UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

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

For the Fiscal Year Ended: **December 31, 2018**

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 every Interactive Data File required to be submitted 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 such files). Yes [X] No [ ]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [ ]

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definition of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer [ ]	Accelerated Filer [ ]
Non-Accelerated Filer [ ]	Smaller reporting company [X]
	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, 2018, based on a closing price of $3.10 was $36,419,135. As of March 29, 2019, the registrant had 12,482,708 shares of its common stock, no par value per share, outstanding.

Documents Incorporated By Reference: **None** .

AKERS BIOSCIENCES, INC.
FOR THE FISCAL YEAR ENDED
DECEMBER 31, 2018

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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," "plan," "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.

Medical Device Business

On October 8, 2018, we announced that following a review of the Company's commercial and product development strategies, the Board of Directors has determined that it is in the best interests of the Company to focus primarily on the commercialization of its Particle Immuno-Filtration Assay (PIFA®) Technology platform. PIFA® technology is a patented immunoassay method which rapidly and accurately detects target antigens or antibodies. It is the technology platform utilized in the Company's core commercialized products, the PIFA® Heparin/PF4 and PIFA® Pluss/PF4 rapid assays, which test for an allergic reaction to Heparin. These products account for the significant majority of the Company's current revenues.

We will continue to manufacture BreathScan Alcohol Detectors (based on the Company's Micro Particle Catalyzed (MPC®) Biosensor technology platform) and Tri-Cholesterol products (based on the Company's Rapid Enzymatic Assay (REA™) technology platform). Furthermore, we have determined that it is not economically appropriate to further develop or pursue approval of the PIFA PLUSS Chlamydia Rapid Assay device. As of December 31, 2018, the Company's marketed products consist solely of its PIFA® Heparin/PF4, Tri-Cholesterol and BreathScan Alcohol Detectors.

All of Akers' rapid, single-use tests are performed in vitro (outside the body) and are designed to enhance patient well-being and reduce the cost of healthcare. The Company's current product offerings focus on delivering diagnostic assistance in a variety of healthcare fields/specialties, including diagnostic rapid manual point-of-care tests for the detection of allergic reactions to Heparin, for cholesterol screening and for on- and off-the-job alcohol safety initiatives.

Akers believes that low-cost, single-use testing not only saves time and money, but allows for more frequent, near-patient testing which may save lives. We believe that our FDA-cleared rapid diagnostic tests help facilitate targeted diagnoses and real-time treatment. We also believe that our 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 a medical condition can be performed on single-patient specimens without sacrificing accuracy.

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

- cost pressures/efficiency of healthcare delivery; and
- need for easy to use, accurate at-home tests for individuals to monitor their personal health and wellness

Strategy

Akers' strategy for the medical device business is to leverage where possible its distributor relationships, while exploring strategies for further reducing its costs.

Akers has developed and currently maintains strategic relationships with established companies in the following key market segments:

- Clinical Laboratories;
- Physicians' Office and Urgent Care Clinics; and
- Retail;

Current Testing Platform Technologies

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 or serum) 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.

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 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.

Rapid Enzymatic Assay

Rapid Enzymatic Assay ("REA") technology enables the rapid detection of metabolites in blood 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.

Current Sample Preparation Technology

Rapid Blood Cell Separation Technology

Akers' Rapid Blood Cell Separation ("Separator") Technology, labeled 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 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. The seraSTAT ® Rapid Blood Cell Separation Technology is currently protected by two U.S. patents and three international patents.

Current Product Portfolio

Akers is positioned as a provider of rapid diagnostic solutions.

At present, Akers' commercialized product portfolio incorporates the four aforementioned proprietary platform testing and sample preparation technologies: PIFA ® , MPC Biosensor, REA and Rapid Blood Cell Separation Technology.

The following table sets forth our marketed products, identifies the appropriate "prescription use" or "OTC" designation and the required clearance that has been obtained.

Our marketed and emerging products include:

Product	Platform	Marketed/Pipeline	FDA Clearance Required Prescription Use/OTC	FDA Clearance Status Obtained/Needed	Description
BreathScan ™	MPC	Marketed	OTC	Obtained	Disposable breath alcohol detector
PIFA ® Heparin/PF4 & PIFA PLUSS ® PF4	PIFA	Marketed	Prescription Use	Obtained	Rapid tests for Heparin/PF4 antibodies to detect an allergy to the widely used blood thinner, Heparin
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

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. 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 for potential sales in the EU; the PIFA Heparin/PF4 Rapid Assay is already CE-marked.

MPC Biosensor Technology

Breath Alcohol Products

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.

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.

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 has been to focus on distribution activities to the OTC markets in the U.S. through partners such as Abbott 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' patented Rapid Blood Cell Separation ("Separator") Technology, marketed under the brand name seraSTAT ® , which 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 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.

Currently, seraSTAT ® is integrated into PIFA PLUSS PF4 devices. The seraSTAT ® Rapid Blood Cell Separation Technologies is 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 Alere/Abbott, ACON Laboratories, Inc., 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.

That said, 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

Our revenue comes from selling rapid, screening and testing products, largely through our distributor networks. Most 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.

Our Current Markets

Regarding the Company's test for the heparin drug allergy, the testing market largely resides within the clinical hospital laboratories of medical facilities.

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

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, personnel, 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.

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.

Effective February 2, 2018, the Company's quality management system was certified as compliant with the International Standards Organization's ("ISO") 13485:2016 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 indirect distribution channels in the U.S. with, among others, Cardinal Health 200, Inc. ("Cardinal Health") and Fisher Healthcare, a Division of Thermo Fisher Scientific Inc. ("Fisher Healthcare") 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.

The Company's PIFA Heparin/PF4 assays are also sold direct to certain hospitals and buying groups.

With respect to the Company's breath alcohol product, Akers has 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.

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 ® .

The following table summarizes the U.S. and international utility patents that currently protect Akers intellectual property for actually marketed products:

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

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; and Tri-Cholesterol "Check" 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 healthcare fraud and abuse, anti-kickback, false claims, HIPAA, environmental protection, safe working conditions, manufacturing practices, fire hazard control and, among other things, the generation, handling, transportation and disposal of hazardous substances.

Exploration of Strategic Alternatives

On November 7, 2018, we announced that our board of directors had initiated a process to evaluate strategic alternatives to maximize shareholder value. This process will consider a range of potential strategic alternatives including, but not limited to, business combinations, while simultaneously supporting the Company's management and employees in the execution of the Company's current business activities. On November 19, 2018, the Company further announced that in its evaluation of strategic alternatives it will consider a range of potential strategic alternatives including, but not limited to, business combinations in sectors different than that currently engaged in, including cannabis related industries. Furthermore, members of the Company's board have recently met with a number of companies in cannabis related industries at the MJBizCon conference in Las Vegas, Nevada, and the Company has engaged the firm of Feuerstein Kulick LLP as a legal advisor as the board continues its evaluation of opportunities within the cannabis and related space.

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 13 full-time equivalent employees, contractors or consultants, which include four in general and administrative, three in regulatory compliance and six 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.

Overview

We have been focused on the development, production and sales of rapid screening and testing products designed to deliver quick and cost-effective medical devices to healthcare providers and consumers. On November 7, 2018, we announced that our board of directors had initiated a process to evaluate strategic alternatives to maximize shareholder value. This process will consider a range of potential strategic alternatives including, but not limited to, business combinations, while simultaneously supporting the Company's management and employees in the execution of the Company's current business activities. On November 19, 2018, the Company further announced that the process to evaluate strategic alternatives will consider a range of potential strategic alternatives including, but not limited to, business combinations in alternative sectors including cannabis related industries. There can be no assurances that the Company will be successful in such process.

Risks Related to Our Medical Device 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, 2018 and 2017 were $10,849,034 and $7,366,310, respectively. Our accumulated deficit at December 31, 2018 was $115,694,881. Our strategy for the medical device business is to leverage where possible its distributor relationships, while exploring strategies for further reducing its costs. Overall, we are working to reduce our cash burn in order to have sufficient cash funds available to execute on a transaction which would result from our pursuit of strategic alternatives. There can be no assurance of success in reducing our loss or becoming profitable.

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, 2018, 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. For the year ended December 31, 2018, Cardinal Health and Fisher accounted for approximately 69% 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, 2018, two customers accounted for 73% of our trade receivables as compared to the fiscal year ended December 31, 2017 where 59% 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. 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.

During the first half of 2018, we experienced lower yields in the process of extracting antigen from the supplier provided platelets used to produce our PIFA Heparin product. At these yield levels, our production of this product was under target levels, which had resulted in backorders. Our engineers and representatives from our supplier have been working together to adjust our processes in order to restore the yield to appropriate levels. Furthermore, we are evaluating and testing a solution that may involve one or more alternative antigen suppliers and processes.

We may require additional capital in the future to 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 expect cash flows from our current operations to be inadequate to cover our anticipated expenses. We may need to obtain significant additional financing, both in the short and long-term to cover operating expenses and to fund potential acquisitions. 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 flows in the future.

Because we may not be able to maintain necessary regulatory clearances 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 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 for a potential new product 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 the 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.

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. 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".

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 device. 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 were 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 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.

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. 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 year ended December 31, 2018, two customers generated 57% and 14%, or 71% in the aggregate, of the Company's revenue. For the year ended December 31, 2017, three customers generated 32%, 26% and 15%, or 73% in the aggregate, of the Company's revenue. In the future, if we are unable to maintain existing relationships, our competitive position would likely suffer and our business would be harmed.

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.

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.

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, 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 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.

We may fail to retain qualified personnel.

We have substantially reduced the number of our employees in order to reduce our costs. Accordingly, retaining such personnel in the future will be critical to our success. If we fail to retain and motivate these highly skilled personnel, we may be unable to continue our operating activities, and this could have a material adverse effect on the Company's business, financial condition, results of operations and future prospects.

We rely on the key executive officer of the management team.

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.

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 to 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.

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 be at risk that our former employees may wrongfully use or disclose our trade secrets.

In addition to patent protection, we rely heavily upon know-how and trade secret protection, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants, and third parties, to protect our confidential and proprietary information, especially where we do not believe patent protection is appropriate or obtainable. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee, former employee, consultant, former consultant or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed.

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.

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 our Pursuit of Strategic Alternatives

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.

If we are unable to make acquisitions and investments, or successfully integrate them into our business, our business could be harmed.

As part of our business strategy, we may acquire other companies or businesses. However, we may not be able to find suitable acquisition candidates, and we may not be able to complete acquisitions on favorable terms, if at all. Acquisitions involve numerous risks, any of which could harm our business and negatively affect our operating results, including:

- difficulties in integrating the technologies, operations, existing contracts and personnel of an acquired company;
- difficulties in supporting and transitioning clients and suppliers, if any, of an acquired company;
- diversion of financial and management resources from existing operations or alternative acquisition opportunities;
- failure to realize the anticipated benefits or synergies of a transaction;
- failure to identify all of the problems, liabilities or other shortcomings or challenges of an acquired company or technology, including issues related to intellectual property, regulatory compliance practices, revenue recognition or other accounting practices, or employee or client issues;
- risks of entering new markets in which we have limited or no experience;
- potential loss of key employees, clients, vendors and suppliers from either our current business or an acquired company's business;
- inability to generate sufficient revenue to offset acquisition costs;
- additional costs or equity dilution associated with funding the acquisition; and
- possible write-offs or impairment charges relating to acquired businesses.

The Company, if it acquires a new business, will have a limited operating history in such new industry, specifically the Cannabis industry, and may not succeed.

The Company will have a limited operating history within the Cannabis industry and may not succeed. The Company will be subject to all risks inherent in a developing business enterprise. The Company's likelihood of continued success must be considered in light of the problems, expenses, difficulties, complications, and delays frequently encountered in connection with manufacturing specialty products and the competitive and regulatory environment in which the Company operates. For example, the Cannabis is a new industry that, as a whole, may not succeed, particularly if the Federal government changes course and decides to prosecute those dealing in Cannabis under Federal law. If that happens, there may not be an adequate market for the Company's products. As a new industry, there are not established players on whose business models the Company can follow or build upon. Similarly, there is limited information about comparable companies available for potential investors to review in making a decision about whether to invest in the Company. Furthermore, as the industrial hemp industry is a new market, it is ripe for technological advancements that could limit or eliminate the need for the Company's products. Furthermore, unanticipated expenses, problems, and technical difficulties may occur and they may result in material delays in the operation of the Company's business, in particular with respect to the Company's new products. The Company may not be able to successfully address these risks and uncertainties or successfully implement the Company's operating strategies. If the Company fails to do so, such failure could materially harm the Company's business to the point of having to cease operations and could impair the value of the Company's common stock to the point investors may lose their entire investment.

Risks Relating to our Common Stock

The market price of our common stock is likely to be volatile and could subject us to litigation.

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;
- recruitment or departure of key personnel;

- any actions taken against the Company by former executives;
- Potential delisting from the NASDAQ Stock Market;
- any class action lawsuits brought against the Company; 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. Specifically, on or about June 15, 2018, certain parties have brought certain class action lawsuits against the Company, and a former executive has threatened to sue the Company, Board members, and executives under the New Jersey CEPA, N.J. Stat. Ann. § 34-19.1 over the termination of his employment. Both, the class action lawsuits brought against the Company and CEPA action threatened by a former executive could result in substantial costs and diversion of management's attention and resources, which could harm the value of your investment in our common stock and materially and adversely affect our business, operating results and financial condition.

The restatement of our previously issued financial statements contained in our Forms 10-Q for the periods ended June 30, 2017 and September 30, 2017 and the Form 10-K for the year ended December 31, 2017 may lead to additional risks and uncertainties, including regulatory, stockholder or other actions, loss of investor confidence and negative impacts on our stock price.

Our Audit Committee, after consultation with management and discussing with outside counsel, external auditors and third-party consultants, concluded that our previously issued consolidated financial statements for the quarterly periods ended June 30, 2017 and September 30, 2017 and for the year ended December 31, 2017 should be restated. The Company determined that certain revenue transactions did not qualify for revenue recognition under generally accepted accounting principles, that certain obligations were not recorded as expenses on a timely basis and that the Company did not properly value its inventory. The Company concluded that the impact of applying corrections for these errors was materially different from its previously reported results under its historical practice. As a result, the Company restated its consolidated financial statements for the periods impacted, as more fully described within each of the respective amended reports, as filed on July 13, 2018. Financial information included in our previously filed Form 10-K for the year ended December 31, 2017 and our Quarterly Reports on Form 10-Q for the periods ended June 30, 2017 and September 30, 2017 and all earnings press releases and similar communications issued by us, for such periods, should not be relied upon and are superseded in their entirety by the above described amended Quarterly and Annual reports.

Accordingly, the Form 10-K, as of and for the year ended December 31, 2017 included: (1) changes to our Consolidated Balance Sheet, our Consolidated Statement of Operations and our Consolidated Statements of Shareholders' Equity as of December 31, 2018; (2) expanded risk factor disclosures within Part I, Item 1A, and (3) additional disclosures and conclusions regarding Controls and Procedures in Part II, Item 9A.

As a result of the 2017 restatements and associated non-reliance on previously issued financial information, we have become subject to a number of additional costs and risks, including unanticipated costs for accounting and legal fees in connection with or related to the restatement and the remediation of our ineffective disclosure controls and procedures and material weakness in internal control over financial reporting. Likewise, the attention of our management team has been diverted by these efforts. In addition, we could also be subject to additional shareholder, governmental, regulatory or other actions or demands in connection with the restatement or other matters. Any such proceedings will, regardless of the outcome, consume a significant amount of management's time and attention and may result in additional legal, accounting, insurance and other costs. If we do not prevail in any such proceedings, we could be required to pay damages or settlement costs. In addition, the restatement and related matters could impair our reputation or could cause our customers, shareholders, or other counterparties to lose confidence in us. Any of these occurrences could have a material adverse effect on our business, results of operations, financial condition and stock price.

