable to a near-term severe impact should the relationships be terminated.

For the year ended December 31, 2016, three customers generated 10% or more of the Company's revenue. Sales to these customers accounted for 75% of the Company's revenue. As of December 31, 2016, the amount due from these customers was $490,725.

Note 20 - Major Suppliers

For the year ended December 31, 2017, no suppliers accounted for 10% or more of the Company's purchases.

For the year ended December 31, 2016, one supplier accounted for 10% or more of the Company's purchases. This supplier accounted for 27% of the Company's total purchases. As of December 31, 2016, the amount due to this supplier was $164,049.

Note 21 – Contingencies

On October 17, 2016 the Company was served with a notice that Pulse Health LLC (“Pulse”) filed a lawsuit against the Company on September 30, 2016 in United States Federal District Court, District of Oregon, alleging a breach of contract under the settlement agreement entered into by the Company and Pulse on April 8, 2011 which settled all claims and disputes between the Company and Pulse arising from a previously executed Technology Development Agreement entered into by the Company and Pulse and damages resulting from said alleged breach. Additionally, Pulse alleges false advertising and unlawful trade practices in connection with the Company’s sales activities related to the Company’s OxiChek™ products.

The Company filed a series of motions with the Court seeking (1) to dismiss the Pulse complaint for lack of jurisdiction or, in the alternative, transfer the matter to the District Court for the District of New Jersey, Camden Vicinage and (2) to dismiss the unfair competition claims for failure to state a claim on which relief could be granted. Oral arguments on these motions were heard by the Court on March 10, 2017.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

The Court decided by order dated April 14, 2017 in favor of the Company and has dismissed with prejudice the claims brought by Pulse for unfair competition (both federal and state counts). The court decided against the Company in its motions for transfer of venue and for lack of jurisdiction. As such, the case shall proceed in the District Court of Oregon.

Pulse subsequently filed an Amended Complaint, in which Pulse seeks not less than $500,000 in damages and, among other items, an injunction prohibiting the Company from manufacture, use and sale of the OxiChek product. The Company answered the Amended Complaint on May 11, 2017. Discovery concluded on January 22, 2018. The Court has received the Company's summary judgment motion. A trial date may be set if Pulse's last remaining claim for breach of contract survives the motion.

The Company intends to establish a rigorous defense of all claims. The Company is unable to assess the potential outcome, so no accrual for losses was made as of December 31, 2017. All legal fees were expensed as and when incurred.

Note 22 – Segment Information (restated)

The Company is organized and operates as one operating segment. In accordance with FASB ASC 280 "Segment Reporting", the Chief Operating Officer is the chief operating decision-maker who reviews operating results to make decisions on allocation of resources and assessment of performance for the entire company.

The total revenue by different product lines was as follows:

	Years ended December 31,	
Product Line	2017	2016
	(restated)	
MicroParticle Catalyzed Biosensor ("MPC")	$381,228	$282,516
Particle ImmunoFiltration Assay ("PIFA")	2,232,684	2,577,148
Rapid Enzymatic Assay ("REA")	133,848	-

Other	556,952	97,498
Product Revenue Total	$3,304,712	$2,957,162
License Fees	50,000	3,750
Total Revenue	$3,354,712	$2,960,912

The total revenue by geographic area determined based on the location of the customers was as follows:

	Years ended December 31,	
Geographic Region	2017	2016
	(restated)	
United States	$2,679,549	$2,330,723
People's Republic of China	502,131	502,998
Rest of World	173,032	127,191
Total Revenue	$3,354,712	$2,960,912

The Company had long-lived assets totaling $59,830 and $61,081 located in the People’s Republic of China and $1,305,950 and $1,500,086 located in the United States as of December 31, 2017 and 2016, respectively.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

Note 23 - Subsequent Events

1,755 shares of the Series B Convertible Preferred Stock converted to 11,700,002 shares of common stock during the period of January 2, 2018 through January 11, 2018.

During the period January 17, 2018 through March 30, 2018, the Company received $5,717,345 from the exercise of 30,492,070 warrants.