In connection with the restatement of our financial statements for the quarterly periods ended June 30, 2017 and September 30, 2017 and for the year ended December 31, 2017, our management identified material weaknesses in our internal control over financial reporting, as described in Item 9A, "Control and Procedures" of this Form 10-K. A material weakness is a deficiency, or combination of deficiencies in internal controls over financial reporting that results in a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Further, management determined that control deficiencies existed with respect to certain aspects of our historical financial reporting and, accordingly, management has concluded that management's reports related to the effectiveness of internal and disclosure controls may not have been correct.

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.

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.

Our ability to grow and compete in the future will be adversely affected if adequate capital is not available to us or not available on terms favorable to us.

Historically, our cash generated from operations has not been sufficient to meet our expenses. We have financed our operations principally through the raising of equity capital, debt and through trade credit with our vendors. Our ability to continue our operations and to pay our obligations when they become due is contingent upon obtaining additional financing. If we are unable to obtain sufficient amounts of additional capital, we may be required to reduce the scope of our planned market development activities, and/or consider reductions in personnel costs or other operating costs. These conditions raise substantial doubt about the Company's ability to continue as a going concern.

Obligations associated with being a public company require significant company resources and management attention, which may have a material adverse effect on our financial condition and results of operations.

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the "Exchange Act," and the other rules and regulations of the SEC, including the Sarbanes-Oxley Act. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and financial condition and the Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. These reporting and other obligations place significant demands on our management, administrative, operational and accounting resources, make certain activities more time-consuming and cause us to incur significant legal, accounting and other expenses. In order to comply with these obligations, we may need to upgrade our systems or create new systems, implement additional financial and management controls, reporting systems and procedures, expand or outsource our internal audit function, and hire additional accounting and finance staff. Because our resources are limited compared to many public companies, these requirements may impose a disproportionate financial burden on us. Furthermore, our limited management resources may exacerbate the difficulties in complying with these reporting and other requirements and prevent us from focusing on executing our business strategy. In addition, if we are unable to comply with the financial reporting requirements and other rules that apply to reporting companies, the market price of our common stock could be adversely affected.

As an "emerging growth company" and a "smaller reporting company" we intend to continue to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" or "smaller reporting companies," including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and other scaled disclosure requirements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. In general, we will remain an "emerging growth company" until December 31, 2019, although a variety of circumstances could cause us to lose that status earlier, and will remain a "smaller reporting company" for each fiscal year where our public float remains below $75 million as of the last day of the second fiscal quarter of the prior fiscal year. We intend to take advantage of some or all of these exemptions and reduced reporting requirements until we are no longer an "emerging growth company" and/or a "smaller reporting company," at which time, we expect to incur significant additional expenses and devote substantial management effort toward ensuring compliance with these additional requirements.

Exercise of options or warrants may have a dilutive effect on percentage ownership and may result in a dilution of 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 or warrants could result in significant dilution in the percentage ownership interest of a shareholders' percentage ownership interest and in a significant dilution of voting rights and earnings per share.

As of March 28, 2019, we had outstanding warrants to purchase up to 2,110,737 shares of our common stock at a weighted exercise price of $3.10 per share.

Additionally, the issuance of up to 10,502 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 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.

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 twelve 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 had executed a lease for a satellite office in Ramsey, New Jersey on June 23, 2017 which is the Company terminated effective February 28, 2019.

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.

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 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.

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.

The Company filed a Motion for Summary Judgment on January 24, 2018. On June 21, 2018, the Court ruled in favor of the Company on some issues and determined that other issues warranted a trial. As part of its ruling on the Motion for Summary Judgment, the Court held "While it seems likely that Plaintiff did suffer some amount of damages, Plaintiff has so far failed to provide a sufficient evidentiary foundation from which the trier of fact could reasonably calculate the value of its injury." The Court stated that it was "reasonably certain that Plaintiff suffered some damage" and found that Pulse Health "may be entitled to nominal damages." The Court further determined that equitable relief, such as an injunction, "may be warranted." Following such rulings, the Company discovered certain deficiencies in its discovery responses and is taking the appropriate steps to supplement the record and correct these deficiencies. In addition, the Court has ordered a settlement conference in front of a U.S. magistrate to be held on August 31, 2018. Trial has been set for November 13, 2018 in Portland, Oregon.

On September 17, 2018, the Company and Pulse entered into a settlement. Pursuant to the settlement reached between the Plaintiff and the Company, on October 9, 2018 the Company paid $930,000 to the Plaintiff. The Company has also agreed to a permanent injunction and will not make, use, sell or offer to sell the BreathScan OxiChek™ product, any product that detects aldehydes or oxidative stress in exhaled human breath or breath condensate using either basic fuchsin or sodium metabisulfite or any form, analog or equivalent thereof, and the BreathScan Lync device, or any equivalent thereof, as part of a test for aldehydes or oxidative stress in human exhaled breath or breath condensate. The Company does not anticipate a material impact on revenues as a result of the withdrawal of the BreathScan OxiChek™ product from sale. The Settlement Agreement does not contain any admission of liability, wrongdoing, or responsibility by any of the parties.

Faulkner v. Akers Biosciences, Inc. , No. 2:18-cv-10521 (D.N.J.) and *Gleason v. Akers Biosciences, Inc. , No. 2:18-cv-10805 (D.N.J.)*

On June 13, 2018, Plaintiff Tim Faulkner filed a class action complaint alleging securities violations against Akers Biosciences, Inc. ("Akers"), John J. Gormally, and Gary M. Rauch ("Individual Defendants") (together with Akers, "Defendants") on behalf of all persons and entities who purchased publicly traded Akers securities from May 15, 2017 through June 5, 2018 (the "Faulkner Action"). The complaint alleges violations of Section 10(b) of the Exchange Act and Rule 10b-5 against all Defendants, and violations of Section 20(a) of the Exchange Act against the Individual Defendants. In particular, the complaint alleges that Defendants made false and/or misleading statements and/or failed to disclose in its first, second, and third quarter 2017 10-Qs and its 2017 10-K that: (1) Akers was improperly recognizing revenue for the fiscal year ended December 31, 2017; and, (2) Akers had downplayed weaknesses in its internal controls over financial reporting and failed to disclose the true extent of those weaknesses. On June 20, 2018, Plaintiff David Gleason filed a class action complaint under the caption *Gleason v. Akers Biosciences, Inc.* , No. 2:18-cv-10805 (D.N.J.) based on the same allegations and causes of action (the "Gleason Action"). On November 21, 2018, the Faulkner and Gleason Actions were consolidated under the *Faulkner Action* docket. The parties conducted a mediation on January 10, 2019, and agreed to a settlement in principle disposing of the consolidated action as to all Defendants, including the Individual Defendants. On March 8, 2019, the parties signed a settlement agreement, subject to approval by the Court, whereby the Company agreed to pay $2,250,000 in exchange for full releases and discharge of all claims against the Company. On the same day, Lead Plaintiffs filed a motion for preliminary approval of the settlement and to establish notice procedures. That motion remains pending.

Watts v. Gormally, et al., No. 2:18-15992 (D.N.J.)

On November 9, 2018, Plaintiff Cale Watts filed a verified shareholder derivative complaint alleging violations of the Securities Exchange Act of 1934, breach of fiduciary duty, unjust enrichment, and waste of corporate assets based on alleged material weaknesses in controls, management, and documentation (the "Watts Action"). On January 14, 2019, the parties reached an agreement in principle to settle the Watts Action that included corporate reforms and a payment of attorneys' fees of $200,000. The parties finalized a Stipulation of Settlement on March 4, 2019. On March 22, 2019, Plaintiffs filed a motion for preliminary approval of the proposed Settlement, approving the proposed form and method of providing notice of the settlement, scheduling a hearing for final approval of the settlement. That motion remains pending.

Chan v. Gormally, et al. , No. 2:19-cv-4989 (D.N.J.)

On February 7, 2019, Tiffany Chan, Jasmine Henderson, and Don Danesh filed a verified shareholder derivative complaint alleging violations of Section 14(a) of the Exchange Act and SEC Rule 14a-9, breach of fiduciary duty, unjust enrichment, and waste of corporate assets based on the same circumstances as the Watts Action. The Chan Action further alleges that the Company should not have settled the Watts Action because the Watts Action plaintiffs lacked standing and the settlement would cause irreparable harm to the Company and its shareholders. Defendants must respond to the Chan Action by April 9, 2019.

Faulkner, Gleason, Watts and Chan Matters

As of December 31, 2018, with regard to the Faulkner, Gleason, Watts and Chan matters, the Company believes that other than the Company's retention requirement under its D&O liability insurance coverage of $500,000, the Company has no additional liability. The D&O liability insurance coverage provides insurance coverage to both the Company and the Directors and Officers for covered defense and indemnification. Furthermore, during the year ended December 31, 2018, the Company recorded a charge of $500,000, representing the full amount of such retention requirement. Therefore, assuming that the settlements are approved, as discussed above, the Company believes it has no further liability with respect to these matters.

Typenex Medical, LLC v. Akers Biosciences, Inc., JAMS Ref. No. 1450005929

On November 15, 2018, Typenex Medical LLC ("Typenex"), a telemarketing entity with whom the Company had entered into a marketing and commission agreement dated September 30, 2016 (the "Marketing Contract"), filed an arbitration against the Company before JAMS ADR (the "Arbitration"), and an arbiter was appointed to the Arbitration on December 14, 2018. In the Arbitration, Typenex has stated that it seeks "at least" $220,500 based on the allegation that the Marketing Contract entitles Typenex to a commission on sales of certain of the Company's heparin-related products in the period two years from the Marketing Contract's expiration, and in the alternative, Typenex seeks relief for breach of the implied covenant of good faith and fair dealing, and/or unjust enrichment. The Company vigorously opposes Typenex's interpretation of the Marketing Contract and will continue to defend this action in the Arbitration.

A former executive has threatened to sue the Company and executives over the termination of executive's employment and for contractual severance pay. The executive asserts that Company was terminated the executive for using sick leave in violation of New Jersey law and that the termination was without cause within the meaning of an employment agreement which provides for severance of one year's salary in the event of termination without cause.

A former executive threatened sue the Company over the termination of the executive's employment. The executive contends that the termination was in retaliation for complaints to the employer protected under California whistleblower protection laws. The executive also contends that the Company failed to pay a bonus in violation of an employment contract.

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 through March 28, 2019, our shares were listed on AIM under the symbol "AKR.L". Our shares began trading on AIM in May 2002.

(b) Holders

As of December 31, 2018, there were approximately 32 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 and 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, 2018.

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	10,502	$ 30.41	2,033,440
Equity compensation plans not approved by security holders	-	$ -	-
Total	10,502	$ 30.41	2,033,440

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, 2018, 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.

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.

Key Events, Management's Plans and Basis of Presentation

On April 25, 2018, the Board of Directors of the Company terminated Dr. Raymond F. Akers from his position as Executive Chairman of the Board and from each of his officer positions as Chief Scientific Director and Secretary of the Company. Dr. Raymond F. Akers continued as a member of the Board of Directors until his resignation on May 27, 2018.

On April 25, 2018, the Board appointed Richard Carlyle Tarbox III, a director of the Company, as the interim Non-Executive Chairman of the Board, to hold that position until his successor is appointed, and to the position of Secretary of the Company.

By way of a letter dated May 22, 2018, the Listing Qualifications Department of NASDAQ advised the Company that it did not comply with NASDAQ Listing Rule 5250(c)(1) for continued listing because NASDAQ has not received the Company's Quarterly Report. Company filed a Current Report on a Form 8-K with the Securities and Exchange Commission on May 25, 2018, that NASDAQ has informed the Company that the Company is required to submit a plan to regain compliance with NASDAQ's filing requirements for continued listing within 60 calendar days of the date of the Notice. NASDAQ informed the Company that it is in Compliance with NASDAQ Listing Rule 5250(c)(1) on July 12, 2018.

On June 11, 2018, the Company received a letter from the Listing Qualifications Department NASDAQ notifying the Company that it has determined that the Company violated the shareholder approval requirements of Listing Rule 5635(c). Listing Rule 5635(c) requires shareholder approval prior to the issuance of securities when a stock option or purchase plan is to be established or materially amended or other equity compensation arrangement made or materially amended, pursuant to which stock may be acquired by officers, directors, employees or consultants.

Prior to the Company's public offering and listing on NASDAQ, the Company's 2013 Incentive Stock and Award Plan (the "2013 Plan") was approved by its Board of Directors. NASDAQ has concluded that the 2013 Plan was materially amended on two occasions after the Company's public offering and listing on NASDAQ. The first amendment, as approved by the Board on January 9, 2015, increased the number of shares available under the 2013 Plan from 50,000 to 100,000 shares and the second amendment, as approved by the Board on October 5, 2016, increased the number of shares under the 2013 Plan from 100,000 to 103,750 shares (the "2013 Plan Amendments").

During the first quarter of 2018, the Company promptly notified NASDAQ, as required by Listing Rule 5625, when it became aware of its potential non-compliance with Listing Rule 5635(c). On May 4, 2018, the Staff requested additional information from the Company with respect to such non-compliance and on May 31, 2018, the Company responded. On June 25, 2018, the Company submitted a plan to NASDAQ to remediate this matter (the "5635 Compliance Plan"). The 5635 Compliance Plan included that a proposal for shareholders of the Company to ratify the 2013 Plan Amendments be included in the proxy statement for the Company's 2018 annual meeting of the shareholders of the Company and that the Company shall suspend the trading of each share granted, and each share granted upon the exercise of any option granted, in excess of 50,000 shares under the 2013 Plan (the number of shares properly approved pursuant to the 2013 Plan prior to the 2013 Plan Amendments until shareholder ratification). The 5635 Compliance Plan also proposes to prevent the exercise of any option granted under the 2013 Plan until shareholder ratification.

On July 12, 2018, NASDAQ approved of the 5635 Compliance Plan and granted the Company until December 10, 2018, to regain compliance with Listing Rule 5635. The Company had a shareholder meeting on December 7, 2018 to approve the amendments to the 2013 Plan.

On or about June 15, 2018, certain parties brought certain class action lawsuits against the Company.

On July 26, 2018, the Company implemented a reduction in workforce plan which resulted in the elimination of six staff positions in four operating departments.

On September 6, 2018, with the recommendation of the Nominating and Corporate Governance Committee (the "N&G Committee") the Board appointed Mr. Joshua Silverman as a Director of the Company for a term that expires at the Company's 2018 Annual Meeting of Stockholders, or until his earlier death, disability, resignation or removal.

On September 17, 2018, the Company reached an amicable resolution by way of a settlement agreement and release (the "Settlement Agreement") with Pulse Health, LLC, an Oregon limited liability company (the "Plaintiff") with respect to the lawsuit Plaintiff filed against the Company, in the United States District Court, District of Oregon (the "Court"), Case No.:3:16-CV-01919-HZ (the "Litigation"), effective upon the Court entering a permanent injunction against the Company, which the Court has entered on to the docket on October 4, 2018. Pursuant to the settlement reached between the Plaintiff and the Company, on October 9, 2018 the Company paid $930,000 to the Plaintiff. The Company has also agreed to a permanent injunction and will not make, use, sell or offer to sell the BreathScan OxiChek™ product, any product that detects aldehydes or oxidative stress in exhaled human breath or breath condensate using either basic fuchsin or sodium metabisulfite or any form, analog or equivalent thereof, and the BreathScan Lync device, or any equivalent thereof, as part of a test for aldehydes or oxidative stress in human exhaled breath or breath condensate. The Company does not anticipate a material impact on revenues as a result of the withdrawal of the BreathScan OxiChek™ product from sale. The Settlement Agreement does not contain any admission of liability, wrongdoing, or responsibility by any of the parties.

On October 5, 2018, John J. Gormally submitted to the Board his resignation from his position as the Chief Executive Officer of the Company and as a member of the Board, effective immediately. Mr. Gormally's resignation was voluntary and not a result of any disagreement with the Company or its executive officers on any matter relating to the Company's operations, policies or practices. In connection with his resignation from the Board, Mr. Gormally entered into a Resignation Agreement with the Company.

Effective on October 5, 2018, the Board appointed Howard R. Yeaton, who through Financial Consulting Strategies LLC ("FCS") served previously as a consultant to the Company, to serve as the Chief Executive Officer and interim Chief Financial Officer of the Company. Mr. Yeaton is the managing principal of FCS and the Company's relationship with FCS shall continue, with FCS continuing to provide accounting services to the Company. FCS is considered to be a related party. During the year ended December 31, 2018, the Company expensed $104,749 to FCS in connection with these services. As of December 31, 2018, the Company owed FCS $29,407 which is included in trade and other payables on the Consolidated Balance Sheet.

On October 6, 2018, finnCap Ltd, the Company's Nominated Adviser on the AIM market of the London Stock Exchange ("finnCap"), gave the Company formal three months' notice of its resignation as the Company's Nominated Adviser and Broker. Should finnCap cease to act as the Company's Nominated Adviser and the Company does not appoint a replacement Nominated Adviser, the Company's shares will be suspended from trading on AIM with immediate effect. The Company would then have one further month to appoint a replacement Nominated Adviser failing which the admission of its AIM securities will be cancelled. On December 19, 2018, the Company announced that finnCap had agreed to extend its notice period to March 31, 2019 so as to allow the Company sufficient time to proceed with a cancellation of its AIM listing.

On October 8, 2018, the Board, following a review of the Company's commercial and product development strategies, determined that it is in the best interests of the Company to focus primarily on the commercialization of its Particle Immuno-Filtration Assay (PIFA®) Technology platform, and to explore other commercial opportunities for the deployment of PIFA® technology, which is also utilized in the Company's core commercialized products, the PIFA® Heparin/PF4 and PIFA® Pluss/PF4 rapid assays, which test for an allergic reaction to Heparin. The Company will continue to manufacture BreathScan Alcohol Detectors (based on the Company's Micro Particle Catalyzed (MPC®) Biosensor technology platform) and Tri-Cholesterol products (based on the Company's Rapid Enzymatic Assay (REA™) technology platform.

On October 18, 2018, Richard C. Tarbox III submitted to the Board his resignation from his positions as interim Non-Executive Chairman of the Board, as Secretary of the Company, as a member of the Board and as a member of each of the committees of the Board upon which he serves, effective immediately. Mr. Tarbox's resignation was voluntary and as a result of his other business commitments, and not a result of any disagreement with the Company or its executive officers on any matter relating to the Company's operations, policies or practices.

On October 19, 2018, as a result of Mr. Tarbox's resignation from the Board and its committees the Board appointed Joshua Silverman to its Audit Committee, Compensation Committee, and Nominating and Corporate Governance Committee, having determined that he satisfies all applicable requirements to serve on such committees, including without limitation the applicable requirements of NASDAQ.

On November 7, 2018, effective as of November 8, 2018, the Company filed a Certificate of Amendment (the "Certificate of Amendment") to its Amended and Restated Certificate of Incorporation with the Secretary of State of the State of New Jersey to effect a reverse stock split of its common stock at a ratio of eight-for-one (8-for-1). The reverse stock split affected all stockholders uniformly and did not alter any stockholder's percentage interest in the Company's equity, except to the extent that the reverse stock split would have resulted in a stockholder owning a fractional share. Fractional shares have not been issued as a result of the reverse stock split; instead, the board of directors of the Company determined to effect an issuance of shares to holders that would otherwise have been entitled to a fractional share such that any fractional shares were rounded up to the nearest whole number.

On November 7, 2018, the Company announced that the Board of Directors has initiated a process to evaluate strategic alternatives to maximize shareholder value. This process will consider a range of potential strategic alternatives including, but not limited to, business combinations, while simultaneously supporting the Company's management and employees in the execution of the Company's current business activities. The Company does not plan to disclose or comment on developments regarding the strategic review process until it is complete or further disclosure is deemed appropriate. There can be no assurance that the exploration of strategic alternatives will result in any transaction or other alternative.

On November 19, 2018, the Company announced that it will consider a range of potential strategic alternatives including, but not limited to, business combinations in alternative sectors including cannabis related industries. Members of the Company's board have recently met with a number of companies in cannabis related industries at the MJBizCon conference in Las Vegas, Nevada. Furthermore, the Company has engaged the firm of Feuerstein Kulick LLP as a legal advisor as the board continues its evaluation of opportunities within the cannabis space.

There can be no assurance that the exploration of strategic alternatives will result in any transaction or other alternative.

On March 29, 2019, the Compensation Committee of the Board of Directors approved Board compensation, payable as follows. Lump sum of $64,000 to be paid to each of directors Schreiber and White and a lump sum of $56,000 to be paid to director Silverman. Such amounts shall be paid during April 2019. Beginning for the month of April 2019, each director shall be paid $8,000 per month. Further, each director was granted 124,827 Restricted Stock Units ("RSU"). Such RSUs shall vest on January 1, 2020, with vesting accelerated upon a change of control. Such RSUs are able to be settled in cash or stock, including on a net tax basis, at the discretion of the holder.

During the year ended December 31, 2018, the Company has in large part relied on equity financing to fund its operations, raising $9,105,200, net of expenses, in a private offering and from the exercise of warrants. The Company has experienced recurring losses and negative cash flows from operations. Management's strategic plans include the following:

- evaluating strategic alternatives to maximize shareholder value, including the consideration of a range of potential strategic alternatives including, but not limited to, business combinations;
- continuing to monitor and implement cost control initiatives to conserve cash.
- Reducing the cost of the Company's Particle Immuno-Filtration Assay (PIFA®) Technology platform

At December 31, 2018, Akers had cash (including restricted cash of $500,000) and marketable securities of $5,954,753, working capital of $4,696,628, shareholders' equity of $5,833,753 and an accumulated deficit of $115,694,881. In order to execute our long-term strategy, including being able to execute upon our pursuit of potential strategic alternatives including but not limited to business combinations, we expect to need to raise additional funds through equity offerings, debt financing or other means. There are no assurances that we will be able to produce such funds on acceptable terms or at all.

Revenue

Akers' revenue for the year ended December 31, 2018 totaled $1,665,570, a 50% decrease from the same period in 2017. The table below summarizes our revenue by product line for the year ended December 31, 2018 and 2017 as well as the percentage of change year-over-year:

	For the Year Ended December 31,		
Product Lines	2018	2017	Percent Change
Particle ImmunoFiltration Assay ("PIFA")	$ 1,422,361	$ 2,232,684	(36)%
MicroParticle Catalyzed Biosensor ("MPC")	123,941	381,228	(67)%
Rapid Enzymatic Assay ("REA")	68,750	133,848	(49)%
Other	50,518	556,952	(91)%
Product Revenue Total	1,665,570	3,304,712	(50)%
License Fees	-	50,000	(100)%
Total Revenue	$ 1,665,570	$ 3,354,712	(50)%

Revenue from the Company's PIFA Heparin/PF4 Rapid Assay products decreased 36% to $1,422,361 (2017: 2,232,684) during the year ended December 31, 2018, over the same period of 2017. The decline in revenues was principally a result of reduced order flow from our primary distributors due to previous overstocking, reduced demand and reduced production capacity for the first half of 2018 due to reduced antigen yields.

The Company's MPC product sales decreased by 67% to $123,941 (2017: $381,228) during the year ended December 31, 2018, due to the withdrawal of the OxiChek products from the market place.

The Company's REA products generated $68,750 (2017: $133,848) during the year ended December 31, 2018.

Other revenue decreased to $50,518 (2017: $556,952) during the year ended December 31, 2018. The category is made up of the sales of miscellaneous raw material components, sub-assembled products and fees billed for shipping and handling charges. The decline was due to the 2017 one-time sale of raw material components and sub-assembled products to a distributor, not being repeated during 2018.

Gross Margin

The Company's gross margin declined to 8% (2017: 28%) for the year ended December 31, 2018, principally on account of the write off of OxiChek inventory upon the termination of manufacturing the product, as well as the charges to write down raw materials and components for other products that are no longer being marketed.

Cost of sales for the year ended December 31, 2018 decreased by 36% to $1,538,285 (2017: $2,406,132). The cost of sales decrease was principally on account of the 50% decrease in product revenue.

Administrative Expenses

Administrative expenses for the year ended December 31, 2018, totaled $5,666,018, which was a 39% increase as compared to $4,082,313 for the year ended December 31, 2017.

The table below summarizes our administrative expenses for the year ended December 31, 2018 and 2017 as well as the percentage of change year-over-year:

	For the year ended December 31,		
Description	2018	2017	Percent Change
Other General and Administrative Costs	1,529 ,935	1,114,058	37%
Professional Service Costs	2,455,933	1,358,354	81%
Personnel Costs	998,605	1,173,964	(15)%
Stock Market & Investor Relations Costs	681, 545	435,937	56%
Total General and Administrative Expense	$ 5,666,018	$ 4,082,313	39%

Other general and administrative expenses increased by 37%. The increase of $415,877 was principally attributable to board fees of $400,000 not incurred during 2017 and business insurance costs of $368,917 (2017: $154,241), offset by bad debt expense of $185,335 (2017: $494,436)

Professional service costs increased by 81% for the year ended December 31, 2018 as compared to the same period of 2017. A significant increase in legal fees $1,551,798 (2017: $899,032)), accounting and audit services $657,045 (2017: $258,578)) and general consulting services of $134,625 (2017: $62,975) were offset partially by a decrease in engineering fees $37,029 (2017: $94,472). The increase in the legal and accounting fees were principally in connection with our Board's 2018 investigation and the resulting restatement of our previously issued financials, as well in connection with litigation matters. Configuration and implementation expenses for the planned NetSuite Financial System also contributed to the increased accounting and general consulting service costs.

Personnel expenses decreased by 15% for the year ended December 31, 2018 as compared to the same period of 2017 due to a reduction in personnel.

Stock market and investor fees increased 56% for the year ended December 31, 2018. The fees included costs associated with the Company's nominated advisor, stock transfer agents, investor relations team and stock exchange fees. Investor relations fees of $364,388 (2017: $222,448), transfer agent fees of $117,722 (2017: $59,807) and stock exchange fees of $100,084 (2017: $55,889) contributed to the increase.

Sales and Marketing Expenses

Sales and marketing expenses for the year ended December 31, 2018 totaled $1,782,315 which was a 13% decrease compared to $2,048,571 for the year ended December 31, 2017.

The table below summarizes our sales and marketing expenses for the year ended December 31, 2018 and 2017 as well as the percentage of change year-over-year:

	For the Year Ended December 31,		
Description	2018	2017	Percent Change
Personnel Costs	$ 1,001,781	$ 1,106,313	(9)%
Royalties and Outside Commission Costs	296,154	323,817	(9)%
Professional Service Costs	258,484	256,611	1%
Other Sales and Marketing Costs	225,896	361,830	(38)%
Total Sales and Marketing Expenses	$ 1,782,315	$ 2,048,571	(13)%

During the year ended December 31, 2018, the ChubeWorkx royalty totaled $59,584 (2017: $202,126) and was partially off-set by an increase in commissions to independent sales representatives, which were $236,570 (2017: $121,691), which contributed to the decline in royalty and outside commission costs during the year ended December 31, 2018.

The reductions in other sales and marketing costs were principally on account of reduced spending on advertising and media production costs.

Litigation Settlement Expense

Litigation settlement expenses for the year ended December 31, 2018, were $1,505,000 as compared to $0 for the year ended December 31, 2017.

These expenses principally consisted of the settlement of the Pulse Litigation which resulted in a one-time charge of $930,000 and $500,000 in connection with the class action and derivative lawsuits.

Amortization of Non-Current Assets

Amortization of non-current assets for the year ended December 31, 2018 totaled $171,108, which was a 0% change as compared to $171,108 for the year ended December 31, 2017.

Research and Development

Research and development expenses for the year ended December 31, 2018 totaled $1,063,253, which was a 16% decrease as compared to $1,260,378 for the year ended December 31, 2017. This decrease was largely due to a reduction in research and development personnel.

The table below summarizes our research and development expenses for the year ended December 31, 2018 and 2017 as well as the percentage of change year-over-year:

	For the year ended December 31, 2018,		
Description	2018	2017	Percent Change
Personnel Costs	$ 670,117	$ 954,632	(30)%
Professional Service Costs	207,366	123,942	67%
Other Research and Development Costs	183,925	179,351	3%
Clinical Trial Costs	1,845	2,453	(25)%
Total Research and Development Expenses	$ 1,063,253	$ 1,260,378	(16)%

Personnel costs decreased 30% during the year ended December 31, 2018 as compared to the same period of 2017. The Company's termination of an executive in April 2018 combined with additional reductions in the number of staff in the department resulted in the decline in personnel costs.

Other (Income)/Expense

Other income, net of expense, for the year ended December 31, 2018 was a net expense of $788,625 compared to $752,520 for the year ended December 31, 2017.

Other (income) expense includes an impairment charge of $716,148, principally on account of terminating marketing of the OxiChek product and a loss of $156,493 for the disposal of equipment used to produce the OxiChek product.

Realized gains, interest and dividend income increased to $165,840 (2017: $10,753). The Company's available capital for investment activities increased significantly due to the capital raise in December 2017, the subsequent exercises of warrants and the equity offering during the year ended December 31, 2018 resulting in the increase in investment income.

Income Taxes

As of December 31, 2018 and 2017, the Company had Federal net operating loss carry forwards of approximately $80,500,000 and $69,001,000, respectively, expiring through the year ending December 31, 2038. As of December 31, 2018 and 2017, the Company had New Jersey state net operating loss carry forwards of approximately $29,700,000 and $19,400,000, respectively, expiring the year ending December 31, 2025.

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.

Liquidity and Capital Resources

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, 2018 and 2017 were $10,849,034 and $7,366,310, respectively.

On November 7, 2018, the Company announced that the Board of Directors has initiated a process to evaluate strategic alternatives to maximize shareholder value. This process will consider a range of potential strategic alternatives including, but not limited to, business combinations, while simultaneously supporting the Company's management and employees in the execution of the Company's current business activities. The Company does not plan to disclose or comment on developments regarding the strategic review process until it is complete or further disclosure is deemed appropriate. There can be no assurance that the exploration of strategic alternatives will result in any transaction or other alternative.

On November 19, 2018, the Company announced that it will consider a range of potential strategic alternatives including, but not limited to, business combinations in alternative sectors including cannabis related industries. Members of the Company's board have recently met with a number of companies in cannabis related industries at the MJBizCon conference in Las Vegas, Nevada. Furthermore, the Company has engaged the firm of Feuerstein Kulick LLP as a legal advisor as the board continues its evaluation of opportunities within the cannabis space.

We expect to continue to incur losses from operations for the near-term and these losses could be significant. We are closely monitoring our cash balances, cash needs and expense levels. The accompanying financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that might result in the possible inability of the Company to continue as a going concern.

Capital expenditures for the year ended December 31, 2018 were $68,214 (2017: $54,507).

Operating Activities

Our net cash consumed by operating activities totaled $8,517,370 during the year ended December 31, 2018. Cash was consumed by the loss of $10,849,034 reduced by non-cash adjustments principally consisting of impairment of intangible assets of $716,148, reserve for obsolete inventory of $279,029, $234,486 for depreciation and amortization of non-current assets, $156,835 for the allowance of doubtful accounts, $50,647 for share based compensation less $11,011 for accrued interest and dividends on marketable securities. For the year ended December 31, 2018, within changes of assets and liabilities, cash provided consisted of a decrease in trade receivables of $631,510, a decrease in inventories of $83,316, an increase in trade and other payables of $188,462, off-set by an increase in prepaid expenses of $225,586.

Our 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 $123,855 and an increase in trade and other payables of $87,607 provided cash, primarily related to routine changes in operating activities. A net increase in inventory of $119,613, trade receivables of $781,508, and other assets of $9,280 consumed cash from operating activities.

Investing Activities

The Company's net cash used in investing totaled $344,507 (2017: $5,041,701) principally by capital expenditures of $68,214.

Financing Activities

The Company's net cash provided by financing activities was $9,105,200 (2017: $10,460,845), consisting principally of net proceeds from the sale of common stock of $1,950,000 and net proceeds from the exercise of warrants of $7,155,200.

Sale of Common Stock

On November 2, 2018, the Company, entered into a securities purchase agreement with certain investors (the "Purchase Agreement") pursuant to which the Company agreed to sell an aggregate of 694,446 shares of common stock and warrants to purchase approximately 694,446 shares of common stock (the "Warrants"). The combined purchase price for one share of common stock and each Warrant will be priced at $2.88 (the "Offering"). The Purchase Agreement contains customary representations, warranties, and covenants by the Company.

Each Warrant has an initial exercise price of $3.76 per share, will be exercisable immediately after the date of issuance and will expire five years from the date it becomes exercisable. Subject to limited exceptions, a holder of the Warrants will not have the right to exercise any portion of such securities if the holder, together with its affiliates, would beneficially own in excess of 4.99% of the number of shares of the Company's common stock outstanding immediately after the exercise. The exercise price of the Warrants, and in some cases the number of shares of common stock issuable upon exercise of the Warrants, will be subject to adjustment in the event of stock splits, stock dividends, combinations, rights offerings and similar events affecting the common stock.

In addition, the Warrants provide that, in the event of a fundamental transaction (as such term is described in the Warrant), the holder of such Warrant, at the holder's option, may receive, for each warrant share (as such term is described in the Warrant) that would have been issuable upon such exercise immediately prior to the occurrence of such fundamental transaction, the number of shares of common stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration receivable as a result of such fundamental transaction by a holder of the number of shares of common stock for which the Warrant is exercisable immediately prior to such fundamental transaction. If holders of common stock are given any choice as to the securities, cash or property to be received in a fundamental transaction, then the holder shall be given the same choice as to the alternate consideration it receives upon any exercise of the Warrant following such fundamental transaction. The Company shall cause any successor entity (as such term is described in the Warrant), at the option of the holder, to deliver to the holder in exchange for the Warrant a security of the successor entity evidenced by a written instrument substantially similar in form and substance to the Warrant which is exercisable for a corresponding number of shares of capital stock of such successor entity (or its parent entity) equivalent to the shares of common stock acquirable and receivable upon exercise of the Warrant (without regard to any limitations on the exercise of this Warrant) prior to such fundamental transaction, and with an exercise price which applies the exercise price hereunder to such shares of capital stock.

The Offering was made pursuant to a shelf registration statement on Form S-3 (File No. 333-214214), previously filed with the Securities and Exchange Commission on October 24, 2016 and declared effective on November 16, 2016. Such securities are being offered only by means of a prospectus.

Warrants

During the year ended December 31, 2018, warrant holders from the December 21, 2017 public offering exercised 4,770,180 warrants with an exercise price of $1.50 per common share, raising net proceeds of $7,155,200.

Critical Accounting Policies

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 is presented within the footnotes in the consolidated financial statements presented with in the annual report.

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. Transactions in which the Company issues stock-based compensation to employees and directors are accounted for based on the fair value of the equity instruments on grant date. Transactions in which the Company issues stock-based compensation to consultants and for goods or services received from non-employees are accounted for based on the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measureable. 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-38 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 Controls and Procedures

Pursuant to Rule 13a- 15(b) under the Exchange Act, the Company carried out an evaluation, with the participation of the Company's management, including the Company's Principal Executive Officer ("PEO") and Principal Financial Officer ("PFO"), of the effectiveness of the Company's disclosure controls and procedures (as defined under Rule 13a-15(e) under the Exchange Act) as of the end of the period covered by this report.

Subsequent to the filing of the Company's Form 10-K for the year ended December 31, 2017, the Company determined that there were material errors within its Quarterly Reports on Form 10-Q for the periods ended June 30, 2017 and September 30, 2017 and in its Annual Report on Form 10-K for the year ended December 31, 2017. Specifically, the Company determined that certain revenue transactions did not qualify for revenue recognition under generally accepted accounting principles, that certain obligations were not recorded as expenses on a timely basis and that the Company did not properly value its inventory. The Company concluded that the impact of applying corrections for these errors was materially different from its previously reported results under its historical practice.

As of December 31, 2018 and based upon that evaluation, and in light of the restatement discussion above, the Company's PEO and PFO concluded that the Company's disclosure controls and procedures were not effective to ensure that information required to be disclosed by the Company in the reports that the Company files or submits under the Exchange Act, are 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 the Company's management, including the Company's PEO and PFO, as appropriate, to allow timely decisions regarding required disclosure.

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) the engaging of additional experienced financial resources, (ii) the development and implementation of enhanced controls designed to evaluate the appropriateness of revenue 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.

(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, 2018, 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 resources, (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.

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

The Company has implemented additional controls around sales transactions to (i) further validate shipping terms including, the date for which risk of ownership transfers to the purchaser and (ii) that shipped product met purchasers' specifications. On October 5, 2018, the Company hired Mr. Howard Yeaton as its CEO and interim Chief Financial Officer. Mr. Yeaton replaced the former CEO, Mr. John Gormally who resigned on October 5, 2018. There have been no other changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Rules 13a-15 or 15d-15 under the Exchange Act that occurred during the fiscal quarter ended December 30, 2018 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
Howard R. Yeaton	64	Chief Executive Officer, Interim Chief Financial Officer
Christopher C. Schreiber	53	Co-Independent Lead Director
Joshua Silverman	48	Co-Independent Lead Director
Bill J. White	57	Independent Director

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

Howard R. Yeaton , has been the Company's Chief Executive Officer and Interim Chief Financial Officer since October 5, 2018. Mr. Yeaton has been the Managing Principal of Financial Consulting Strategies, LLC since 2003, a firm serving principally early stage public companies with financial reporting support and other related strategic services. Mr. Yeaton currently serves as a director, Vice Chairman and Chairman of the audit committee for Stewardship Financial Corporation, a community bank. Mr. Yeaton has served as Interim Chief Financial Officer of Propel Media, Inc. since 2014 and, from July 2014 to July 2015, Mr. Yeaton served as Interim Chief Financial Officer of Energous Corporation, a public company listed on the Nasdaq Capital Market; both clients of Financial Consulting Strategies, LLC. In addition, prior to founding Financial Consulting Strategies, LLC, Mr. Yeaton served in various financial leadership positions for Konica and Teco Energy. Mr. Yeaton began his career with Deloitte, an international accounting and auditing firm. Mr. Yeaton has a BS in accounting from Florida State University in Tallahassee, FL, and a Master's in Business Administration from the University of Connecticut in Storrs, CT.

Christopher C. Schreiber , has been a director of the Company since August 8, 2017. Mr. Schreiber 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.

Joshua Silverman, has been a director of the Company since September 6, 2018. Mr. Silverman currently serves as the Managing Member of Parkfield Funding LLC. Mr. Silverman was the co-founder, and a Principal and Managing Partner of Iroquois Capital Management, LLC, an investment advisory firm. Since its inception in 2003 until July 2016, Mr. Silverman served as Co-Chief Investment Officer of Iroquois. While at Iroquois, he designed and executed complex transactions, structuring and negotiating investments in both public and private companies and has often been called upon by the companies solve inefficiencies as they relate to corporate structure, cash flow, and management. From 2000 to 2003, Mr. Silverman served as Co-Chief Investment Officer of Vertical Ventures, LLC, a merchant bank. Prior to forming Iroquois, Mr. Silverman was a Director of Joele Frank, a boutique consulting firm specializing in mergers and acquisitions. Previously, Mr. Silverman served as Assistant Press Secretary to The President of the United States. Mr. Silverman currently serves as a director of DropCar, Inc., Protagenic Therapeutics, and Neurotrope, Inc., all of which are public companies. He previously served as a Director of National Holdings Corporation from July 2014 through August 2016. Mr. Silverman received his B.A. from Lehigh University in 1992.

Bill J. White , has been a director of the Company since August 8, 2017. Mr. White 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.

Family Relationships

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

Board Composition and Committees and Director Independence

On December 7, 2018, the shareholders of the Company reelected Christopher C. Shcreiber, Joshua Silverman, and Bill J. White, as members of the Board. Mr. Silverman, Mr. Schreiber, and Mr. White comprise the Board's Audit Committee, Compensation Committee, and Nominating and Corporate Governance Committee. Mr. White acts as Chairman of the Audit 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. Christopher C. Schreiber, Mr. Joshua Silverman, and Mr. Bill J. White 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 sixteen times during 2018 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 2018 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 four times, four times and once, respectively, during 2018, 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. Silverman 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. Christopher C. Schreiber, Mr. Joshua Silverman, and Mr. Bill White. 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. Christopher C. Schreiber, Mr. Josh Silverman, and Mr. Bill White. 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.

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

On September 25, 2018, each director serving at such time (Mr. Christopher C. Schreiber, Mr. Bill J. White, and Mr. Richard C. Tarbox III (former director)) received a $100,000 payment, otherwise, there was no other compensation for directors during the year ended December 31, 2018.

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, and Mr. Howard R. Yeaton, who did not file a form 3, which was due on October 15, 2018. Mr. Bill J. White filed his Form 3 on April 10, 2018. Mr. Richard C. Tarbox filed his Form 3 on April 10, 2018. Mr. Christopher C. Schreiber filed his Form 3 on September 21, 2018. Mr. Howard R. Yeaton filed his Form 3 on October 16, 2018.

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 2018 and 2017 is set forth in detail in the Summary Compensation Table and other tables and the accompanying footnotes and narrative that follow this section.

Our named executive officers who appear in the 2018 Summary Compensation Table are:

Howard R. Yeaton	Chief Executive Officer and Interim Chief Financial Officer

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 2018 and 2017.

Name and Principal Position	Year	Salary $	Cash Bonus $	Stock Awards $	Option Awards $	All Other $	Total $
Howard R. Yeaton (1)							
Chief Executive Officer and Interim	2018	71,774	-	20,941	-	-	92,715
Chief Financial Officer	2017	-	-	-	-	-	-
John J. Gormally (2)	2018	260,360	100,000	-	-	6,500(3)	366,860
Former Chief Executive Officer	2017	322,115	50,000	132,000	-	7,800(3)	511,915
Raymond F. Akers, Jr PhD (4)	2018	115,231	-	-	-	3,250(5)	118,481
Secretary and Chief Scientific Director	2017	288,462	-	-	-	7,800(5)	296,262

(1) Mr. Yeaton was appointed as Chief Executive Officer and Interim Chief Financial Officer on October 5, 2018. During the year ended December 31, 2018, both before and after Mr. Yeaton's appointment, FCS, a consulting firm owned by Mr. Yeaton, provided services to the Company valued at $104,749.

(2) Mr. Gormally resigned as Chief Executive Officer on October 5, 2018.

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

(4) Dr. Akers resigned as an Officer on March 27, 2018.

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

Employment Agreements

Effective on October 5, 2018, the Board appointed Howard R. Yeaton, who through Financial Consulting Strategies LLC ("FCS") served previously as a consultant to the Company, to serve as the Chief Executive Officer and interim Chief Financial Officer of the Company. Mr. Yeaton is the managing principal of FCS and the Company's relationship with FCS shall continue, with FCS continuing to provide accounting services to the Company. During the year ended December 31, 2018, the Company paid a total of $104,749 to FCS in connection with these services. In connection with his appointment as the Chief Executive Officer and interim Chief Financial Officer of the Company, the Company and Mr. Yeaton entered into an offer of employment, dated October 5, 2018 (the "Employment Agreement"). The Employment Agreement provides for the following compensation for Mr. Yeaton: (i) twenty-five thousand dollars ($25,000) per month in base salary, (ii) a monthly grant of three thousand seven hundred fifty (3,750) unrestricted shares of the Common Stock pursuant to the Plan, (iii) Mr. Yeaton will be afforded other Company employee benefits including, health insurance, dental insurance, basic life and accidental death and dismemberment insurance, long and short term disability insurance and participation in the Company's 401(k) Plan, and (iv) will be reimbursed for reasonable and necessary travel and business expenses including the expenses of travel and hotel stays in or near Thorofare, New Jersey.

The Company may terminate the Employment Agreement for any reason or no reason, and Mr. Yeaton may voluntarily resign for any reason or no reason, in either case upon 60 days advance written notice to the other party. In the event that the Employment Agreement is terminated as a result of a Change of Control (as defined in the Employment Agreement), the company will award twenty five thousand (25,000) unrestricted shares of the Common Stock pursuant to the 2017 Plan.

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)
Howard R. Yeaton Chief Executive Officer and Interim Chief Financial Officer	-	-	-	-		-	-	-	-
Christopher C. Scheiber Co-Independent Lead Director	-	-	-	-		-	-	-	-
Josh Silverman Co-Independent Lead Director	-	-	-	-		-	-	-	-
Bill J. White Director	-	-	-	-		-	-	-	-

Effective October 5, 2016, the Board amended, upon recommendation from the Compensation Committee of the Board, the Akers Biosciences, Inc. First Amended and Restated 2013 Incentive Stock and Award 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.

On August 7, 2017, the shareholders approved of the Company adopted the 2017 Equity Incentive Plan (the "2017 Plan") which will provide for the issuance of up to 168,750 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, 2018, grants totaling 36,032 shares of restricted Common Stock have been issued pursuant to the 2017 Plan and 132,718 shares of Common Stock remain available for grants 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 168,750 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, 2018, 2,033,440 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.

Effective on October 5, 2018, the Board appointed Howard R. Yeaton. In connection with his appointment as the Chief Executive Officer and interim Chief Financial Officer of the Company, the Company and Mr. Yeaton entered into an offer of employment, dated October 5, 2018 (the "Employment Agreement"). The Employment Agreement provides for a monthly grant of three thousand seven hundred fifty (3,750) unrestricted shares of the Common Stock pursuant to the Plan.

On October 5, 2018, John J. Gormally submitted to the Board his resignation from his positions as the Chief Executive Officer of the Company and as a member of the Board. In connection with his resignation from the Company, the Company and Mr. Gormally acknowledge that, in June 2016, the Company attempted to grant Mr. Gormally twenty seven thousand and five hundred (27,500) restricted shares of Company's common stock, no par value (the " Common Stock ") pursuant to the Company's 2013 Equity Incentive Plan (the " 2013 Shares "), and the Company and Mr. Gormally agree that ten (10) business days after the execution of the Resignation Agreement the Company and Mr. Gormally shall cancel the 2013 Shares and shall grant to Mr. Gormally twenty seven thousand and five hundred (27,500) restricted shares of Common Stock pursuant to the Company's 2017 Equity Incentive Plan (the " Plan "), and those shares to be deemed fully vested on that date.

Effective December 7, 2018, the shareholders of the Company, upon the recommendation of the Board of Directors of the Company, approved and adopted the Akers Biosciences, Inc. 2018 Equity Incentive Plan (the "2018 Plan") which supplemented the Company's existing Amended and Restated 2013 Incentive Stock and Award Plan and the 2017 Equity Incentive Plan. The 2018 Plan provides for the issuance of up to 1,875,000 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, 2018, 1,875,000 are shares reserved for future issuances under our Plan. All future grants will be made pursuant to the 2018 Plan at the market price per share on the date of issuance.

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, 2018.

Name	Fees earned or paid in cash ($)	Stock Awards ($)	Option Awards ($)	Non-equity incentive plan compensation ($)	All other compensation ($)	Total ($)
Christopher Schreiber	100,000	-	-	-	-	100,000
Josh Silverman(1)	-	-	-	-	-	-
William White	100,000	-	-	-	-	100,000
Richard Tarbox (2)	100,000	-	-	-	-	100,000
Raymond Akers, Jr. (3)	-	-	-	-	-	-
John J. Gormally (4)	-	-	-	-	-	-

(1) Effective September 7, 2018, Mr. Silverman was appointed to the Board of Directors.
(2) On October 18, 2018, Richard C. Tarbox III submitted to the Board of the "Company his resignation from his positions as interim Non-Executive Chairman of the Board, as Secretary of the Company, as a member of the Board and as a member of each of the committees of the Board upon which he served
(3) 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. Effective March 27, 2018, Dr. Akers resigned as an officer of the Company.
(4) Effective October 5, 2018, Mr. Gormally resigned as Chief Executive Officer and Director of the Company.

On March 29, 2019, the Compensation Committee of the Board of Directors approved Board compensation, payable as follows. Lump sum of $64,000 to be paid to each of directors Schreiber and White and a lump sum of $56,000 to be paid to director Silverman. Such amounts shall be paid during April 2019. Beginning for the month of April 2019, each director shall be paid $8,000 per month. Further, each director was granted 124,827 Restricted Stock Units ("RSU"). Such RSUs shall vest on January 1, 2020, with vesting accelerated upon a change of control. Such RSUs are able to be settled in cash or stock, including on a net tax basis, at the discretion of the holder.

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

The following table sets forth, as of March 27, 2019, information regarding beneficial ownership of our capital stock by:

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

Beneficial ownership is determined according to the rules of the SEC and generally means that a person has beneficial ownership of a security if he, she or it possesses sole or shared voting or investment power of the applicable security, including options that are currently exercisable or exercisable within 60 days of March 29, 2019. 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 12,482,708 shares of our common stock issued and outstanding as of March 29, 2019.

Common stock subject to stock options currently exercisable or exercisable within 60 days of March 29, 2018, 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 29, 2019	**Percentage of Ownership as of March 29, 2019**
Name of Beneficial Owner:		
5% Shareholders:		
	-	-%
Named Executive Officers and Directors:		
Bill J. White	-	-%
Joshua Silverman	-	-%
Christopher C. Schreiber	-	-%
Howard R. Yeaton (1)	22,500	*%
All executive officers and directors as a group (4 person)	22,500	*%

* Less than 1%.

(1) In connection with his appointment as the Chief Executive Officer and interim Chief Financial Officer of the Company, the Company and Mr. Yeaton entered into an offer of employment, dated October 5, 2018 (the "Employment Agreement"). The Employment Agreement provides for, among other compensation, a monthly grant of three thousand seven hundred and fifty (3,750) unrestricted shares of the Common Stock pursuant to the 2017 Plan. Twenty-two thousand five hundred shares (22,500) unrestricted shares of the Common Stock have to date been issued to Mr. Yeaton pursuant to the Plan.

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 2017 restatements of Forms 10-Q/A and 10-K/A and 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.

	2018	2017
Audit Fees	$ 100,000	$ 113,000
Audit-Related Fees	$ 232,100	$ 97,000
Tax Fees	$ 10,000	$ 9,500
All Other Fees	$ 4,369	$ 44,795
TOTAL	$ 346,469	$ 264,295

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).
3.8	Amendment to Amended and Restated By-Laws, dated October 19, 2018 (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 October 19, 2018).
3.9	Certificate of Amendment (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 November 9, 2018).
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).
4.8	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 October 31, 2018).
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).
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).
10.25	Form of Resignation 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 October 11, 2018).
10.26	Offer of Employment, dated October 5, 2018 (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 October 11, 2018).
10.27	Form of Securities Purchase Agreement, dated October 31, 2018, by and among the Company and the investors signatory thereto (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 October 31, 2018).
10.28	Akers Biosciences, Inc. 2018 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 December 7, 2018).
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)).
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.
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: April 1, 2019

By: */s/ Howard Yeaton*
Name: Howard Yeaton
Title: Chief Executive Officer and Interim Chief Financial Officer (Principal Executive Officer, Principal Financial Officer and Principal Accounting 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/ Howard Yeaton Howard Yeaton	Chief Executive Officer and Interim Chief Financial Officer (Principal Executive Officer)	April 1 , 2019
/s/ Christopher C. Schreiber Christopher C. Schreiber	Co- Independent Lead Director	April 1 , 2019
/s/ Joshua Silverman Joshua Silverman	Co- Independent Lead Director	April 1 , 2019
/s/ Bill J. White Bill J. White	Director	April 1 , 2019

FINANCIAL STATEMENTS

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Stockholders 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, 2018 and 2017, 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, 2018, 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, 2018 and 2017, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

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 1, 2019

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Consolidated Balance Sheets
December 31, 2018 and 2017

	As of December 31,	
	2018	**2017**
ASSETS		
Current Assets		
Cash	$ 181,755	$ 438,432
Marketable Securities	5,272,998	5,011,607
Trade Receivables, net	176,326	964,671
Deposits and other receivables	9,347	16,590
Inventories, net	585,267	947,612
Prepaid expenses	444,435	396,987
Total Current Assets	6,670,128	7,775,899
Non-Current Assets		
Prepaid expenses	298,256	120,118
Restricted Cash	500,000	-
Property, Plant and Equipment, net	83,456	235,113
Intangible Assets, net	243,411	1,130,667
Other Assets	12,002	76,093
Total Non-Current Assets	1,137,125	1,561,991
Total Assets	$ 7,807,253	$ 9,337,890
LIABILITIES		
Current Liabilities		
Trade and Other Payables	1,973,500	1,785,037
Total Liabilities	1,973,500	1,785,037
Commitments and Contingencies		
SHAREHOLDERS' EQUITY		
Convertible Preferred Stock, No par value, 50,000,000 shares authorized, 0 and 1,755 shares issued and outstanding as of December 31, 2018 and 2017	-	1,755,000
Common Stock, No par value, 500,000,000 shares authorized, 12,482,708 and 5,534,692 issued and outstanding as of December 31, 2018 and 2017	121,554,547	110,647,169
Deferred Compensation	-	(3,469)
Comprehensive Loss	(25,913)	-
Accumulated Deficit	(115,694,881)	(104,845,847)
Total Shareholders' Equity	5,833,753	7,552,853
Total Liabilities and Shareholders' Equity	$ 7,807,253	$ 9,337,890

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,	
	2018	**2017**
Revenues:		
Product Revenue	$ 1,665,570	$ 3,304,712
License Fees	-	50,000
Total Revenues	1,665,570	3,354,712
Cost of Sales:		
Product Cost of Sales	(1,538,285)	(2,406,132)
Gross Income	127,285	948,580
Administrative Expenses	5,666,018	4,082,313
Sales and Marketing Expenses	1,782,315	2,048,571
Research and Development Expenses	1,063,253	1,260,378
Litigation Settlement Expenses	1,505,000	-
Amortization of Non-Current Assets	171,108	171,108
Loss from Operations	(10,060,409)	(6,613,790)
Other (Income)/Expenses		
Impairment of Intangible Assets	716,148	-
Impairment of Other Assets	64,092	
Loss on Disposal of Property and Equipment	156,493	-
Foreign Currency Transaction (Gain)/Loss	6,726	(1,659)
Other Income	(4,172)	-
Loss on Investments	15,178	-
Warrant Modification Expense	-	764,932
Interest and Dividend Income	(165,840)	(10,753)
Total Other Expense	788,625	752,520
Loss Before Income Taxes	(10,849,034)	(7,366,310)
Income Tax Benefit	-	-
Net Loss Attributable to Common Shareholders	(10,849,034)	(7,366,310)
Other Comprehensive Loss		
Net Unrealized Loss on Marketable Securities	(25,913)	-
Total Other Comprehensive Loss	(25,913)	-
Comprehensive Loss	$ (10,874,947)	$ (7,366,310)
Basic and Diluted loss per common share	$ (0.99)	$ (6.29)
Weighted average basic and diluted common shares outstanding	10,973,830	1,171,683

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

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Consolidated Statement of Changes in Shareholders' Equity
For the Years Ended December 31, 2018 and 2017

	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 January, 2017	-	$ -	681,569	$ 100,891,786	$ (24,572)	$ (97,479,537)	$ -	$ 3,387,677
Net loss	-	-	-	-	-	(7,366,310)	-	(7,366,310)
Public offering of common stock, net of offering costs of $494,406	-	-	223,688	1,652,994	-	-	-	1,652,994
Private offering of common stock, net of offering costs of $267,443	-	-	181,050	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	2,691,962	2,390,586	-	-	-	6,065,586
Warrant modification	-	-	-	764,932	-	-	-	764,932
Exercise of warrants for common stock	-	-	115,627	981,948	-	-	-	981,948
Conversion of preferred stock to common stock	(1,920)	(1,920,000)	1,602,658	1,920,000	-	-	-	-
Amortization of deferred compensation	-	-	-	-	21,103	-	-	21,103
Issuance of stock grants to officers	-	-	23,284	163,924	-	-	-	163,924
Issuance of stock grants to key employees	-	-	13,604	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	-	-	1,250	5,455	-	-	-	5,455
Balance at December 31, 2017	1,755	$ 1,755,000	5,534,692	$ 110,647,169	$ (3,469)	$ (104,845,847)	$ -	$ 7,552,853
Net loss	-	-	-	-	-	(10,849,034)	-	(10,849,034)
Exercise of warrants for common stock	-	-	4,778,015	7,155,200	-	-	-	7,155,200
Conversion of preferred stock to common stock	(1,755)	(1,755,000)	1,464,930	1,755,000	-	-	-	-
Private offering of common stock, net of offering costs of $50,000	-	-	694,446	1,950,000	-	-	-	1,950,000
Amortization of deferred compensation	-	-	-	-	3,469	-	-	3,469
Issuance of stock grants to key employees	-	-	10,625	27,702	-	-	-	27,702
Stock-based compensation - stock options	-	-	-	6,931	-	-	-	6,931
Stock-based compensation - restricted stock	-	-	-	12,545	-	-	-	12,545
Net unrealized loss on marketable securities	-	-	-	-	-	-	(25,913)	(25,913)
Balance at December 31, 2018	-	$ -	12,482,708	$ 121,554,547	$ -	$ (115,694,881)	$ (25,913)	$ 5,833,753

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,	
	2018	**2017**
Cash flows from operating activities		
Net loss	$ (10,849,034)	$ (7,366,310)
Adjustments to reconcile net loss to net cash used in operating activities:		
Accrued income on marketable securities	(11,011)	(1,412)
Depreciation and amortization	234,486	249,894
Disposal of property and equipment (net)	156,493	-
Impairment of intangible assets	716,148	-
Impairment of other assets	64,092	-
Reserve for obsolete inventory	279,029	1,208,522
Reserve for doubtful accounts	156,835	450,000
Expenses related to modification of warrants	-	764,932
Amortization of deferred compensation	3,469	21,103
Share based compensation to employees - options	6,931	17,274
Share based compensation to employees	27,702	95,770
Share based compensation to officers	-	163,924
Share based compensation to non-employees - options	-	2,183
Share based compensation to non-employees	12,545	5,455
Changes in assets and liabilities:		
(Increase)/decrease in trade receivables	631,510	(781,508)
Decrease in deposits and other receivables	7,243	7,192
(Increase)/decrease in inventories	83,316	(119,613)
(Increase)/decrease in prepaid expenses	(225,586)	123,855
Increase in other assets	-	(9,280)
Increase in trade and other payables	188,462	87,607
Net cash used in operating activities	(8,517,370)	(5,080,412)
Cash flows from investing activities		
Purchases of property, plant and equipment	(68,214)	(54,507)
Purchases of marketable securities	(6,589,623)	(7,709,341)
Proceeds from sale of marketable securities	6,313,330	2,749,147
Net cash consumed by investing activities	(344,507)	(5,014,701)
Cash flows from financing activities		
Net proceeds from issuance of common stock	1,950,000	5,803,897
Proceeds from issuance of preferred stock	-	3,675,000
Net proceeds from exercise of warrants for common stock	7,155,200	981,948
Net cash provided by financing activities	9,105,200	10,460,845
Net increase in cash and restricted cash	243,323	365,732
Cash and restricted cash at beginning of year	438,432	72,700
Cash and restricted cash at end of year	$ 681,755	$ 438,432
Supplemental cash flow information:		
Cash paid for:		
Interest	$ -	$ -
Income Taxes	$ 2,070	$ 1,706
Supplemental Schedule of Non-Cash Financing and Investing Activities		
Net unrealized gains/(losses) on marketable securities	$ (25,913)	$ -
Conversion of Series B Preferred Stock to common shares	$ 1,755,000	$ -

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

Note 1 – Organization and Description of Business

Akers Biosciences, Inc. ("Akers"), is a New Jersey corporation. These consolidated financial statements include two wholly owned subsidiaries, Akers Acquisition Sub, Inc. and Bout Time Marketing Corporation, (together, the "Company"). All material intercompany transactions have been eliminated in consolidation.

On November 7, 2018, the Company announced its intention to explore strategic alternatives in order to maximize shareholder value. As announced, this process will consider a range of potential strategic alternatives including, but not limited to, business combinations, while simultaneously supporting the Company's management and employees in the execution of the Company's current business activities.

Furthermore, the Company has undertaken steps to reduce its expenses, including reducing the number of personnel, reducing its office footprint, eliminating services from non-critical vendors and a shareholder initiative to withdraw its shares from registration on the AIM exchange in the United Kingdom.

The Company's medical device business has as its current focus the production and sale of disposable diagnostic testing devices that can be performed in minutes, to facilitate time sensitive therapeutic decisions. The Company's principal products are a rapid test detecting the antibody causing an allergic reaction to Heparin, breath alcohol detectors used for health and safety and a consumer product used to screen for levels of cholesterols.

Note 2 – Significant Accounting Policies

(a) Basis of Presentation

The accompanying consolidated financial statements for the years ended December 31, 2018 and 2017 have been prepared in accordance and in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") and applicable rules and regulations of the Securities and Exchange Commission ("SEC") regarding consolidated financial information.

On November 8, 2018, the Company effectuated a reverse stock split of its shares of Common Stock whereby every eight (8) pre-split shares of Common Stock were exchanged for one (1) post-split share of the Company's Common Stock ("Reverse Stock Split"). No fractional shares were issued in connection with the Reverse Stock Split. Shareholders who would otherwise have held a fractional share of the Common Stock were given one additional full share of the Company's Common Stock. Numbers presented in these consolidated financial statements have been adjusted to reflect the Reverse Stock Split.

(b) Use of Estimates and Judgments

The preparation of financial statements in conformity with U.S. 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 are included in the following notes for revenue recognition, allowances for doubtful accounts, inventory valuations, impairment of intangible assets and valuation of share based payments.

Note 2 - Significant Accounting Policies, continued

(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 cash balances denominated in Foreign Currencies, are recorded in the consolidated statements 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.

(e) Cash and Cash Equivalents

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.

(f) Restricted Cash

At December 31, 2018, restricted cash included in non-current assets on the Company's consolidated balance sheet was $500,000 representing cash in trust for the purpose of funding legal fees for certain litigations.

Note 2 - Significant Accounting Policies, continued

(g) 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 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.

Note 2 - Significant Accounting Policies, continued

Following is a description of the valuation methodologies used for assets measured at fair value as of December 31, 2018 and 2017.

U.S. Agency 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.

	Quoted Prices in Active Markets for Identical Assets or Liabilities (Level 1)	Quoted Prices for Similar Assets or Liabilities in Active Markets (Level 2)	Significant Unobservable Inputs (Level 3)
Marketable securities at December 31, 2018	$ -	$ 5,272,998	$ -
Marketable securities at December 31, 2017	$ -	$ 5,011,607	$ -

Marketable securities include U.S. agency securities, which 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 and losses relating to the available for sale investment securities were recorded in the Consolidated Statement of Changes in Shareholders' Equity as comprehensive (loss) income. These amounts were an increase of $25,913 in unrealized losses for the year ended December 31, 2018 and $0 in unrealized loss for the year ended December 31, 2017.

Gross gains and losses, resulting from these sales, amounted to a loss of $15,178 and a gain of $3,375 for the years ended December 31, 2018 and 2017, respectively.

(h) Trade Receivables 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. 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, 2018 and 2017, allowances for doubtful accounts for trade receivables were $606,835 and $596,196. Bad debt expenses for trade receivables were $185,335 and $494,436 for the years ended December 31, 2018 and 2017.

Note 2 - Significant Accounting Policies, continued

(i) Concentrations

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of cash on deposit with financial institutions and accounts receivable. At times, the Company's cash in banks is in excess of the FDIC insurance limit. The Company has not experienced any loss as a result of these cash deposits. These cash balances are maintained with two banks.

Major Customers

For the year ended December 31, 2018, two customers generated 57% and 14%, or 71% in the aggregate, of the Company's revenue. For the year ended December 31, 2017, three customers generated 32%, 26% and 15%, or 73% in the aggregate, of the Company's revenue.

Two customers accounted for 59% and 14%, or 73% in the aggregate, of gross trade receivables, before accounting for allowance for doubtful accounts, as of December 31, 2018. As of December 31, 2018, the Company had $458,902 and $111,037 in trade receivables, respectively, from these customers. These concentrations makes the Company vulnerable to a near-term severe impact should these relationships be terminated.

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

Major Suppliers

For the year ended December 31, 2018, one supplier accounted for 14% of the Company's purchases.

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

Two vendors accounted for 14% and 10%, or 24%, in the aggregate, of trade payables as of December 31, 2018.

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

Note 2 - Significant Accounting Policies, continued

(j) 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)/expense" in the consolidated statement of operations and comprehensive loss.

Depreciation is recognized in the consolidated statements of operations and comprehensive 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.

Note 2 - Significant Accounting Policies, continued

(k) Intangible Assets

The Company's long-lived intangible assets, other than goodwill, are assessed for impairment when events or circumstances indicate there may be an impairment. These assets were initially recorded at their estimated fair value at the time of acquisition and assets not acquired in acquisitions were recorded at historical cost. However, if their estimated fair value is less than the carrying amount, other intangible assets with indefinite life are reduced to their estimated fair value through an impairment charge to the consolidated statements of operations and comprehensive loss.

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, 2018, 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. Management intends to protect all other intellectual property (e.g. copyrights, trademarks and trade secrets) using all legal remedies available to the Company.

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 and assessed for impairment when necessary. Patent pending costs for patents that are not approved are charged to the consolidated statements of operations and comprehensive loss 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 and assessed for impairment when necessary.

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.

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

Note 2 - Significant Accounting Policies, continued

(l) 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.

(m) 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.

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.

Note 2 - Significant Accounting Policies, continued

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.

(n) 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. The accrual for estimated sales returns was $57,446 and $0 as of December 31, 2018 and 2017, respectively. 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 may provide for rebates to the distributors under limited circumstances. The Company established an accrual of $23,179 and $126,471, which is a reduction of revenue as of December 31, 2018 and 2017. Accounts receivable will be reduced when the rebates are applied by the customer. The Company recognized $105,247 and $296,164 during the years ended December 31, 2018 and 2017 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.

(o) 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.

Note 2 - Significant Accounting Policies, continued

(p) Shipping and Handling Fees and Costs

The Company charges actual shipping costs plus a handling fee to customers, which amounted to $50,518 and $59,985 for the years ended December 31, 2018 and 2017. 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 $93,558 and $136,145 for the years ended December 31, 2018 and 2017, respectively.

(q) Research and Development Costs

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

(r) 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 scheduled 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.

The Company has elected to account for forfeiture of stock based awards as they occur.

(s) 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.

The calculation of basic and diluted loss per share for the years ended December 31, 2018 and 2017 was based on the loss attributable to common shareholders of $10,849,034 and $7,366,310, respectively. The basic and diluted weighted average number of common shares outstanding for the years ended December 31, 2018 and 2017 was 10,973,830 and 1,171,683, respectively.

Note 2 - Significant Accounting Policies, continued

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

The following securities are excluded from the calculation of weighted average dilutive common shares because their inclusion would have been anti-dilutive:

	For the Years Ended December 31,	
	2018	2017
Incentive and Award Stock Options	10,502	31,875
Unvested Restricted Shares of Common Stock	-	1,146
Warrants	2,110,737	6,186,471
Total potentially dilutive shares	2,121,239	6,219,492

(t) Recently Issued Accounting Pronouncements

Recently Issued Accounting Pronouncements Adopted

As the Company is an emerging growth company, it has elected to adopt recently issued accounting pronouncements based on effective dates applicable to other than public business entities.

On March 30, 2016, the FASB issued ASU No. 2016-09, "Compensation – Stock Compensation (Topic 718)". This update requires that all excess tax benefits and tax deficiencies arising from share-based payment awards should be recognized as income tax expense or benefit on the income statement. The amendment also states that excess tax benefits should be classified along with other income tax cash flows as an operating activity. In addition, an entity can make an entity-wide accounting policy election to either estimate the number of awards expected to vest or account for forfeitures as they occur. The provisions of this update are effective for annual and interim periods beginning after December 15, 2017. The Company adopted this standard effective January 1, 2018. The adoption did not have a material effect on the Company's consolidated financial statements.

In November 2016, the FASB issued ASU No. 2016-18, Statement of Cash Flows (Topic 230), Restricted Cash. The amendments in this Update require that a statement of cash flows explains the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of period and end-of-period total amounts shown on the statement of cash flows. The amendments in this Update do not provide a definition of restricted cash or restricted cash equivalents. The amendments in this Update are effective for public business entities for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. For all other entities, the amendments 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. The Company adopted this as of January 1, 2018 (See Note 2(f)).

Note 2 - Significant Accounting Policies, continued

Recently Issued Accounting Pronouncements Not Adopted

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 for entities other than public business entities, and to annual reporting periods beginning after December 15, 2017, including interim reporting periods within that reporting period for public business entities. 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 and will adopt this Update as of January 1, 2019.

In February 2016, the FASB issued ASU 2016-02—Leases (Topic 842) ("ASU-2016-02"), which requires an entity to recognize right-of-use assets and lease liabilities on its balance sheet and disclose key information about leasing arrangements. ASU 2016-02 offers specific accounting guidance for a lessee, a lessor, and sale and leaseback transactions. Lessees and lessors are required to disclose qualitative and quantitative information about leasing arrangements to enable a user of the financial statements to assess the amount, timing and uncertainty of cash flows arising from leases. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. ASU 2016-02 is effective for annual reporting periods beginning after December 15, 2019, including interim periods within that reporting period, and requires a modified retrospective adoption, with early adoption permitted. The Company is currently evaluating the effect this guidance will have on its consolidated financial statements and related disclosure, and anticipates the guidance to result in increases in its assets and liabilities as most of its operating lease commitments will be subject to the new standard and recognized as right-of-use assets and lease liabilities.

In June 2018, the FASB issued ASU 2018-07, Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting, which expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The guidance is effective for public business entities, certain not-for-profit entities, and certain employee benefit plans for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. For all other entities, ASU 2018-07 is effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606. The Company is evaluating the impact of adopting this pronouncement.

In July 2018, the FASB issued ASU No. 2018-09, Codification Improvements, to makes changes to a variety of topics to clarify, correct errors in, or make minor improvements to the Accounting Standards Codification. Certain items of the amendments in ASU 2018-09 will be effective for the Company in annual periods beginning after December 15, 2018. The Company is currently evaluating the effects the adoption of ASU 2018-09 will have on the consolidated financial statements.

Note 3 – Recent Developments and Management's Plans

By way of a letter dated November 28, 2017, the Listing Qualifications Department of NASDAQ advised the Company that it did not comply with NASDAQ Listing Rule 5550(a)(2) for continued listing, because the Company's Common Stock did not meet NASDAQ's minimum $1.00 bid price requirement (the "Price Requirement"). The Company informed Nasdaq that the Company is fully committed to regain compliance with the Price Requirement as quickly as possible and, therefore, proposed to institute a reverse stock split. NASDAQ approved of the Company's proposal of a reverse stock split and granted the Company until November 26, 2018, for the Company to be in compliance with the Price Requirement. The Company's stock price did remain priced above $1.00 November 22, 2018, it is expected that Nasdaq, thereafter notified the Company that it had regained compliance with the NASDAQ Price Requirements.

On April 25, 2018, the Board of Directors of the Company terminated Dr. Raymond F. Akers from his position as Executive Chairman of the Board and from each of his officer positions as Chief Scientific Director and Secretary of the Company. Dr. Raymond F. Akers continued as a member of the Board of Directors until his resignation on May 27, 2018.

On April 25, 2018, the Board appointed Richard Carlyle Tarbox III, a director of the Company as the interim Non-Executive Chairman of the Board, to hold that position until his successor is appointed, and to the position of Secretary of the Company.

By way of a letter dated May 22, 2018, the Listing Qualifications Department of NASDAQ advised the Company that it did not comply with NASDAQ Listing Rule 5250(c)(1) for continued listing because NASDAQ has not received the Company's Quarterly Report. Company filed a Current Report on a Form 8-K with the Securities and Exchange Commission on May 25, 2018, that NASDAQ has informed the Company that the Company is required to submit a plan to regain compliance with NASDAQ's filing requirements for continued listing within 60 calendar days of the date of the Notice. NASDAQ informed the Company that it is in Compliance with NASDAQ Listing Rule 5250(c)(1) on July 12, 2018.

On June 11, 2018, the Company received a letter from the Listing Qualifications Department NASDAQ notifying the Company that it has determined that the Company violated the shareholder approval requirements of Listing Rule 5635(c). Listing Rule 5635(c) requires shareholder approval prior to the issuance of securities when a stock option or purchase plan is to be established or materially amended or other equity compensation arrangement made or materially amended, pursuant to which stock may be acquired by officers, directors, employees or consultants.

Prior to the Company's public offering and listing on NASDAQ, the Company's 2013 Incentive Stock and Award Plan (the "2013 Plan") was approved by its Board of Directors. NASDAQ has concluded that the 2013 Plan was materially amended on two occasions after the Company's public offering and listing on NASDAQ. The first amendment, as approved by the Board on January 9, 2015, increased the number of shares available under the 2013 Plan from 50,000 to 100,000 shares and the second amendment, as approved by the Board on October 5, 2016, increased the number of shares under the 2013 Plan from 100,000 to 103,750 shares (the "2013 Plan Amendments").

Note 3 – Recent Developments and Management's Plans, continued

During the first quarter of 2018, the Company promptly notified NASDAQ, as required by Listing Rule 5625, when it became aware of its potential non-compliance with Listing Rule 5635(c). On May 4, 2018, the Staff requested additional information from the Company with respect to such non-compliance and on May 31, 2018, the Company responded. On June 25, 2018, the Company submitted a plan to NASDAQ to remediate this matter (the "5635 Compliance Plan"). The 5635 Compliance Plan included that a proposal for shareholders of the Company to ratify the 2013 Plan Amendments be included in the proxy statement for the Company's 2018 annual meeting of the shareholders of the Company and that the Company shall suspend the trading of each share granted, and each share granted upon the exercise of any option granted, in excess of 50,000 shares under the 2013 Plan (the number of shares properly approved pursuant to the 2013 Plan prior to the 2013 Plan Amendments until shareholder ratification). The 5635 Compliance Plan also proposes to prevent the exercise of any option granted under the 2013 Plan until shareholder ratification.

On July 12, 2018, NASDAQ approved of the 5635 Compliance Plan and granted the Company until December 10, 2018, to regain compliance with Listing Rule 5635. The Company intends to have a shareholder meeting on December 7, 2018 to approve the amendments to the 2013 Plan. On December 7, 2018, the Company's Shareholders approved the 2013 Plan.

On or about June 15, 2018, certain parties brought certain class action lawsuits against the Company (See Note 11).

On July 26, 2018, the Company implemented a reduction in workforce plan which resulted in the elimination of six staff positions in four operating departments.

On September 6, 2018, with the recommendation of the Nominating and Corporate Governance Committee (the "N&G Committee") of the Board appointed Mr. Joshua Silverman as a Director of the Company for a term that expires at the Company's 2018 Annual Meeting of Stockholders, or until his earlier death, disability, resignation or removal.

On September 17, 2018, the Company reached an amicable resolution by way of a settlement agreement and release (the "Settlement Agreement") with Pulse Health, LLC, an Oregon limited liability company (the "Plaintiff") with respect to the lawsuit Plaintiff filed against the Company, in the United States District Court, District of Oregon (the "Court"), Case No.:3:16-CV-01919-HZ (the "Litigation"), effective upon the Court entering a permanent injunction against the Company, which the Court has entered on to the docket on October 4, 2018. Pursuant to the settlement reached between the Plaintiff and the Company, on October 9, 2018 the Company paid $930,000 to the Plaintiff. The Company has also agreed to a permanent injunction and will not make, use, sell or offer to sell the BreathScan OxiChek™ product, any product that detects aldehydes or oxidative stress in exhaled human breath or breath condensate using either basic fuchsin or sodium metabisulfite or any form, analog or equivalent thereof, and the BreathScan Lync device, or any equivalent thereof, as part of a test for aldehydes or oxidative stress in human exhaled breath or breath condensate. The Company does not anticipate a material impact on revenues as a result of the withdrawal of the BreathScan OxiChek™ product from sale. The Settlement Agreement does not contain any admission of liability, wrongdoing, or responsibility by any of the parties.

On October 5, 2018, John J. Gormally submitted to the Board his resignation from his position as the Chief Executive Officer of the Company and as a member of the Board, effective immediately. Mr. Gormally's resignation was voluntary and not a result of any disagreement with the Company or its executive officers on any matter relating to the Company's operations, policies or practices. In connection with his resignation from the Board, Mr. Gormally entered into a Resignation Agreement with the Company.

Effective on October 5, 2018, the Board appointed Howard R. Yeaton, who through Financial Consulting Strategies LLC ("FCS") served previously as a consultant to the Company, to serve as the Chief Executive Officer and interim Chief Financial Officer of the Company. Mr Yeaton is entitled to receive 3,750 shares per month as part of his compensation and 25,000 shares upon termination due to a change in control.

Note 3 – Recent Developments and Management's Plans, continued

On October 6, 2018, finnCap Ltd, the Company's Nominated Adviser on the AIM market of the London Stock Exchange ("finnCap"), gave the Company formal three months' notice of its resignation as the Company's Nominated Adviser and Broker. Should finnCap cease to act as the Company's Nominated Adviser and the Company does not appoint a replacement Nominated Adviser, the Company's shares will be suspended from trading on AIM with immediate effect. The Company would then have one further month to appoint a replacement Nominated Adviser failing which the admission of its AIM securities will be cancelled. On December 19, 2018, the Company announced that finnCap had agreed to extend its notice period to March 31, 2019 so as to allow the Company sufficient time to proceed with a cancellation of its AIM listing. See below discussion of the Company's withdrawal from AIM.

On October 8, 2018, the Board, following a review of the Company's commercial and product development strategies, determined that it is in the best interests of the Company to focus primarily on the sale of its Particle Immuno-Filtration Assay (PIFA®) Technology platform, which is also utilized in the Company's core commercialized products, the PIFA® Heparin/PF4 and PIFA® Pluss/PF4 rapid assays, which test for an allergic reaction to Heparin. The Company will continue to manufacture BreathScan Alcohol Detectors (based on the Company's Micro Particle Catalyzed (MPC®) Biosensor technology platform) and Tri-Cholesterol products (based on the Company's Rapid Enzymatic Assay (REA™) technology platform. The Company is taking steps to improve its market presence for these products including the use of specialized independent sales representatives and through 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.

On October 18, 2018, Richard C. Tarbox III submitted to the Board his resignation from his positions as interim Non-Executive Chairman of the Board, as Secretary of the Company, as a member of the Board and as a member of each of the committees of the Board upon which he serves, effective immediately. Mr. Tarbox's resignation was voluntary and as a result of his other business commitments, and not a result of any disagreement with the Company or its executive officers on any matter relating to the Company's operations, policies or practices.

On October 19, 2018, as a result of Mr. Tarbox's resignation from the Board and its committees the Board appointed Joshua Silverman to its Audit Committee, Compensation Committee, and Nominating and Corporate Governance Committee, having determined that he satisfies all applicable requirements to serve on such committees, including without limitation the applicable requirements of NASDAQ.

On November 2, 2018, the Company entered into a securities purchase agreement with certain investors (the "Purchase Agreement") pursuant to which the Company agreed to sell shares of Common Stock in addition to warrants to purchase shares of Common Stock (See Note 9).

On November 7, 2018, the Company announced that its Board of Directors had initiated a process to evaluate strategic alternatives to maximize shareholder value. This process will consider a range of potential strategic alternatives including, but not limited to, business combinations, while simultaneously supporting the Company's management and employees in the execution of the Company's current business activities. There can be no assurance that the exploration of strategic alternatives will result in any transaction or other alternative.

On December 19, 2018, the Company announced its intent to delist from the AIM Market of the London Stock Exchange. The Company believes that due to the relatively low liquidity in the Company's common stock, reaming listed does not merit the ongoing costs and regulatory complexities associated with maintaining the AIM listing. On March 5, 2019, the Company held a special meeting of shareholders who then voted in favor of the Company delisting from the AIM Market. The delisting took effect on March 29, 2019.

Note 3 – Recent Developments and Management's Plans, continued

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. During the first quarter of 2018, the Company raised an additional $7,155,200 from the exercise of warrants (Note 8). On November 2, 2018, the Company raised gross proceeds of $2,000,000 through the sale of 694,446 shares of the Company's Common Stock. Each share includes a warrant to purchase one share of Common Stock at an exercise price of $3.76. As of March 22, 2019, the Company had cash and marketable securities of approximately $4.7 million (excluding restricted cash of $500,000) and working capital of approximately $4.6 million.

The Company believes that its current working capital position will be sufficient to meet its obligations as they fall due within one year after these financial statements are issued.

Note 4 – 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 overhead based on normal operating capacity.

Inventories consist of the following:

	December 31, 2018	December 31, 2017
Raw Materials	$ 542,761	$ 458,441
Sub-Assemblies	711,181	886,274
Finished Goods	635,565	815,505
Reserve for Obsolescence	(1,304,240)	(1,212,608)
	$ 585,267	$ 947,612

Obsolete inventory charged to cost of goods during the years ended December 31, 2018 and 2017 totaled $453,761 and $1,208,522, respectively.

For the year ended December 31, 2018, the Company reserved $279,031 of inventory, principally in connection with the removal of OxiChek from the market, which is included in cost of goods sold and wrote-off, against the reserve, $187,399 of inventory, principally the expired BreathScan Alcohol products, resulting in a net increase of $91,632 in the reserve for obsolescence as of December 31, 2018 compared to that as of December 31, 2017.

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.

Note 5 - Property, Plant and Equipment

Property, plant and equipment consists of the following:

	December 31, 2018	December 31, 2017
Computer Equipment	$ 17,514	$ 114,771
Computer Software	7,806	40,681
Office Equipment	39,959	39,959
Furniture & Fixtures	38,357	38,356
Machinery & Equipment	1,153,830	1,138,134
Molds & Dies	645,272	868,570
Leasehold Improvements	249,960	222,593
	2,152,698	2,463,064
Less		
Accumulated Depreciation	2,069,242	2,227,951
	$ 83,456	$ 235,113

Depreciation expense totaled $63,378 and $78,786 for the years ended December 31, 2018 and 2017, respectively.

Note 6 – Intangible Assets

Intangible assets as of December 31, 2018 and 2017 are as follows:

	December 31, 2018		
	Cost or Deemed Cost	Accumulated Amortization and Impairment	Net Book Value
Patents & Trademarks	$ 2,626,996	$ (2,383,585)	$ 243,411
Distributors & Customer Relationships	1,270,639	(1,270,639)	-
Total	$ 3,897,635	$ (3,654,224)	$ 243,411

	December 31, 2017		
	Cost or Deemed Cost	Accumulated Amortization and Impairment	Net Book Value
Patents & Trademarks	$ 2,626,996	$ (1,496,329)	$ 1,130,667
Distributors & Customer Relationships	1,270,639	(1,270,639)	-
Total	$ 3,897,635	$ (2,766,968)	$ 1,130,667

Intangible assets as of December 31, 2018 and 2017 were $243,411 and $1,130,667, respectively. Intangible assets at December 31, 2018 consisted of patents, trademarks and customer lists of $3,897,635 net of accumulated amortization and impairment of $3,654,224.

Note 6 – Intangible Assets, continued

Effective on October 9, 2018, the Company pulled the OxiChek product line from the market (See Note 3). This served as a triggering event for testing whether or not our intangible assets were impaired. The Company then performed a recoverability analysis and determined that as of December 31, 2018, there was an impairment of $716,148.

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. Amortization expense was $171,108 and $171,108 for the years ended December 31, 2018 and 2017, respectively.

The following is an annual schedule of approximate future amortization of the Company's intangible assets:

Period	Amount
2019	41,336
2020	41,336
2021	41,336
2022	41,336
2023	34,696
Thereafter	43,371
Total	$ 243,411

Note 7 - Trade and Other Payables

Trade and other payables consists of the following:

	December 31, 2018	December 31, 2017
Trade Payables	$ 686,578	$ 988,772
Accrued Expenses	1,227,172	736,515
Deferred Compensation	59,750	59,750
	$ 1,973,500	$ 1,785,037

See also Note 12 for related party information.

Note 8 - 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 50,000 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.

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 100,000 shares.

On September 30, 2016, the Board of Directors increased the number of authorized shares of Common Stock subject to the Amended Plan to 103,750 shares. As of December 31, 2018, grants of restricted stock and options to purchase 78,028 shares of Common Stock have been issued, pursuant to the Amended Plan, and are unvested or unexercised and 25,722 shares of Common Stock remain available for grants under the Amended Plan.

On August 7, 2017, the Shareholders approved and the Company adopted the 2017 Equity Incentive Plan (the "2017 Plan") which will provide for the issuance of up to 168,750 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, 2018, grants totaling 36,032 shares of restricted Common Stock have been issued pursuant to the 2017 Plan and 132,718 shares of Common Stock remain available for grants under the Plan.

On December 7, 2018, the Shareholders approved and the Company adopted the 2018 Equity Incentive Plan (the "2018 Plan") which provides for the issuance of up to 1,875,000 shares. The purpose of the 2018 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, 2018, there were no grants under the 2018 Plan and 1,875,000 shares of Common Stock remain available for grants under the Plan.

The Plans are 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.

During the year ended December 31, 2018 the Company issued 10,625 shares of Common Stock under the above plans (See Note 9).

Note 8 - Share-based Payments, continued

Stock Options

The following table summarizes the option activities for the year ended December 31, 2018:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Balance at December 31, 2017	31,878	$ 33.98	$ 20.49	2.02	$ -
Granted	-	-	-	-	-
Exercised	-	-	-	-	-
Forfeited	(21,376)	35.74	22.00	0.82	-
Canceled/Expired	-	-	-	-	-
Balance at December 31, 2018	10,502	$ 30.41	$ 17.42	1.43	$ -
Exercisable as of December 31, 2018	10,502	$ 30.41	$ 17.42	1.43	$ -

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the closing stock price of $1.13 for the Company's common shares on December 31, 2018.

As of December 31, 2018, all of the Company's outstanding stock options were fully vested and exercisable.

During the years ended December 31, 2018 and 2017, the Company incurred stock option expenses totaling $6,931 and $19,457, respectively.

Note 8 - Share-based Payments, continued

Stock Warrants

The table below summarizes the warrant activity for the year ended December 31, 2018:

	Number of Warrants	Weighted Average Exercise Price	Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Balance at December 31, 2017	6,186,471	$ 1.79	4.95	$ -
Granted	694,446	3.76	-	
Exercised	(4,770,180)	1.50	-	
Forfeited	-	-	-	
Canceled/Expired	-	-	-	
Balance at December 31, 2018	2,110,737	$ 3.10	4.21	$ -
Exercisable as of December 31, 2018	2,110,737	$ 3.10	4.21	$ -

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the closing stock price of $1.13 for the Company's common shares on December 31, 2018. All warrants were vested on date of grant.

Note 9 - 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 had 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 January 13, 2017, the Company completed a public offering of 223,688 common shares, raising net proceeds of $1,652,994. In addition to the common shares issued, the Company also issued 111,844 warrants with an exercise price of $12.00 per common share. All of the warrants issued have a five-year term.

On March 30, 2017, the Company completed a private placement of 181,050 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. In addition to the common shares issued, the Company also issued 99,578 warrants with an exercise price of $15.68 per common share with a five-year term.

On April 11, 2017, the Company issued 1,250 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. During the year ended December 31, 2017, $5,455 was recognized as stock-based compensation expense. The remaining $12,545 fair value of restricted shares issued was recognized during the three months ended March 31, 2018 as sales and marketing expenses on the Consolidated Statement of Operations and Comprehensive Loss.

On October 12, 2017, the Company entered into Warrant Exercise Agreements with the existing holders of 90,525 warrants from the March 2017 private placement with an original exercise price of $15.68 per share to exercise their current warrants at $8.00 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 $10.08 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 $15.68 to $8.00 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 90,525 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 90,525 warrants.

Note 9 – Equity, continued

On October 17, 2017, the Board of Directors issued 36,888 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 $7.04 per share. The fair value of the restricted shares totaled $259,694 and were expensed immediately.

On December 21, 2017, the Company completed a public offering of 2,691,962 common shares and 3,675 Series B convertible preferred shares, raising net proceeds of $6,065,586.

In addition to the common shares issued, the Company also issued 5,750,000 warrants with an exercise price of $1.50 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, 1,920 shares of the Company's Series B Preferred Stock, no par value, were converted into 1,602,658 shares of Common Stock at an exercise price of $1.50 per share.

During the year ended December 31, 2017, warrant holders from the January 13, 2017 public offering exercised 25,101 warrants with an exercise price of $12.00 per common share, raising net proceeds of $301,200.

During the year ended December 31, 2018, the Company issued 7,500 shares of Common Stock to Mr. Yeaton pursuant to his employment agreement. These shares had a fair value of $16,702 on date of grant.

During the year ended December 31, 2018, the Company issued 3,125 shares of Common Stock to a former executive officer of the Company. These shares had a fair value of $11,000 on date of grant.

On November 2, 2018, the Company entered into the Purchase Agreement pursuant to which the Company agreed to sell an aggregate of 694,446 shares of Common Stock and warrants to purchase approximately 694,446 shares of Common Stock (the "Warrants"). The combined purchase price for one share of Common Stock and each Warrant was priced at $2.88 (the "Offering"). The Purchase Agreement contains customary representations, warranties, and covenants by the Company. Through the Offering, the Company raised proceeds of $1,950,000, net of offering costs of $50,000.

Each Warrant has an initial exercise price of $3.76 per share, will be exercisable immediately after the date of issuance and will expire five years from the date it becomes exercisable. Subject to limited exceptions, a holder of the Warrants will not have the right to exercise any portion of such securities if the holder, together with its affiliates, would beneficially own in excess of 4.99% of the number of shares of the Company's Common Stock outstanding immediately after the exercise. The exercise price of the Warrants, and in some cases the number of shares of Common Stock issuable upon exercise of the Warrants, will be subject to adjustment in the event of stock splits, stock dividends, combinations, rights offerings and similar events affecting the Common Stock.

Note 9 – Equity, continued

In addition, the Warrants provide that, in the event of a fundamental transaction (as such term is described in the Warrant), the holder of such Warrant, at the holder's option, may receive, for each warrant share (as such term is described in the Warrant) that would have been issuable upon such exercise immediately prior to the occurrence of such fundamental transaction, the number of shares of Common Stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration receivable as a result of such fundamental transaction by a holder of the number of shares of Common Stock for which the Warrant is exercisable immediately prior to such fundamental transaction. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a fundamental transaction, then the holder shall be given the same choice as to the alternate consideration it receives upon any exercise of the Warrant following such fundamental transaction. The Company shall cause any successor entity (as such term is described in the Warrant), at the option of the holder, to deliver to the holder in exchange for the Warrant a security of the successor entity evidenced by a written instrument substantially similar in form and substance to the Warrant which is exercisable for a corresponding number of shares of capital stock of such successor entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon exercise of the Warrant (without regard to any limitations on the exercise of this Warrant) prior to such fundamental transaction, and with an exercise price which applies the exercise price hereunder to such shares of capital stock.

The Offering was made pursuant to a shelf registration statement on Form S-3 (File No. 333-214214), previously filed with the Securities and Exchange Commission on October 24, 2016 and declared effective on November 16, 2016. Such securities are being offered only by means of a prospectus.

On November 7, 2018, effective as of November 8, 2018, the Company filed a Certificate of Amendment (the "Certificate of Amendment") to its Amended and Restated Certificate of Incorporation with the Secretary of State of the State of New Jersey to effect a reverse stock split of its Common Stock at a ratio of eight-for-one (8-for-1). As a result of the reverse stock split, there are approximately 12,482,708 shares of Common Stock outstanding. The reverse stock split affected all shareholders uniformly and did not alter any shareholder's percentage interest in the Company's equity, except to the extent that the reverse stock split would have resulted in a shareholder owning a fractional share. Fractional shares have not been issued as a result of the reverse stock split; instead, the board of directors of the Company determined to effect an issuance of shares to holders that would otherwise have been entitled to a fractional share such that any fractional shares were rounded up to the nearest whole number.

During the year ended December 31, 2018, 1,755 shares of the Company's Series B Preferred Stock, no par value, were converted into 1,464,930 shares of Common Stock.

During the year ended December 31, 2018, warrant holders from the December 21, 2017 public offering exercised 4,778,015 warrants with an exercise price of $1.50 per common share, raising net proceeds of $7,155,200.

Note 10 - Income Taxes

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

	Years Ended December 31,	
	2018	2017
Current	$ -	$ -
Deferred	(2,941,000)	$ (6,003,000)
Change in Valuation Allowance	2,941,000	$ 6,003,000
Income Tax Benefit	$ -	$ -

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, 2018 and 2017 are as follows:

	Years Ended December 31,	
	2018	2017
Statutory U.S. Federal Income Tax Rate	(21.0)%	(35.0)%
New Jersey State income taxes, net of U.S.		
Federal tax effect	(5.1)%	(6.0)%
Disallowed research and development expenditures	0.1%	-%
True-up for prior year deferred tax assets	(0.9)%	-%
Research and development tax credit	(0.2)%	-%
Tax rate change	-%	122.0%
Change in Valuation Allowance	27.1%	(81.0)%
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, 2018 and 2017, the Company had Federal net operating loss carry forwards of approximately $80,500,000 and $69,001,000, expiring through the year ending December 31, 2038. As of December 31, 2018 and 2017, the Company had New Jersey state net operating loss carry forwards of approximately $29,700,000 and $19,392,000, expiring through the year ending December 31, 2025. The timing and manner in which the Company can utilize operating loss carryforwards in any year may be limited by provisions of the Internal Revenue Code regarding changes in ownership of corporations. Such limitation may have an impact on the ultimate realization of its carryforwards and future tax deductions.

The principal components of the deferred tax assets and related valuation allowances as of December 31, 2018 and 2017 are as follows:

	Years Ended December 31,	
	2018	2017
Reserves and other	$ 523,000	$ 718,000
Net operating loss carry-forwards	18,417,000	15,762,000
Research and development tax credit	481,000	-
Valuation Allowance	(19,421,000)	(16,480,000)
Net	$ -	$ -

Note 10 - Income Tax Expense, continued

The valuation allowance for deferred tax assets as of December 31, 2018 and 2017 was $21,894,000 and $16,480,000. The change in the total valuation for the years ended December 31, 2018 and 2017 was an increase of $2,941,000 and a decrease of $6,003,000, respectively. 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, 2018, the Company had no unrecognized tax benefits and no charge during 2018, and accordingly, the Company did not recognize any interest or penalties during 2018 related to unrecognized tax benefits. There is no accrual for uncertain tax positions as of December 31, 2018.

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, 2015 and thereafter are subject to examination by the relevant taxing authorities.

Note 11 – Commitments and Contingencies

Lease Commitments

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, 2018 and 2017 totaled $164,996 and $161,807, 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 $25,980 and $25,980 for the years ended December 31, 2018 and 2017, respectively. 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 $40,245 and $16,670 for the years ended December 31, 2018 and 2017, respectively. 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.

Note 11 – Commitments and Contingencies, continued

Lease Commitments, continued

The schedule of lease commitments is as follows:

	Thorofare Lease	Ramsey Lease	Pitman Lease	Equipment Lease	Total
Next 12 Months	$ 132,000	$ 4,330	$ 39,650	$ 5,130	$ 181,110

ChubeWorkx

On August 17, 2016, pursuant to a Settlement Agreement (the "Settlement Agreement") with ChubeWorkx Guernsey Limited ("ChubeWorkx"), 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").

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 $59,584 and $202,126 for the years ended December 31, 2018 and 2017, respectively, which are included in sales and marketing expenses on the Consolidated Statement of Operations and Comprehensive Loss. As of December 31, 2018, the Company owed ChubeWorkx royalties of $9,083 which is included in trade and other payables.

Other terms of the Settlement included: 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.

Note 11 – Commitments and Contingencies, continued

ChubeWorkx, continued

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.

Litigation and Settlements

Pulse Health

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.

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.

The Company filed a Motion for Summary Judgment on January 24, 2018. On June 21, 2018, the Court ruled in favor of the Company on some issues and determined that other issues warranted a trial. As part of its ruling on the Motion for Summary Judgment, the Court held "While it seems likely that Plaintiff did suffer some amount of damages, Plaintiff has so far failed to provide a sufficient evidentiary foundation from which the trier of fact could reasonably calculate the value of its injury." The Court stated that it was "reasonably certain that Plaintiff suffered some damage" and found that Pulse Health "may be entitled to nominal damages." The Court further determined that equitable relief, such as an injunction, "may be warranted." Following such rulings, the Company discovered certain deficiencies in its discovery responses and took the appropriate steps to supplement the record and correct these deficiencies. In addition, the Court had ordered a settlement conference in front of a U.S. magistrate that was held on August 31, 2018.

Note 11 – Commitments and Contingencies, continued

Litigation and Settlements, continued

Pulse Health, continued

On September 17, 2018, the Company and Pulse entered into a settlement. Pursuant to the settlement reached between the Plaintiff and the Company, the Company accrued $930,000 payable to Pulse as of September 30, 2018, which was paid on October 9, 2018. The Company has also agreed to a permanent injunction and will not make, use, sell or offer to sell the BreathScan OxiChek™ product, any product that detects aldehydes or oxidative stress in exhaled human breath or breath condensate using either basic fuchsin or sodium metabisulfite or any form, analog or equivalent thereof, and the BreathScan Lync device, or any equivalent thereof, as part of a test for aldehydes or oxidative stress in human exhaled breath or breath condensate. The Company does not anticipate a material impact on revenues as a result of the withdrawal of the BreathScan OxiChek™ product from sale. The Settlement Agreement does not contain any admission of liability, wrongdoing, or responsibility by any of the parties.

Faulkner v. Akers Biosciences, Inc., No. 2:18-cv-10521 (D.N.J.) and Gleason v. Akers Biosciences, Inc., No. 2:18-cv-10805 (D.N.J.)

On June 13, 2018, Plaintiff Tim Faulkner filed a class action complaint alleging securities violations against Akers Biosciences, Inc. ("Akers"), John J. Gormally, and Gary M. Rauch ("Individual Defendants") (together with Akers, "Defendants") on behalf of all persons and entities who purchased publicly traded Akers securities from May 15, 2017 through June 5, 2018 (the "Faulkner Action"). The complaint alleges violations of Section 10(b) of the Exchange Act and Rule 10b-5 against all Defendants, and violations of Section 20(a) of the Exchange Act against the Individual Defendants. In particular, the complaint alleges that Defendants made false and/or misleading statements and/or failed to disclose in its first, second, and third quarter 2017 10-Qs and its 2017 10-K that: (1) Akers was improperly recognizing revenue for the fiscal year ended December 31, 2017; and, (2) Akers had downplayed weaknesses in its internal controls over financial reporting and failed to disclose the true extent of those weaknesses. On June 20, 2018, Plaintiff David Gleason filed a class action complaint under the caption Gleason v. Akers Biosciences, Inc., No. 2:18-cv-10805 (D.N.J.) based on the same allegations and causes of action (the "Gleason Action"). On November 21, 2018, the Faulkner and Gleason Actions were consolidated under the Faulkner Action docket. The parties conducted a mediation on January 10, 2019, and agreed to a settlement in principle disposing of the consolidated action as to all Defendants, including the Individual Defendants. On March 8, 2019, the parties signed a settlement agreement, subject to approval by the Court, whereby the Company agreed to pay $2,250,000 in exchange for full releases and discharge of all claims against the Company. On the same day, Lead Plaintiffs filed a motion for preliminary approval of the settlement and to establish notice procedures. That motion remains pending.

Watts v. Gormally, et al., No. 2:18-15992 (D.N.J.)

On November 9, 2018, Plaintiff Cale Watts filed a verified shareholder derivative complaint alleging violations of the Securities Exchange Act of 1934, breach of fiduciary duty, unjust enrichment, and waste of corporate assets based on alleged material weaknesses in controls, management, and documentation (the "Watts Action"). On January 14, 2019, the parties reached an agreement in principle to settle the Watts Action that included corporate reforms and a payment of attorneys' fees of $200,000. The parties finalized a Stipulation of Settlement on March 4, 2019. On March 22, 2019, Plaintiffs filed a motion for preliminary approval of the proposed Settlement, approving the proposed form and method of providing notice of the settlement, scheduling a hearing for final approval of the settlement. That motion remains pending.

Note 11 – Commitments and Contingencies, continued

Litigation and Settlements, continued

Chan v. Gormally, et al., No. 2:19-cv-4989 (D.N.J.)

On February 7, 2019, Tiffany Chan, Jasmine Henderson, and Don Danesh filed a verified shareholder derivative complaint alleging violations of Section 14(a) of the Exchange Act and SEC Rule 14a-9, breach of fiduciary duty, unjust enrichment, and waste of corporate assets based on the same circumstances as the Watts Action. The Chan Action further alleges that the Company should not have settled the Watts Action because the Watts Action plaintiffs lacked standing and the settlement would cause irreparable harm to the Company and its shareholders. Defendants must respond to the Chan Action by April 9, 2019.

Faulkner, Gleason, Watts and Chan Matters

As of December 31, 2018, with regard to the Faulkner, Gleason, Watts and Chan matters, the Company believes that other than the Company's retention requirement under its D&O liability insurance coverage of $500,000, the Company has no additional liability. The D&O liability insurance coverage provides insurance coverage to both the Company and the Directors and Officers for covered defense and indemnification. Furthermore, during the year ended December 31, 2018, the Company recorded a charge of $500,000, representing the full amount of such retention requirement. Therefore, assuming that the settlements are approved, as discussed above, the Company believes it has no further liability with respect to these matters.

Typenex Medical, LLC v. Akers Biosciences, Inc., JAMS Ref. No. 1450005929

On November 15, 2018, Typenex Medical LLC ("Typenex"), a telemarketing entity with whom the Company had entered into a marketing and commission agreement dated September 30, 2016 (the "Marketing Contract"), filed an arbitration against the Company before JAMS ADR (the "Arbitration"), and an arbiter was appointed to the Arbitration on December 14, 2018. In the Arbitration, Typenex has stated that it seeks "at least" $220,500 based on the allegation that the Marketing Contract entitles Typenex to a commission on sales of certain of the Company's heparin-related products in the period two years from the Marketing Contract's expiration, and in the alternative, Typenex seeks relief for breach of the implied covenant of good faith and fair dealing, and/or unjust enrichment. The Company vigorously opposes Typenex's interpretation of the Marketing Contract and will continue to defend this action in the Arbitration.

Other

A former executive has threatened to sue the Company and executives over the termination of executive's employment and for contractual severance pay. The executive asserts that the Company terminated the executive for using sick leave in violation of New Jersey law and that the termination was without cause within the meaning of an employment agreement which provides for severance of one year's salary in the event of termination without cause. With respect to this matter, the Company believes that the ultimate liability from the settlement of this matter will not be material to the Company's consolidated financial statements.

Subsequent to December 31, 2018, a former executive threatened to sue the Company over the termination of the executive's employment. The executive contends that the termination was in retaliation for complaints to the employer protected under the California whistleblower protection laws. The executive also contends that the Company failed to pay a bonus in violation of an employment contract. The Company's management and legal counsel believes it is too early to determine the probable outcome of this matter.

The Company intends to establish a rigorous defense of all claims. All legal fees were expensed as and when incurred.

Note 12 – Related Parties

Hainan Savvy

On March 9, 2015, the Company contributed capital of $64,091 to Hainan Savy Akers Biosciences, Ltd. ("Hainan"), a company incorporated in the People's Republic of China, resulting in an initial 19.9% ownership interest. On December 31, 2018, the Company recorded a charge of $64,091 for the full impairment of its investment in Hainan. This investment was included in other assets in the Consolidated Balance Sheet as of December 31, 2017 and the investment was accounted for using the cost method.

The Company began purchasing manufacturing molds and plastic components through Hainan and its related party during the year ended December 31, 2016. The Company purchased a total of $20,936 and $41,731 in such components during the years ended December 31, 2018 and 2017, respectively. As of December 31, 2018, the Company owed Hainan and its related party $0 which was included in trade and other payables.

CEO and Interim CFO

Effective on October 5, 2018, the Board appointed Howard R. Yeaton, to serve as the Chief Executive Officer and interim Chief Financial Officer of the Company (See Note 3). Mr. Yeaton is the managing principal of FCS and the Company's relationship with FCS shall continue, with FCS continuing to provide accounting services to the Company. FCS is considered to be a related party. During the year ended December 31, 2018, the Company expensed $ 104,749 to FCS in connection with these services. As of December 31, 2018, the Company owed FCS $29,407 which is included in trade and other payables on the Consolidated Balance Sheet.

Note 13 – Revenue Information

Revenue by product lines was as follows:

	Years Ended December 31,	
Product Line	**2018**	**2017**
MicroParticle Catalyzed Biosensor ("MPC")	$ 123,941	$ 381,228
Particle ImmunoFiltration Assay ("PIFA")	1,422,361	2,232,684
Rapid Enzymatic Assay ("REA")	68,750	133,848
Other	50,518	556,952
Product Revenue Total	1,665,570	3,304,712
License Fees	-	50,000
Total Revenue	$ 1,665,570	$ 3,354,712

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

	Years Ended December 31,	
Geographic Region	**2018**	**2017**
United States	$ 1,576,765	$ 2,679,549
People's Republic of China	-	502,131
Rest of World	88,805	173,032
Total Revenue	$ 1,665,570	$ 3,354,712

The Company had long-lived assets totaling $14,294 and $59,830 located in the People's Republic of China and $312,573 and $1,305,950 located in the United States as of December 31, 2018 and 2017, respectively.

Note 14 – Employee Benefit Plan

The Company maintains a defined contribution benefit plan under section 401(k) of the Internal Revenue Code covering substantially all qualified employees of the Company (the "401(k) Plan"). Under the 401(k) Plan, the Company matches 100% up to a 3% contribution, and 50% over a 3% contribution, up to a maximum of 5%.

During the year ended December 31, 2018, the Company made matching contributions to the 401(k) Plan of $55,360.

Note 15 – Subsequent Events

On March 29, 2019, the Compensation Committee of the Board of Directors was granted 124,827 Restricted Stock Units ("RSU"). Such RSUs shall vest on January 1, 2020, with vesting accelerated upon a change of control. Such RSUs are able to be settled in cash or stock, including on a net tax basis, at the discretion of the holder.

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Amendment to No. 1 to Form S-3 dated November 15, 2016 of Akers Biosciences, Inc. and the related Prospectus included therein, of our report dated April 1, 2019, relating to our audit of the consolidated financial statements of Akers Biosciences, Inc. appearing in the Company's Annual Report on Form 10-K of Akers Biosciences, Inc. for the year ended December 31, 2018.

/s/ Morison Cogen LLP

Blue Bell, Pennsylvania
April 1, 2019

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Howard Yeaton, certify that:

1. I have reviewed this Form 10-K of Akers Biosciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13-a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, 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;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 1, 2019

By: */s/ Howard Yeaton*
Howard Yeaton
Chief Executive Officer and Interim Chief Financial Officer
(Principal Executive Officer, Principal Financial Officer and
Principal Accounting Officer)
Akers Biosciences, Inc.

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF
THE SARBANES-OXLEY ACT OF 2002

In connection with this Annual Report of Akers Biosciences, Inc. (the "Company"), on Form 10-K for the fiscal year ended December 31, 2018, as filed with the U.S. Securities and Exchange Commission on the date hereof, I, Howard Yeaton, Chief Executive Officer and Interim Chief Financial Officer of the Company, certify to the best of my knowledge, pursuant to 18 U.S.C. Sec. 1350, as adopted pursuant to Sec. 906 of the Sarbanes-Oxley Act of 2002, that:

(1) Such Annual Report on Form 10-K for the fiscal year ended December 31, 2018, fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in such Annual Report on Form 10-K for the fiscal year ended December 31, 2018, fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 1, 2019

By: */s/ Howard Yeaton*
Howard Yeaton
Chief Executive Officer and Interim Chief Financial Officer
(Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)
Akers Biosciences, Inc.